

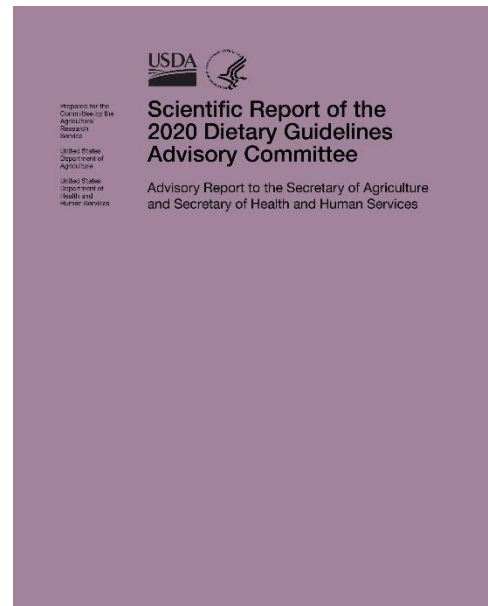


Scientific Report of the 2020 Dietary Guidelines Advisory Committee

Advisory Report to the Secretary of Agriculture and Secretary of Health and Human Services

First Print: July 2020

This is the first print of the Scientific Report of the 2020 Dietary Guidelines Advisory Committee and is being provided to the public online. The report will be formatted for publication and available in hard copy later this year. Online-only supplementary materials for data analysis, food pattern modeling, and NESR systematic reviews can be found through DietaryGuidelines.gov.



Suggested citation: Dietary Guidelines Advisory Committee. 2020. *Scientific Report of the 2020 Dietary Guidelines Advisory Committee: Advisory Report to the Secretary of Agriculture and the Secretary of Health and Human Services*. U.S. Department of Agriculture, Agricultural Research Service, Washington, DC.

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June 30, 2020

The Honorable Sonny Perdue
Secretary of Agriculture
1400 Independence Avenue, SW
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The Honorable Alex Azar
Secretary of Health and Human Services
200 Independence Avenue, SW
Washington DC 20201

Dear Secretaries Perdue and Azar,

The 2020 Dietary Guidelines Advisory Committee, appointed on February 21, 2019, has completed its review of topics and questions requested by the Departments of Agriculture and of Health and Human Services and is submitting the attached report for use in preparing the *2020-2025 Dietary Guidelines for Americans*. The work of the Committee has been guided by the Federal Advisory Committee Act as well as recent changes in the process to develop the *Dietary Guidelines for Americans*. In part, improvements in developing the Committee's report were implemented in response to the 2017 National Academies of Sciences, Engineering, and Medicine (NASEM) report, *Redesigning the Process for Establishing the Dietary Guidelines*, to make the process more transparent, inclusive, and science-driven. In addition, the Agricultural Act of 2014 mandates the inclusion of infants and toddlers and women who are pregnant or lactating in the *2020-2025 Dietary Guidelines for Americans*. As a result, this edition will cover the full lifespan.

The Committee's report emphasizes 2 major themes that can inform the development of the *2020-2025 Dietary Guidelines for Americans*:

- **The importance of considering life stage in the *Dietary Guidelines for Americans***
 - These life stages include pregnancy, lactation, birth to age 24 months, childhood, adolescence, and adulthood.
 - Special nutrition considerations exist at each life stage, and improvements in recommended food patterns at each stage have the potential to influence healthy food choices at the next life stage.
- **Dietary patterns provide a framework for the *Dietary Guidelines for Americans* within and across life stages**
 - Healthy dietary patterns are defined by the quality of foods that are included, as well as foods that should be limited.
 - A high-quality dietary pattern can promote health, achieve nutrient adequacy and energy balance, and reduce the risk of diet-related chronic diseases.
 - The evidence on specific dietary components (e.g., beverages, seafood, added sugars, dietary fats, macronutrient profile) consistently supports the importance of foods consumed in healthy dietary patterns as a framework for the Guidelines.

The Committee identified these themes to address the major public health challenges in the U.S. population of overweight and obesity and their related co-morbidities that are associated with dietary patterns in which typical food choices result in excess energy intake and inadequate nutritional quality. The Committee's work culminated in the development of this report, which summarizes the Committee's review of nearly 1,500 primary research articles included in original NESR systematic reviews, 16 existing NESR systematic reviews, more than 50 analyses of Federal data sets, and numerous food pattern modeling analyses that represented, for the first time, the entire lifespan. In addition, the Committee relied on evidence from the 2015 Committee report and the NASEM Dietary Reference Intake recommendations. To complete its tasks, the Committee worked in subcommittees, and their protocols, conclusions, and recommendations were brought forward for full Committee discussion in public meetings. Work on the questions was prioritized to enable the Committee to provide advice that is most relevant to the charge in the Committee's charter. In addition, the work of the Committee was posted on the Dietary Guidelines website in draft form as it evolved, to facilitate transparency and opportunities for public comment. An additional strength of the current process is that all of the systematic reviews that provided the evidence considered by the Committee underwent peer review before inclusion in the full report.

The Committee began its work in March 2019. As the 2020 Committee submits its report and the *2020-2025 Dietary Guidelines for Americans* are prepared, we are in the midst of the COVID-19 epidemic. As more is learned about infection by SARS-CoV-2 and the development of COVID-19, it is clear that it has significant nutritional implications. These parallel epidemics, one non-infectious (obesity and diet-related chronic diseases) and one infectious (COVID-19), appear to be synergistic. Those at most risk for the most serious outcomes of COVID-19, including hospitalization and death, are people afflicted by diet-related chronic diseases (obesity, type 2 diabetes, and cardiovascular disease). Finally, throughout the world, the consequences of physical isolation and financial disruption by the threat of COVID-19 infection has led to significant increases in food insecurity and hunger, further increasing susceptibility to both infectious and diet-related chronic diseases. Thus, these interrelationships between chronic diseases, COVID-19, and social determinants of health, emphasize the critical importance of improving dietary patterns. These parallel epidemics demonstrate the central role of nutrition and healthy dietary patterns in susceptibility to both infections and diet-related chronic diseases and these relationships should be further examined in future dietary guidelines.

The public comments received by the Committee provided useful insights as the Committee developed its protocols for examining the relevant evidence. However, many comments identified areas that were beyond the scope of the Committee's charge. For example, comments identified the need to evaluate dietary patterns that are effective in the management, support, and treatment of those with chronic diseases and disabilities to determine their value in clinical practice. In addition, comments identified the importance of evaluating sustainability of recommended dietary patterns, addressing the social and economic aspects of access to foods that are components of healthy dietary patterns, and considering systemic changes to encourage behavior change consistent with the guidelines. These comments point to areas that are important for USDA and HHS to address through appropriate mechanisms, and their consideration may provide useful approaches for implementing the recommendations in the *Dietary Guidelines for Americans*.

To develop this report, the Committee had outstanding support from the staff at USDA and HHS. The Committee, through its subcommittees, was responsible for developing the protocols, grading the evidence, and drafting conclusions and recommendations that are a part of each chapter. However, our work would not have been possible without the diligent and careful work of the staff to assemble all of the information needed for these reviews and evaluations. It is hard to put into words the scope of the work and the outstanding quality of the staff's contributions to the process, other than to simply state that the Committee could not have done its work without this support. The Committee also benefitted from the peer review process organized by USDA's Agricultural Research Service. These reviews provided useful feedback on the systematic reviews and we appreciate the input from the Federal scientists who participated.

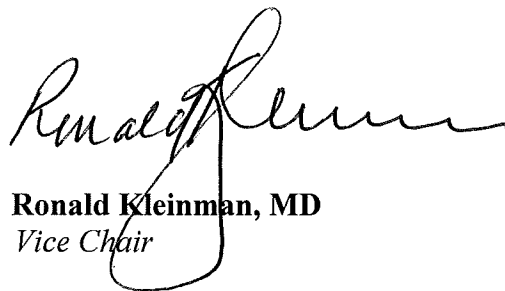
The National Nutrition Monitoring and Related Research Act of 1990 mandates that the Secretaries of USDA and HHS review and release the *Dietary Guidelines for Americans* at least every 5 years so that they reflect "the preponderance of scientific and medical knowledge that is current at the time the report is prepared." We believe that this report accomplishes this goal. As chair and vice-chair of the Committee, we are grateful to our fellow Committee members for their incredible commitment to the work of this Committee, even as their work environments changed due to the COVID-19 epidemic. Each member's expertise brought a unique and essential contribution to the report. The members have analyzed large volumes of material, synthesized it into conclusions and recommendations, and placed our findings in context to illustrate how our assessment can be used in the *2020-2025 Dietary Guidelines for Americans*. By exhibiting respect for the opinions of their fellow Committee members, evaluating public comments, providing constructive suggestions on drafts, and keeping the focus on the scientific evidence, the members have developed a report that reflects the analysis and advice of the Committee as a whole. It has been a pleasure to work with, and learn from, the entire group.

We look forward to seeing the contributions of our Committee incorporated into the *2020-2025 Dietary Guidelines for Americans*.

Sincerely,



Barbara Schneeman, PhD
Chair



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PART A. EXECUTIVE SUMMARY

The Departments of Agriculture and of Health and Human Services established the 2020 Dietary Guidelines Advisory Committee for the single, time-limited task of examining the evidence on specific nutrition and public health topics and providing independent, science-based advice to the Federal government as the Departments develop the next edition of the *Dietary Guidelines for Americans*. The 2020 Committee used 3 approaches to examine the evidence: data analysis, food pattern modeling, and NESR systematic reviews. Each of these approaches has its own rigorous, protocol-driven methodology, and played a unique, complementary role in examining the science. For the first time, the USDA and HHS identified topics and scientific questions to be examined by the 2020 Committee before establishing the Committee. The type of information the Committee needed to answer each scientific question determined which approach they would use to review the evidence (see **Part C. Methodology** for more information on the Committee's evidence review process).

As was true for the 2010 and 2015 Committees, the 2020 Committee's work took place against a backdrop of several significant nutrition-related issues in the United States.

- More than 70 percent of Americans have overweight or obesity, and the prevalence of severe obesity has increased over the past 2 decades. The increasing prevalence of overweight and obesity at young ages is of particular concern because of their effects on the current health of the child as well as the risks of persistent overweight or obesity into adulthood.
- The high rates of overweight and obesity are an important public health problem in and of themselves, and they are a driver for prevalent diet-related chronic diseases, such as cardiovascular disease (CVD), type 2 diabetes, and some types of cancer. At present, 6 in 10 Americans have a chronic condition and 4 in 10 Americans have 2 or more chronic conditions. Various factors contribute to the prevalence of these chronic diseases. Prominent among these are unhealthy dietary patterns and a lack of physical activity.
- Food insecurity and lack of access to affordable healthy food is a persistent problem. In 2018, more than 37 million people, including 6 million children, lived in households that were uncertain of having, or unable to acquire, enough food to meet their needs. Certain populations are disproportionately affected, including low-income, Black non-Hispanic, and Hispanic households, households with young children, and households headed by a single woman or man.

The 2020 Committee's report responds to this backdrop with 2 distinguishing features. The first feature is the lifespan approach the Committee took in its review of evidence. This report continues the traditional emphasis on individuals ages 2 years and older and, for the first time, expands upon it to reflect the growing body of evidence about appropriate nutrition during the earliest stages of life. The Committee reviewed the period from birth to age 24 months and also conducted a review of diet and health issues in pregnancy and lactation. The findings confirm that a healthy diet during these life stages is essential to support healthy growth and development during infancy and childhood and to promote health and prevent chronic disease through childhood, adolescence, and adulthood. The Committee's review and conclusions will enable USDA and HHS to take a full lifespan approach in the *2020-2025 Dietary Guidelines for Americans*.

The second feature is the Committee's focus on dietary patterns, which began with the 2010 Committee and was continued by the 2015 Committee. The 2020 Committee built on this work and has made dietary patterns a centerpiece of its report. This emphasis acknowledges the reality that people do not consume nutrients or foods in isolation but in various combinations over time. It also reflects growing evidence that components of a dietary pattern may have interactive, synergistic, and potentially cumulative relationships that can predict overall health status and disease risk more fully than can individual foods or nutrients.

The remainder of this Executive Summary provides brief summaries of the Committee's topic-specific evidence reviews. Each of these reviews also generated recommendations for research to fill gaps in the current evidence (see **Part E. Future Directions** for a compilation of these recommendations). The Committee's report also includes a chapter, summarized here, that integrates its findings and conclusions on a lifespan approach to healthy dietary patterns.

CURRENT DIETARY INTAKES THROUGH THE LIFE COURSE

Diet is a modifiable factor that is critically relevant to the primary and secondary prevention of most non-communicable diseases and the leading causes of disability and death affecting Americans. Consistent and well-conducted Federal monitoring and surveillance have shown that most Americans have 1 or more chronic diet-related health conditions, including overweight and obesity, heart disease, stroke, type 2 diabetes, hypertension, liver disease, certain types of cancer, dental caries, and/or metabolic syndrome. The Committee's review of current dietary intakes shows that the American dietary landscape has not changed appreciably over time. Across the lifespan, the typical diet Americans consume result in overconsumption of total

energy, saturated fats, sodium, added sugars, and for some consumers, alcoholic beverages. Intakes of fruits, vegetables, and whole grains are lower than current recommendations. After early childhood, dairy intakes decrease over the life course, except for a small uptick in older adults. Though the diets of women who are pregnant or lactating are higher in key food groups, they still fall below recommendations. These trends in food intake have ramifications for nutrient intakes and status throughout life. For Americans ages 1 year and older, dietary intake distributions, along with biological endpoints, clinical indicators, and prevalence of health conditions measured through validated surrogate markers, suggest that current underconsumption of vitamin D, calcium, dietary fiber, and potassium is of public health concern. Similarly, patterns of food group intakes across the life course contribute to higher than recommended intakes of food components of public health concern, such as added sugars, sodium, and saturated fat.

Each individual life stage holds unique implications for dietary intake and the risk of disease. In terms of life stages, while young infants appear to be generally well-nourished, some gaps exist. The risk of chronic disease begins early in life, with important health consequences for the fetus based on the dietary intake of the mother and subsequent feeding behaviors in infancy and early childhood. Early life nutritional exposures have emerged as an etiological risk factor associated with later-life chronic disease risk. Diet quality is higher in young children but tends to decline with age throughout childhood and into adolescence. The poor diets of adolescent females are quite concerning, both at the individual level and for the potential intergenerational impacts. The nutritional quality of the diet improves somewhat for older adults, though several specific nutrient concerns remain.

Within each life stage, opportunities exist to provide specific advice to individuals about food components that provide key nutrients at that life stage and for ways they can make healthy food choices. Opportunities also exist to think about healthy food intake patterns that should be carried forward into the next stage of life. This approach recognizes that although nutrient needs vary over the lifespan, early food preferences influence later food choices.

DIET AND HEALTH RELATIONSHIPS: PREGNANCY AND LACTATION

Pregnancy and lactation are a crucial period of life for mothers and infants. Although this time can be viewed as discreet stages in the lifespan with distinct nutritional needs, their outcomes are influenced by the woman's health status before pregnancy and they can, in turn,

influence her and her child's future health trajectory. These cross-cutting influences highlight the potential for long-term benefits to be gained from improving nutrition during pregnancy and lactation.

Pregnancy

The Committee examined relationships between aspects of maternal diet during pregnancy and infant perinatal outcomes. It also examined longer-term child outcomes, including neurodevelopment and the risk of food allergies and atopic allergic diseases. Evidence suggests that consuming foods within healthy dietary patterns before and/or during pregnancy may modestly reduce the risk of gestational diabetes, hypertensive disorders of pregnancy, and preterm birth. The components of these beneficial dietary patterns are the same as the dietary components associated with overall chronic disease risk reduction. The Committee's reviews also suggested that seafood intake before pregnancy as part of a healthy dietary pattern, particularly intake of fish high in omega-3 fatty acids, may be related to reduced risk of gestational diabetes and hypertensive disorders, and that consumption during pregnancy may be related to reduced risk of hypertensive disorders and preterm birth and better cognitive development and language and communication development in children. Therefore, the Committee concurred with existing recommendations that women who are pregnant should consume at least 8 and up to 12 ounces of a variety of seafood per week from choices that are lower in methylmercury and higher in omega-3 fatty acids. Consumption of common allergenic foods, such as eggs and cow milk, during pregnancy did not appear to be associated with an increased risk of food allergies, asthma, and related atopic disease outcomes in the child, nor is the restriction of these foods associated with a decreased risk of these conditions. Folic acid supplementation is associated with better maternal folate status during pregnancy. It also may reduce the risk of hypertensive disorders among women at high-risk or with a previous history of these disorders. Limited evidence suggests that omega-3 fatty acid supplementation during pregnancy can result in favorable cognitive development in children.

Lactation

Nutrient requirements during lactation are intended to support the nutritional status of the mother and to provide the additional amounts of energy and nutrients associated with milk synthesis and the secretion of nutrients into human milk. Due to a lack of evidence, the Committee was unable to draw conclusions regarding maternal dietary patterns or frequency of

eating during lactation and postpartum weight loss. However, the Committee's review suggested that seafood choices are important components of a healthy dietary pattern for women. Therefore, the Committee concurred with existing recommendations that women who are lactating should continue to consume seafood at the same amounts recommended during pregnancy. Because of insufficient evidence, the Committee was unable to draw conclusions about relationships between dietary patterns during lactation and infant developmental outcomes, between supplementation with omega-3 fatty acids and infant developmental outcomes, or between dietary patterns or consumption or avoidance of specific foods and food allergy, atopic dermatitis, allergic rhinitis or asthma. Moderate evidence did indicate that in women who are lactating, consuming folic acid supplements resulted in higher serum and red blood cell folate concentrations, but no difference in human milk folate concentrations, compared to non-supplement users. Despite the importance of the topics examined for the long-term health of the child, the available evidence for many questions was insufficient to form conclusion statements, highlighting the critical need for additional research.

DIET AND HEALTH RELATIONSHIPS: BIRTH TO AGE 24 MONTHS

Nutritional exposures during the first 1,000 days of life not only contribute to long-term health but also help shape taste preferences and food choices. Human milk or infant formula are the young infant's primary sustenance until about age 6 months, when the introduction of complementary foods and beverages (CFB) is recommended. The complementary feeding period typically continues to age 24 months as the child transitions fully to family foods. The Committee examined relationships between nutrition and health outcomes for several topics important to this life stage, including exclusive human milk and/or infant formula, CFB, and dietary supplementation with iron or vitamin D.

Exclusive Human Milk and/or Infant Formula Feeding

The Committee examined how various exposures to human milk and/or infant formula are linked to selected outcomes in offspring. The strongest evidence found was that ever being breastfed may reduce the risk of overweight or obesity, type 1 diabetes, and asthma, compared to never being breastfed. Evidence also suggested that a longer duration of any breastfeeding is associated with lower risk of type 1 diabetes and asthma, although the optimal duration of breastfeeding with respect to these outcomes is not well understood. Exclusivity of

breastfeeding also was found to be associated with a lower risk of type 1 diabetes. This evidence supports existing American Academy of Pediatrics and World Health Organization recommendations for breastfeeding in the United States and globally. The Committee also investigated associations between infant milk-feeding practices and nutrient status of the infant, including for iron, zinc, iodine, vitamin B₁₂, vitamin D, and fatty acids. For most of these questions, the evidence was scant or nonexistent, which prevented conclusions from being drawn. However, evidence does suggest that human milk feeding may be related to infant fatty acid status, depending on maternal diet. The Committee therefore supports recommendations for women who are lactating to consume food sources of long-chain polyunsaturated fatty acids, such as fish. Despite the importance of the topics examined for the long-term health of the child, the available evidence for many questions was insufficient to form conclusion statements, highlighting the critical need for additional research.

Complementary Foods and Beverages

The Committee examined the relationship of the timing of introduction of, and types of, CFB on the child's nutritional status, growth and body composition, neurocognitive development, bone health, and risk of food allergies and atopic diseases. The reviews confirmed existing guidelines that CFBs should not be introduced to infants before age 4 months, and the Committee found that introduction at age 4 to 5 months, as compared to 6 months, does not offer long-term advantages or disadvantages with respect to the outcomes reviewed. The reviews also support guidance to provide foods that are rich in iron and zinc during the second 6 months of life among breastfed infants, and the need to provide CFBs that contain adequate amounts of polyunsaturated fatty acids. The Committee's review indicated that introducing peanut and egg, in an age appropriate form, in the first year of life (after age 4 months) may reduce the risk of food allergy to these foods. The evidence for such protective effects is less clear for other types of foods, but the Committee found no evidence that avoiding such foods in the first year of life is beneficial with regard to preventing food allergies or other atopic diseases. Avoiding consumption of sugar-sweetened beverages (SSB) by children younger than age 2 years is important for several reasons. First, the energy contributed by such beverages leaves less "room" for energy from nutritious CFBs, leading to potential nutrient gaps. Second, limited evidence suggests that SSB consumption by infants and young children is related to subsequent risk of child overweight. Lastly, intake of SSB in early life may set the stage for greater intake of SSB later in life, with potentially adverse health consequences.

Dietary Supplements

The Committee's examination of evidence on the relationships of supplemental iron to growth, size, and body composition showed no positive effects, and possibly negative effects, on growth when iron supplements were given to breastfed infants younger than age 9 months, compared with infants not given iron or given a placebo. However, for iron-deficient children, providing sufficient iron (from foods, supplements, or fortified foods) is important for reducing iron-deficiency anemia and its consequences, including impaired neurobehavioral development. The Committee's review of vitamin D and bone health in infancy or early childhood showed little to no statistically significant differences in bone health indicators based on doses of vitamin D supplementation greater than 400 IU. Thus, at this time, the existing body of evidence does not provide a basis for recommending vitamin D supplementation above 400 IU per day during infancy (the current American Academy of Pediatrics recommendation).

USDA Food Patterns for Children Younger than Age 24 Months

Establishing healthy dietary patterns in early childhood is crucial to support immediate needs for growth and development and to promote lifelong health. In keeping with the Departments' mandate to include dietary recommendations for infants and toddlers in the *2020-2025 Dietary Guidelines for Americans*, the 2020 Committee explored the possibility of creating USDA Food Patterns for the 6 month to 24 month age range. Using the USDA Food Patterns for individuals ages 2 years and older as a starting point, the Committee modeled several scenarios that incorporated the potential contribution from human milk or infant formula and reflected the total energy needs at ages 6 to 12 months and 12 to 24 months. The Committee was not able to establish a recommended food pattern for infants ages 6 to 12 months but was able to develop potential combinations of CFB that come close to meeting all nutrient needs. The Committee encourages further work to explore options for meeting all nutrient recommendations during that age range. For toddlers ages 12 to 24 months who are fed neither human milk nor infant formula, the Committee was able to establish a recommended Food Pattern. The Pattern allows for a variety of nutrient-rich animal-source foods, including meat, poultry, seafood, eggs, and dairy products, as well as nuts and seeds, fruits, vegetables, and grain products, prepared in ways that are developmentally appropriate for this age. Key aspects to emphasize include choosing potassium-rich fruits and vegetables, prioritizing seafood, making whole grains the predominant type of grains offered, and choosing oils over solid fats. A Pattern also was

established for toddlers ages 12 to 24 months who are fed lacto-ovo vegetarian diets and neither human milk nor infant formula.

Because nutrient needs are high relative to energy requirements for children ages 6 to 24 months, and the amounts of CFB that can be consumed are relatively low, especially at the younger ages, it was challenging to develop these Food Patterns. The modeling exercises revealed the importance of prioritizing nutrient-rich food groups and making careful food choices within food groups. Like the USDA Food Patterns for those ages 2 years and older, a strength of the Patterns for younger children is that they provide examples of amounts of food groups and subgroups that can be consumed, but do not dictate specific types of foods. This gives families substantial flexibility to accommodate cultural preferences and cost considerations, and provides opportunities to introduce children to a wide variety of healthy foods that are important in shaping healthy dietary patterns.

DIET AND HEALTH RELATIONSHIPS: INDIVIDUALS AGES 2 YEARS AND OLDER

The Committee examined a number of topics related to dietary intakes by those ages 2 years and older, including the relationship between overall dietary patterns and 8 broad health outcomes and the relationships of specific aspects of “what” and “how” people eat to various health outcomes.

Dietary Patterns

People eat foods and drink beverages for many reasons, including, but certainly not limited to, nourishment. The quantities, proportions, variety or combination of different foods, drinks, and nutrients in diets and the frequency with which they are habitually consumed, constitute dietary patterns. The Committee found consistent evidence that certain dietary pattern components are associated with beneficial outcomes for all-cause mortality, CVD, overweight and obesity, type 2 diabetes, bone health, cancer (breast, colorectal, and lung), and neurocognitive health. Common characteristics of dietary patterns associated with positive health outcomes include higher intake of vegetables, fruits, legumes, whole grains, low- or non-fat dairy, lean meat and poultry, seafood, nuts, and unsaturated vegetable oils and low consumption of red and processed meats, sugar-sweetened foods and drinks, and refined grains. In addition, the Committee found that negative (detrimental) health outcomes were

associated with dietary patterns characterized by higher intake of red and processed meats, sugar-sweetened foods and beverages, and refined grains.

Collectively, these observations have major implications for recommending dietary patterns to the U.S. population. The healthy patterns the Committee examined in its review comprised various combinations of foods and were identified with many different names (e.g., DASH, Mediterranean). This suggests that a healthy diet that promotes optimum growth and development while minimizing risk factors for chronic diseases can be created and tailored to suit cost considerations and a wide variety of personal and cultural preferences.

Dietary Fats and Seafood

Fats are an important component of the American diet, contributing about one-third of the total calories consumed after infancy. The types and food sources of fats consumed have distinct metabolic and health effects. The Committee's review found that reducing saturated fat intake by replacing it with unsaturated fats, particularly polyunsaturated fat, lowers the incidence of CVD in adults. Replacing saturated with unsaturated fats in the diet also reduces serum total and low-density lipoprotein cholesterol in all adults and some children, especially boys. However, the benefits of replacing saturated fat with carbohydrates are less clear. In addition, because dietary cholesterol is found only in animal-source foods that are typically also sources of saturated fat, the independent effects of dietary cholesterol on CVD are difficult to assess. The recommended shift from saturated to unsaturated fats occurs best within the context of a healthy dietary pattern consisting of higher intakes of vegetables, fruits, legumes, whole grains, nuts and seeds, with some vegetable oils, low-fat dairy, lean meat and poultry, and fatty fish and lower intakes of red and processed meats, sugar-sweetened foods and drinks, and refined grains.

The Committee also conducted a review of relationships between seafood consumption during childhood and adolescence and risk of CVD and neurocognitive outcomes during the lifespan. Available evidence was insufficient to make a conclusion about seafood intakes during these life stages and risk of later CVD or neurocognitive outcomes. However, no adverse associations were reported.

Beverages

Beverages are broadly defined as any type of energy or non-energy-yielding drink. They contribute substantially to the dietary patterns of Americans in both favorable and adverse ways.

The Committee reviewed available data on the relationships between beverage consumption and achieving nutrient and food group recommendations. It also examined evidence on the relationship between beverage consumption and growth, size, body composition, and risk of overweight and obesity for children and adults. All beverages contribute to hydration needs, and many beverages, such as milk and 100% juice, can help people attain recommended nutrient intake goals. Other beverages, such as SSB, provide energy but contribute very little toward meeting nutrient and food group recommendations. Sweetened beverages, not including coffee and tea with added sugar, account for approximately one-third of total beverage consumption and contribute approximately 30 percent, 50 percent, and 60 percent of added sugars to the diet of young children, adolescents, and adults, respectively. Among the beverages examined, only SSB intake was associated with adiposity, and this was true for both children and adults. Because of their low nutrient to energy content ratio and the high prevalence of overweight and obesity in the population, it is important to continue encouraging only limited intake of SSB. Limited evidence suggests that low- or no-calorie sweetened beverage consumption is associated with reduced adiposity in adults. The evidence was insufficient to evaluate the effects of SSB compared to low- or no-calorie sweetened beverage in children.

Alcoholic Beverages

The majority of U.S. adults consume alcoholic beverages, though not consuming alcohol also is a preference for many Americans. Alcohol consumption and binge drinking are increasing in the United States, and excessive alcohol consumption is a leading behavioral risk factor for a variety of morbidity and mortality outcomes, social harms, and economic costs. Aside from energy, alcohol has little nutritional value. Binge drinking is consistently associated with increased risk compared to not binge drinking, and more frequent binge drinking is associated with increased risk compared to less binge drinking. Similarly, among those who drink, consuming higher average amounts of alcohol is associated with increased mortality risk compared to drinking lower average amounts. The Committee concurred with the recommendation of the *2015-2020 Dietary Guidelines for Americans* that those who do not drink should not begin to drink because they believe alcohol would make them healthier. Although alcohol can be consumed at low levels with relatively low risk, for those who choose to consume alcohol, evidence points to a general rule that drinking less is better for health than drinking more. Therefore, the focus should remain on reducing consumption among those who drink, particularly among those who drink in ways that increase the risk of harms. The Committee concluded that no evidence exists to relax current *Dietary Guidelines for Americans*

recommendations, and there is evidence to tighten them for men such that recommended limits for both men and women who drink would be 1 drink per day on days when alcohol is consumed. As with previous editions of the *Dietary Guidelines*, recommended limits pertain to days on which alcohol is consumed.

Added Sugars

As part of its focus on healthy dietary patterns that include nutrient-dense foods consumed at appropriate energy levels, the *2015-2020 Dietary Guidelines for Americans* recommended that Americans consume less than 10 percent of energy from added sugars. The 2020 Committee revisited this topic, with an examination of the relationship between added sugars consumption and risk of CVD. It also examined the impact of added sugars on achieving nutrient recommendations and considered how much added sugars could be accommodated in a healthy dietary pattern. For Americans ages 1 year and older, average consumption of added sugars represent 13 percent of daily energy intake, meaning that most Americans consume diets that exceed current *Dietary Guidelines* recommendations. Nearly 70 percent of added sugars intake comes from 5 food categories: sweetened beverages, desserts and sweet snacks, coffee and tea (with their additions), candy and sugars, and breakfast cereals and bars. Evidence suggests that adverse effects of added sugars, particularly from SSB, may contribute to unhealthy weight gain and obesity-related health outcomes. Reducing the amount of added sugars in the diet, either through changes in consumer behavior or in how food is produced and sold, is an achievable objective that could improve population health. After considering the scientific evidence for the potential health impacts of added sugars intake, along with findings from model-based estimations of energy available in the dietary pattern after meeting nutrient requirements, the Committee suggests that less than 6 percent of energy from added sugars is more consistent with a dietary pattern that is nutritionally adequate while avoiding excess energy intake from added sugars than is a pattern with less than 10 percent energy from added sugars.

Frequency of Eating

Eating is a behavior that provides humans with nutrients for growth, function, and body maintenance. Eating behaviors can support or weaken health and strongly influence the quality and length of life. A person's daily nutrient intake, and overall nutritional status, are determined by a complex interplay of 3 factors surrounding food choice: type, amount, and frequency. The

Committee examined national cross-sectional data to learn about the state of eating frequency in the United States and conducted a systematic review of studies to examine the relationships between eating frequency and growth, body size and composition, overweight and obesity, CVD, type 2 diabetes, and all-cause mortality. Although the Committee was unable to find adequate evidence to answer the questions on the relationship between eating frequency and health outcomes, its analysis of eating frequency in the United States revealed a wide variety of eating frequency patterns that varied by socioeconomic and demographic factors. Diet quality was higher when self-reported meal intake increased from 2 meals per day to 3, whereas late-night eating often contained food components recommended to be consumed in moderation. Despite the importance of this topic, the available evidence for many questions was insufficient to form conclusion statements, highlighting the critical need for additional research.

USDA Food Patterns for Individuals Ages 2 Years and Older

The USDA Food Patterns represent the types and amounts of foods groups and subgroups that aim to provide sufficient nutrients or food components to meet Dietary Reference Intakes and *Dietary Guidelines for Americans* recommendations. The Food Patterns are updated every 5 years and are presented to the Committee for its assessment of how well the Patterns align with the most current evidence on diet, health, and nutrient adequacy. The 3 current USDA Food Patterns are the Healthy U.S.-Style Pattern, the Healthy Vegetarian Pattern, and the Healthy Mediterranean-Style Pattern. Based on its review of the evidence, the Committee confirmed that these Food Patterns represent healthy dietary patterns in that they provide the majority of energy from plant-based foods, such as vegetables, fruits, legumes, whole grains, nuts and seeds; provide protein and fats from nutrient-rich food sources; and limit intakes of added sugars, solid fats, and sodium. The Committee noted that the types of foods that individuals should eat are remarkably consistent and that these Patterns can be applied across life stages, even taking into account specific nutrient needs at particular life stages. Because the risk of chronic disease begins early in life, taking steps to apply the best understanding of healthy dietary intakes in the earliest days of life can support lifelong chronic disease risk reduction and improved quality of life.

INTEGRATING THE EVIDENCE

The research the Committee reviewed supports a lifespan approach because it reinforces the importance of implementing dietary patterns that are most associated with nutrition adequacy, energy balance, and reduced risk of diet-related chronic health conditions. Achieving goals at each life stage not only supports health at that point in time, but also provides a sound basis for transitioning to the next life stage from a position of nutritional advantage. Integrating the evidence reviewed for the topics addressed in this report, the 2020 Committee concludes that every life stage provides an opportunity to make food choices that promote health and well-being, achieve and maintain appropriate weight status, and reduce risk of diet-related chronic disease.

In summarizing the findings of the dietary patterns reviews, the Committee also noted that a powerful aspect of using a dietary patterns approach is that it enables multiple adaptations to fit cultural, personal, and individual needs and preferences in food choices. Though the Committee did not review questions on topics such as the food environment, the overall food system, or strategies to support behavior change, it emphasized the importance of these topics and strongly encourages the Secretaries of USDA and HHS to examine these topics to support improved dietary intake among Americans. The Committee also identified several resource needs for the next Dietary Guidelines Advisory Committee (such as updates to the Dietary Reference Intakes for macronutrients, for birth to age 24 months, and for pregnancy and lactation), and pointed to the need for additional research on the birth to age 24 months life stage. Finally, the Committee suggested ways to incorporate its major findings into updates of the *2015-2020 Dietary Guidelines for Americans* overarching principles for achieving an overall healthy dietary pattern.

PART B. CHAPTER 1: INTRODUCTION

Since it was first published in 1980, the *Dietary Guidelines for Americans* has provided science-based advice to promote health, reduce risk of diet-related chronic diseases, and meet nutrient needs. Early editions focused on healthy members of the general public but, recognizing the growing prevalence of diet-related chronic diseases, such as heart disease, type 2 diabetes, obesity, and some forms of cancer, more recent editions have covered individuals with increased risk of chronic disease as well.

By law (Public Law 101-445, Title III, 7 U.S.C. 5301 et seq.) the *Dietary Guidelines for Americans* is published by the Federal government every 5 years. Since the 1985 edition, the U.S. Departments of Agriculture (USDA) and Health and Human Services (HHS) have fulfilled this requirement by establishing a Dietary Guidelines Advisory Committee of nationally recognized experts in the field of nutrition and health to review the scientific and medical knowledge current at the time. The 2020 Dietary Guidelines Advisory Committee was established for the single, time-limited task of examining the evidence on specific nutrition and public health topics and scientific questions and of providing independent, science-based advice and recommendations to the Federal government. This report presents the Committee's advice to the Secretaries of Agriculture and of Health and Human Services for use as USDA and HHS develop the *2020-2025 Dietary Guidelines for Americans*.

THE ROLE OF DIET IN HEALTH PROMOTION AND DISEASE PREVENTION

In the United States, more than half of all adults have one or more preventable chronic diseases, many of which are related to unhealthy dietary intakes. Unhealthy dietary intakes, tobacco use, and not enough physical activity, among other risk factors, are related to the leading causes of deaths in the United States.

Up-to-date nutrition advice in the Dietary Guidelines can help improve the health of Americans by encouraging food and beverage choices that are affordable, enjoyable, promote health, and help prevent chronic disease, taking into account that availability and access to nutritious food is important for all Americans, including those who are food insecure. Data from 2018 show that food insecurity and lack of access to affordable healthy food affect more than 37 million people, including 6 million children,

AN EVOLVING FOCUS FOR DIETARY GUIDANCE

The Federal government has provided dietary advice for the public for more than 100 years. The earliest focus of dietary guidance was on food groups in a healthy diet, food safety, food storage, and ensuring that people got enough vitamins and minerals to prevent deficiency diseases. As nutrition science evolved, researchers learned that diet also played a role in disease prevention and health promotion, and dietary guidance also evolved to reflect the rapidly growing knowledge base about the relationships between diet and health.

Since 1980, the Dietary Guidelines, and the science on which they have been based, have been remarkably consistent on the majority of components that make up a healthy diet, but they also have evolved in several substantial ways.

Expanding to New Populations

Historically, the *Dietary Guidelines for Americans* focused on nutrition and food-based recommendations for health promotion and disease prevention for individuals ages 2 years and older. Over the years, however, a growing body of evidence made it increasingly clear that proper nutrition during the earliest stages of life was critical to support healthy growth and development during childhood and help promote health and prevent chronic disease through adulthood, that is, across the lifespan.

In 2012, the USDA and HHS initiated a multi-phase project to generate information that could help the Departments develop dietary recommendations for infants and toddlers.¹ The first phase was completed in 2012-2013. In February 2014, Congress passed the Agricultural Act of 2014, which mandated that, beginning with the 2020-2025 edition, the *Dietary Guidelines for Americans* expand to include dietary guidance for infants and toddlers (from birth to age 24 months) as well as women who are pregnant. As a result, USDA and HHS adjusted the purpose, timeline, and scope of the project to reflect the addition of pregnant women. The project was tasked with conducting comprehensive systematic reviews on diet and health that are of public health importance for women who are pregnant and infants and toddlers from birth to 24 months of age.

The 2020 Committee has used the evidence generated from this project, in addition to conducting its own systematic reviews, as the foundation for its advice to USDA and HHS on components of a healthy diet for women who are pregnant or lactating and infants and toddlers from birth to age 24 months. USDA and HHS will use this evidence to include, for the first time

in recent editions, dietary guidance for these populations in the *2020-2025 Dietary Guidelines for Americans*.

Evolving from Nutrients to Dietary Patterns

Previous Dietary Guidelines Advisory Committees focused on evidence that looked at the relationships between individual nutrients, foods, and food groups and health outcomes. Although this science base continues to be substantial, researchers and public health experts began to consider a broader perspective. Science was acknowledging that just as nutrients are not consumed in isolation, foods and beverages are not consumed separately either. Rather, they are consumed in various combinations over time—a dietary pattern.

The evolving evidence showed that components of a dietary pattern could have interactive, synergistic, and potentially cumulative relationships, such that they could predict overall health status and disease risk more fully than could individual foods or nutrients. The 2010 Committee acknowledged the importance of dietary patterns and recommended additional research in this area. The 2015 Committee made dietary patterns a central focus of its evidence review and concluded that a healthy diet could be attained with many dietary patterns adaptable to personal and cultural preferences.

The 2020 Committee continues this same focus with an even deeper examination of the relationships between dietary patterns and specific health outcomes. Future Committees will continue to address the evolving public health concerns and nutrition needs of the U.S. public by examining the latest body of nutrition science.

FROM THE 2020 DIETARY GUIDELINES ADVISORY COMMITTEE REPORT TO THE *DIETARY GUIDELINES FOR AMERICANS*

A major goal of the 2020 Committee is to summarize and synthesize the evidence to support USDA and HHS in developing the *Dietary Guidelines for Americans*—the nutrition recommendations for reducing the risk of chronic disease while meeting nutrient requirements and promoting health for all Americans.

The U.S. Government uses the *Dietary Guidelines for Americans* as the basis of its food assistance programs, nutrition education efforts, and decisions about national health objectives. For example, the National School Lunch Program and the Elderly Nutrition Program incorporate the Dietary Guidelines in menu planning, the Special Supplemental Nutrition Program for

Women, Infants, and Children (WIC) applies the Dietary Guidelines in its program and educational materials, and the *Healthy People* objectives for the Nation include objectives based on the Dietary Guidelines.

The Dietary Guidelines also provides a critical framework for state and local health promotion and disease prevention initiatives. In addition, it provides foundational evidence-based nutrition guidance for use by individuals and those who serve them in public and private settings, including health professionals, public health and social service agencies, health care and educational institutions, researchers, and business. The Committee also hopes that the *2020-2025 Dietary Guidelines for Americans* will encourage the food industry to grow, manufacture, and sell foods and beverages that promote health and contribute to the U.S. population consuming the appropriate level of calories while meeting recommendations for food groups, nutrients, and other dietary components.

A GUIDE TO THE 2020 COMMITTEE'S REPORT

This Report contains several major sections. Part A provides an Executive Summary to the Report. Part B sets the stage for the Report through this Introduction. A second chapter in this section provides an integration of major findings.

Part C describes the methodology the Committee used to conduct its work and review the evidence on diet and health. Part D: Evidence on Diet and Health provides the results of the Committee's review of the evidence, presented in 14 chapters. Part E: Future Directions includes the Committee's recommendations on topics for possible consideration by the nutrition and public health community, including its research recommendations.

The Report concludes with a number of Appendices, including a glossary; a summary of the process used to collect public comments; biographical sketches of Committee members; a list of Subcommittee and Working Group members; and Acknowledgments.

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PART B. CHAPTER 2: INTEGRATING THE EVIDENCE

INTRODUCTION

This chapter provides an overview of the themes that emerged from the 2020 Dietary Guidance Advisory Committee's examination of the evidence pertaining to the questions addressed. This review and resulting recommendations are provided to the Secretaries of Agriculture (USDA) and of Health and Human Services (HHS) for the development of the *2020-2025 Dietary Guidelines for Americans*. The Committee's integrated review of the evidence to address the topics and questions in its charge strongly supports a life stage approach in the *2020-2025 Dietary Guidelines for Americans* that encompass dietary patterns that provide recommended nutrient intakes in a culturally acceptable manner.

This edition of the Committee's report is the first to extensively review the period from birth to age 24 months as well as to fully integrate evidence reviewed on pregnancy and lactation. This will enable USDA and HHS to take a full lifespan approach in its dietary recommendations.

A lifespan approach highlights the importance of implementing dietary patterns that are most associated with nutrition adequacy, energy balance, and reduced risk of diet-related chronic health conditions starting at the earliest life stages. This orientation further emphasizes the importance of adhering to these nutrient-dense dietary patterns throughout each subsequent life stage to meet nutritional needs appropriate to each life stage and to maintain health and well-being. Due to the high prevalence of obesity and obesity-related chronic diseases, this approach also emphasizes the consumption of foods within dietary patterns that reduce the risk of developing overweight and obesity and the co-morbid conditions associated with them, as well as the specific dietary patterns that are independently associated with the prevalence of chronic diseases, such as type 2 diabetes, cardiovascular disease (CVD), osteoporosis, hypertension and certain types of cancers. As opposed to a focus on weight status at one point in life, the recommended dietary intakes support healthy weight trajectories at each stage of life, including healthy growth and development from infancy through adolescence, appropriate weight gain during pregnancy, energy needs during pregnancy and lactation, weight stability during mid-life, and healthy body composition late in life. The recommended dietary intakes can help prevent excess weight gain at every life stage, and support health even apart from considerations of energy intake.

SETTING THE STAGE: THE PUBLIC HEALTH CHALLENGE

Part D. Chapter 1: Current Intakes of Foods, Beverages, and Nutrients of the Committee's report illustrates the public health challenge that arises from the high prevalence of chronic diseases that affect the American public, both children and adults, stemming from the dietary patterns that are currently consumed by Americans. Of substantial concern is the increasing prevalence of overweight and obesity beginning at younger ages that can be carried into later life stages and worsen in adulthood. These high rates are a driver for diet-related chronic disease risk and are strongly associated with adverse maternal and fetal outcomes, including pregnancy outcomes and initiation and duration of breastfeeding. More than 70 percent of American adults are overweight or obese and the prevalence of severe obesity has increased over the past two decades. The Committee included evidence from studies that included people with overweight and obesity to reflect this reality of our current population.

Additionally, statistics from the Centers for Disease Control and Prevention (CDC) indicate that 6 in 10 American adults have a chronic disease and 4 in 10 have 2 or more disease conditions.¹ Various factors contribute to the prevalence of chronic disease. Prominent among these are poor nutrition, lack of physical activity, and excessive alcohol use. The consequences of these chronic conditions affect all Americans, given their impact on quality of life, vulnerability to emerging infectious diseases, and the cost burden to society, particularly the health care system.

The 2010 Committee introduced the importance of dietary patterns in understanding the relationship between food choices and risk of chronic diseases. Their review was the catalyst for the Departments' Dietary Patterns Systematic Review Project,² which informed the 2015 Committee's review and their recommendation that thinking about diet and health relationships should evolve from food groups and nutrients to dietary patterns. The 2020 Committee has further expanded this approach, using a growing body of evidence. Data from What We Eat in America (WWEIA), the dietary intake component of the National Health and Nutrition Examination Survey (NHANES), were analyzed to determine the degree to which current American eating patterns are consistent with the *2015-2020 Dietary Guidelines for Americans* recommendations for reducing risk of chronic health conditions. The *2015-2020 Dietary Guidelines*³ recommended a healthful eating pattern for ages 2 years and older based on food groups to include as well as food groups and related food components to limit.

The Committee's comparison of current intakes to these recommendations across various energy levels and life stages indicated that, across all age groups ages 2 years and older, the intake of fruits and vegetables, dairy products, and whole grains is less than recommended and

the balance among protein sources (i.e., plant, seafood, meat, poultry, eggs, and dairy) does not meet recommendations for most groups. The underconsumption of these food groups leads to less than recommended intake of specific nutrients and increased disease risk.

Additionally, the food components of added sugars, solid fats, and sodium, which are highlighted as components to limit, are consumed in excess of recommendations. These components are derived primarily through consumption of sweetened beverages (including coffee and tea), desserts and sweet snacks, candy and sugars, breakfast cereals and bars, burgers and sandwiches, higher fat dairy products, food items that are predominantly fat (e.g., butter, lard, hydrogenated oils), and mixed dishes, such as pizza. Across all life stages, many of these foods also contribute to total grain consumption that is predominantly refined grains rather than whole grains. The overconsumption of foods high in added sugars, saturated fats, and sodium is associated with displacement of more nutritious foods from the eating pattern, excess intake of fats associated with CVD risk, and can result in excess energy consumption that results in weight gain. These and additional nutritional considerations exist at each life stage (see **Part D. Chapter 1**).

The *2015-2020 Dietary Guidelines for Americans* did not include recommendations specific to the ages of birth to 24 months to enable a similar comparison for this age group. However, recommendations developed by CDC and the American Academy of Pediatrics (AAP) are available and comparison of current intake patterns to these recommendations illustrates that improvements are needed (see **Part D. Chapter 5: Foods and Beverages Consumed During Infancy and Toddlerhood** and **Part D. Chapter 6: Nutrients from Supplements During Infancy and Toddlerhood**). Such gaps include lower than optimal rates of initiation and duration of breastfeeding, the introduction of complementary foods and beverages (CFB) too early, especially in formula-fed infants, and the feeding of foods and beverages that primarily contribute energy to the diet rather than needed nutrients (e.g., added sugars from sugar-sweetened beverages [SSB]). Overall, the diet quality is higher in young children and tends to decline with age.

Efforts are needed at every life stage to improve typical eating patterns and reinforce the recommended eating patterns for Americans to achieve adequate nutrient intakes, avoid excess energy intake, and lower risk of chronic diseases. The gaps between recommended and current eating patterns across all life stages after the first year of life illustrate certain trends in diet quality across the life stages but also suggest that improving diet quality at one stage could result in beneficial effects in all subsequent life stages, if a better diet quality is carried forward.

IMPORTANCE OF CONSIDERING LIFE STAGE IN THE DIETARY GUIDELINES FOR AMERICANS

The chapters of this report are organized by life stage, based on available evidence about the relationship of diet to health outcomes unique to pregnancy, lactation, birth through age 24 months, childhood and adolescence, and maturity, from young to older adults. However, this timeline is continuous and underlying core concepts that are important for health promotion and disease prevention hold throughout.

Achieving goals at each life stage not only supports health at that point in time, but also provides a sound basis for transitioning to the next life stage from a position of nutritional advantage. For example:

- Maternal nutritional status before and during pregnancy influences pregnancy outcomes, initiation and continuation of breastfeeding and human milk composition, as well as the health of the infant and the mother. The influence of dietary patterns that are associated with lower risk of overweight and obesity, diet-related chronic health conditions, and all-cause mortality begins in utero, with maternal nutrition playing a role in fetal development and continuing postpartum through lactation.
- Rapid weight gain in the first year of life is consistently related to risk of childhood obesity, and development of overweight and obesity in childhood, particularly adolescence, often tracks into adulthood and increases the risk and severity of associated co-morbidities over time.
- Bone mass, including peak bone mass, is influenced by dietary patterns in childhood and adolescence, and influences the time course to onset of osteoporosis.

More broadly, adopting dietary patterns that favor foods that provide energy with little or no recommended nutrients or fiber early in life may initiate subclinical biologic processes that lead to disease expression in later years and this can be exacerbated by high levels of use of such foods throughout the lifespan. Conversely, establishing and perpetuating dietary patterns that favor fruits, vegetables, whole grains, lean meats, fish, nuts and appropriate dairy foods, should minimize diet-related chronic disease risk. Figure B2.1 depicts the Committee's 2 major themes of considering *dietary patterns* within and across *life stages* to support health and wellness. This figure builds upon Figure D8.1 (see **Part D. Chapter 8: Dietary Patterns**), which highlights the connections between dietary patterns, their component parts, and health outcomes, by integrating the importance of these factors across the life stages.

Figure B2.1. Foods and beverages consumed at each life stage can affect health and wellness within and across life stages



This figure depicts the connection between dietary patterns and their component parts within and across life stages. Diet quality runs throughout each component of the pattern. As an individual adheres to a healthy dietary pattern, health and wellness improve. Conversely, less healthy patterns can negatively influence health and wellness. Social determinants of health and individual factors, such as food access, food security, and environmental settings, also play a role in influencing the diet quality of a dietary pattern. Achieving a healthy dietary pattern at each life stage not only supports health and wellness at that point in time, but also provides a sound basis for transitioning to the healthy dietary pattern most appropriate for the next life stage.

Most of the available evidence on dietary patterns that the Committee reviewed was derived from studies conducted in adults, with fewer studies among children. Nevertheless, the importance of sound nutrition in early life and across life stage transitions is evident and building acceptance and preferences for healthful dietary patterns at early ages is important. Infants younger than age 6 months depend on a single food, preferably human milk, and through their early years require that a parent, guardian or caregiver nourish them in a manner that promotes a healthy lifestyle, supporting physical growth and cognitive and behavioral development. Existing evidence supports that breastfeeding and appropriate early nourishment are important for reducing risk factors for diet-related chronic diseases (e.g., obesity, type 2 diabetes, and atopic conditions, such as asthma and food allergies) that may begin during childhood. An infant's first exposure to flavor is through amniotic fluid followed by human milk.⁴ The AAP

recommends that a healthful dietary pattern during infancy includes breastfeeding and that complementary foods be introduced no earlier than age 4 months and preferably not until about age 6 months. Children ages 6 to 12 months need foods that are even more nutrient-dense than typical family foods, particularly with respect to iron and zinc.

Additionally, exposure to allergenic complementary foods (e.g., peanuts and eggs) during the first year of life is associated with lower risk of food allergy and other allergic conditions that may be induced by food, such as atopic dermatitis. Introducing a variety of foods at this time that fit a pattern consistent with good health, prepared in a safe-for-age way, has the potential to favorably influence food preferences and health outcomes. The evidence reviewed is consistent with this approach. By age 2 years, children are consuming a variety of foods that other members of their family also are consuming.

Throughout childhood and adolescence, children are exposed to the dietary patterns available in their household, school, and community. During later childhood, as children spend more time out of the home in daycare or school, additional influences on their eating behaviors and new foods and eating occasions become a part of their routine. Adolescents acquire ever-greater independence in their food choices as they mature, but they also remain financially and emotionally linked to parents or guardians where healthy lifestyles, if reinforced, may help sustain such behaviors. The onset of puberty, along with menarche, growth spurts, and hormonal changes, is a crucial time to reinforce the need for physical activity and for meeting requirements for specific nutrients, such as iron, while maintaining a healthful eating pattern. Eventual transition to autonomy from parental influences and the formation of bonds with others often brings new culinary experiences and preferences, creating new challenges for establishing eating patterns consistent with health and longevity. When sub-optimal patterns persist or are followed consistently in adulthood, they are a significant contributor to the risk and prevalence of chronic diseases at this stage of life,

In older adults, changes in metabolism, due in part to age-related loss in skeletal muscle, and physical activity may require adjustments in eating frequency and portion sizes. They also may generate special needs for selected nutrients, such as protein and vitamin B₁₂, especially among women.

Throughout all the life stages, physical activity levels, sleep quality and duration, and other unique personal lifestyle factors may affect health and nutrient requirements. Knowledge of healthful dietary patterns and strategies to reinforce healthy behaviors should be promoted and encouraged in all settings of home life, work, and play (e.g., daycare, schools, workplace food service) and at all life stages to promote improved health outcomes. Such knowledge and

communications are needed in a manner that is relevant to the setting and the life stage. Integrating the evidence reviewed for the topics addressed in this report, the 2020 Committee concludes that every life stage provides an opportunity to make food choices that promote health and well-being and reduce risk of diet-related chronic disease.

DIETARY PATTERNS PROVIDE A FRAMEWORK FOR THE DIETARY GUIDELINES RECOMMENDATIONS WITHIN AND ACROSS LIFE STAGES

Evidence on the association between dietary patterns and reduced risk of diet-related chronic diseases has expanded substantially since the 2015 Committee's review of this topic,⁵ further supporting and strengthening the idea that dietary patterns are a useful foundation for the recommendations in the *2020-2025 Dietary Guidelines for Americans*. From this evidence base, it is clear that the most important features of dietary patterns are the quality and types of foods recommended for greater intake and the nature of the foods to be used in a more limited fashion. Dietary patterns can be characterized in various ways and can have different names and descriptions that are not always consistent or transparent with respect to the foods included or excluded from the pattern. Consequently, the Committee focused on the important features of dietary patterns to evaluate their relationship to health.

An advantage of the dietary pattern approach is the emphasis on foods that people can choose to eat rather than on specific nutrients for which food sources may be unfamiliar to many consumers. This approach to communication illustrates how food choices as a whole, rather than isolated food components, are important for healthful eating practices. It also provides the flexibility to tailor food combinations that are not just healthful, but also appealing to population subgroups and take into account cultural and culinary preferences. Dietary recommendations are only as good as the level of adherence to them, and respecting culture-based preferences with relevant eating patterns should help improve adherence and health outcomes.

Across several types of experimentally defined dietary patterns and types of studies, the Committee found strong evidence that, in adults, a core dietary pattern characterized as higher in vegetables, fruits, nuts, legumes, whole grains, lean meats and seafood, appropriate dairy foods, and unsaturated vegetable oils, while being lower in red and processed meats, saturated fatty acids and cholesterol, and beverages and foods with added sugars is associated with reduced risk of all-causes of mortality. For women who are pregnant, a similar healthful dietary pattern is associated with reduced risk of poor maternal-fetal outcomes.

In addition, the evidence reviewed indicates that these core elements of the dietary pattern are appropriate across life stages from childhood (ages 2 years and older) to older adulthood. In early childhood, elements of healthful dietary patterns that should be preserved as young children transition into later childhood include higher intakes of dairy, vegetables, and fruits, as well as lower intakes of added sugars, saturated fats, and sodium. In some studies in adults, where alcohol consumption was considered in the context of the healthy dietary pattern, lower intakes of alcohol were associated with more favorable outcomes compared to higher intakes. The healthfulness of this dietary pattern was affirmed across several other outcomes, including CVD, type 2 diabetes, risk of overweight and obesity, bone health, and several cancers. In addition, the recommendations and conclusions in chapters that evaluated evidence from studies on seafood, saturated fats, non-alcoholic and alcoholic beverages, and added sugars reinforce the nature of this dietary pattern. The core elements of this dietary pattern are consistent with the Key Recommendations outlined in the *2015-2020 Dietary Guidelines for Americans*.

The Committee considered studies from the United States and abroad, with broad representation across a number of populations and demographic groups. This suggests that no matter where in the world a healthful dietary pattern is consumed, using the foods unique to the culture and region, a consistent association occurs. One major implication of this consistency of findings is that individuals have the opportunity to use a range of foods to customize the dietary pattern to meet their own individual preferences and lifestyle needs. With this type of pattern, a variety of foods within the designated food groups can be included to fit preferences based on culture, regional food availability, sensory appeal, or other individual factors and context such as income. This pattern also embodies a range of flexibility in the balance of macronutrients that can be achieved while still meeting the overall goals of the dietary pattern. Ultimately, this pattern of eating, no matter the designated research label, is highly flexible and customizable.

The Committee also examined whether specific macronutrient-defined dietary patterns are associated with a reduced risk of diet-related chronic diseases. It did not examine evidence relating certain macronutrient profiles (i.e., ratios of carbohydrates, fats, and protein to energy intake) to weight loss or treatments for specific diseases or categories of disease. From this evaluation, the Committee found that characterizing a macronutrient profile alone is not sufficient to evaluate the predictive value of these dietary patterns to promote health and reduce risk of diet-related chronic diseases. To evaluate macronutrient-based dietary patterns, an understanding of the quality of the included food choices is needed to provide an assessment of health outcomes. A reductionist approach that focuses on a single macronutrient or food

component is not sufficient to identify its potential contributions to disease risk. These components must be put into the context of the total composition of the diet to be useful in making evidence-based recommendations. Several examples illustrate the importance of providing a bridge from studies on a single macronutrient or food component to relevant dietary patterns:

- For infants fed human milk, during the period of complementary feeding, patterns that include iron- and zinc-rich foods (e.g., meats, fortified cereals) and that also provide adequate protein and other minerals and vitamins, are essential to healthy growth and development.
- Added sugars is a food component to limit in the diet. However, the connection to a healthful dietary pattern is the evidence on limiting the foods in the diet that are the top sources of added sugars (e.g., sweetened beverages, including additions to coffee and tea, and sweet snacks and desserts).
- Few Americans achieve or exceed the Adequate Intake for dietary fiber, and a dietary pattern that encourages the intake of fiber-rich foods, including whole grains, fruits, vegetables, nuts and legumes, and other plant-based foods would be beneficial to increase fiber intakes.
- To reduce saturated fat intake, the dietary pattern should replace sources of saturated fat with sources of polyunsaturated fats by substituting certain animal-source foods, especially processed meats and certain high-fat dairy products, with sources of polyunsaturated fats, such as seafood, seeds, nuts, legumes, and appropriate vegetable oils. In addition, if meat and dairy foods are included in the dietary pattern, choosing lean cuts and lower fat dairy options is preferred.

Importantly, these examples work together to improve overall dietary quality and nutrient density. As illustrated by food pattern modeling (see **Part D. Chapter 12: Added Sugars**), replacing typical food choices that are high in added sugars and saturated fats with more nutrient-dense food choices improves the nutritional quality of the diet for adolescent girls and can help them achieve a healthy energy balance.

As noted above, a powerful aspect of using a dietary patterns approach for the *2020-2025 Dietary Guidelines for Americans* is that it enables multiple adaptations to fit cultural, personal and individual needs and preferences in food choices. Individuals may not have the tools to assess and align their dietary choices with the evidence-based patterns studied in the scientific literature but they can incorporate the core elements of a healthful pattern. The Committee used

food pattern modeling to illustrate these core elements of dietary patterns that are consistent with these recommendations. As done in previous editions of the *Dietary Guidelines for Americans*, the 2020-2025 edition can provide examples of ways to modify an individual's dietary pattern to meet different energy needs and food preferences. Such a tool can also illustrate where specific gaps in nutrient intake might occur within a pattern and how to address them.

The What We Eat in America data illustrate that the typical choices many Americans make among food groups are likely to result in excess energy intake and inadequate intake of foods that could improve the nutritional quality of their eating pattern. One of the most important steps many Americans can take to achieve a dietary pattern associated with health and lowered risk of chronic diseases is to identify the foods that provide energy with little or no recommended nutrients or fiber in their current eating pattern, reduce their intake of these items, and shift their food choices to more healthful foods and beverages to meet energy goals. Such an approach enables individuals to focus on strategies to improve their dietary pattern that are most relevant at their life stage and can be carried forward to the next stage.

CONTEXT FOR THE *DIETARY GUIDELINES FOR AMERICANS*

The *Dietary Guidelines for Americans* have informed Federal nutrition policies since they were first published in 1980. The 2020 Committee has added to the evidence supporting the recommendations that are in the current edition and expanded the evidence in new and emerging areas. The strength of the *Dietary Guidelines for Americans* is their basis in the most credible scientific evidence relating to the dietary factors associated with health and disease risk reduction.

Although Americans still need to make many dietary improvements, it is important to note that some healthful changes in food composition and intake have occurred. For example, the implementation of labeling requirements for *trans* fat and manufacturing changes have resulted in substantial reductions in *trans* fat intake. Consumers also have changed their behaviors, resulting in some modest reductions in the intake of added sugars and sugar sweetened beverages, and have made small changes to include more sources of whole grains into their diets. Many Americans also have greater knowledge of dietary factors that are associated with their health status. However, more effort is needed to encourage behavior change, consistent with individual food preferences, that results in healthier food choices and dietary patterns. The translation of the Committee's scientific review into the *Dietary Guidelines for Americans* should

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extend beyond topics incorporated within the specific questions addressed by the Committee and should include related dietary practices that remain of public health concern including those that have been reviewed by previous Committees. These include, but are not limited to, keeping the intake of *trans* fats low, reducing sodium intake, building and maintaining bone mass, preventing dental caries, maintaining hydration, making healthful snacking choices, and maintaining at least a moderate level of physical activity and appropriate sleep patterns in daily life.

The 2020 Committee was asked to address certain questions that consider not only what individuals eat but how they eat. For example, the Committee considered questions about the frequency of eating occasions, but found that evidence was insufficient to draw scientific conclusions on this aspect of eating patterns. However, this question is important to pursue in future cycles. Eating behaviors in the United States have changed markedly since the inception of the *Dietary Guidelines for Americans*. Snacking is more prevalent—almost universal—and recently, many Americans have chosen to follow varying temporal meal patterns (e.g., meal skipping, intermittent fasting) to achieve targeted health outcomes. Additionally, new technologies related to production, processing, and delivery of foods (e.g., increased convenience) influence food choices as well as eating frequency and portion sizes. Understanding how these factors influence health and well-being is important in making dietary recommendations.

Based on its experience, the Committee believes that continuing to examine the information contained in current, nationally representative surveillance data on food intake may provide insights into these areas to inform dietary guidelines. For the birth to age 24 months population, it is especially important to examine the “how” of feeding behaviors, not just the “what” aspect. Parents, guardians and caregivers exert the primary influence on dietary intake for the first few years of life. Dietary intakes of children resemble those of their parents, suggesting the importance of understanding more about this feeding environment to improve dietary intake during childhood. For children, their food intake data should be linked to their family’s intake data to track these patterns over time to better understand how best to support consumption of foods and food patterns linked to better health outcomes in children and improve population health. Although the Committee has provided some references to these areas in its report, further examination of this topic is important for future editions of the *Dietary Guidelines for Americans*.

The Committee’s review and discussion, as well as the public comments submitted during the Committee’s review period, reinforce the need to consider the *Dietary Guidelines for*

Americans in the context of the food environment and the overall food system. Such topics include areas such as sustainability of the food supply and food insecurity (i.e., the chronic or episodic limited access to safe, nutrient-dense foods to support health), which is experienced by many Americans. Improved understanding also is needed of approaches to encourage behavior change to better meet the recommendations for healthful eating. The *2015-2020 Dietary Guidelines for Americans* included the Social-Ecological Model to illustrate how various sectors have a role in improving eating and physical activity behaviors, and this information remains relevant for implementation of the *2020-2025 Dietary Guidelines for Americans* and can be adapted to understand how the structural barriers and facilitators of behavior related to food choice vary across the lifespan.

The Committee has not evaluated evidence related to these topics and they are not part of our conclusions and recommendations. However, the Committee encourages the Secretaries to identify mechanisms to examine the connections between the recommendations in the *Dietary Guidelines for Americans* and these aspects of the food system and food environment. Health status and a sustainable food system are both complex entities that are dependent on multiple interacting factors that are particularly important in low socioeconomic populations that are at high risk for nutrition sensitive health conditions. Understanding and mapping these factors can enable decision-making that supports the health and well-being of the U.S. population. Such an examination and development of relevant connections are important for making the types of system-oriented changes that will enable more Americans to take steps to improve their diet and lower their risk of overweight, obesity, and diet-related chronic diseases. Partnerships among Federal agencies can be a mechanism to initiate such a discussion. USDA and HHS have acted on many of the recommendations in the 2017 National Academies of Sciences, Engineering, and Medicine (NASEM) report *Redesigning the Process for Establishing the Dietary Guidelines*,⁶ and the Committee encourages further follow up on the recommendation from this report that, “The secretaries of USDA and HHS should commission research and evaluate strategies to develop and implement systems approaches into the DGA. The selected strategies should then begin to be used to integrate systems mapping and modeling into the DGA process.”

RESOURCES THAT ARE IMPORTANT FOR SCIENCE-BASED DIETARY GUIDELINES FOR AMERICANS

The expectation is that the *Dietary Guidelines for Americans* will be reviewed and released every 5 years so that these Guidelines reflect “the preponderance of scientific and medical knowledge that is current at the time the report is prepared”.⁷ To meet this standard and provide science-based advice to the Secretaries, the Committee based its conclusions and recommendations on robust, well-defined protocols for systematic reviews of peer-reviewed literature, analysis of data from NHANES, food composition data that can be used for modeling, and the Dietary Reference Intakes (DRIs) established by NASEM (**Part C. Methodology**). Because these elements are essential for establishing the scientific base for the *Dietary Guidelines for Americans*, the Committee has identified in **Part E. Future Directions**, the priority needs for future research. Research that informs the development of the guidelines must meet the standards that enable their inclusion in systematic reviews. The Committee benefitted from having the recent updates to the DRIs (e.g., calcium, vitamin D, sodium, and potassium), as well as access to the data on prevalence of disease and food intake from NHANES, food composition data from USDA, and the systematic reviews from the Pregnancy and Birth to 24 Months Project.⁸ This latter project was conducted after the *2015-2020 Dietary Guidelines for Americans* was released.

For the next cycle of the Dietary Guidelines process, the DRIs for macronutrients, for the ages of birth to 24 months, and for pregnancy and lactation need to be updated so that they provide current knowledge on nutrient requirements based on these life stages. The inclusion of pregnancy, lactation, and birth to age 24 months is an important addition to the *Dietary Guidelines for Americans*. However, the evidence to answer the questions in the birth to age 24 months population was often scarce or insufficient, pointing to the need for additional research in this area as well as the need for data related to human milk composition as a part of dietary patterns in this age group. The inclusion of all life stages in the *Dietary Guidelines for Americans* also highlights the importance of longitudinal data from intergenerational studies to examine sequential life-stage influences on dietary exposures and interactions with health outcomes.

CONSIDERATIONS FOR UPDATING THE GUIDELINES

The *2015-2020 Dietary Guidelines for Americans* identified 5 principles as overarching guidelines. This Committee's analysis reinforces the continuing relevance of these overarching guidelines and suggests modifications and expansion of these guidelines to reflect new evidence. These suggestions on the overarching guidelines are in addition to the specific conclusions and advice to USDA and HHS in each chapter.

Each of the overarching guidelines is listed below in bold and by number and is followed by suggestions for ways they can be updated. These suggestions reflect the Committee's recommendation that the *2020-2025 Dietary Guidelines for Americans* incorporate a recognition of the special nutrient concerns that exist at each life stage. Recognizing these concerns can help Americans improve their dietary practices at that life stage and potentially influence the practice of healthful food choices at the next life stage. Dietary patterns can incorporate foods consistent with cultural preferences and socioeconomic factors and should be structured around the identified core foods that meet nutrient needs, are associated with health, and reduce risk of chronic disease.

1. Follow a healthy eating pattern across the lifespan.

Suggested Update for 2020-2025: This guideline should introduce the importance of a healthful dietary pattern to support each life stage and of maintaining healthful dietary patterns across each life stage. For the *2020-2025 Dietary Guidelines for Americans*, the life stages include pregnancy and lactation, birth to age 24 months, children ages 2 years and older, adolescents, and adults. Concepts that the Committee recommends be included in the overarching guidelines:

- a. Initiate a healthful dietary pattern early in life for infants and young children.
- b. Follow a healthful dietary pattern appropriate for the nutritional needs of each life stage.
- c. Modify the dietary pattern over the lifespan to meet the nutritional needs of each life stage.

2. Focus on variety, nutrient density, and amount.

Suggested Update for 2020-2025: The Committee's review focused on the core elements of healthful dietary patterns, including the nutritional quality of food choices when incorporating variety. The review also focused on frequency of eating, as determinants of the amount of food consumed. Concepts that the Committee recommends be included in the overarching guidelines:

- a. Focus on nutritional quality of food choices, portion size and frequency of eating.
- b. For the earliest life stage, focus on breastfeeding and human milk for optimal nutrition and gradual introduction of a variety of nutrient-rich complementary foods during the second half of infancy.

3. Limit calories from added sugars and saturated fats and reduce sodium intake.

Suggested Update for 2020-2025: The Committee's review emphasized the importance of identifying the foods to limit or replace in the diet to limit intake of certain food components. For those who consume alcoholic beverages, current evidence indicates that lower intakes are better than higher intakes and some groups should not drink alcoholic beverages. Concepts that the committee recommends be included in the overarching guidelines:

- a. Limit foods and beverages that are sources of added sugars, saturated fats, alcohol, and salt to reduce intake of excess energy, solid fats, and sodium.
- b. Replace foods and beverages that are sources of added sugars, saturated fats, alcohol, and sodium with more healthful choices.
- c. In the first 2 years, foods such as sugar-sweetened beverages should be avoided.

4. Shift to healthier food and beverage choices.

Suggested Update for 2020-2025: The Committee's review found that this approach is linked to achieving the first guideline. In addition, this approach can help individuals understand that it is never too late to start making improvements in their dietary pattern. To use this approach effectively, an individual will need to recognize what food and beverage choices are most important to shift. Concepts that the Committee recommends be included in the overarching guidelines:

- a. Shift eating patterns to food and beverage choices that have a higher nutrient-to-energy ratio
- b. Shift to higher quality food and beverage choices at every age to achieve a more healthful dietary pattern.

5. Support healthy eating patterns for all.

Suggested Update for 2020-2025: The Committee's discussion emphasized the importance of supporting the ability of all Americans at all ages to have access to foods that enable a healthful dietary pattern. To support access to healthful foods and dietary patterns for all Americans, consideration needs to be given to the cultural, ethnic, and socioeconomic factors that influence food preferences and access to healthful foods and beverages, as well as the importance of tools and resources for individuals to plan and monitor their diets. Concepts that the Committee recommends be included in the overarching guidelines:

- a. Support access to healthful foods and beverages in all food environments for all Americans at all ages.
- b. Promote and support breastfeeding.
- c. Support healthful eating patterns for all ages where people live, learn, work, play, and gather.

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INTRODUCTION

The 2020 Dietary Guidelines Advisory Committee was established to review scientific evidence to be considered by the U.S. Departments of Agriculture (USDA) and Health and Human Services (HHS) as the Departments develop the next edition of the *Dietary Guidelines for Americans*. The Committee's work culminated in the development of this report, which summarizes the Committee's review of the evidence. More than 270,000 articles were screened to identify the nearly 1,500 primary research articles included in 33 original systematic reviews supported by USDA's Nutrition Evidence Systematic Review (NESR) team. In addition, 16 existing NESR systematic reviews were considered; more than 155 analyses of Federal data sets were conducted; and numerous food pattern modeling analyses that represented, for the first time the entire lifespan, were carried out.

The Methodology outlined in this chapter has many similarities to that described in the reports of the 2010 and 2015 Dietary Guidelines Advisory Committees, but has evolved with the fields of nutrition science and systematic review methods to ensure the processes remain state-of-the-art and rigorous. In 2016, Congress directed the Secretary of Agriculture to engage the National Academies of Sciences, Engineering, and Medicine to conduct a comprehensive study of the process used to establish the *Dietary Guidelines*. The study culminated in 2 reports, one on the process for selecting the Dietary Guidelines Advisory Committee¹ and another on the remaining aspects of the *Dietary Guidelines* development process.² As the Departments are committed to supporting a transparent, inclusive, and science-driven process, USDA and HHS added some new steps to the 2020 Committee process in response to recommendations from the National Academies' recommendations and stakeholder feedback, and also adopted updated best practices of reviewing nutrition science and developing guidance. These new steps are noted throughout this chapter. As an example, and as described below, before establishing the Committee, the Departments identified, and asked for public comments on, the topics and scientific questions to be examined in the Committee's review of the evidence.

IDENTIFYING THE TOPICS AND SCIENTIFIC QUESTIONS

For the first time, USDA and HHS identified topics and scientific questions to be examined by the 2020 Committee before establishing the Committee. The Departments added this step for a number of reasons, including to promote a deliberate and transparent process, identify

expertise needed on the Committee, help manage resources, and ensure the scientific review conducted by the Committee would address Federal nutrition policy and program needs.

About the Topic Identification Process

The process used to identify topics and scientific questions was led by the USDA Center for Nutrition Policy and Promotion and the HHS Office of Disease Prevention and Health Promotion, and vetted by the USDA Acting Deputy Under Secretary of Food, Nutrition, and Consumer Services and HHS Assistant Secretary for Health.

Other Federal agencies and the public also contributed to the process. Federal nutritionists, including scientists and programmatic experts from USDA, HHS, U.S. Department of Veterans Affairs, U.S. Environmental Protection Agency, and U.S. Agency for International Development, participated in developing proposed topics and supporting questions. The initial list was informed by the needs of Federal nutrition-related programs and initiatives. It also reflected the Agricultural Act of 2014, which mandated that starting with the 2020-2025 edition, the *Dietary Guidelines* provide guidance for women who are pregnant, as well as for infants and toddlers from birth to age 24 months.

Next, USDA and HHS posted the topics and supporting scientific questions for public comment. During the open public comment period of February 28, 2018, to March 30, 2018, the public sent in more than 12,000 comments through more than 6,000 submissions to Regulations.gov. (Form letters accounted for 74 percent of all comments.) Simultaneously, Federal agencies also provided comments on the topics and scientific questions.

In refining the topics and questions, USDA and HHS considered each public and agency comment in relation to the following 4 criteria:

- Relevance to creating the *Dietary Guidelines for Americans*,
- Importance to public health,
- Potential impact on Federal food and nutrition programs, and
- Desire to avoid duplication of Federal efforts.

USDA and HHS posted the revised topics and scientific questions reflecting public and Federal agency comments on September 6, 2018, with the call for public nominations to the Committee. The main topic areas remained the same, with changes reflecting priority issues.

The topics and questions reflect USDA's and HHS' decision that the 2020-2025 *Dietary Guidelines* will take a lifespan approach, spanning from birth through older adulthood. In addition, the topics and supporting scientific questions reflect a continued focus on what

individuals eat and drink *as a whole*, on average and over time, from birth into older adulthood to support development of guidance on dietary patterns that can help people prevent disease and stay healthy.

CHARTERING THE 2020 DIETARY GUIDELINES ADVISORY COMMITTEE

As required by the Federal Advisory Committee Act (FACA), a charter must be prepared and filed with Congress before a Federal advisory committee can meet or take any action. The charter provides the advisory committee's mission or charge, specific duties, and general operational characteristics. More information about Federal advisory committee charters and other information related to the FACA is available through the U.S. General Services Administration (GSA). The charter for the 2020 Dietary Guidelines Advisory Committee was filed with Congress on October 5, 2018.

The responsibility for chartering a Dietary Guidelines Advisory Committee every 5 years rotates between the USDA and HHS. USDA was responsible for chartering the 2020 Dietary Committee and serving as the administrative lead for the *2020-2025 Dietary Guidelines*.

Recent Dietary Guidelines Advisory Committees have had Co-executive Secretaries from both USDA and HHS. Legally required changes were made to the 2020 Committee's charter in response to an issue raised by the GSA Committee Management Secretariat, the Federal entity that is responsible for all matters relating to Federal advisory committees (5 U.S.C. App. 2 § 7(a)). Section 708 of the Consolidated Appropriations Act, 2018, a government-wide provision, prohibits the interagency financing of advisory committees. Additionally, the FACA requires that only 1 agency may be responsible for support services at any one time, even if the advisory committee reports to more than 1 agency (5 U.S.C. § App. 2 § 12(b)). For these reasons, the Co-executive Secretaries for the 2020 Dietary Guidelines Advisory Committee are from USDA. However, in accordance with the National Nutrition Monitoring and Related Research Act, USDA and HHS continue to work together to support development of the *Dietary Guidelines*, and the Committee's report is submitted to the Secretaries of USDA and HHS.

New to the charter for the 2020 Committee is reference to the Agricultural Act of 2014, which mandates the addition of dietary guidance for women who are pregnant and infants and toddlers from birth to age 24 months beginning with the 2020-2025 edition of the *Dietary Guidelines*. Additionally, the charter notes the new step the Departments took to identify the topics and scientific questions to be examined in the review of evidence by the Committee.

The charter also outlines the Committee's specific duties or charge. The Committee was re-established to examine the evidence on the topics and questions identified by the Departments, including new scientific evidence and current resource documents, and then develop a report to be submitted to the Secretaries of USDA and HHS that outlines its science-based recommendations and rationale, which will be considered by the Secretaries in developing the *2020-2025 Dietary Guidelines*.

COMMITTEE APPOINTMENT

The Committee was formed and governed under the FACA. The process to re-establish the Committee included a public call for nominations, review of nominations by programmatic staff and ethics officials, including screening for financial conflicts of interest, agreement on membership by USDA and HHS leadership, and appointment to the Committee.

Call for Nominations

On September 6, 2018, USDA and HHS issued a 30-day public request for nominations to the 2020 Committee (USDA Press Release No. 0173.18). Information on what was required in the nomination package was identified in the *Federal Register* notice (Docket ID: FNS-2018-0039), and the Departments outlined factors that would be considered in reviewing nominations:

- **Educational background**—Advanced degree in nutrition- or health-related field, including registered dietitians, nutrition scientists, physicians, and those with public health degrees.
- **Professional experience**—At least 10 years of experience as an academic, researcher, practitioner, or other health professional in a field related to 1 or more of the topics to be examined; consideration of leadership experience and participation on previous committees or panels.
- **Demonstrated scientific expertise**—Expertise related to 1 or more of the topics to be examined by the Committee, as demonstrated by number and quality of peer-reviewed publications and presentations.

Two additional factors were important to the formation of the Committee:

- Selection of members to ensure that the Committee was balanced fairly in points of view and type of expertise was an **obligation of the Federal Advisory Committee Act**.
- Including, to the extent possible, women, persons with disabilities, and representatives from different races and ethnicities, geographic areas, and institutions fulfilled **requirements regarding a balanced membership**.

The list of topics and supporting scientific questions were made available on DietaryGuidelines.gov so that the public could consider the areas of expertise needed when submitting nominations.

Approximately 180 complete nomination packages were received and reviewed by the Departments.

Review of Nominations

All complete nomination packages were reviewed by program staff from USDA Food, Nutrition, and Consumer Services (FNCS), the USDA Research, Education, and Economics (REE), and the HHS Office of the Assistant Secretary for Health (OASH). Nominees were then evaluated by the USDA Acting Deputy Under Secretaries of FNCS and REE, in consultation with the HHS Assistant Secretary for Health. Each nomination package was examined using the factors listed above. For the first time, USDA and HHS also outlined specific information needed in all nomination packages, including education, employment, peer-reviewed publications, presentations, blogs, funding sources, and other affiliations. These elements were reviewed and considered in establishing a Committee with broad representation and balance across many factors, including topic areas, points of view, education, and expertise.

The vetting process also included a background check by the USDA Office of the Secretary to determine whether any of the candidates had a financial, ethical, legal, and/or criminal conflict of interest that would prohibit them from serving on the Committee.

Each Committee member submitted a completed Confidential Financial Disclosure Report (known as the OGE Form 450) to the USDA Office of Ethics. By law, completed financial disclosure reports are not permitted to be shared publicly. Therefore, to be transparent about the information all Committee members were required to provide before appointment, a copy of Form 450 was posted on DietaryGuidelines.gov. Each completed Form 450 was reviewed by USDA ethics officials for financial conflicts of interest and compliance with Federal ethics rules. Officials from USDA's Office of Ethics ensured interests and affiliations of appointed Committee members complied with applicable conflict of interest statutes, regulations issued by the U.S.

Office of Government Ethics, supplemental agency requirements, and other applicable Federal ethics rules. Some potential candidates were not moved forward for additional consideration following this review.

Appointment to the Committee

The Secretaries of USDA and HHS reviewed formal nomination recommendations, then jointly agreed on individuals to appoint to serve on the Committee, and as Chair and Vice Chair. On February 21, 2019, USDA and HHS announced the appointment of 20 nationally recognized experts to serve on the 2020 Committee (USDA Press Release No. 0022.19). See ***Dietary Guidelines Advisory Committee Membership and Federal Support Staff***. The Committee included a mix of practitioners, epidemiologists, clinical scientists, trialists, and others from every region of the United States.

The Committee served without pay and worked under the regulations of the FACA. As with previous Dietary Guidelines Advisory Committees, members of the 2020 Committee were appointed as Special Government Employees (SGEs), selected based on recognized expertise or expert knowledge relevant to the Committee. As SGEs, the Committee members were subject to Federal employee ethics laws and regulations while serving in this role. Ethics training was provided to members of the 2020 Committee by USDA ethics officials before the first public meeting.

Management of Conflicts of Interest During Committee Selection

Managing potential conflicts of interest and minimizing bias throughout the *Dietary Guidelines* development process is critical. As described above, in preparation for selecting the 2020 Committee, all individuals under final consideration for appointment were required to submit a Confidential Financial Disclosure Report before being appointed. This was the first time this review was completed before appointing Committee members and as part of the selection process. Historically, this review was completed after the Committee was appointed. The completed report was reviewed by USDA ethics officials with extensive expertise in this area, as USDA was the administrative lead for the 2020 Committee. The USDA ethics official concluded that “none of the 20 committee members reported any entries on their OGE Form 450 that would prevent them from being appointed and providing the complete range of duties required of a Dietary Guidelines Advisory Committee member in full compliance with the Federal ethics rules applicable to Special Government Employees.”

The specific information USDA and HHS required in all nomination packages—education, employment, peer-reviewed publications, presentations, blogs, funding sources, and other affiliations—were reviewed and considered by the Departments when establishing the Committee to ensure the Committee had broad representation and balance across many considerations, including topic areas, points of view, education, and expertise. Additional information on managing conflicts of interest during the Committee’s service is provided below.

THE COMMITTEE PROCESS

Committee Meetings

To prepare for its work in conducting the scientific review for USDA and HHS, the 2020 Committee participated in administrative training on March 7, 2019, before its first meeting. This session was offered to the members by webinar and included an overview of the Committee’s charter, operations, and timeline; ethics training; a public affairs briefing; an overview of DietaryGuidelines.gov; and an introduction to the FACA. Slides and materials from the training were posted at DietaryGuidelines.gov for full public access.

All meetings of the full Committee were held publicly. The Committee initiated its work at its first meeting on March 28-29, 2019, and concluded its work when it submitted this report to the Departments. The Committee met 6 times to discuss its review of the scientific evidence and make plans for future Committee work. Meetings of the Committee were open for the public to attend through webcast. Meetings 1 through 4 also allowed for in-person attendance. Meeting 5 was originally scheduled for in-person attendance, but the format was changed to webcast in response to COVID-19. For the first time in the Dietary Guidelines process, the 6th and final meeting focused on the Committee’s draft report. This meeting was added to allow discussion and deliberation by the full Committee before submitting its report. This meeting was originally scheduled for May 11, 2020, but the date was changed to June 17, 2020, with an extension to the Committee’s timeline by 1 month in response to COVID-19. Also for the first time in the Dietary Guidelines process, the public had the opportunity to provide oral comments to the Committee twice, rather than once. Meetings 2 and 4 provided this opportunity for oral public comments to the Committee (see **Appendix F-2: Public Comments**). For the first time in 20 years, the Committee held a meeting outside the Washington, DC, metro area, in Houston, TX. The meeting dates and host cities were as follows:

- Meeting 1: March 28-29, 2019 (Washington, DC)

- Meeting 2: July 10-11, 2019 (Washington, DC)
- Meeting 3: October 24-25, 2019 (Washington, DC)
- Meeting 4: January 23-24, 2020 (Houston, TX)
- Meeting 5: March 12-13, 2020 (Webcast only)
- Draft Report Meeting: June 17, 2020 (Webcast only)

Meeting materials, including transcripts, recordings, and presentation slides were posted at DietaryGuidelines.gov following the meetings.

Public Comments

Throughout the Committee's review of the scientific literature and data, over almost 16 months, the public was encouraged to submit written comments to the Committee related to the topics and supporting scientific questions being examined. A general description of the types of comments received and the process used for collecting public comments is described in

Appendix F-2: Public Comments.

Committee Working Structures and Processes

The Committee's scientific review was directed by the topics and supporting questions, and focused on what individuals eat and drink as a pattern over time, from birth into older adulthood.

To accomplish its objectives, Committee members worked within Subcommittees. The 2020 Committee had 6 topic area Subcommittees (Pregnancy and Lactation, Birth to 24 Months, Dietary Patterns, Dietary Fats and Seafood, Beverages and Added Sugars, and Frequency of Eating) and 1 cross-cutting working group (Data Analysis and Food Pattern Modeling) that corresponded to the topics and questions specified by the Departments. The purpose of Subcommittees was to review evidence for the topics and questions specified by the Departments. Each Subcommittee conducted its work between Committee meetings and reported on its work to the full Committee at its meetings, all of which were held publicly.

The Subcommittees were made up of 4 to 8 Committee members, with 1 Committee member serving as the Subcommittee Chair. In addition, the Committee's Chair or Vice Chair served as a representative on each Subcommittee. The membership of each Subcommittee is listed in ***Appendix F-4: Membership of Dietary Guidelines Advisory Committee Subcommittees and Groups.***

Subcommittees typically met weekly by webinar and communicated regularly by e-mail. Subcommittees also met in person in association with the full Committee meetings. At meetings of the full Committee, which were all open to the public, each Subcommittee was responsible for presenting its evidence reviews and findings, describing the rationale for its draft conclusion statements and advice to the full Committee, responding to questions from the Committee, and making changes based on the discussion. The advice included in this report reflects the consensus of the entire Committee from deliberations in the public meetings.

The Committee members were supported by a Designated Federal Officer (DFO) from USDA's Center for Nutrition Policy and Promotion. The DFO led the administrative effort for the Committee's work and served as one of two Co-executive Secretaries. The second Co-executive Secretary, from USDA's Agricultural Research Service, was responsible for coordinating peer review of NESR systematic reviews (discussed below). Support staff for managing Committee operations consisted of more than 60 HHS and USDA staff, including invaluable administrative support from the HHS Office of Disease Prevention and Health Promotion, staff from USDA's Nutrition Evidence Systematic Review Team, and the Federal Data Analysis Team. Staff support are listed in ***Dietary Guidelines Advisory Committee Membership and Federal Support Staff***.

APPROACHES USED TO ANSWER QUESTIONS

The 2020 Committee used 3 approaches to examine the evidence: data analysis, food pattern modeling, and NESR systematic reviews. Each of these approaches has its own rigorous, protocol-driven methodology, and played a unique, complementary role in examining the science. For each approach, staff from USDA and HHS supported the Committee's review of the evidence. The type of information the Committee needed to answer each scientific question determined which approach they would use to review the evidence.

- **Data analysis:** A collection of analyses that uses national data sets to describe the current health and dietary intakes of Americans. These data help make the *Dietary Guidelines* practical, relevant, and achievable.
- **Food pattern modeling:** Analyses that illustrates how changes to the amounts or types of foods and beverages in a dietary pattern might affect meeting nutrient needs across the U.S. population.

- **NESR systematic review:** Research projects that answer questions on diet and health by searching for, evaluating, and synthesizing all relevant, peer-reviewed studies within a specified date range.

To answer each scientific question, the Committee developed a protocol—or a plan—that described how the Committee would apply the methodology of 1 of the 3 approaches to examine the evidence related to that specific question. A protocol was created before the Committee examined any evidence, and, for the first time, was posted online for the public to view to understand how a specific scientific question would be answered and to have the opportunity to submit public comments.

For all topics and questions, regardless of the path used to identify and evaluate the scientific evidence, the Committee developed conclusion statements. Each draft conclusion statement described the state of the science, based on the evidence considered, in order to answer the specific question examined. The Committee took the strengths and limitations of the evidence base into consideration when formulating conclusion statements. As described below, for questions answered using NESR systematic reviews, evidence was graded as Strong, Moderate, Limited, or Grade Not Assignable. The grading rubric used for questions answered using NESR systematic reviews does not apply to questions answered using data analysis or food pattern modeling. Therefore, data analysis and food pattern modeling conclusion statements were not graded.

As it finalized its work, the Committee looked across all of the conclusion statements to develop overarching advice for USDA and HHS to consider as the Departments develop the next edition of the *Dietary Guidelines*. More information about the methodologies for each of the 3 scientific approaches is provided below. Each of the chapters in **Part D. Evidence on Diet and Health** has a methodology section that provides additional details on how the approach was applied to answer each specific question.

Management of Conflicts of Interest During the Committee's Scientific Review

As noted above, members of the 2020 Committee were appointed as SGEs. SGEs are selected based on recognized expertise or expert knowledge relevant to the Committee. In contrast, none of the members was appointed as Representative Members, who are individuals appointed for the purpose of presenting the points of view of outside interest groups or stakeholders.

USDA ethics officials conducted an annual review of each Committee member's OGE Form 450 to manage potential conflicts of interest throughout the proceedings. As noted above, USDA ethics officials provided ethics training on 2 occasions to members of the 2020 Committee.

The approaches the Committee used to examine the evidence—systematic reviews, data analyses, and food pattern modeling—are rigorous, objective, and protocol-driven, and are designed to minimize bias. Protocols for each question being addressed were developed before examining any evidence and were presented at the Committee's meetings and posted to DietaryGuidelines.gov, providing transparency to the public throughout the Committee's deliberations.

The review of evidence was not based on any one member's expertise, nor were the final decisions for the scientific evaluation reached on an individual-by-individual basis. The Committee's review of the evidence was completed in a collaborative manner. The Committee came to its conclusions and advice to USDA and HHS together.

Data Analysis

Data analysis is 1 of the 3 scientific approaches that the 2020 Committee used to review the current scientific evidence. Data analysis provides insights into current eating habits of the U.S. population and diet-related chronic disease rates in the United States.

The 2020 Dietary Advisory Committee used data analysis to address topics and supporting scientific questions from USDA and HHS. These questions looked at:

- Current dietary patterns and beverage consumption
- Current intakes of food groups and nutrients
- Nutrients of public health concern
- Prevalence of nutrition-related chronic health conditions
- Relationships between eating habits and achieving nutrient and food group recommendations

The Committee, with support from Federal staff, developed a protocol for how each question would be answered using data analysis. The protocol, or plan, included an *analytic framework* that described the overall scope and the approach used to answer the question and an *analytic plan* that detailed the data and subsequent analysis to be considered. The *analytic results* of each analysis that were used to answer a data analysis question are summarized in the report.

The Committee examined a collection of analyses to inform their deliberations. Key nationally representative, Federal data sources included the National Health and Nutrition Examination Survey (NHANES), the National Health Interview Survey (NHIS), and Surveillance, Epidemiology and End Results (SEER). Each of these data sources is described below:

National Health and Nutrition Examination Survey

NHANES is a Federal program of studies designed to assess the health and nutritional status of children and adults in the United States. This nationally representative survey includes both interviews and physical examinations that measure dietary intakes and diet-related chronic disease rates in the U.S. population. It is managed by the National Center for Health Statistics (NCHS) of the Centers for Disease Control and Prevention (CDC).

NHANES data are collected continuously and released in 2-year cycles. The most recently available data are from NHANES 2015-2016. In many cases, analysis included data from 2 cycles of NHANES (2013-2014 and 2015-2016) to ensure an appropriate sample size for subgroup analysis. Dietary intakes of infants and toddlers ages 6 to 12 and 12 to 24 months included NHANES 2007-2016 to achieve a sample size stratified by infants receiving human milk and complementary foods and beverages (CFB) or infants receiving any infant formula and CFB. Sample weights for these analyses were recalibrated.

What We Eat in America, NHANES

The dietary component of NHANES, called What We Eat In America (WWEIA)³ is the only nationally representative survey of total food and beverage consumption that captures intakes across life stages on a population level in the United States. The dietary data are collected using the gold standard for dietary assessment: a multiple pass, 24-hour dietary recall.

USDA developed the Automated Multiple-Pass Method 24-hour dietary recall (AMPM), which is conducted by a trained dietary interviewer in the WWEIA portion of NHANES. The AMPM is designed to systematically help participants report their food and beverage intake in great detail while minimizing respondent burden. A standard set of measuring guides is used to help participants report the volume and dimensions of the food items consumed. The AMPM is a research-based, multiple-pass approach designed to enhance complete and accurate food recall using 5 steps that are applied consistently in data collection.

The 5 steps are:

1. Quick List - Participant recalls all foods and beverages consumed the day before the interview (midnight to midnight).

2. Forgotten Foods - Participant is asked about consumption of foods commonly forgotten during the Quick List step.
3. Time and Occasion - Time and eating occasion are collected for each food.
4. Detail Cycle - For each food, a detailed description, amount eaten, and additions to the food are collected. Eating occasions and times between eating occasions are reviewed to elicit forgotten foods.
5. Final Probe – Information on additional foods not remembered earlier is collected.

Each step is based on a strategy to enhance dietary recall. The initial recall is self-defined by the participant and the subsequent steps help the participant to associate eating occasions with the day's events. The interviewer asks about frequently forgotten foods and assists in the placement of foods with eating occasions. The repetition provides opportunities for adding detail to each reported food or beverage.

Using NHANES Data to Understand Eating Habits of the U.S. Population

The strengths and challenges of self-report dietary assessment are well-recognized. Self-report dietary data are valuable for providing important information at a population level regarding intakes (and sources) of foods and beverages and to describe dietary patterns and assess diet quality. Established statistical approaches accounting for day-to-day variability and energy adjustment are used to help reduce potential bias in describing dietary intakes at a population level.

The dietary data collected during the AMPM is linked to databases that are used to identify the nutrient values and food group contribution of foods reported by participants. The following databases were integrated into the analyses of dietary data that provides comprehensive insight into eating habits of the U.S. population.

- Nutrients: USDA Food and Nutrient Database for Dietary Studies (FNDDS) is a database that provides the nutrient values for foods and beverages. Data are available on energy and 64 nutrients for nearly 9,000 foods and beverages. FNDDS allowed the Committee to examine nutrient intakes from foods and beverages reported by Americans.
- Food-guidance Based Food Groups: USDA Food Pattern Equivalents Database (FPED) converts foods and beverages in the FNDDS to 37 USDA Food Patterns components. The FPED allowed the Committee to examine food group intakes (e.g., Whole Fruit, Total Vegetables) from foods and beverages reported by participants.

Using NHANES Data to Assess Physical and Biochemical Indicators of Health

NHANES physical exams and laboratory data are useful components of the broader data used to understand the U.S. population's health. Examples of physical exam measurements include measured height, weight, and blood pressure. The laboratory tests allow for ongoing assessment of U.S. population status of blood and urine biochemical indicators of nutrients consumed and other markers with public health relevance.

National Health Interview Survey

NHIS is a survey on health conducted using in-person, confidential household interviews. Like NHANES, this survey is managed by the NCHS within CDC. It provides data on the U.S. civilian noninstitutionalized population for analyzing health trends and tracking progress toward achieving national health objectives.

These data, continuously collected throughout the year, are used to characterize those with various health conditions.

Surveillance, Epidemiology, and End Results

The Surveillance, Epidemiology, and End Results (SEER) Program is the authoritative source for cancer statistics in the U.S. population. SEER is supported by the Surveillance Research Program (SRP) in the National Cancer Institute's Division of Cancer Control and Population Sciences (DCCPS).

SEER collects and publishes cancer incidence and survival data from population-based cancer registries. These registries routinely collect data on patient demographics, primary tumor site, tumor morphology and stage at diagnosis, first course of treatment, and follow-up for survival status. These data are collected on every cancer case reported from 19 U.S. geographic areas.

The geographic area of data collection is representative of the demographics of the entire U.S. population. This broad coverage allows SEER to account for diverse populations throughout the United States. SEER data can be used to define the rates of diet-related cancers in the U.S. population.

Data Analysis Team

The data analysis team supported the work of the Committee to answer specific topics and questions. The team, which comprised Federal scientists with advanced degrees in nutrition, statistics, and epidemiology, included scientists from the following Departments and agencies:

- United States Department of Agriculture
 - Center for Nutrition Policy and Promotion; Food and Nutrition Service; Food, Nutrition, and Consumer Services
 - Agricultural Research Service; Research, Education, and Economics
- United States Department of Health and Human Services
 - Office of Disease Prevention and Health Promotion; Office of the Assistant Secretary for Health
 - National Cancer Institute; National Institutes of Health
 - National Center for Health Statistics; Centers for Disease Control and Prevention

Food Pattern Modeling

Food pattern modeling is the second of 3 scientific approaches that the Committee used in its review of evidence. The food pattern modeling analysis approach helps explain how changes to food-based dietary recommendations could potentially affect Americans' ability to meet their nutrient needs.

Food pattern modeling is a way to evaluate the impact of specific changes in amounts or types of foods and beverages in a dietary pattern on meeting food group recommendations and nutrient needs. These food pattern modeling tests inform USDA's development of relevant dietary patterns for the American population that reflect health-promoting patterns identified in systematic reviews and meet nutrient recommendations.

Food pattern modeling was used to answer a portion of the topics and supporting scientific questions the 2020 Committee examined. These questions looked at:

- The ability to meet nutrient recommendations for each stage of life through variations in USDA Food Patterns.
- The relationship between added sugars consumption and achieving nutrient and food group recommendations.

The Committee, with support from Federal staff, determined a protocol that included an *analytic framework* that described the overall scope and approach used to answer the question and an *analytic plan* that detailed the data and subsequent analysis to be conducted.

Food Pattern Modeling Process

Food pattern modeling is possible through the modification of food groups and nutrient profiles of each food group. The current USDA Food Patterns provide amounts of 5 major food groups and subgroups, including:

- Fruits
- Vegetables: Dark-green, red and orange, beans and peas, starchy, and other
- Dairy, including calcium-fortified soy beverages
- Grains: Whole grains and refined grains
- Protein Foods: Meats, poultry, and eggs; seafood; nuts, seeds; and soy products

Food groups used in food pattern modeling have a nutrient profile based on a weighted average of nutrient-dense forms of foods. The most nutrient-dense forms of foods are those prepared with the lowest amounts of sodium, saturated fat, and added sugars. The weighted average calculation considers a range of American food choices, but in nutrient-dense forms, and results in a food pattern that can be adapted to fit an individual's preferences.

The food group structure and corresponding nutrient profiles of the food patterns allowed the Committee to use food pattern modeling tests to see how proposed changes to food pattern elements might affect food group amounts and nutrient adequacy across the lifespan. The nutrient content for patterns at 12 energy levels were compared to the Dietary Reference Intakes for more than 30 nutrients.

Four elements can be modified in a food pattern modeling test:

1. Food group amounts and amounts of added sugars, oils, and saturated fat in the patterns
2. Inclusion or exclusion of certain foods or food groups
3. Nutrient goals and constraints
4. Nutrient profiles for a food group or subgroup

The results of food pattern modeling tests are interpreted under the premise of 2 key assumptions. First, modeling tests are based on nutrient profiles of nutrient-dense foods in the U.S. food supply and U.S. population-based dietary data. Population-based patterns articulate

the evidence on the relationships between diet and health in ways that might be adopted by the American public. Second, modeling tests assume population-wide compliance with all food intake recommendations. As with other types of modeling, food pattern modeling is hypothetical and does not predict the behaviors of individuals.

Food Pattern Modeling Team

The food pattern modeling team supported the work of the Committee to answer specific topics and questions. It was comprised of nutrition scientists and data analysts on the Nutrition and Economic Analysis Team at the USDA Center for Nutrition Policy and Promotion within the Food and Nutrition Service.

NESR Systematic Review Process

Systematic review was the third approach that the Committee used to review scientific evidence. Systematic reviews are research projects that answer important public health questions by evaluating scientific evidence on topics relevant to Federal policy and programs. The staff at USDA's NESR specializes in conducting food- and nutrition-related systematic reviews. The systematic review process involves a series of steps, described in the following sections.

Develop a Systematic Review Protocol

For each systematic review question, the Committee developed a systematic review protocol. A systematic review protocol is a plan for how a specific systematic review will be conducted, and includes:

- Analytic framework
- Literature search and screening plan
 - Inclusion and exclusion criteria
 - Electronic databases and search terms
- Literature search and screening results
 - Flow chart of literature search and screening results
 - List of included articles
 - List of excluded articles, with rationale

The Committee established their protocols before any evidence was reviewed and synthesized. This allowed the Committee to establish protocols that would capture the most appropriate, relevant, and direct body of evidence to answer each question. All systematic review protocols were posted online to provide transparency and an opportunity for the public to provide comments. Protocols also were presented and discussed at meetings of the full Committee. Any revisions to protocols that occurred during the course of the Committee's work were documented, posted online, and presented at meetings. The literature search plan (i.e., search terms) and screening results (i.e., flow chart, included and excluded articles) were added to the protocols as they were finalized.

A description of NESR's methodology for developing an analytic framework is below. NESR's methodology for developing inclusion and exclusion criteria and the search strategy, as well as processes related to screening and selecting studies for inclusion in a review, is described, below, in "Search for, Screen, and Select Literature."

Develop an Analytic Framework

The Committee developed an analytic framework for each systematic review question. An analytic framework defines the core elements of the systematic review question, includes definitions for key terms, identifies key confounders and other factors that could affect the relationships examined, and helps ensure that important contributing elements in the causal chain will be examined and evaluated. The analytic framework serves as the foundation for the rest of the systematic review process, and informs the inclusion/exclusion criteria and literature search strategy, data extraction and risk of bias assessments, and the strategy for synthesizing the evidence to develop and grade conclusion statements.

A standard framework, called the PICO framework, was used to define core elements of each systematic review question. The elements of the PICO framework are the Population (for both the intervention/exposure and for the outcome), Intervention and/or exposure, Comparator (i.e., the alternative being compared to the intervention or exposure), and Outcomes. The key terms defined in the Committee's analytic framework were based, when possible, on definitions already established by U.S. Federal government entities, or other leading national and international entities, as appropriate. Committee members identified key confounders and other factors to be considered (i.e., mediators, moderators, covariates) based on their knowledge of the literature and experience as subject matter experts).⁴ Key confounders are considered

during review and evaluation of the evidence, particularly during risk of bias assessment (see “Assess Risk of Bias,” below) and evidence synthesis.

Search for, Screen, and Select Literature

Systematic searching, screening, and selecting the scientific literature is a process through which NESR sought to identify the most complete and relevant body of evidence to answer a systematic review question. The process started with defining inclusion and exclusion criteria a priori (i.e., up front), followed by developing and implementing literature search strategies, and finally screening and selecting search results. The entire process was documented, including a complete list of articles that met criteria for inclusion in the systematic review, and a list of excluded articles, with the rationale for exclusion.

Define Inclusion and Exclusion Criteria

The Committee established inclusion and exclusion criteria to provide an objective, consistent, and transparent framework for determining which articles to include in each systematic review. These criteria were developed before any studies were reviewed to guide selection of the most relevant and appropriate body of evidence for each systematic review question. Additionally, these criteria were framed to increase the utility of the systematic review to inform U.S. Federal policy and programs. To minimize bias, revisions to the criteria after studies had been reviewed were discouraged. Any revisions to the criteria that occurred were documented with dates and rationales.

NESR analysts worked jointly with the Committee members to establish inclusion and exclusion criteria that were tailored to the systematic review question addressed. Considering the perspectives of both NESR and the Committee members helped ensure that the evidence reviewed was:

- Applicable to the U.S. population, including those who are healthy and/or those at risk of chronic disease,
- Relevant to public health nutrition policies and programs, and
- Rigorous from a scientific perspective.

Criteria were established for a number of study characteristics, such as:

- Study design
- Language
- Publication status

- Health status of study subjects
- Publication date
- Country in which the study was conducted
- Subject age
- Independent and dependent variables
- Study duration
- Group size

Although criteria were tailored to the unique characteristics of each systematic review question being addressed, NESR also applied several standard criteria. These standard criteria were designed to align with common practice within the field of systematic review, or to reflect that NESR reviews are used to inform U.S. Federal policy and programs. If there was a strong rationale for why a question-specific deviation from standard criteria was appropriate, the change was discussed between the Committee, NESR, and project leadership, and the justification was documented in the protocol. Following is a description of NESR's standard criteria, and considerations made by the Committee when establishing inclusion and exclusion criteria.

Study Design

NESR systematic reviews are used to inform Federal policies and programs, and thus include study designs that offer the strongest evidence to establish a relationship (e.g., randomized controlled trials [RCTs] and non-RCTs and prospective cohort studies [PCs]). NESR recognizes RCTs as a strong study design, and NESR's grading process ensures that the strengths and weaknesses of each design, as well as each grading element, are thoroughly considered.

NESR systematic reviews typically include RCTs (e.g., individual, cluster, and crossover trials), non-RCTs, Mendelian randomization studies, PCs, retrospective cohort studies, and nested case-control studies. They generally exclude uncontrolled trials, cross-sectional studies, and case-control studies. The decision whether or not to include study designs other than those described above, was determined by the Committee based on what was most appropriate for each systematic review question.

- Relying on RCTs is important, but it is also important to consider that rigorously conducted observational studies (particularly PCs) can provide important evidence that complements that of RCTs.² For example, including observational studies allowed for

examination of diet as it occurs in daily life, or for the study of certain population groups (e.g., infants, toddlers, children, women who are pregnant, the elderly) or long-term or rare outcomes (e.g., childhood leukemia) that are not typically examined in RCTs.⁵

- When determining and describing a study's design, NESR analysts considered the data relevant to the systematic review question. In some cases, the study design for a particular analysis or publication differed from the design of the original study. For example, data from a PCS may have been analyzed cross-sectionally, and therefore, was excluded if cross-sectional study designs were not part of the inclusion criteria.
- In addition, the NESR systematic review process included a number of steps in which study design was considered, ensuring that the conclusions drawn and the strength of evidence grades assigned reflected a thorough assessment and consideration of the strengths and limitations of various study designs.

Language

NESR included studies published in English, and excluded studies published in languages other than English. NESR does not have the ability to translate manuscripts. It is rare for NESR literature searches to identify studies published in languages other than English, as the searches are designed to identify evidence that pertains to studies that are relevant to U.S. national policies and programs.

Publication Status

NESR included peer-reviewed studies, and excluded grey and/or unpublished literature. Relying on peer-reviewed studies supported the quality and objectivity of information used to inform Federal programs and policies. Issues related to publication bias were addressed in the NESR systematic review process during synthesis and grading of the strength of evidence. In addition, the search and screening process was conducted thoroughly to ensure that articles from predatory journals, or those journals without adequate peer review processes, and retracted articles were not included.^{6,7}

Health Status of Study Participants

To reflect the U.S. population as a whole, the evidence base that informs the *Dietary Guidelines* must be comprised of studies conducted with people who are representative of the general public. This includes healthy people and those with a range of diet-related chronic diseases, including obesity and type 2 diabetes. Studies focused solely on people who already

have a diet-related chronic disease and are being treated for that disease were excluded from NESR reviews. This was done because nutrition in these cases becomes part of broader *clinical practice* guidance—that is, medical guidance that physicians and allied health professionals use to develop a specialized disease treatment or management plan to meet each individual patient’s needs and to care for individuals with specific diseases and conditions.

Thus, NESR included studies that comprise participants who are representative of the general public, including studies done in participants who are healthy and/or who are at risk for a chronic disease. NESR also included studies that enroll some subjects with a disease, including those with obesity, or with the health outcome of interest (intermediate or health outcomes). NESR excluded studies that exclusively enrolled participants with a disease or the health outcome of interest (i.e., studies designed to medically treat individuals who already have the disease outcome of interest). In systematic reviews that examined the relationship between diet and risk of obesity, for example, studies that enrolled some participants classified as having obesity, as well as people at risk of obesity and healthy people were included; studies that *exclusively* enrolled individuals with obesity, like those that aim to treat individuals with obesity, were excluded.

Publication Date

All NESR reviews require that criteria for publication date be established. The Committee determined the appropriate date range criteria for each question. When establishing publication date range criteria, the Committee considered a number of factors, including whether:

- The question built on evidence reviewed by a previous Dietary Guidelines Advisory Committee or evaluated as part of an existing NESR systematic review,
- Research on the topic was emerging, and therefore, little research existed before a certain date, and
- A new analytical technique had recently been established in the field, making previous research findings less valid or reliable.

Country

NESR relied on the Human Development Index (HDI), which ranks and categorizes countries based on a summary measure of average achievement in key dimensions of human development.⁸ NESR’s standard criteria included studies conducted in countries ranked as high or very high on the HDI, and excluded studies conducted in countries ranked as medium or low. NESR applied the HDI classification based on the year the study intervention occurred or data

were collected. If the study did not report the year in which the intervention occurred or data were collected, the HDI classification for the year of publication was applied. HDI values are available from 1980, and then from 1990 to present. If a study was conducted before 1990, the HDI classification from 1990 was applied. When a country was not included in the HDI ranking, the current country classification from the World Bank was used instead.⁹

Study Duration

For some NESR reviews, the Committee established criteria for study duration. NESR did not have standard criteria for study duration that was uniformly applied to all reviews because the appropriate study duration is dependent on the intervention or exposure, outcomes, and populations of interest. Therefore, the Committee determined whether or not study duration criteria was necessary for a particular question, and then tailored the criteria to that question. For example, when establishing criteria for study duration, the Committee considered both the appropriate duration for the intervention or exposure of interest, as well as the appropriate duration for the outcomes of interest to occur. For questions where study duration criteria was established, the rationale for the criteria selected is documented in the chapter's methodology section.

Risk of Bias

NESR included all studies regardless of their risks of bias. The Committee considered risk of bias when synthesizing and grading the strength of evidence.

Developing and Implementing the Literature Search Strategy

Once the inclusion and exclusion criteria were set, the NESR librarian used the analytic framework and inclusion and exclusion criteria to guide development of a comprehensive literature search strategy. The literature search strategy included selecting and using the appropriate bibliographic databases (e.g., PubMed/MEDLINE, Cochrane, Embase, CINAHL), identifying search terms appropriate for the databases being searched, and employing search refinements, such as search filters. The librarian worked in collaboration with the NESR staff and Committee members to construct a preliminary search strategy using PubMed operators and search terms. This was used to conduct a test search, preview the results, and correct any syntax, spelling, or grammatical errors. The search strategy underwent multiple revisions to refine and adjust the search before it was finalized for use, and was peer-reviewed by a second

designated librarian to provide additional rigor to the process. The peer-review librarian reviewed the search strategy, and provided feedback regarding:

- The accuracy of translating the research questions into search concepts and terminology,
- Proper use of search operators, fields, limiters or filters, and spelling and syntax of search terms/strings,
- The accuracy of adapting the search strategy for each database interface,
- Inclusion of relevant subject headings, such as Medical Subject Headings (MeSH), and Emtree thesaurus with free-text search terms, and
- Provision of additional relevant search terms and/or original databases.

The NESR librarian used the feedback from the designated peer-review librarian to finalize the search strategies, and shared the revised search strategy with the Committee and NESR analyst(s) for final approval. The search strategy was documented and all database searches were reported to provide transparency and reproducibility of the systematic review. The search strategies were included in all of NESR's published systematic reviews. Each component of the literature search strategy described above is discussed in more detail below.

Identify Bibliographic Databases

The NESR librarian selected electronic bibliographic databases based on the systematic review topic. PubMed/MEDLINE, Cochrane, and Embase are the primary databases used to identify studies relevant to NESR systematic reviews on food, nutrition, and health. If the topic of the systematic review related to pregnancy, lactation, or the birth to age 24 months population, CINAHL also was searched.

Develop Search Terms

NESR analysts helped identify initial key terms and/or relevant articles to ensure that the NESR librarian had an understanding of the scope and intent of the systematic review question. The Committee also provided help on subject or topic terminology and technical terms to aid the librarian in choosing the most appropriate and comprehensive set of search terms possible. Search terms also were refined by reviewing key terms and the indexing of related publications, such as existing systematic reviews. Librarians also were responsible for checking each bibliographic database's search features to ensure that all related search terms for a particular systematic review question were captured.

Because NESR reviews often focus on health outcomes such as cardiovascular disease, type 2 diabetes, body weight (including obesity and overweight), and energy intake, standard subject/thesauri terms (such as those found from the MeSH database in PubMed) were routinely used when conducting a search. The librarian checked each database's search features to ensure that all related search terms for these common health outcomes were captured for each database.

Apply Search Filters

For NESR searches, filters that are commonly used include: English language, human studies, date, or publication type (e.g., to filter out news, editorial, and comments). Sometimes, study design also was used as a filter (e.g., systematic reviews and meta-analyses).

In some cases, searches were filtered or limited to identify studies done in subpopulations of interest, such as in a specific country or in women who are pregnant. In addition, filters or limits for sex (e.g., male or female) or specific age groups (e.g., children and adolescents [ages 2 to 18 years] or adults [ages 18 to 65 years]) were applied in some cases.

Implement the Literature Search Strategy

After finalizing the search strategies for each of the databases, the NESR librarian began the process of conducting all of the electronic searches. When searching multiple databases, overlap in the literature identified is common; the librarian electronically eliminated duplicate records at the search level using a citation management program (EndNote X9; Clarivate Analytics, Philadelphia, PA). Additional duplicates were identified by NESR analysts during the course of screening, and were removed from the search results manually. In addition, because some journals publish articles electronically, in advance of the print journal, the search captured these articles, and they were eligible for inclusion in the review, even though there was a possibility that they would be assigned an official publication date outside the window of the search date range.

Once the electronic searches were done, the librarian documented the total number of unique articles identified, indicating how many were identified from each database searched. This documentation included the total, raw search results, as well as search results after removal of duplicates.

Screen and Select Studies

Two NESR analysts independently screened all search results, which was facilitated by use of a web-based tool (i.e., DistillerSR) and screening forms that were developed based on the inclusion and exclusion criteria identified for each systematic review. In some cases, where multiple literature searches were run to identify articles for a question or family of questions, the search results were uploaded into the web-based tool, combined, and screened together. The goal of screening was to review the search results and exclude those that did not meet the inclusion criteria. Screening was done at 3 levels. The first level of screening was done using only the title of each article. If an article was not excluded by both analysts at this level, it moved forward to the second level, where the abstract was screened. Finally, if an article passed the first 2 levels, it moved to the third level, where the full text of the article was screened. After 2 NESR analysts completed independent screening of all 3 levels, the analysts reconciled any discrepancies between the 2 screenings. If necessary, a third analyst was consulted to resolve differences.

If multiple articles were identified that presented data from the same study or cohort, the article that most directly addressed the systematic review question was included to avoid duplicative data. If the articles addressed unique data related to the question, or were needed to comprehensively present information from a study or cohort, then all articles were included. Included articles from the same study or cohort were noted in the review, and this was taken into consideration when weighing the amount of evidence to answer a question.

Conduct Manual Searches

NESR analysts also completed manual searches, a mandatory part of a comprehensive search strategy, for every systematic review.¹⁰ Manual searching was done to find peer-reviewed published articles not identified through the electronic database search. This was typically due to inadequate indexing or filtering limitations of a database. The primary approach used for the manual search was hand searching, in which an analyst systematically searched the reference sections of included articles and related systematic reviews and meta-analyses. Potential articles also may have been suggested by others engaged in the process, such as Committee members, analysts working on the project, or the general public through public comments. Two NESR analysts independently screened all relevant citations at the abstract and full-text levels to determine whether the articles addressed the systematic review question and met all inclusion and exclusion criteria, as outlined above.

If articles were identified through a manual search, the librarian reviewed the search strategy to determine why they were not found through the electronic searches. If a potential gap in the literature search strategy was identified, the electronic search was updated and rerun to include additional search terms or filters, and any new references identified were screened against the inclusion and exclusion criteria, as described above.

Document the Search Results

After the electronic and manual searches were completed, NESR analysts and librarians prepared materials to document the literature search and screening results. They compiled lists of the Committee's included and excluded citations, along with the rationale for exclusion. These lists were provided to the Committee for review and approval. The analysts and librarian also documented the search strategy and results, including:

- Inclusion and exclusion criteria
- Search strings (e.g., search terms, filters, and limits) used for each electronic database searched
- Date of each search
- A brief description of how the search was developed and implemented
- A flow chart of the number of included and excluded citations retrieved through electronic and manual searching
- A list of all included articles
- A table that listed all excluded articles with rationales for exclusion

The list of articles excluded after full text review is publicly available on the NESR website. The list of articles excluded after title or abstract review is documented and archived by NESR.

It is uncommon for a literature search to be updated after other steps in the NESR systematic review process are under way. This was true for the Dietary Guidelines Advisory Committee because of the number of questions under review. The timeframe for each review, however, was documented transparently.

Extract Data and Assess Risk of Bias

NESR analysts extracted and summarized data from each included article to objectively describe the body of evidence available to answer a systematic review question. In addition, NESR analysts assessed the risk of bias for each included article. The extracted data and assessment of risk of bias were used to populate evidence tables. Using one consistent format,

the evidence tables presented the key data from all studies included in the systematic review that the Committee used to synthesize the body of evidence (described, below, in “Synthesize Evidence, Develop Conclusion Statements, Grade the Evidence, and Identify Research Recommendations”).

Extract Data

Determine Types of Data to Extract

With Committee guidance, NESR analysts determined the specific types of data to extract from each included study. The focus was on information that was critical for answering the systematic review question. Types of data typically extracted include study design, sample size (i.e., baseline and analytic sample size, attrition) and participant characteristics (i.e., age, sex, race/ethnicity, socioeconomic status, and health status), the independent and dependent variables and their measurement methods, statistical adjustments, results, limitations, and funding sources.

Extract the Data

Once the types of data to be extracted were determined, a data extraction form was developed and used to facilitate accurate and consistent data extraction. This form ensured that the same information from each article was formatted consistently, which made the content easier to compare and contrast during synthesis. NESR analysts typically used web-based tools to extract data (e.g., DistillerSR).

One NESR analyst extracted data from each included article using the data extraction form. In some cases, the required data were not reported in the article. In those situations, the data were recorded as “not reported.” However, if the required data were reported in an article’s protocol or related publication, the analyst extracted the data and noted the publication from which it was extracted. Next, a second analyst reviewed the extracted data for completeness, accuracy, and consistent presentation and formatting. Discrepancies noted by the second analyst, if any, were discussed and resolved. If a discrepancy could not be resolved or needed additional clarification, the analysts consulted with a third NESR analyst and/or the Committee to reach resolution.

Create Evidence Tables

When data extraction was completed for all studies included in the systematic review, the analyst created evidence tables. The number of evidence tables created varied depending on the size and scope of the systematic review. NESR analysts and the Committee determined the content and organization of evidence tables based on the analytic framework. For example, some tables provided descriptive information about the studies' design, methods, study participants, and funding sources. Other tables presented studies' results. Evidence tables were used to facilitate and provide transparency to the Committee's review, synthesis, and grading of the body of evidence available to answer the systematic review question.

Assess Risk of Bias

Each article included in a systematic review conducted by NESR underwent a formal risk of bias assessment. Risk of bias is the likelihood of a systematic error or deviation from the truth, in results or inferences, which can lead to underestimation or overestimation of either the true effect of an intervention on an outcome or the true association between an exposure and outcome. The design and conduct of a study affects the extent to which its results are at risk of bias. Studies with lower risk of bias (i.e., studies with rigorous designs and sound analytic methods) are more likely to report results that are closer to the truth. The assessment is specific to identifying the *risk* of bias because the results of a study may in fact be unbiased despite a methodological flaw).¹¹⁻¹³

Conducting a formal risk of bias assessment is a critical part of the systematic review process. The assessment provided important information regarding each included article and the body of evidence under review, which the Committee considered when synthesizing the evidence, drawing conclusions, and grading the strength of evidence underlying those conclusions.¹⁴

Use of a risk of bias tool was key to ensuring that risk of bias assessments were done consistently across studies, and that the results of the assessment were transparent. Systematic review methodology, including that related to risk of bias, is continuously evolving. NESR has followed these evolutions, routinely evaluating and refining its methods to ensure they remain state-of-the-art. In order to align with other systematic review organizations, NESR used several tools, and applied their respective guidance, to assess risk of bias for primary studies included in its systematic reviews.

NESR assessed the risk of bias of RCTs, including parallel group trials, cluster-randomized trials, and cross-over trials, using the “Cochrane risk-of-bias tool for randomized trials” (RoB 2.0; August 2016 version).¹⁵ This tool addressed the following types of bias:

- Bias arising from the randomization process
- Bias arising from the timing of identification and recruitment of individual participants in relation to timing of randomization (cluster randomized trials only)
- Bias due to deviations from intended interventions
- Bias due to missing outcome data
- Bias in measurement of the outcome
- Bias in selection of the reported result

NESR assessed the risk of bias of non-RCTs using the “Risk of Bias in Non-randomized Studies-of-Interventions” tool (ROBINS-I).¹⁶ The tool addressed the following types of bias:

- Bias due to confounding
- Bias in selection of participants into the study
- Bias in classification of interventions
- Bias due to deviations from intended interventions
- Bias due to missing data
- Bias in measurement of the outcome
- Bias in selection of the reported result

NESR assessed the risk of bias of observational studies using the Risk of Bias for Nutrition Observational Studies tool (RoB-NObs) (Table C-1). NESR created the RoB-NObs by making modifications to the ROBINS-I and a preliminary instrument designed to assess risk of bias in non-randomized studies of exposures because a universally accepted tool for assessing risk of bias in observational studies does not currently exist.^{17,18} Modifications were made to ensure that the tool was applicable to observational studies of food, nutrition, and public health, though many questions and the guidance for answer the questions are nearly identical.^{19,20} The tool addressed the following types of bias:

- Bias due to confounding
- Bias in selection of participants into the study
- Bias in classification of exposures
- Bias due to departures from intended exposures
- Bias due to missing data

- Bias in measurement of the outcome
- Bias in selection of the reported result

Table C-1. Risk of Bias for Nutrition Observational Studies (RoB-NObs) Tool

Bias due to confounding
1.1 Is there potential for confounding of the effect of exposure in this study?
1.2. <i>If Y or PY to 1.1:</i> Was the analysis based on splitting follow-up time according to exposure received?
1.3. <i>If Y or PY to 1.2:</i> Were exposure discontinuations or switches likely to be related to factors that are prognostic for the outcome?
1.4. <i>If N or PN to 1.3:</i> Did the authors use an appropriate analysis method that adjusted for all the critically important confounding variables at baseline?
1.5. <i>If N or PN to 1.3:</i> Were confounders that were adjusted for measured validly and reliably by the variables available in this study?
1.6. <i>If N or PN to 1.3:</i> Did the authors avoid adjusting for post-exposure variables?
1.7. <i>If Y or PY to 1.3:</i> Did the authors use an appropriate analysis method that adjusted for all the critically important confounding variables, including baseline and time-varying confounding?
1.8. <i>If Y or PY to 1.7:</i> Were confounders that were adjusted for measured validly and reliably by the variables available in this study?
Bias in selection of participants into the study
2.1. Was selection of participants into the study (or into the analysis) based on participant characteristics observed after the start of exposure?
2.2. <i>If Y or PY to 2.1:</i> Were the post-exposure variables that influenced selection of participants (into the study or analysis) associated with exposure?
2.3. <i>If Y or PY to 2.2:</i> Were the post-exposure variables that influenced selection of participants (into the study or analysis) associated with the outcome?
2.4 Do start of follow-up and start of exposure coincide for most participants?
2.5 <i>If Y or PY to 2.2 and 2.3, or N or PN to 2.4:</i> Were adjustment techniques that were likely to correct for the presence of selection biases used?
Bias in classification of exposures
3.1. Is the exposure that was assessed clearly defined?
3.2. Does the exposure that was assessed represent the exposure of interest?
3.3. Were the methods used to assess the exposure clearly described?
3.4. Were the methods used to measure the exposure valid and/or reliable?
3.5. Were the same methods used to assess the exposure status for all participants/groups?
3.6. Were the methods used to define exposure status for participants/groups clearly described?
3.7. Were the methods used to define exposure status for participants/groups likely to result in minimal random or systematic exposure misclassification?
3.8. Could classification of exposure status been affected by the presence of the outcome, knowledge of the outcome or risk of the outcome?
Bias due to departures from intended exposures
4.1. Is there concern that changes in exposure status occurred among participants that were unbalanced across groups and likely to impact the outcome?
4.2 Were any critical co-exposures that occurred unbalanced between exposure groups and likely to impact the outcome?
4.3. <i>If Y or PY to 4.1, or 4.2:</i> Were adjustment techniques that are likely to correct for these issues (i.e., changes in exposure status and/or unbalanced co-exposures) used?

Bias due to missing data
5.1 Were there missing outcome data?
5.2 Were participants excluded due to missing data on exposure status?
5.3 Were participants excluded due to missing data on other variables (besides outcome data and exposure status) needed for the analysis?
5.4 <i>If Y or PY to 5.1, 5.2 or 5.3:</i> Are the proportion of participants and reasons for missing data similar across exposure groups?
5.5 <i>If Y or PY to 5.1, 5.2 or 5.3:</i> Were appropriate statistical methods used to account for missing data?
Bias in measurement of outcomes
6.1 Could the outcome measure have been influenced by knowledge of the exposure received?
6.2 Were outcome assessors aware of the exposure received by study participants?
6.3 Were the methods of outcome assessment the same across exposure groups?
6.4 Were any systematic errors during measurement of the outcome related to exposure received?
Bias in selection of reported result
7.1. Is the reported effect estimate likely to be selected on the basis of the results from multiple <i>outcome measurements</i> within the outcome domain?
7.2 Is the reported effect estimate likely to be selected on the basis of the results from multiple <i>analyses</i> of the exposure-outcome relationship?
7.3 Is the reported effect estimate likely to be selected on the basis of the results from different <i>subgroups</i> ?

Each of these tools included signaling questions that address several types, or domains, of bias, and guidance that provided instructions and considerations for answering the individual signaling questions and for making overall judgements for each type of bias. The guidance for both the ROBINS-I and RoB-NObs specify that the signaling questions be answered by considering how the non-randomized or observational study compares to a randomized “target” trial conducted in the same population that had no flaws in its conduct.⁴ Thus, they identify potential biases that may arise due to lack of randomization. In addition, the systematic review protocol developed by the Committee helped to further inform how the guidance was applied (i.e., which key confounders were evaluated). The ROB 2.0 tool had domain-level judgements of low, high, and some concerns, whereas the ROBINS-I and RoB-NObs had domain-level judgements of low, moderate, serious, critical, and no information.

NESR used a dual, independent process for risk of bias assessments. For each article included in a NESR systematic review, 2 NESR analysts independently completed the risk of bias tool appropriate for the study’s design. Analysts answered the signaling questions based only on the data that was extracted for the systematic review. Risk of bias assessments were completed at the results level. Therefore, if a study included multiple results that were extracted to answer the systematic review question (i.e., continuous and categorical analyses of the exposure, or multiple different outcomes of interest), the NESR analysts considered each result

when responding to the items, and in some cases, completed multiple iterations of the tool to address each result independently. If necessary, analysts referred to previous and/or related publications to obtain information to complete items in the tool. The analysts' responses were compared, and disagreements, if any, were discussed and reconciled. If a disagreement could not be resolved by the 2 analysts, an additional member of the NESR staff was asked to provide a third-party consultation. The Committee also was consulted, as needed, to ensure consistency and accuracy of risk of bias assessments.

The results of each risk of bias assessment were displayed in a risk of bias table. This table reported on each study included in the review, and provided transparency to the domain-level risk of bias judgements using a color-coded system. If a study included multiple results to be considered in the systematic review, and their risk of bias judgements differed, then each result's risk of bias was reported separately.

Later in the process of conducting the systematic review, NESR's predefined criteria were used to evaluate and grade the strength of the evidence supporting each conclusion statement. One of the criteria was risk of bias. The risk of bias criterion considers the likelihood that systematic errors in the design and conduct of the studies could have affected reported results across the body of evidence. The criterion relied on a review of the domain-level judgements of risk of bias. NESR's process for grading the strength of evidence is described in the following section in "Synthesize Evidence, Develop Conclusion Statements, Grade the Evidence, and Identify Research Recommendations."

Synthesize Evidence, Develop Conclusion Statements, Grade the Evidence, and Identify Research Recommendations

Synthesize Evidence

Evidence synthesis is the process by which evidence from multiple studies is described, compared and contrasted, and combined qualitatively, or narratively, to answer the systematic review question. This synthesis of the body of evidence involves identifying overarching themes or key concepts from the findings, identifying and explaining similarities and differences between studies, and determining whether certain factors may have affected the relationships being examined.

NESR analysts drafted a description of the studies included in the systematic review to begin the process of synthesizing the evidence. This description included information about the study designs, sample sizes (i.e., baseline and analytic sample size, attrition) and subject characteristics (i.e., age, sex, race/ethnicity, socioeconomic status, and health status), the

independent and dependent variables and their measurement methods, statistical adjustments, results, limitations, and funding sources. NESR analysts used the analytic framework and systematic review protocol to guide how the evidence was organized and described.

Next, the Committee synthesized the evidence. NESR analysts provided the Committee with the description of the evidence, along with the raw extracted data, risk of bias assessments, and full-text articles for their review. The Committee reviewed these materials, assessing the included articles individually, and the body of evidence collectively. In their review, they considered study design, key associations between the intervention/exposure and outcome(s) of interest in the systematic review question, along with key factors addressed in grading the strength of the evidence (risk of bias, consistency, directness, precision, and generalizability). Patterns of agreement and disagreement among the findings were examined, and methodological differences between the studies were assessed to potentially help explain disagreement. Gaps in the body of evidence also were identified.

The Committee provided their feedback to the NESR analysts, who drafted text that synthesized the evidence. In addition, the analysts created evidence tables to describe the body of evidence and provide transparency to the Committee's review, synthesis, and grading of the body of evidence available to answer the systematic review question.

Develop Conclusion Statements

After the Committee synthesized the body of evidence, they drafted a conclusion statement. A conclusion statement is one or more summary statement(s) carefully constructed to answer the systematic review question. It reflects the evidence reviewed, as outlined in the analytic framework (e.g., PICO elements), and does not take evidence from other sources into consideration. Conclusion statements do not draw implications, and should not be interpreted as dietary guidance.

Conclusion statements should:

- Indicate the strength of the evidence grade,
- Focus on general agreement among the studies and/or acknowledge areas of disagreement where they exist,
- Identify the relevant parameters, when appropriate (e.g., if cited papers studied only 1 sex, age group, ethnicity, or level of health risk), and
- Be concise and written using elements of “plain language” so they can be understood by a broad audience.

The Committee members reviewed, discussed, and revised the conclusion statement until they reached agreement on wording that accurately reflected the body of evidence.

Grade the Evidence

The Committee then assigned a grade to each conclusion statement. The grade communicates the strength of the evidence supporting a specific conclusion statement to decision makers and stakeholders.

NESR has predefined criteria, based on 5 grading elements that the Committee used to evaluate and grade the strength of the evidence supporting each conclusion statement. The 5 grading elements are: risk of bias, consistency, directness, precision, and generalizability of the evidence. Study design was also considered during the grading process. NESR's grading rubric (Table C-2) is a tool used to facilitate the Committee's grading process. Use of the grading rubric ensures that the final grade reflects consideration of *all* of the grading criteria, promotes consistency across systematic reviews, and allows for the Committee's assessment of each element to be transparently documented.

Each element of NESR's grading criteria is described below. Development of these elements was informed by other grading approaches, including the GRADE approach, and methods used by the Agency for Healthcare Research and Quality and the Office of Health Assessment and Translation.²¹⁻²³

- **Risk of Bias** considers the likelihood that systematic errors resulting from the design and conduct of the studies could have affected the accuracy of the reported results across the body of evidence. Assessment of this element is informed by a review of the risk of bias domain-level judgements across the body of evidence. NESR's process for assessing risk of bias for each study included in the body of evidence is described above, in "Assess Risk of Bias."
- **Consistency** considers the degree of similarity in the direction and magnitude of effect across the body of evidence. It also considers whether any inconsistency can be explained by differences in study designs and methods (e.g., differences in populations, exposure measurement methods).
- **Directness** considers how well the primary research studies are designed to address the systematic review question. Specifically, directness occurs when the populations, intervention, comparators, and outcomes of interest are directly related to the systematic review question.

- **Precision** considers the degree of certainty around an effect estimate for a given outcome. This assessment includes consideration of sample size, number of studies, and variability within and across studies.
- **Generalizability** considers whether the study participants, interventions and/or exposures, comparators, and outcomes examined in the body of evidence are applicable to the U.S. population.

Study design also was a critical consideration in the process of grading. The evidence was grouped by study design to determine the overall grade, or strength, of the evidence supporting the conclusion statement. Evidence from each design (e.g., RCTs, longitudinal cohort studies) was assessed collectively against the elements of the NESR grading rubric. This assessment ensured that the strengths and weaknesses of each design, as well as each grading element, were thoroughly considered. In addition, because the risk of bias tools used by NESR are inherently designed to capture potential biases in non-randomized and observational studies that arise due to lack of randomization, the grading element of risk of bias also allows for consideration of study design in the process of grading.

It should be noted that some other grading methodologies consider publication bias as a formal criterion, whereas NESR does not. NESR acknowledges that publication bias is important and is prevalent in nutrition research (as in other biomedical research). Because of the challenges associated with relying on funnel plots for assessing publication bias and given that no other gold-standard tools exist, particularly for observational studies, NESR does not address it as a separate grading element. Rather, NESR considers it in the evidence synthesis process by considering the extensiveness of the search, and whether large and small studies were included in the review, in particular small studies with null findings.

Next, the assessments made using the NESR grading rubric were used to facilitate the Committee's discussion and selection of an overall grade. A conclusion statement received a grade of Strong, Moderate, or Limited. If a conclusion statement could not be drawn due to no or insufficient evidence, no grade was assigned (i.e., Grade Not Assignable). A summary of the grades used by the NESR team is found in Table C-3. Rationale for the determination of a grade was documented by the NESR analysts.

Table C-2. NESR grading rubric

Elements	Strong	Moderate	Limited	Grade Not Assignable
Risk of bias	Across the body of evidence, there is a <u>strong</u> likelihood that the design and conduct of the studies has prevented or minimized bias such that the reported results are the true effects of the intervention/ exposure, and plausible bias and/or potential limitations are unlikely to alter the results	Across the body of evidence, there is a <u>moderate</u> likelihood that the design and conduct of the studies has prevented or minimized bias such that the reported results are the true effects of the intervention/ exposure, and plausible bias and/or potential limitations are unlikely to alter the results	Across the body of evidence, there is a <u>limited</u> likelihood that the design and conduct of the studies has prevented or minimized bias such that the reported results may not be the true effects of the intervention/ exposure, and plausible bias and/or potential limitations may have altered the results	A <u>grade is not assignable</u> for this element because it cannot be adequately assessed
Consistency	The body of evidence demonstrates findings with <u>strong</u> consistency in direction and magnitude of effect; or, any inconsistencies in findings can be explained by methodological differences	The body of evidence demonstrates findings with <u>moderate</u> consistency in direction and magnitude of effect; some of the inconsistencies in findings can be explained by methodological differences	The body of evidence demonstrates findings with <u>limited</u> consistency in direction and magnitude of effect; few of the inconsistencies in findings can be explained by methodological differences	A <u>grade is not assignable</u> for this element because it cannot be adequately assessed
Directness	The body of evidence demonstrates <u>strong</u> directness, such that studies are designed to directly examine the relationships among intervention/exposure, comparator, and outcomes of primary interest in the systematic review question	The body of evidence demonstrates <u>moderate</u> directness, such that some studies are designed to directly examine the relationships among intervention/exposure, comparator, and/or outcomes of primary interest in the systematic review question	The body of evidence demonstrates <u>limited</u> directness, such that few studies are designed to directly examine the relationships among intervention/exposure, comparator, and/or outcomes of primary interest in the systematic review question	A <u>grade is not assignable</u> for this element because it cannot be adequately assessed
Precision	The body of evidence demonstrates <u>strong</u> precision based on a substantial number of sufficiently-powered studies with a narrow assessment of variance	The body of evidence demonstrates <u>moderate</u> precision based on an adequate number of sufficiently-powered studies with a narrow assessment of variance	The body of evidence demonstrates <u>limited</u> precision based on an inadequate number of sufficiently-powered studies with a narrow assessment of variance	A <u>grade is not assignable</u> for this element because it cannot be adequately assessed
Generalizability	The body of evidence demonstrates <u>strong</u> generalizability to the	The body of evidence demonstrates <u>moderate</u> generalizability to the U.S.	The body of evidence demonstrates <u>limited</u> generalizability to the	A <u>grade is not assignable</u> for this element

	U.S. population of interest with regard to: a) the participant characteristics b) the intervention/exposure and outcomes studied	population of interest with regard to: a) the participant characteristics b) the intervention/exposure and outcomes studied	U.S. population of interest with regard to the: a) participant characteristics b) intervention/exposure and outcomes studied	because it cannot be adequately assessed

Table C-3. Definitions of grades used by NESR for the 2020 Committee

Grade	Definition
Strong	The conclusion statement is based on a strong body of evidence as assessed by risk of bias, consistency, directness, precision, and generalizability. The level of certainty in the conclusion is strong, such that if new evidence emerges, modifications to the conclusion are unlikely to be required.
Moderate	The conclusion statement is based on a moderate body of evidence as assessed by risk of bias, consistency, directness, precision, and generalizability. The level of certainty in the conclusion is moderate, such that if new evidence emerges, modifications to the conclusion may be required.
Limited	The conclusion statement is based on a limited body of evidence as assessed by risk of bias, consistency, directness, precision, and generalizability. The level of certainty in the conclusion is limited, such that if new evidence emerges, modifications to the conclusion are likely to be required.
Grade Not Assignable	A conclusion statement cannot be drawn due to either a lack of evidence, or evidence that has severe limitations related to risk of bias, consistency, directness, precision, and/or generalizability.

Identify Research Recommendations

The Committee identified and documented research gaps and methodological limitations throughout the systematic review process. These gaps and limitations were used to develop research recommendations that describe the research, data, and methodological advances that are needed to strengthen the body of evidence on a particular topic. Rationales for the necessity of additional or stronger research also may have been provided with the research recommendations.

Develop Systematic Review Reports

To help meet goals for transparency and reproducibility, all of the Committee's NESR systematic reviews were made accessible to the public when complete. A complete report for each systematic review was peer-reviewed and published on the NESR website at nesr.usda.gov.

Each systematic review report contains complete documentation from each step of the review process, and includes a plain language summary, a technical abstract, and a full systematic review.

Write Plain Language Summaries

NESR plain language summaries provide an overview of NESR systematic reviews using concise, non-technical language for a range of audiences, regardless of their technical or scientific expertise.

The NESR plain language summaries include the systematic review question and the answer to that question, as well as a brief description of why the question was asked, how it was answered, what evidence was found, and how up-to-date the systematic review was.

NESR plain language summaries were drafted by NESR analysts and reviewed by the Committee.

Write Technical Abstracts

The purpose of a NESR technical abstract is to provide a short, technical synopsis of the systematic review. The technical abstract is structured to help readers quickly determine the overall scope, methodology, and findings of the systematic review, without having to read the entire report. A technical abstract is typically longer and more detailed than abstracts prepared for peer-reviewed publications and/or scientific meetings. The intended audiences of a NESR technical abstract include those with a scientific background, including scientific experts, Federal stakeholders, and researchers, as well as the general public.

A NESR technical abstract contains the following sections:

- **Background:** Describes (3-4 sentences) the rationale and objective of the systematic review.
- **Conclusion Statement(s) and Grade(s):** Answers the review question, with a grade that represents the strength of evidence supporting that conclusion statement.
- **Methods:** Describes the literature search strategy and processes used to extract data, assess risk of bias, synthesize evidence, develop conclusion statements, and grade the strength of evidence.
- **Summary of Evidence:** Summarizes the body of evidence included in the review, including a description of included studies, study results, and gaps and limitations.

NESR technical abstracts were drafted by NESR analysts and reviewed by the Committee.

Write Full Systematic Review

The purpose of the full systematic review is to present comprehensive details of the entire systematic review, including details about the methodology and protocol, as well as in-depth information about the body of evidence reviewed. The intended audiences of the full systematic review includes those with a scientific background, including scientific experts, Federal stakeholders, and researchers, as well as the general public.

The full systematic review contains the following sections:

- **Methodology:** Briefly describes the systematic review methodology used. .
- **Protocol:** Provides information about the systematic review protocol, including the analytic framework, inclusion and exclusion criteria, literature search strategy, and literature search and screening results (flow chart of screening results, list of included articles, and list of excluded articles with rationale for exclusion).
- **Conclusion statement(s) and grade(s):** Answer(s) the review question, with a grade that represents the strength of evidence supporting that conclusion statement.
- **Summary of the evidence:** Provides the key points from the review.
- **Description of the evidence:** Describes the included articles, focusing on subject characteristics, interventions/exposures and outcomes examined, methodology used, and a summary of study results.
- **Evidence synthesis:** Discusses overall themes in the body of evidence and provides an assessment of the strength of the evidence.
- **Research recommendations:** Suggests future research based on the gaps and limitations identified in the evidence.
- **Included articles:** Provides reference list of articles included in the review.

The full systematic review was drafted by NESR analysts throughout the course of the systematic review process and reviewed by the Committee.

Use and/or Update Existing NESR Systematic Reviews

Using an existing NESR systematic review to answer a question can prevent duplication of effort and promote time and resource management. NESR was created to meet the needs of the Federal government, which develops population-wide guidance, programs, and policies. Therefore, previous NESR work may be relevant to the work of the Advisory Committee. If an existing NESR review is out of date, it may need to be updated. This section describes NESR's methodology for how the Committee used and/or updated existing NESR systematic reviews.

The process began once the Committee developed a systematic review protocol (described above in “Develop a Systematic Review Protocol”). The protocol was used to determine whether an existing NESR systematic review was relevant to the Committee’s question. An existing NESR systematic review was determined to be relevant if it addressed the same, or very similar, population, intervention and/or exposure, comparator, and outcomes outlined in the protocol. In addition, the existing review should have applied the same or very similar definitions for key terms and inclusion and exclusion criteria for selecting studies to include in the review. In some cases, existing reviews completed by a previous Dietary Guidelines Advisory Committee were determined to be relevant to a question, and the 2020 Committee used the same methods described below to build upon the review to answer a question.

Having identified existing NESR systematic reviews or non-NESR reviews completed by previous Committees that were relevant to the question being addressed, NESR analysts confirmed the determination with the Committee. At this point, the NESR analysts and librarian reviewed the included articles of the existing reviews to determine whether any articles were included in the review that had since been retracted.⁷ If retracted articles had been included, the Committee determined whether the removal of the retracted article(s) would alter the conclusion statement and grade of the systematic review.

If one or more relevant existing systematic reviews were identified, a determination was made as to whether the existing review reflected the current state of science on the topic, or whether reviewing newly published evidence would likely result in changes to the conclusion statement and/or grade, thus warranting the investment of time and resources in a full systematic review update. This determination was made based on a number of considerations, such as:

- **The date range of the literature search conducted for the existing review.** For example, if the review did not include articles published in the past several years or more (e.g., more than 2 years), an update may have been needed to capture recently published evidence.
- **The Committee’s knowledge of a particular field of research.** For example, if the topic was actively being researched, or a methodological advancement in the field had occurred, an update may have been needed to ensure that the current state of science was reflected.
- **The grade assigned to the conclusion statement in the existing review.** For example, if the existing review’s conclusion statement had a grade of Limited or Grade

Not Assignable, review of new evidence could result in changes to the conclusion or grade.

- **A systematic evidence scan.** In a few cases, when the need for an update was uncertain, a NESR systematic evidence scan was conducted to search for and screen newly published articles. A systematic evidence scan is a type of scoping activity that provides objective data to facilitate systematic review-related decision making, but is not a full systematic review.
 - This type of evidence scan involved a formal, systematic literature search, and screening of the search results using inclusion and exclusion criteria, following previously described NESR methodology (see “Search for, Screen, and Select Literature”).
 - The results of the scan were a list of all newly published articles that met inclusion criteria, and a brief description of the volume and relevant characteristics of those articles (e.g., study design, country, or age of study participants).
 - Committee members reviewed the newly published evidence to determine whether or not an update of a systematic review was warranted. To make this determination, the Committee considered whether results of the newly published articles were consistent with the body of evidence from the existing NESR systematic review, or if newly published studies address key gaps or limitations identified in the existing review. If, based on the systematic evidence scan, the existing review was determined to reflect the current state of the science, a formal update of the review was not conducted. The results of the scan were documented, including a list of all new articles that met criteria for inclusion, along with the rationale for not updating the review.

If one or more relevant existing reviews were determined to reflect the current state of science, the Committee documented their rationale, and used the existing NESR review(s) to answer the systematic review question, carrying forward the conclusion(s) and grade(s) from the review(s). If the relevant existing review(s) were determined to be out of date, the review was updated using the methods described below.

Updating a NESR systematic review was a formal process used to search for, evaluate, analyze, and synthesize newly published evidence that built on or expanded the evidence included in an existing review. NESR’s systematic review methodology was implemented to search for and screen studies, extract data, assess risk of bias, and describe the evidence,

based on the updated protocol developed by the Committee. If the Committee's updated protocol differed from that of the existing review, the differences were documented. Then, the Committee synthesized the new evidence with that of the existing review. This synthesis took different forms, depending on the volume and characteristics of the new evidence. Below is a description of the synthesis approaches used by the Committee.

- **Assessment of new evidence as it relates to existing conclusions.** In one form of synthesis, the new evidence was described, and then discussed as it related to the conclusions or findings of the existing review. Revisions may have been made to the conclusion statement or grade based on the new evidence, and rationale for any changes was documented. This approach was generally used when relatively few new articles were found, and/or the methods and results reported in those articles were consistent with articles in the existing review.
- **Separate synthesis of new evidence.** In another form of synthesis, the new evidence was synthesized separately from the existing review, and used to draw and grade a conclusion statement based solely on the new evidence. This typically occurred when aspects of the updated protocol differed from the original, or the scientific methodology used to examine the topic had changed. Then, the Committee integrated both conclusions in their report, and provided a discussion about similarities and differences.

Regardless of what synthesis approach was used, NESR's systematic review methodology (described above in "Synthesize Evidence, Develop Conclusion Statements, Grade the Evidence, and Identify Research Recommendations") for developing conclusion statements and grading the strength of the evidence was applied. In addition, the complete systematic review update was documented, including details about the protocol and methodology, the full description and synthesis of the evidence, and conclusion statements and grades.

Using and/or updating an existing NESR systematic review to answer a question helped the Committee leverage work completed by previous expert groups, prevent duplication of effort, and promote time and resource management, all while ensuring that all of its conclusions reflect the current state of science on the topic.

NESR Team

The NESR is a team of scientists who are experts in systematic review methodology at USDA's Food and Nutrition Service, Center for Nutrition Policy and Promotion (CNPP).

NESR staff hold advanced degrees in nutrition, public health, epidemiology, library science, and related fields. Staff also receive extensive hands-on training and ongoing professional development to be able to independently perform each step of the systematic review process.

Each NESR project is coordinated by a team of NESR staff composed of analysts and librarians. The Committee makes all substantive decisions throughout the process of conducting its systematic reviews, and NESR analysts support the Committee by helping to facilitate and document the work necessary for timely execution of the systematic reviews in accordance with NESR methodology. Librarians work with the analysts to develop, implement, refine, and document the literature search strategies. NESR analysts and librarians are listed in ***Appendix F-5: Acknowledgements***.

Peer Review of NESR Systematic Reviews

New to the 2020 process, the Departments added a step for peer review of the NESR systematic reviews conducted by the Committee. This step was added in response to recommendations from the National Academies, as well as stakeholder comments and in acknowledgement that peer review is a best practice for conducting systematic reviews. Per the Committee's charter, peer review was coordinated by the Co-executive Secretary from USDA's Agricultural Research Service (ARS), which developed a peer-review process analogous to that used for academic journal articles.

Each systematic review was peer reviewed by 2 Federal scientists. In total, 47 Federal scientists from USDA, HHS (including the National Institutes of Health, CDC, and the Food and Drug Administration), Department of Defense, and the Department of Veterans Affairs participated in the process. Peer reviewers were asked to self-identify their systematic review question(s) of interest to review. Each reviewer was asked to provide a personal expert opinion on the systematic reviews, and not to provide comments on behalf of their position within the Federal government or their agency. The peer review process was anonymous and confidential. The peer reviewer was not identified to the Committee members or NESR staff, and in turn, the reviewers were asked not to share or discuss the review. Before peer review began, the NESR lead provided a presentation to the peer reviewers on the NESR systematic review methodology.

Peer review occurred after draft conclusion statements were discussed by the full Committee at Meetings 4 and 5. Following full Committee discussion, the NESR lead sent drafts of each systematic review to the ARS Co-executive Secretary to distribute to assigned reviewers. Peer reviewers were asked to complete their review within 14 days. Each reviewer received drafts of the full systematic review for their assigned question(s), including:

- Conclusion statement and grade,
- Summary of the evidence,
- Description and synthesis of the evidence,
- Research recommendations,
- Included articles, and
- Protocol

Following peer review, the ARS Co-executive Secretary shared peer-review comments with the NESR lead. NESR staff then reviewed the comments, addressed editorial comments, and proposed edits to the relevant Subcommittee in response to comments related to clarity and rationale for decisions made by the Committee. Substantive comments were reviewed and discussed by Subcommittees, and revisions were made to the systematic review, as needed, based on the Subcommittee's discussion. Following peer review, NESR staff sent the ARS Co-executive Secretary responses to each peer reviewer's comments, who shared them with the respective peer reviewers.

All new NESR systematic reviews underwent peer review, except for reviews with no included articles. Peer reviewers are listed in ***Appendix F-5: Acknowledgements***.

Committee Report Development and Structure

Reflecting the Committee's focus on lifespan, the bulk of this report consists of 14 science-based chapters organized by life stage: Pregnancy and Lactation, Birth to Age 24 Months, and Ages 2 Years and Older. The draft organization of the report was discussed at Meetings 3 and 5. Chapters were drafted by the members with support from Federal staff. Once developed, the chapters underwent editorial review and were shared for full Committee review. To ensure each chapter received a focused review, 2 Committee members conducted a cross-review of each chapter. Each chapter summarizes the evidence assessed and evaluated by the Committee and concludes with discussion and summary sections. The Executive Summary was drafted by the Science Writer following her editorial review of each chapter. The Integration Chapter was drafted by the Chair and Vice Chair, with iterative review and contributions from the Integration

Writing Group and review by the full Committee. Future Directions were drafted by Subcommittees to highlight research recommendations that could advance knowledge in nutrition science and inform future Federal food and nutrition guidance. Committee members reviewed the draft report before the Committee meeting on June 17, 2020. The Committee then finalized the report based on member review and discussion at the meeting. The Committee's report was submitted to the Secretaries of USDA and HHS on June 30, 2020.

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PART D. CHAPTER 1: CURRENT INTAKES OF FOODS, BEVERAGES, AND NUTRIENTS

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INTRODUCTION

Diet is directly related to health, and most Americans suffer from health conditions or suboptimal nutritional status that have the potential to be prevented or ameliorated through diet. The *Dietary Guidelines for Americans* focus on the quality of the overall dietary pattern and food choices, as well as how Americans can meet nutrient and food group recommendations to optimize health. Overweight and obesity remain as epidemic public health challenges directly, as well as indirectly through their role with type 2 diabetes, heart disease, metabolic diseases and health conditions, and some types of cancer. An overview of specific diet-related causes of morbidity and mortality, as well as surrogate measures of these outcomes, are presented in the following sections. Physical activity and social and environmental causes of chronic disease and nutrition risk also are critical dimensions that must be understood and addressed but are not discussed in the context of nutrition in this chapter. Rather, the purpose of this chapter is to provide a comprehensive update on the American diet and health landscape, using information from data sources collected or assessed by the U.S. government.

Although specific questions within this chapter focus on individual “nutrients,” the potential health effects of the diet are likely determined by the sum and interaction of many different food components, many of which may not technically be nutrients. The National Academies of Sciences, Engineering, and Medicine (NASEM) defines the term “food component” as being comprised of energy and a range of nutrient and non-nutrient dietary constituents, including but not limited to, macronutrients, micronutrients, fiber, amino acids, fatty acids, sugars, caffeine, and water. To be consistent with the NASEM terminology, this report also will serve to identify potential food components of public health concern.

In this report, the 2020 Dietary Guidelines Advisory Committee considered how intakes of food groups and subgroups and food category sources contribute to intakes of food components across the life course in the United States. The Committee examined various dimensions of eating patterns with a multidimensional lens to understand foods as consumed, referred to as food category sources (e.g., burgers and sandwiches), intakes of food groups (e.g., Vegetables) and subgroups (e.g., dark green leafy), as well as food components consumed (e.g., fiber, nutrients, or energy). Understanding the extent to which the entire population and various subgroups (e.g. age, sex, race and ethnic origin, food security status, income) achieve food group and food component intake recommendations is the foundation for tailoring powerful public health communication strategies focusing first on food-based strategies, but with the recognition that supplementation or fortification may be warranted for certain food components or for certain population subgroups considered to be at potential risk.

Although not specifically addressed in this chapter, many different dietary patterns have been described that can contribute positively and negatively to health (see **Part D. Chapter 8: Dietary Patterns**). Dietary patterns are shaped by a complex interaction of personal preferences (e.g., taste), social context, culture, structural facilitators and barriers to choices, and behavioral aspects that are formed early in development, play out iteratively across the lifespan, and that may be static or dynamic. It should be noted that the typical American dietary pattern is not currently nor has it ever been aligned with recommendations issued by the *Dietary Guidelines for Americans* since their inception in 1980. Thus, understanding the complexity of changing established patterns of food choice is critical to advancing the mission of the *Dietary Guidelines for Americans*.

Diet quality is examined by comparing intakes of foods and beverages to the Healthy Eating Index (HEI) (see Question 3, Summary of the Evidence, below), which is only possible among those ages 2 years and older. To the extent possible, a life stage¹ approach was used, recognizing the special needs for certain periods of development such as growth, pregnancy, and lactation. Given that this is the first Committee to address birth to age 24 months, existing food group compliance metrics are not available, as they have not been previously developed. Thus, for questions surrounding food group compliance, the focus is generally on Americans ages 2 years and older. When questions focus on nutrients or food components for which Dietary References Intakes (DRIs) have been established, the Committee used the NASEM age grouping that includes toddlers ages 12 to 24 months with the age group of 1 to 3 years. Questions were also examined by population subgroups, including sex, race, and Hispanic origin, and measures of socioeconomic status (e.g., income, food security).

Given the complexity of dietary intakes, the Committee presents data organized by food groups, by nutrients, and by overall dietary quality rather than within each of the 5 specific

¹ **Life Stages:**

- Infants and toddlers: These are not overlapping age groupings.
 - Younger infants (ages 0 to 6 months; refers to 0 to age 5.99 months)
 - Older infants (ages 6 to 12 months; refers to ages 6 to 11.99 months)
 - Toddlers (ages 12 to 24 months; refers to ages 12 to 23.99 months)
- Children and adolescents (ages 2 to 19 years)*
- Adults (ages 20 to 64 years)*
- Women who are pregnant (ages 20 to 44 years)
- Women who are lactating (ages 20 to 44 years)
- Older adults (ages 65 years and older)

*Ages vary for some data sources

questions below. Within each question or topic area, a conclusion statement is presented, but it should be noted that these conclusion statements differ from the grading rubric used by the Committee for other questions, which addressed the totality of the evidence of research available from NESR. This chapter focuses on summarizing existing dietary and health-related data from Federal resources.

LIST OF QUESTIONS

1. What is the current prevalence of nutrition-related chronic health conditions?
2. What are the current intakes of food groups?
3. What are the current patterns of food and beverage intake?
4. Which nutrients present a substantial public health concern because of underconsumption or overconsumption?
5. How does dietary intake, particularly dietary patterns, track across life stages from the introduction of foods, into childhood, and through older adulthood?

METHODOLOGY

Questions 1 through 5 in this chapter were answered using data analysis. To address questions on the current status and trends in food and nutrient intakes, and the prevalence of diet-related chronic diseases in the U.S. population, the Committee relied on analysis of data from several nationally representative Federal data sources.

Food and Nutrient Intakes

Many of the questions relied on analysis of data from What We Eat in America (WWEIA), the dietary component of the National Health and Nutrition Examination Survey (NHANES), using either existing data tables or new analyses conducted by the Data Analysis Team (DAT) upon request of the Committee (see **Part C. Methodology**). Complete documentation of the data analysis protocol and the referenced results are available on the following website: <https://www.dietaryguidelines.gov/2020-advisory-committee-report/data-analysis>. Existing data tables were used when available to answer questions about nutrient intake, food group intake, intake of beverages, and dietary patterns. In some cases, new analyses were conducted by DAT to provide additional information on food or nutrient intake, for example, by specific

population groups, such as infants and toddlers and women who are pregnant or lactating. A majority of analyses relied on the most current cycle of WWEIA NHANES 2015-2016; however, data from NHANES 2013-2016 were used when larger samples were needed. Of particular note, data from WWEIA NHANES 2007-2016 were combined for examining intakes of infants and toddlers ages 6 to 12 and 12 to 24 months. The dietary intake data are not without limitations regarding recall bias. Additional limitations related to estimates of intakes among infants and toddlers are noted. Proxy reporting and associated measurement error are not well understood. What may be considered “usual” intakes is difficult to define in such a dynamic portion of the population. The Committee categorized infants into two groups: those with reports of human milk and no infant formula, and those with any reported intake of infant formula. This allowed the Committee to explore differences between the groups, but the limitations of this strategy were considered. The Committee did not evaluate data on nutrient intakes for infants younger than age 6 months. Infants from birth to younger than age 6 months rely on human milk and/or infant formula for a high proportion of energy and nutrient needs. Direct assessment of the volume and composition of human milk consumed is a challenge and imputed estimates have been published elsewhere.¹⁻³

Throughout the description of the data, some observed differences are noted though significance testing was not done. These limitations were taken into consideration when drawing conclusions.

Nutrients or Food Components of Public Health Concern

In the process of evaluating risk for potential inadequacy or excess of food components, the Committee developed a decision tree a priori (Figure D1.1) to identify potential food components using the “3-pronged approach” developed by previous Dietary Guidelines Advisory Committees and subsequently endorsed by NASEM.⁴ The 3 prongs broadly represent analysis of one, both, or all of the Federal data sources, including (1) dietary intake data (Table D1.1),⁴ (2) biomarkers and clinical indicators, and (3) prevalence of health conditions measured directly or indirectly through validated surrogate markers. The Committee utilized the totality of this evidence to the fullest extent possible, plus (1) the extensive scientific efforts of the Food and Drug Administration with regard to labeling standards,⁵ (2) specific food components that were addressed posed to the 2020 Committee in questions, and (3) food components previously identified in the 2015 Committee’s report. For consideration of potential food components of concern among the birth to age 24 months subgroup, the 3-pronged approach

also was augmented with expert opinion from members of the 2020 Committee and guided as detailed below.

Table D1.1. Framework to begin the process of identifying nutrients and other food components as underconsumed, overconsumed, or of potential public health concern

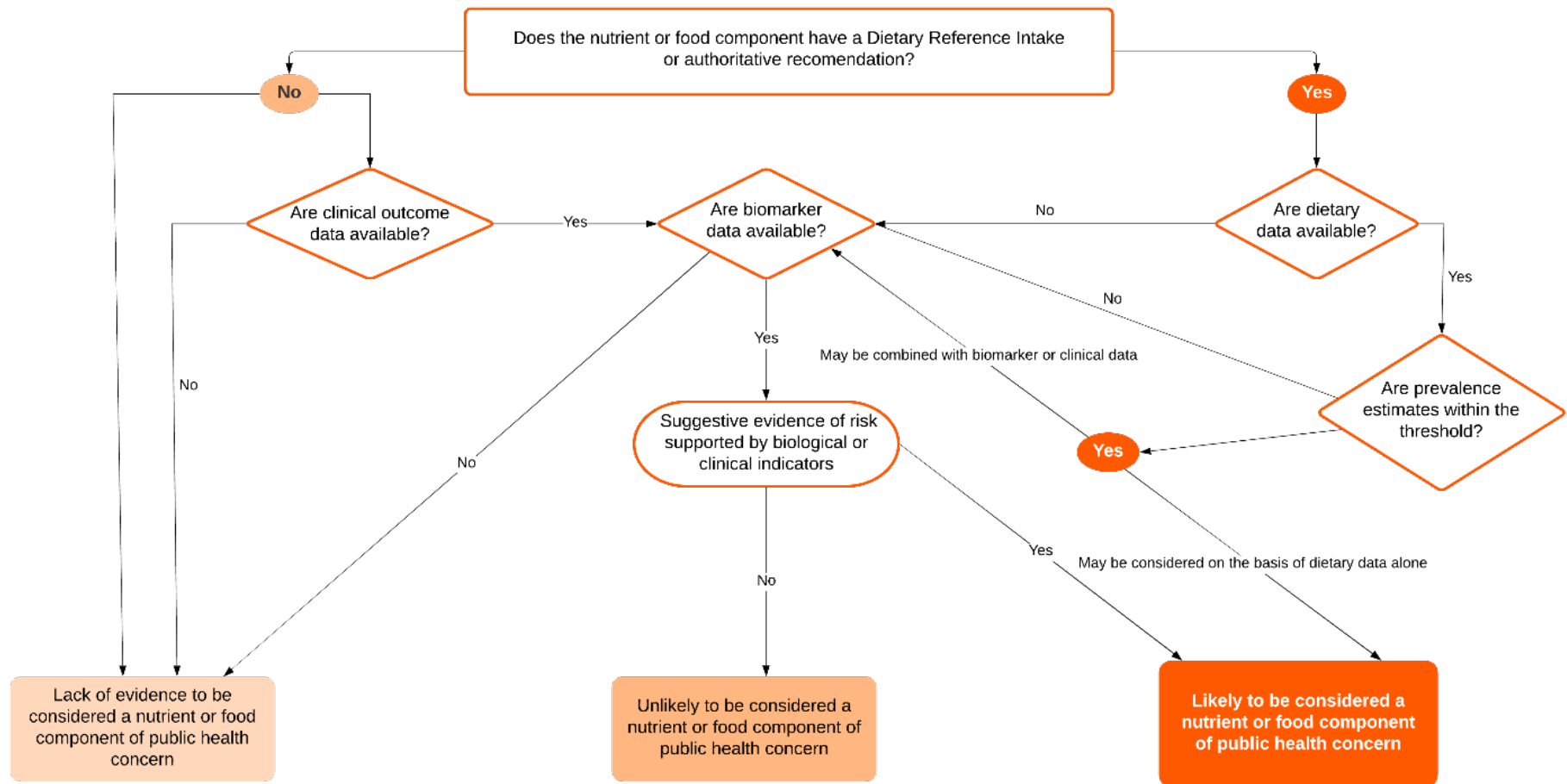
Proposed Term	Proposed Definition
<i>Underconsumed nutrient or food component</i>	A nutrient or food component that is underconsumed by 5 percent or more of the population or in specific groups relative to the EAR, AI, or other quantitative authoritative recommendations from the diet alone. ^{1,2} Underconsumed is used to replace the term “shortfall nutrient.”
<i>Overconsumed nutrient or food component</i>	A nutrient or food component that is consumed in potential excess of the UL, CDRR, or other quantitative authoritative recommendations by 5 percent or more of the population or in specific groups from the diet alone. ^{1,2}
<i>Nutrient or food component of public health concern</i>	Underconsumed and overconsumed nutrients or food components with supporting evidence through biochemical indices or functional status indicators, if available, plus evidence that the inadequacy or excess is directly related to a specific health condition, indicating public health relevance.
<i>Nutrient or food component that poses special challenges</i>	Nutrient or food component for which it was difficult to identify at-risk groups or for which dietary guidance to meet recommended intake levels was challenging to develop.

AI=Adequate Intake; CDRR=Chronic Disease Risk Reduction; EAR=Estimated Average Requirement; UL=Tolerable Upper Intake Level

¹ Existing authoritative quantitative threshold include existing Federal guidance, inclusive to 10 percent energy recommendations for added sugars and saturated fats from the *2015-2020 Dietary Guidelines for Americans*.⁶

² The 5 percent threshold was set to identify potential food components that the Committee should examine further if biomarker or clinical data support the potential for public health concern justification.

Note: This does not mean that all food components identified by this threshold are considered by the Committee to be at risk for inadequate or excessive dietary intakes.

Figure D1.1. Decision-making path diagram for identifying nutrients and other food components of public health concern¹

¹ The starting point on the decision path does not always start with dietary data. For example, dietary data are not available for iodine, but it could be considered in this pathway based on biomarker or clinical data.

Evaluation of Dietary Intake Data

The Committee evaluated means and usual intake distributions of energy, macronutrients, and selected food components in comparisons to the Dietary Reference Intakes (DRIs) published by NASEM or other authoritative recommendations when such standards exist. The Committee first evaluated intakes from foods and beverages alone from NHANES, before also examining the contributions from dietary supplements. When available, it also considered scientific evidence on the relationship between nutrient inadequacy or excess and clinical health consequences (e.g., cardiovascular disease [CVD], cancer) or validated surrogate endpoints such as biochemical indices in addition to dietary intakes of nutrients.

For infants, children, and women who are pregnant or lactating, food components identified by the NASEM report on the Special Supplemental Nutrition Program for Women, Infants, and Children were examined.⁷ This NASEM panel prioritized the nutrients that need to be increased to prevent disease and promote health, including: iron and zinc for older breast-fed infants; iron, fiber, and potassium for young children; calcium, iron, vitamin D, fiber, and potassium for young children ages 24 to 59.9 months; and, calcium, iron, folate, vitamin D, fiber, potassium, and choline for women who are pregnant, lactating, or post-partum. The panel also prioritized the nutrients to limit, including sodium and added sugars for toddlers; and sodium, added sugars, and saturated fat for young children ages 24 to 59.9 months and women who are pregnant or lactating.⁷

Nutrition-related Chronic Health Conditions

Information on the prevalence of nutrition-related health conditions came from the U.S. Centers for Disease Control and Prevention (CDC) NHANES data tables and reports, and from Federally authored peer-reviewed literature. To supplement data from NHANES, additional data sources were drawn upon to answer questions on the prevalence of health conditions. These sources included the National Health Interview Survey (NHIS), the National Vital Statistics System (NVSS), and the National Cancer Institute's Surveillance Epidemiology and End Results (SEER) cancer registry statistics.

Health conditions include:

- Cardiovascular health
- Metabolic syndrome, prediabetes, and diabetes
- Growth, size, and body composition, including overweight and obesity
- Reduced muscle strength and bone mass

- Gestational diabetes mellitus
- Chronic liver disease
- Cancer
- Dental health
- Food allergy

The Committee took the strengths and limitations of data analyses into account in formulating conclusion statements. The grading rubric used for questions answered using NESR systematic reviews does not apply to questions using data analysis. Therefore, data analysis conclusions were not graded.

REVIEW OF THE SCIENCE

Question 1: What is the current prevalence of nutrition-related chronic health conditions?

Approach to Answering Question: Data analysis

Conclusion Statement

Nutrition-related chronic health conditions are common across every life stage of the U.S. population; conditions for which an unhealthy diet is a risk factor, including overweight, and obesity remain highly prevalent among all age groups. There are disparities in the severity of the prevalence, incidence, or mortality rate of chronic health conditions between groups classified by sex, age, race-ethnicity, income level, and weight status. In general, chronic health conditions have become more prevalent over time and are highest among older populations, different racial and ethnic subgroups, and those with lower income levels.

Summary of the Evidence

The following sections summarize findings from the health conditions, and key findings are highlighted with **bolding**. Data analyses conducted for the Committee are found in the data analysis supplements and are referenced below as the Chronic Health Conditions Data Supplement (CH_DS).

Cardiovascular Health

Elevated blood pressure in childhood is associated with increased risk of CVD later in adulthood.⁸ For adolescents ages 12 to 17 years, elevated blood pressure is defined as blood pressure from $\geq 90^{\text{th}}$ to $< 95^{\text{th}}$ percentile or systolic blood pressure ≥ 120 millimeters of mercury (mm Hg). Hypertension is defined as blood pressure in the $\geq 95^{\text{th}}$ percentile, blood pressure of $\geq 130/80$ mm Hg, or use of an antihypertensive medication. The Committee used 2013-2016 NHANES data on estimated hypertension prevalence. The overall prevalence of hypertension among adolescents ages 12 to 19 years was 4.1 percent. Prevalence increased with age. The prevalence among adolescents ages 12 to 17 years was 3.2 percent vs 7.5 percent among adolescents ages 18 to 19 years. Males ages 12 to 19 years had a higher prevalence of hypertension (5.8 percent) than females (2.4 percent). Non-Hispanic Black adolescents ages 12 to 19 years had the highest prevalence of hypertension (6.27 percent). Adolescents who are classified with a healthy weight and overweight had the same prevalence of hypertension (1.9 percent). **Among children, those with severe obesity had the highest prevalence (14.7 percent) of hypertension.**

Hypertension in adults was defined based on definitions used during the NHANES 2015-2016 examination: having a systolic blood pressure of ≥ 140 mm Hg, or a diastolic blood pressure of ≥ 90 mm Hg, or currently taking medication to control blood pressure.⁹ The overall prevalence of hypertension among adults ages 18 years and older was 29.0 percent, which was similar to the prevalence of hypertension since 2007-2008 (29.6 percent). **Hypertension prevalence increased with older age groups:** 7.5 percent in adults ages 18 to 39 years, 33.2 percent in adults ages 40 to 59 years, to **63.1 percent in those ages 60 and older**. Before the age of 60 years, men had a higher prevalence of hypertension compared to women. However, among those ages 60 years and older, women (66.8 percent) had a higher prevalence of hypertension than did men (58.5 percent). Non-Hispanic Blacks have the highest prevalence of hypertension at 40.3 percent for both men and women. Non-Hispanic Whites, non-Hispanic Asians, and Hispanics have a prevalence of hypertension at 27.8 percent, 25.0 percent, and 27.8 percent, respectively. Based on results from the 2017 NHIS,¹⁰ the prevalence of hypertension was lower among those with relatively higher levels of education, with the highest prevalence (32.3 percent) occurring among adults without a high school diploma. Hypertensive disorders of pregnancy, including gestational hypertension and preeclampsia, is estimated to be 7.1 percent.¹¹

In adults ages 20 years and older, the overall prevalence of high total blood cholesterol (defined as greater than or equal to 240 mg/dL) has decreased since 2007-2008

from 14.3 percent to 12.4 percent.^{12,13} Women ages 20 years and older have a higher prevalence of high total cholesterol (17.7 percent) than do men (11.4 percent). The prevalence of high total cholesterol peaks between the ages of 40 to 59 years for both men and women. Among those ages 60 and older, women have a much higher prevalence of high total cholesterol (17.2 percent) compared to men (6.9 percent). Non-Hispanic White women have the highest prevalence of high total cholesterol (14.8 percent) compared to other race-ethnicity or sex subgroups. Hispanic males have the highest prevalence of high total cholesterol (13.1 percent) compared to other male race-ethnicity subgroups.

The prevalence of low high-density lipoprotein cholesterol (HDL-C) in adults age 20 years and older has decreased since 2007-2008 (22.2 percent) to 18.4 percent.^{12,13} Unlike the prevalence of high total blood cholesterol, compared to women, men have a higher prevalence of low HDL-C. The prevalence of low HDL-C peaks for men between the ages of 40 to 50 years (31.9 percent) and for women between the ages of 20 to 39 years (10.1 percent). Hispanic men (36.2 percent) and women (13.8 percent) have the highest prevalence of low HDL-C compared to other race-ethnicity subgroups. Among adolescents ages 12 to 19 years, the prevalence of low serum HDL-C is approximately 16 percent and high serum low-density lipoprotein cholesterol (LDL-C) is approximately 5 percent. Low HDL-C is more prevalent among adolescents ages 12 to 15 years when compared with those ages 16 to 19 years. However, high LDL-C follows the opposite pattern, being more prevalent in those ages 16 to 19 compared to adolescents ages 12 to 15. Boys have a higher prevalence of elevated LDL-C and low HDL-C than do girls. Youths with obesity have a higher prevalence of abnormal lipid profiles than youths with overweight or normal weight. Non-Hispanic White youths have the highest prevalence of elevated LDL-C and low HDL-C among all race-ethnicity groups.

The age-adjusted prevalence of coronary heart disease (CHD), including coronary artery disease, angina, or heart attack, was estimated based on self-reported data from the 2017 NHIS.¹⁰ Among adults ages 18 years and older, the prevalence of CHD was 5.6 percent. For males, the prevalence of CHD was 7.2 percent while it is 4.2 percent for females. As with the risk factors for CHD, **the prevalence of CHD increases with age.** The prevalence of CHD was 0.9 percent for those ages 18 to 44 years, 6.4 percent for ages 45 to 64 years, 14.0 percent for ages 65 to 74 years, and 23.8 percent for ages 75 years and older. American Indian/Alaskan Natives had the highest prevalence of CHD (9.0 percent) compared to other race-ethnicity groups. As educational attainment increases, a lower prevalence of CHD was observed. The highest prevalence of CHD is among adults without a high school diploma (7.7 percent), followed by those with a high school diploma or General Educational Development (GED) and

no college (7.5 percent), those with some college (6.7 percent), and those with a college degree or higher (4.8 percent).

The 2017 NHIS was also used to assess the age-adjusted prevalence of stroke among adults ages 18 years and older.¹⁰ The overall prevalence of stroke in 2017 was 2.9 percent, with a slightly higher prevalence of stroke among men (3.3 percent) compared to women (2.5 percent). The prevalence of stroke also increases with age and was 0.6 percent among those ages 18 to 44 years, 3.3 percent among adults ages 45 to 64 years, 6.4 percent among those 65 to 74 years, and 12.0 percent among adults 75 years and older. By race-ethnicity, non-Hispanic Blacks have the highest prevalence of stroke (4.2 percent). The prevalence of stroke is lowest among those with the highest education: 5.5 percent among those with a high school diploma, 3.2 percent among those with a high school diploma or GED but no college, 3.7 percent among those with some college, and 2.1 percent among those with at least a college degree.

Metabolic Syndrome, Prediabetes, and Diabetes

Prediabetes is defined as a hemoglobin A1c (HbA1c) of 5.7 to 6.4 percent or a fasting plasma glucose of 100 to 125 milligrams per deciliter (mg/dL). Diabetes is defined as an HbA1c of ≥ 6.5 percent, fasting plasma glucose of ≥ 126 mg/dL, or use of anti-diabetes medication.

The prevalence of diabetes among adolescents ages 12 to 19 years is 0.5 percent. **The prevalence of prediabetes and diabetes among children ages 12 to 19 years is 23.1 percent.**¹⁴ Data by race-ethnicity were unavailable. The prevalence of prediabetes and diabetes in this age group has been stable since 1999 (21.9 percent).

Among adults ages 18 years and older, the prevalence of prediabetes is 33.9 percent.

Data by race-ethnicity were unavailable. As age increases, so does the prevalence of prediabetes. The prevalence of prediabetes is 23.7 percent for ages 18 to 44 years, 40.9 percent for ages 45 to 64 years, and 48.3 percent for ages 65 years and older. Men have a higher prevalence (36.9 percent) than do women (31.1 percent).¹⁴

A proportion of the diabetes prevalence is in those who are undiagnosed. It is estimated that the prevalence of undiagnosed diabetes among adults ages 20 years and older is 2.8 percent. The prevalence of diagnosed diabetes is 10.2 percent; therefore, the total prevalence of diabetes among adults ages 20 years and older is 13.0 percent. For both diagnosed and undiagnosed diabetes, men (11.0 percent and 3.1 percent, respectively) have a higher prevalence than do women (9.5 percent and 2.5 percent, respectively). The prevalence of all diabetes categories (total, diagnosed, and undiagnosed) increases with age. For ages 18 to 44

years, the prevalence of total diabetes is 4.2 percent. For ages 45 to 64 years, the prevalence of total diabetes is 17.5 percent, and is 26.8 percent for ages 65 years and over. The race-ethnicity group with the highest prevalence of diagnosed (13.3 percent) and total diabetes (16.4 percent) is non-Hispanic Blacks. However, the group with the highest prevalence of undiagnosed diabetes is Asians (4.6 percent).¹⁴ As body weight status increases from normal weight to obesity, the prevalence of all diabetes categories increases as well. The prevalence of total diabetes for those in the underweight or normal weight category is 6.2 percent, 11.8 percent for those in the overweight category, and 20.7 percent for those in the obesity category.

Metabolic syndrome is defined as having 3 or more of the following measurements: abdominal obesity (waist circumference of ≥ 40 inches or ≥ 102 centimeters in men, and ≥ 35 inches or ≥ 88 centimeters in women); triglyceride level of ≥ 150 mg/dL; HDL-C < 40 mg/dL in men or < 50 mg/dL in women; systolic blood pressure of ≥ 130 mm Hg, diastolic blood pressure of ≥ 85 mmHg or greater, or use of anti-hypertensive medication; and fasting plasma glucose of ≥ 100 mg/dL or use of anti-diabetes medication (CH_DS).

The overall age-adjusted prevalence of metabolic syndrome among adults 20 years and older is 34.9 percent (CH_DS). The prevalence of metabolic syndrome increases with age. Individuals ages 20 to 39 years have a prevalence of 19.5 percent; ages 40 to 59 years have a prevalence of 40.7 percent; and ages 60 years and older have a prevalence of 52.2 percent. Hispanics have the highest prevalence (38.1 percent) compared to other race-ethnicity groups. Non-Hispanic Whites, non-Hispanic Blacks, and non-Hispanic Asians have prevalence of metabolic syndrome of 35.4 percent, 33.7 percent, and 22.7 percent, respectively. Overall, the prevalence of metabolic syndrome is similar between men and women. However, women older than 60 years have a higher prevalence of metabolic syndrome compared to men in the same age group. Among men, Hispanics and non-Hispanic Whites (36.7 percent) have the highest prevalence compared to other men of different race-ethnicity groups. Among women, the race-ethnicity with the highest prevalence is Hispanics (39.2 percent).

Growth, Size, and Body Composition, Including Overweight and Obesity

The World Health Organization's (WHO) sex-specific growth standards, which are recommended by the CDC, were used with NHANES 2015-2016 data to identify the prevalence of low weight-for-recumbent length (-2 z-scores, which corresponds to less than 2.3rd percentile), recumbent length-for-age, and weight-for-age measured among infants and toddlers from birth to age 24 months.¹⁵ Findings included: 1.4 percent of infants from birth to age 24 months have low weight-for-recumbent length, 3.2 percent are low recumbent length-for-age,

and 1.7 percent are low weight-for-age. Using CDC's sex-specific growth chart (less than 5th percentile), 3.9 percent of infants from birth to age 24 months are low weight-for-recumbent length, 5.6 percent are low recumbent length-for-age, and 7.3 percent are low weight-for-age.

NHANES 2015-2016 and WHO's sex-specific growth standards, which are recommended by CDC, were used to identify the prevalence of high weight-for-recumbent length (+2 z-scores, which corresponds to greater than 97.7th percentile) among the birth to age 24 months population.¹⁶ Findings included that 8.9 percent of infants from birth to age 24 months of age have high weight-for-recumbent length. Using CDC's sex-specific growth chart (greater than 95th percentile), 9.9 percent of infants from birth to age 24 months have high weight-for-recumbent length.

The prevalence of low birthweight among U.S. infants by race-ethnicity was examined using data from the NVSS 2017.¹⁷ The prevalence of low birthweight (born at less than 2,500 grams) increased to 8.27 percent in 2017 from 8.17 percent in 2016. The prevalence of moderately low birthweight (born at 1,500 to 2,499 grams) was 6.77 percent, and the prevalence of very low birthweight (born at less than 1,500 grams) was 1.40 percent. From 2016 to 2017, the prevalence of low birthweight: increased for non-Hispanic Black women (13.68 percent to 13.88 percent), increased for Hispanic women (7.32 percent to 7.42 percent), and remained relatively unchanged for non-Hispanic White women (6.97 percent to 7.00 percent). Non-Hispanic Black women have the highest prevalence of low birthweight at 13.88 percent, and the highest prevalence reported since the data started being collected in 1993.

Of note from the above data are these key findings:

- Using the CDC recommended WHO growth standards to define low and high weight metrics in infants, and children from birth to age 24 months:
 - 1.4 percent are low weight-for-recumbent length
 - 3.2 percent are low recumbent length-for-age
 - 1.7 percent are low weight-for-age
 - 8.9 percent are high weight-for-recumbent length
- The prevalence of low birthweight (born at less than 2,500 grams) increased to 8.27 percent in 2017 from 8.17 percent in 2016.
- The prevalence of very low birthweight (born at less than 1,500 grams) was 1.40 percent.
- From 2016-2017, the prevalence of low birthweight babies increased for non-Hispanic Black mothers (13.68 percent to 13.88 percent) and Hispanic mothers (7.32 percent to

7.42 percent) but stayed relatively constant for non-Hispanic White mothers (6.97 percent to 7.00 percent).

- The prevalence of low birthweight babies among non-Hispanic Black mothers is the highest prevalence reported since the data started being collected in 1993.

Body mass index (BMI), a calculation of weight in kilograms (kg) divided by height in meters squared (m^2), is the recommended measure used to classify weight status for children and adults. Overweight in children is defined as a BMI $\geq 85^{th}$ to $<95^{th}$ percentile of sex-specific BMI-for-age growth charts from the CDC. Children with a BMI at or above the 95^{th} percentile are categorized as having obesity; children with a BMI at or above 120 percent of the 95^{th} percentile are categorized as having severe obesity. Among adults, overweight is defined as a BMI of 25 to 29.9 kg/m^2 , while obesity is defined as a BMI $\geq 30 \text{ kg/m}^2$. Severe obesity in adults is defined as a BMI $\geq 40 \text{ kg/m}^2$.¹⁸

Body Weight Status in Children

The prevalence of underweight among all children ages 2 to 19 years is 3 percent, down from 3.7 percent in 2007-2008. Data by race-ethnicity were unavailable. As age increases, so does the prevalence of underweight, particularly among adolescents. Underweight occurs in 2.3 percent of children ages 2 to 5 years, 2.5 percent in ages 6 to 11 years, and 3.7 percent in ages 12 to 19 years. The prevalence of underweight is lower in girls (2.5 percent) than in boys (3.6 percent).¹⁹

Among children ages 2 to 19 years, 41 percent of children are overweight or obese.²⁰

The prevalence of overweight is higher in girls ages 2 to 19 (17.6 percent) than in boys (15.7 percent). However, the prevalence of obesity and severe obesity is higher in boys (19.1 percent and 6.3 percent, respectively) than in girls (17.8 percent and 4.9 percent, respectively).

Since 2007-2008, the prevalence of obesity has increased for boys, girls, and 2 of 3 age categories. Overall, the prevalence of obesity has increased from 16.8 percent to 18.5 percent. Girls had an increase from 15.9 percent to 17.8 percent, while boys had an increase from 17.7 percent to 19.1 percent since 2007-2008. Children ages 2 to 5 years had the largest increase, going from 10.1 percent to 13.9 percent; children 12 to 19 years also had an increase in obesity prevalence (18.1 percent to 20.6 percent). However, children ages 6 to 11 years had a small decrease in the prevalence of obesity, from 19.6 percent to 18.4 percent.

The prevalence of obesity in all children increases with age: 13.9 percent for ages 2 to 5 years, 18.4 percent for ages 6 to 11 years, and 20.6 percent for ages 12 to 19 years.

However, the data show that the prevalence of obesity is similar for boys between the age groups 6 to 11 years (20.4 percent) and 12 to 19 years (20.2 percent).

In boys, the race-ethnicity group with the highest prevalence of obesity is Mexican Americans at 29.2 percent, followed by other Hispanics at 28 percent. The group with the lowest prevalence is non-Hispanic Asians, with a prevalence of 11.7 percent. In girls, the race-ethnicity group with the highest prevalence of obesity is non-Hispanic Blacks at 25.1 percent, followed by Mexican Americans at 24.3 percent, and other Hispanics at 23.6 percent. The group with the lowest prevalence is non-Hispanic Asians with a prevalence of 10.1 percent.

The prevalence of obesity among children ages 12 to 19 years decreases as education of the head of household increases: 22.3 percent for high school diploma or less, 18.1 percent for some college, and 11.6 percent for college graduate. The prevalence of obesity among children changes among metropolitan statistical areas (MSA). The prevalence is 17.1 percent in a large MSA and similarly is 17.2 percent in medium or small MSA, but increases to 21.7 percent for non-MSA (i.e., rural areas).²¹

Body Weight Status in Adults

For adults ages 20 years and older, the overall prevalence of underweight is 1.5 percent, a decrease from 2007-2008 (1.6 percent). The prevalence of underweight among adult women (1.8 percent) is higher than the prevalence of underweight among adult men (1.2 percent). The prevalence of underweight is 2.5 percent from ages 20 to 39 years, 0.8 percent from ages 40 to 59 years, and 0.9 percent for ages 60 years and older.²²

The proportion of adults in the United States that has overweight or obesity is 71.2 percent. The prevalence of overweight has decreased since 2007-2008 from 34.3 percent to 31.6 percent in 2015-2016. However, obesity prevalence has increased from 33.7 percent to 39.6 percent; severe obesity also has increased during this time from 5.7 percent to 7.7 percent. Men have a higher prevalence of overweight (36.5 percent) compared to women (26.9 percent). However, women have higher rates of obesity (41.1 percent) and severe obesity (9.7 percent) compared to men (37.9 percent for obesity and 5.6 percent for severe obesity).²³ Average body weight for men is 197.8 pounds (lbs) (89.7 kg) while mean body weight for women is 170.5 lbs (77.3 kg). The mean waist circumference for men is 40.3 inches (102.3 centimeters (cm)), and the mean waist circumference for women is 38.7 inches (98.4 cm). Although the average body weight and waist circumference have been increasing over time, the mean height for men and women has been relatively stable over time (69 inches or 175.3 cm for men; 63.6 inches or

161.5 cm for women)—consistent with trends in increasing BMI. The mean BMI for men is 29.1 kg/m², while the mean BMI for women is 29.6 kg/m².²⁴

The prevalence of obesity peaks in the 40 to 59 years age group at 42.8 percent.

Those who are ages 20 to 39 years have a prevalence of obesity of 35.7 percent, while those who are 60 years and older have a prevalence of 41.0 percent.

In men, the race-ethnicity group with the highest prevalence of obesity is Mexican Americans (46.2 percent) followed by other Hispanics (43.1 percent). In women, the race-ethnicity group with the high prevalence of obesity is non-Hispanic Blacks (54.8 percent) followed by Mexican Americans (52.3 percent) and other Hispanics (50.6 percent).

Some relationship exists between weight status and educational attainment. College graduates have a lower prevalence of obesity (30.3 percent) compared to those with a high school diploma or less (36.2 percent) or those with some college (43.8 percent). Obesity status also varies by smoking status: current smokers have the lowest prevalence at 31.3 percent compared to never smokers at 35.6 percent and former smokers at 42.0 percent. Adults who live in large MSAs have the lowest obesity prevalence of 31.8 percent, while those in a medium or small MSA have a prevalence of 42.7 percent, and those in a non-MSA have a prevalence of 38.6 percent.²⁵

Reduced Muscle Strength and Bone Mass

Reduced muscle strength contributes to impaired mobility and mortality in older adults.^{26,27} The Committee evaluated NHANES data relative to criteria established by the Foundation for the National Institutes of Health Sarcopenia Project that includes sex-specific criteria to define normal, intermediate, and weak muscle strength based on hand grip measurements that have previously been predictive of gait speed, a proxy measure for mobility impairment.²⁸

Among adults ages 60 years and older, NHANES 2013-2014 data indicate **the overall age-adjusted prevalence of reduced muscle strength is 19.2 percent (CH_DS)**. The prevalence is higher among those 80 years and older (48.6 percent) than those ages 60 to 79 years (10.9 percent). The prevalence of reduced muscle strength is 19.4 percent among women and 19.0 percent among men. Among those 80 years and older, the prevalence is 49.7 percent among women and 47.1 percent among men. The race-ethnicity group with the highest age-adjusted prevalence of reduced muscle strength is non-Hispanic Asians at 31.4 percent, closely followed by Hispanics at 30.4 percent. Non-Hispanic Blacks have a prevalence of 18.8 percent and non-Hispanic Whites have a prevalence of 17.9 percent.

The NHANES 2013-2014 exam used dual-energy X-ray absorptiometry (DXA) to assess bone mass.²⁹ Classifications for bone mass status were made using the WHO criteria. Low bone mass is defined as a T-score between -1.0 and -2.5; osteoporosis is defined as a T-score ≤ -2.5 . The T-score is calculated as the difference between the bone mineral density for the NHANES participant and the mean bone mineral density for the reference group, divided by the standard deviation of the reference group.

The prevalence of low bone mass for all adults ages 50 years and older is 42.8 percent at the femur neck, 27.9 percent at the lumbar spine, and 44.5 percent at either site. Women have higher rates of low bone mass at the femur neck (52.6 percent) and lumbar spine (35.9 percent) compared to men (32.1 percent and 19.2 percent, respectively). Similarly, women have a higher prevalence of low bone mass at either site (52.6 percent) compared to men (35.6 percent). Hispanic women have the highest prevalence of low bone mass (57.0 percent), followed by non-Hispanic Whites (54.6 percent), non-Hispanic Asians (47.0 percent), and non-Hispanic Blacks (40.4 percent). For men, non-Hispanic Asians have the highest rate of low bone mass at 47.7 percent, followed by Hispanics (38.1 percent), non-Hispanic Whites (37.3 percent), and non-Hispanic Blacks (25.7 percent).

The prevalence of osteoporosis among adults ages 50 years and older is 6.3 percent at the femur neck, 7.8 percent at the lumbar spine, and 11.0 percent at either the femur neck or the lumbar spine. Women have more than 3 times the rate of osteoporosis at either site (16.5 percent) compared to men (5.1 percent). The prevalence of osteoporosis at the femur neck is 9.8 percent for women and 2.5 percent for men; at the lumbar spine the prevalence is 11.6 percent for women and 3.6 percent for men. Among women ages 50 years and older, non-Hispanic Asians have the highest rates of osteoporosis at 40.0 percent compared to rates of 17.0 percent for non-Hispanic Whites, 20.5 percent for Hispanics, and 8.2 percent for non-Hispanic Blacks. Among men ages 50 years and older, the prevalence of osteoporosis is highest in non-Hispanic Asians (7.5 percent), followed by 6.0 percent for non-Hispanic Whites, 5.9 percent for Hispanics, and 1.9 percent for non-Hispanic Blacks.²⁹

Gestational Diabetes Mellitus

Gestational diabetes is diabetes that develops and is diagnosed during pregnancy. Birth data from the 2012-2016 NVSS provided information on the prevalence of gestational diabetes in the United States by age, race-ethnicity, educational attainment, and pre-pregnancy BMI.³⁰ The overall prevalence of gestational diabetes among women with a live birth was 6.0 percent in 2018. **The prevalence of gestational diabetes increases with age.** Women younger than age

20 years have a prevalence of gestational diabetes of 1.9 percent, while women ages 25 to 29 years have a prevalence of 5.1 percent, and those ages 35 to 39 years have a prevalence of 9.6 percent. Women ages 40 years and older have a prevalence of gestational diabetes of 12.8 percent. Non-Hispanic Asians have the highest prevalence of gestational diabetes among race-ethnicity subgroups (11.1 percent), followed by American Indian/Alaska Natives (9.2 percent), Native Hawaiian/Pacific Islanders (8.4 percent), Hispanics (6.6 percent), and non-Hispanic Whites (5.3 percent). The race-ethnicity group with the lowest prevalence of gestational diabetes is non-Hispanic Blacks (4.8 percent). The prevalence of gestational diabetes remains relatively stable across levels of education, ranging from 6.2 percent for those with less than a high school education to 5.9 percent and 6.0 percent for those with a college degree or more than college, respectively. The prevalence of gestational diabetes increases with pre-pregnancy BMI. For those with an underweight pre-pregnancy BMI, the prevalence is 2.9 percent. Individuals with a normal weight BMI have a prevalence of 3.6 percent, followed by those in the overweight category at 6.1 percent, obesity class I category (30.0 to 34.9 kg/m²) at 8.8 percent, and those in the obesity class II category (35.0 to 39.9 kg/m²) at 11.2 percent. For those classified with a BMI of obesity class III (40.0 or greater kg/m²), the prevalence of gestational diabetes is 13.9 percent.

Chronic Liver Disease

Given the pleiotropic functions of the liver and the importance of the liver to nutritional health, the Committee examined data on existing liver disease as well as surrogate markers of liver enzymes. Additionally, cirrhosis was examined, as alcohol was a focus of several Committee questions. Among other etiological factors, cirrhosis can result from alcohol abuse³¹ and is not reversible. The NVSS 2016 was used to examine age-adjusted chronic liver disease and cirrhosis mortality in the United States.³² The total age-adjusted deaths per 100,000 population for males was 14.3 and 7.5 for females in 2016. Rates have increased from 12.1 and 5.8, respectively, in 2006. From 2006 to 2016, mortality rates increased in every age group except for males ages 45 to 54 years. **The age-sex group with the highest mortality rate from chronic liver disease was males ages 55 to 64 years** (45.9 per 100,000); the age-sex group with the lowest mortality was females ages 25 to 34 years.

Elevated serum alanine aminotransferase (ALT) and aspartate aminotransferase (AST) may be indicative of underlying liver disease or inflammation. The prevalence of high ALT and AST among adults ages 20 years and older was examined by sex and race-ethnicity using NHANES 2005-2008.³¹ The prevalence of high ALT and high AST among adults 20 years and older was

9.7 percent and 16.0 percent, respectively. Men had a higher prevalence of high AST (24.8 percent) than did women (7.2 percent), but women had a higher prevalence of high ALT (10.0 percent) than did men (9.1 percent). Both the prevalence of high ALT and the prevalence of high AST decrease as age categories increase. Hispanics had the highest prevalence of high ALT (16 percent) and high AST (24.4 percent) among all race-ethnicity groups.

The prevalence of self-reported liver disease among adults ages 18 years and older by sex and race-ethnicity were examined using the 2017 NHIS.³³ Self-reported chronic liver disease was lower than actual chronic liver disease. The total prevalence of self-reported liver disease was 1.7 percent. Males have a slightly higher prevalence (1.8 percent) than do females (1.6 percent). The age group with the highest prevalence rate was adults ages 45 to 64 years (2.7 percent); the age group with the lowest prevalence is adults ages 18 to 44 years (1.1 percent). American Indian/Alaska Natives had the highest rates of self-reported liver disease (4.1 percent), and Asians had the lowest prevalence (1.2 percent). Hispanics had a higher prevalence (2.5 percent) than non-Hispanics (1.6 percent). The education level with the highest prevalence (3.2 percent) was less than a high school diploma, and the education level with the lowest prevalence (1.3 percent) is bachelor's degree or higher. People who were not employed but have worked previously have the highest prevalence (3.0 percent) by employment status.

Cancer

The *2018 Annual Report to the Nation on the Status of Cancer, Parts 1 and II: National Cancer Statistics* contains 2015 cancer statistics data which were used for children in this section of the Committee's report.^{34,35} On March 12, 2020, the report containing 2017 cancer statistics was released.

Leukemia incidence and death rates among children ages 0 to 19 years were examined using age-adjusted SEER Program 2011-2015 information on cancer statistics. The incidence rate of leukemia among children ages 0 to 19 years is 4.7 per 100,000 and the mortality rate is 0.6 per 100,000. The incidence and mortality rates of leukemia among children ages 0 to 19 years is higher among boys (5.1 and 0.7, respectively) than among girls (4.4 and 0.5, respectively).

Cancer outcomes in adults ages 19 years and older were examined using SEER 2016. All rates noted below are per 100,000 people and are age-adjusted to the 2000 U.S. Standard Population.

The incidence rate of female breast cancer in the United States is 127.5 among all ages, 83.9 among women younger than age 65 years, and 428.7 among women ages 65 years and

older. The mortality rate of female breast cancer among women of all ages is 20.6, 10.0 among women younger than age 65 years, and 93.5 among women ages 65 years and older.

The incidence rate of colon and rectal cancer is 38.6 among all ages, 18.3 among those younger than age 65 years, and 178.5 among those ages 65 years and older. The incidence rate is higher in males than in females: among all ages (44.2 and 33.9, respectively), among those younger than 65 years (20.6 and 16.2, respectively), and among those 65 years and older (207.3 and 156.5, respectively). The mortality rate of colon and rectal cancer is 14.2 among all ages and sexes, 4.9 among those younger than age 65 years, and 78.5 among those ages 65 years and older. The mortality rate is higher among males than females: among all ages (16.9 and 11.9, respectively), among people younger than age 65 years (5.8, 4.0), and among people ages 65 years and older (93.9, 66.9).

The incidence rate of esophageal cancer is 4.3 among all ages, 1.7 among those younger than age 65 years, and 21.9 among those ages 65 years and older. The incidence rate is higher in males than in females: among all ages (7.3, 1.8), among those younger than age 65 years (2.9, 0.6), among those ages 65 years and older (38.2, 9.5). The mortality rate of esophageal cancer is 4.0 among all ages, 1.5 among those younger than age 65 years, and 21.3 among those ages 65 years and older. The mortality rate is higher among males than females: among all ages (7.1, 1.5), among those younger than age 65 years (2.6, 0.5), and among those ages 65 years and older (38.3, 8.3).

The incidence rate of prostate cancer is 109.5 among all ages, 44.3 among males younger than age 65 years, and 560.4 among males ages 65 years and older. The mortality rate of prostate cancer is 19.2 among all ages, 1.7 among males younger than age 65 years, and 140.7 among males ages 65 years and older.

The incidence rate of larynx cancer is 3.0 among all ages, 1.5 among those younger than age 65 years, and 13.3 among those ages 65 years and older. The incidence rate is higher in males than in females: among all ages (5.2, 1.1), among those younger than age 65 years (2.3, 0.6), and among those ages 65 years and older (25.0, 4.4). The mortality rate of larynx cancer is 1.0 among all ages, 0.4 among those younger than age 65 years, and 5.2 among those ages 65 years and older. The mortality rate is higher in males than females: among all ages (1.8, 0.4), among those younger than age 65 years (0.6, 0.1), and among those ages 65 years and older (9.6, 1.9).

The incidence rate of lung and bronchus cancer is 54.9 among all ages, 16.4 among those younger than age 65 years, and 320.9 among those ages 65 years and older. The incidence rate is higher among males than females: among all ages (63.0, 48.9), among those younger

than age 65 years (17.3, 15.6), and among those ages 65 years and older (378.8, 279.2). The mortality rate of lung and bronchus cancer is 41.9 among all ages, 11.5 among those younger than age 65 years, and 251.6 among those ages 65 years and older. The mortality rate is higher in males than females: among all ages (51.6, 34.4), among those younger than age 65 years (13.3, 9.8), and among those ages 65 years and older (316.4, 204.0).

The incidence rate of oral cavity and pharynx cancer is 11.3 among all ages, 6.7 among those younger than age 65 years, and 43.0 among those ages 65 years and older. The incidence rate is higher among males than females: among all ages (17.0, 6.4), among those younger than age 65 years (10.0, 3.6), and among those ages 65 years and older (65.5, 25.4). The mortality rate of oral cavity and pharynx cancer is 2.5 among all ages, 1.1 among those younger than age 65 years, and 12.1 among those ages 65 years and older. The mortality rate is higher among males than females: among all ages (3.9, 1.3), among those younger than age 65 years (1.8, 0.5), and among those ages 65 years and older (18.7, 7.1).

The incidence rate of pancreatic cancer is 12.9 among all ages, 4.4 among those younger than age 65 years, and 72.0 among those ages 65 years and older. The incidence rate is higher in males than females: among all ages (14.6, 11.5), among those younger than age 65 years (5.0, 3.7), and among those ages 65 years and older (81.0, 65.0). The mortality rate of pancreatic cancer is 11.0 among all ages, 3.2 among those younger than age 65 years, and 64.8 among those ages 65 years and older. The mortality rate is higher among males than females: among all ages (12.6, 9.6), among those younger than age 65 years (3.8, 2.5), and among those ages 65 years and older (73.2, 58.2).

The incidence rate of endometrial cancer is 27.5 among all ages. The mortality rate of endometrial cancer is 4.7 among all ages.

The incidence rate of liver and intrahepatic bile duct cancer is 8.8 among all ages, 4.7 among those younger than age 65 years, and 37.6 among those ages 65 years and older. The incidence rate is higher among males than females: among all ages (13.6, 4.7) and among those younger than age 65 years (7.5, 2.1). The mortality rate of liver and intrahepatic bile duct cancer is 6.5 among all ages, 2.9 among those younger than age 65 years, and 31.8 among those ages 65 and older. The mortality rate is higher among males than females: among all ages (9.6, 3.9), among those younger than age 65 years (4.5, 1.4), and among those ages 65 years and older (44.8, 21.7).

Of note from the above data are these key findings:

- The cancer with the highest incidence rate among all ages is female breast cancer (127.5 per 100,000), followed by prostate cancer (109.5 per 100,000).

- The age group and cancer type with the highest incidence rate is prostate cancer among males ages 65 years and older (560.4 per 100,000).
- The cancer with the highest mortality rate among all ages is lung and bronchus cancer (41.9 per 100,000).
- The age group and cancer type with the highest mortality rate is lung and bronchus cancer among those ages 65 years and older (251.6 per 100,000).
- Males have a higher incidence and mortality rate than females at all ages across all shared cancer types.
- The incidence and mortality rates are highest among those ages 65 years and older for every cancer type.

Dental Health

The prevalence of dental caries among children ages 2 to 19 years was examined by age, race-ethnicity and income using NHANES 2015-2016.³⁶ **The prevalence of total dental caries (treated and untreated) for children ages 2 to 19 years was 45.8 percent**, while the prevalence of untreated dental caries was 13.0 percent. The prevalence of total caries was lowest in ages 2 to 5 (21.4 percent) and increased in age groups 6 to 11 years (50.5 percent) and 12 to 19 years (53.8 percent). However, untreated dental caries increased with age and decreased again in the 12 to 19 years group (8.8 percent, 15.3 percent, and 13.4 percent, respectively). Hispanic youth are the most likely to have treated and untreated dental caries (57.1 percent), but non-Hispanic Black youth are most likely to have untreated dental caries (17.1 percent). The prevalence of both total caries and untreated caries is highest among low-income groups. Specifically, 56.3 percent of children whose families fell below the Federal poverty threshold had dental caries (treated or untreated) and 18.6 percent had untreated dental caries. By comparison, 34.8 percent of children whose families made 300 percent or more than the Federal poverty level had dental caries and 7.0 percent had untreated dental caries.

A slight downward trend has occurred over time for the prevalence of total dental caries and untreated dental caries among children. In the NHANES 2011-2012, the prevalence of total dental caries in all children ages 2 to 19 years was 50.0 percent (compared to 45.8 percent for 2015-2016), and the prevalence of untreated dental caries was 16.1 percent (compared to 13.0 percent for 2015-2016). However, untreated dental caries increased from 16.1 percent to 18.0 percent in 2013-2014 before dropping to 13.0 percent in 2015-2016.

The prevalence of dental caries and tooth loss among adults ages 20 to 64 years and adults ages 65 years and older in the United States was examined by age, race-ethnicity, and income

using NHANES 2011-2016. **The overall prevalence of dental caries among adults ages 20 to 64 years was 89.9 percent and 96.2 percent among adults ages 65 years and older, respectively.** Women have a higher prevalence (91.5 percent) than men (88.2 percent) among ages 20 to 64 years, but the prevalence converges among adults 65 years and older (women: 96.3 percent, men: 96.1 percent). Non-Hispanic Blacks have the highest prevalence of untreated dental caries among all race-ethnicity groups. The overall prevalence of complete tooth loss is 2.2 percent among adults ages 20 to 64 years and 17.3 percent among adults ages 65 years and older. Tooth loss may compromise dietary intakes.

Food Allergy

The overall prevalence of food allergy among U.S. infants and children ages 0 to 4 years reported by proxy using NHIS 2017 data is 6.6 percent.³⁷ However, these data are based on parental self-report, and the degree to which reported food allergies were diagnosed by a health provider (and if so, based on an actual allergic reaction vs testing results), or parental impression, or a combination of factors, cannot be determined from these data.

To access the data analyses referenced above, visit:

<https://www.dietaryguidelines.gov/2020-advisory-committee-report/data-analysis>

Question 2. What are the current intakes of food groups?

Approach to Answering Question: Data analysis

Conclusion Statements

For Americans ages 2 years and older, intakes of Fruit, Vegetables, Dairy, and Whole Grains are generally below recommended amounts, and intakes of total Grains and total Protein Foods generally meet or exceed recommended amounts for most age-sex groups. Intakes of solid fats and added sugars are above recommended levels for all age-sex groups. Patterns of food group intake have not changed over the last decade.

Breastfeeding initiation rates are high, but exclusive breastfeeding past age 3 months and any duration at age 6 months is 57 percent, with notable differences observed by race and ethnicity. Complementary foods and beverages are introduced before age 6 months for a majority of infants. The timing of introduction, intake patterns, and amount of calories provided by complementary foods and beverages differ by primary feeding mode among infants ages 6 to

12 months. Patterns of food group intakes and sources of food groups among ages 12 to 24 months are similar to those of the U.S. population, ages 2 years and older. A substantial increase in the intake of added sugars is seen when those age 1 year are compared with those younger than age 12 months.

Most women who are pregnant consume diets that are low in Fruits, Vegetables (particularly Dark Green and Red and Orange varieties), Dairy, and Whole Grains and are high in added sugars and saturated or solid fats. Almost half of women who are pregnant consume too little protein on a given day. Intake of seafood and plant-based sources of protein are relatively low among women who are pregnant.

Most women who are lactating consume diets that are low in Fruit, Vegetables (particularly Red and Orange Vegetables), Whole Grains, and Dairy, and are high in added sugars and solid fats. Nearly 1 in 6 women who are lactating consumes total Protein Foods in amounts less than the amounts recommended in the USDA Food Patterns.

Summary of the Evidence

Data analyses conducted for the Committee are found in the data analysis supplements and are referenced below as the Food Group and Nutrient Intakes for Infants and Toddlers Data Supplement (IT_DS), Food Group and Nutrient Intakes for Women Who are Pregnant or Lactating Data Supplement (PL_DS), Intake Distributions Data Supplement (Dist_DS), and Food Category Sources of Food Groups and Nutrients Data Supplement (CAT_DS).

Birth to Age 24 Months

Breastfeeding Initiation and Duration

Using data from the National Immunization Survey 2017-2018, which recorded information among infants born in 2016, the prevalence of breastfeeding initiation was 84 percent.³⁸ Lower rates of any- and exclusive-breastfeeding were observed at ages 3, 6, and 12 months. Both breastfeeding initiation and the duration of breastfeeding varied by race and ethnicity. Exclusive breastfeeding at 3 months was higher among non-Hispanic White (53 percent) and Asian infants (48 percent) when compared to non-Hispanic Black (39 percent) and Hispanic (42 percent) infants; the Healthy People 2020 goal is 46.2 percent. Overall, exclusive breastfeeding rates were 25.4 percent, and the Healthy People 2020 goal is 25.5 percent at age 6 months,

with Asian (32 percent) and non-Hispanic White infants (29 percent) having higher rates than other race-ethnic groups (approximately 20 percent).

Timing of Introduction of Complementary Foods and Beverages

Using data from the National Survey of Children's Health 2016-2018, the prevalence of introduction of complementary foods and beverages (CFB) before age 4 months was 32 percent, which was higher among infants receiving infant formula (42 percent) or a mix of infant formula and human milk (32 percent) than infants fed only human milk (19 percent) (IT_DS).

Types and Amounts of Complementary Foods and Beverages

Although some younger infants (younger than age 6 months) are consuming CFB, the sample size in NHANES was not sufficient to provide a description of intakes. Differences and similarities in the intakes of food groups among older infants and toddlers who have reported only human milk plus CFB and those who have reported any infant formula plus CFB are noted (see Table D1.2). As described in the methods, these data should be interpreted with caution due to limitations in the sample size, and because statistical testing between groups was not done.

Table D1.2. Proportion (%) of infants ages 6 to 12 months with reported intakes of each food group or subgroup, WWEIA, NHANES 2007-2016

		All Infants	HM	FMF
Fruit	Total	84	75	86
	Juice	40	20	45
Vegetables	Total including legumes	80	76	81
	Total starchy	42	37	43
	Total red and orange	64	59	66
	Dark green	6	6†	6
	Other	29	36	28
	Legumes	6	6†	6
Protein foods	Total excluding legumes	47	33	50
	Meat (beef, veal, pork, etc.)	14	7†	16
	Poultry	28	18	30
	Cured meat	7	3†	8
	Total fish and seafood	1†	#	1†
	Eggs	19	17	19
	Peanuts, nuts, seeds	2	3†	2
	Soy products, except soy milk	3	2†	3
Grain	Total	89	81	91
	Whole	59	51	61
Dairy	Total	45	40	46
Oil		57	46	59
Solid fat		60	49	62
Added sugars		63	55	64

Notes:

HM=human milk; FMF=formula or mixed fed

† indicates an estimate that may be less precise than others due to small sample size and/or large relative standard error.

indicates a non-zero value too small to present. Sample based on age at Mobile Examination Center.

Complementary foods include all foods and beverages except human milk and infant formula.

Milk reporting status determined by the report of human milk on either day 1 or day 2.

Older Infants Ages 6 to 12 Months

At ages 6 to 12 months, infants fed infant formula obtain a larger proportion of food groups from baby food sources than do infants who receive only human milk (CAT_DS). A summary of the proportion of infants with intakes of a food group, mean intakes, and food category sources of intakes are described for each food group. Figure D1.2 and Figure D1.3 illustrate the top food category sources of food groups by infant feeding mode for this age group.

Fruit

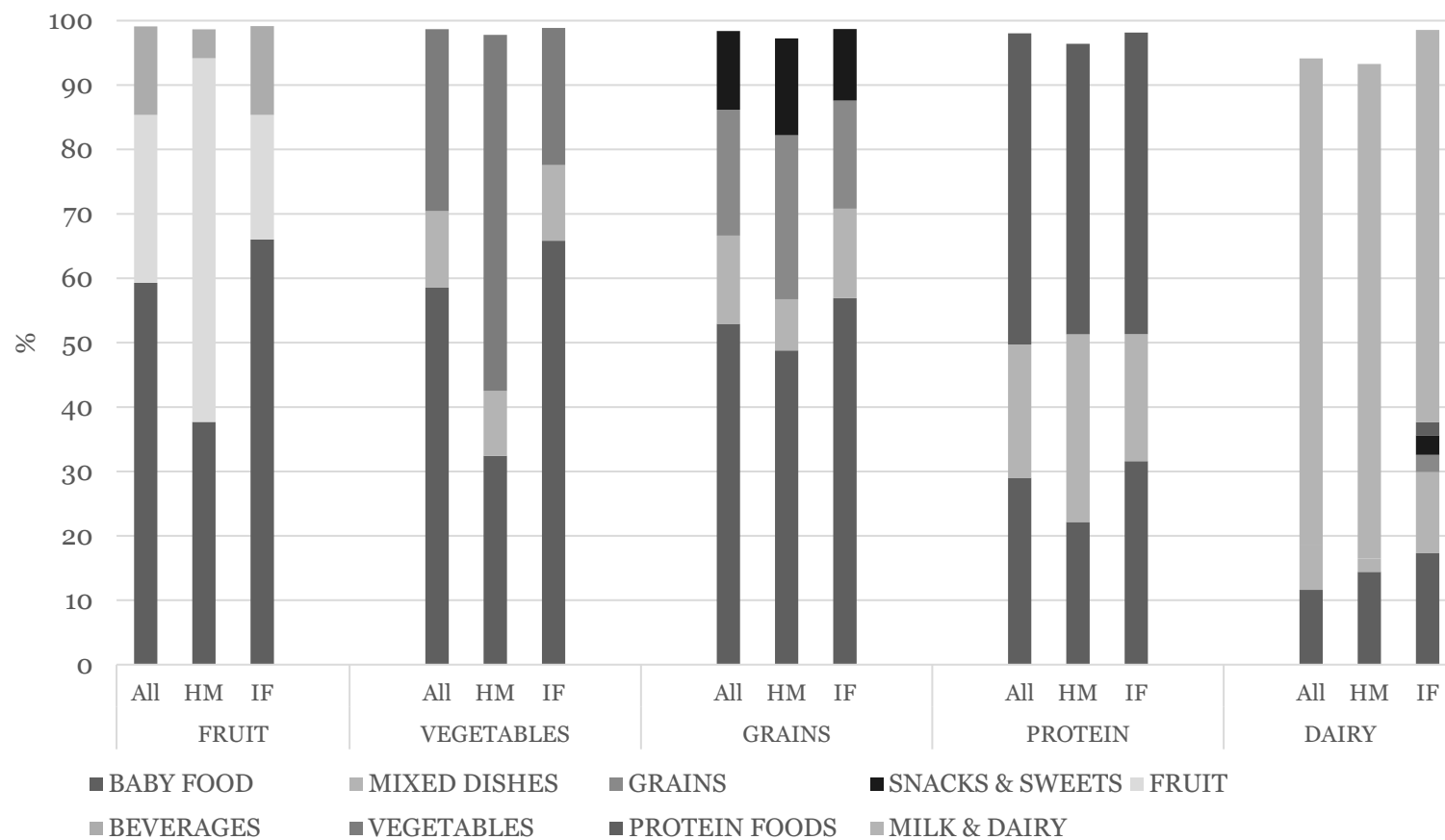
Infants ages 6 to 12 months consume most Fruit group foods from 3 distinct categories: baby foods, whole fruit, and beverages (e.g., fruit juices) (CAT_DS). The majority (59 percent) of fruit intake among all infants ages 6 to 12 months comes from baby food, with 26 percent coming from whole fruit and 14 percent from beverages. Most of the fruit came from the Fruit subgroup Other Fruits (e.g., bananas), followed by 100% fruit Juice (IT_DS). Citrus, Melons, and Berries are the smallest contributors to fruit intake among infants.

The category sources of fruit intake vary between infants consuming only human milk vs infants consuming any formula (CAT_DS). (See Figure D1.2.) Infants who receive human milk consume more fruit as non-baby food sources of fruit, with less as baby food and beverages (fruit drinks) compared to infants receiving any infant formula.

Vegetables

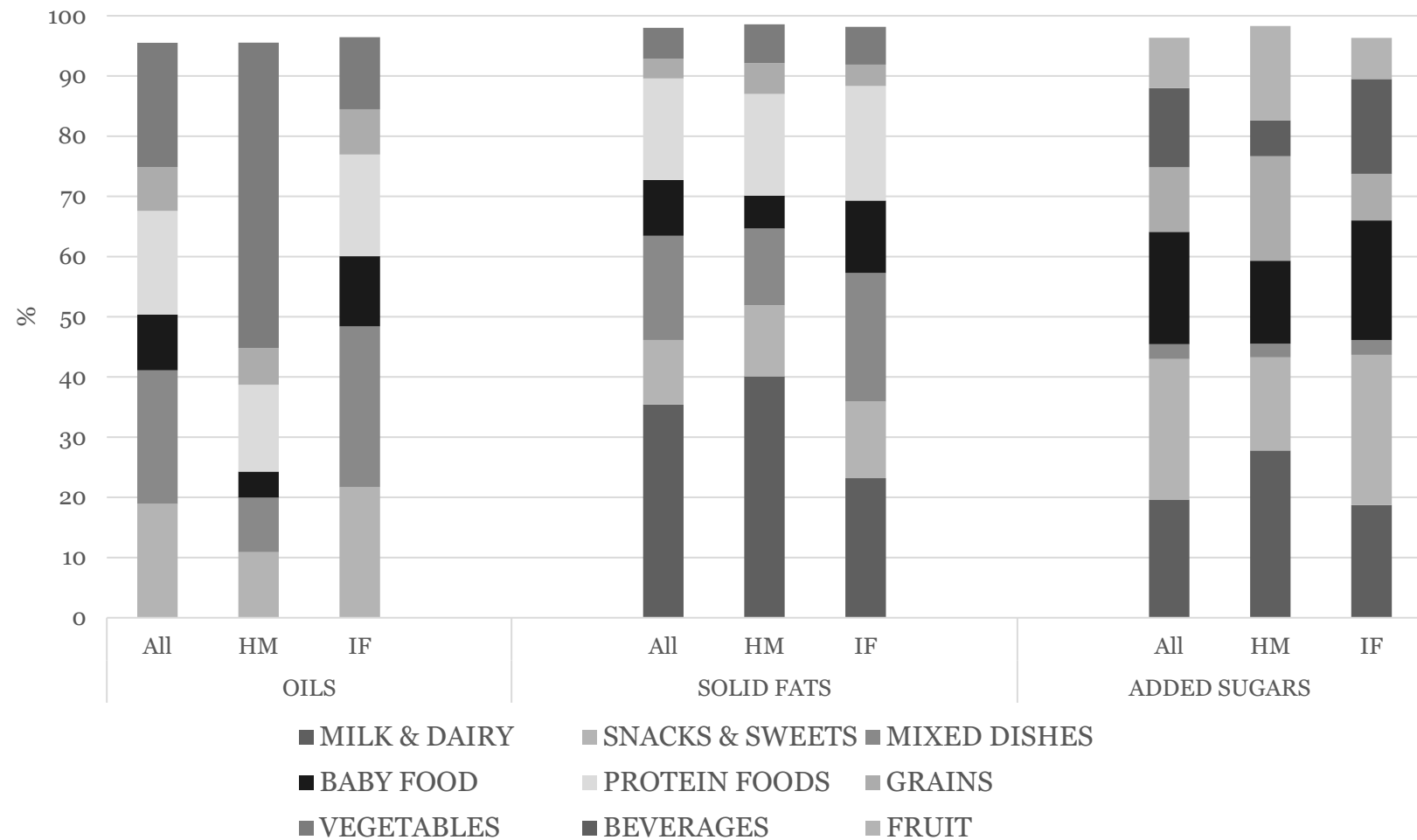
Total intakes from the Vegetable group among those ages 6 to 12 months come primarily from 3 category sources: baby foods, whole vegetables, and mixed dishes (CAT_DS). Although intake from mixed dishes is similar among infants fed human milk vs those fed any infant formula, those receiving human milk received more vegetables as whole vegetables than as baby food sources. (See Figure D1.2.)

About 80 percent of all infants ages 6 to 12 months are provided vegetables on a given day (IT_DS). Other Red and Orange Vegetables (not tomatoes; e.g., carrots) are the most commonly reported (57 percent), followed by other Starchy Vegetables (not potatoes; e.g., green peas) (30 percent), Other Vegetables (e.g., green beans) (29 percent), and potatoes (27 percent). Dark Green Vegetables and Legumes are the least-consumed vegetables, with only 6 percent of infants fed those foods on a given day. Mean intakes of total Vegetables are approximately 0.4 cup equivalents (cup eq) per day (IT_DS).

Figure D1.2. Top food category sources of Fruit, Vegetables, Grains, Protein, and Dairy, by infant feeding mode, ages 6 to 12 mo, WWEIA, NHANES, 2007-2016

Data Source: Food Category Sources of Food Group Intakes Among Infants and Toddlers [<https://www.dietaryguidelines.gov/2020-advisory-committee-report/data-analysis>]

HM=human milk; IF=infant formula

Figure D1.3. Top Food category sources of Oils, Solid Fats, and Added Sugars, by infant feeding mode, ages 6 to 12 mo, WWEIA, NHANES, 2007-2016

Data Source: Food Category Sources of Food Group Intakes Among Infants and Toddlers [<https://www.dietaryguidelines.gov/2020-advisory-committee-report/data-analysis>]

HM=human milk; IF=infant formula

Grains

The majority (89 percent) of infants are fed foods from the Grains food group on a given day (IT_DS). However, only 59 percent of infants receive whole grains. Four main food categories contribute grains in the diets of infants ages 6 to 12 months: baby foods, grains, mixed dishes, and sweets and snacks (CAT_DS). Total grain category sources vary by milk-feeding source, with infants receiving human milk obtaining more grains from snacks and sweets while formula-fed infants received more grains from mixed dishes. Mean total Grain intakes are 1.14 ounce equivalents (oz eq) among those fed any formula and 0.71 oz eq among those receiving only human milk (IT_DS). Whole Grain intakes are less than half of total Grain intakes, with mean intakes of approximately 0.3 oz eq. Note that food category sources of whole grains were not available in this age group. (See Figure D1.2.)

Protein Foods

Foods in the Protein Foods group come from 3 main food category sources in the diets of infants ages 6 to 12 months: approximately half from non-baby food protein foods (such as meats, eggs, fish, plant-based protein foods), 29 percent from baby food, and 21 percent from mixed dishes (CAT_DS). (See Figure D1.2.)

About half of all infants (47 percent) were fed foods from the Protein Foods group on a given day, with disparities by infant milk source; 33 percent of human milk-fed infants received total protein foods compared to 50 percent of infants receiving infant formula (IT_DS). The most commonly reported Protein Foods subgroups consumed by infants ages 6 to 12 months were Poultry (28 percent), Eggs (19 percent), and Meat (14 percent). Only 2 percent of infants reportedly received peanuts and Nuts and Seeds, 3 percent were fed Soy (other than soy beverages), and 6 percent were fed Legumes. Mean intakes of total Protein Foods were 0.28 oz eq among infants in the human milk group and 0.52 oz eq among those in the infant formula group.

Dairy

Less than half (45 percent) of infants ages 6 to 12 months consumed foods from the Dairy group on a given day, with fluid Milk consumed by 34 percent, Cheese consumed by 19 percent, and Yogurt consumed by 11 percent (IT_DS). Infants receiving human milk were more likely to be fed yogurt while those fed formula consumed more dairy as milk and cheese. Mean intakes of total Dairy foods were 0.30 cup eq among those receiving infant formula. Infants in the human milk group had negligible mean intakes of 0.08 cup eq.

Dairy was consumed by infants ages 6 to 12 months through 3 main food categories: milk and dairy, baby food, and mixed dishes (CAT_DS). Among formula-fed infants, a small amount of dairy was also contributed by snacks and sweets, grains, and protein foods (CAT_DS). (See Figure D1.2.)

Other Dietary Components

More than half of infants ages 6 to 12 months consume oils (57 percent), solid fats (60 percent), and added sugars (63 percent) on a given day (IT_DS). The intake of oils, solid fats, and added sugars is more common among infants receiving any formula as compared to those receiving only human milk, though statistical testing between groups was not done.

The main category sources of oils in the diets of infants ages 6 to 12 months include mixed dishes, vegetables, snacks and sweets, protein foods, baby food, and grains (CAT_DS). Condiments and sauces also contribute a small amount of oils in the diets of infants receiving human milk. Category sources of oils in the diets of infants vary greatly by milk source. Infants receiving human milk obtain more oils from vegetables and less from snacks and sweets, mixed dishes, and baby foods than do their formula-fed peers. (See Figure D1.3.)

The main category sources of solid fats in the diets of infants include milk and dairy, mixed dishes, protein foods, snacks and sweets, baby food, vegetables, and grains (CAT_DS). Infants receiving human milk obtain more solid fats from milk and dairy and less from mixed dishes and baby foods than do formula-fed infants. (See Figure D1.3.) Mean intakes of solid fats from CFB are 3 to 4 grams per day (IT_DS).

Added sugars are consumed by infants through a variety of categories, including snacks and sweets (23 percent), milk and dairy (20 percent), baby food (19 percent), beverages (other than 100% juice or fluid milk) (13 percent), grains (11 percent), fruit (8 percent), and mixed dishes (3 percent) (CAT_DS). (See Figure D1.3.) The sources of added sugars among infants vary significantly by milk source. Infants receiving human milk obtain the majority (61 percent) of added sugars through milk and dairy, grains, and fruit, whereas formula-fed infants receive 64 percent of added sugars through snacks and sweets, baby foods, and milk and dairy. Beverages other than 100% fruit juice contribute notably less added sugars to the diets of infants who are fed human milk (6 percent) compared to infants who are fed formula (16 percent). Mean daily intake of added sugars among those in the infant formula group is 1.1 teaspoon equivalents (tsp eq) and 0.7 tsp eq for those in the human milk group (IT_DS).

Toddlers Ages 12 to 24 Months

A summary of the proportion of toddlers with intakes of a food group, mean intakes, and food category sources of intakes are described in the following sections.

Fruit

Almost all (94 percent) toddlers are provided foods from the Fruit group on a given day, with a mean intake of 1.2 cup eq/day (IT_DS). Other Fruit (e.g., apples, bananas) is the most commonly consumed fruit subgroup, followed by 100% Juice (0.56 cup eq/day). Fruit is consumed by those ages 12 to 24 months from the categories of whole fruit (47 percent), fruit juice (41 percent), baby food (4 percent), baby beverages (4 percent), and candy (2 percent) (CAT_DS).

Vegetables

The majority (92 percent) of toddlers consume foods from the Vegetables group on a given day, with a mean daily intake of 0.52 cup eq/day (IT_DS). More than half (56 percent) of toddlers consume Other Vegetables (e.g., green beans) on a given day, followed by tomatoes (53 percent), potatoes (42 percent), other Red and Orange (not tomatoes; e.g., carrots) (34 percent), and other Starchy (not potatoes; e.g., green peas) (27 percent) (IT_DS). Legumes (14 percent) are consumed at about the same level as Dark Green Vegetables (13 percent). Starchy Vegetables and Red and Orange Vegetables each contribute about 0.18 cup eq/day to vegetable intake compared to 0.13 cup eq/day for Other Vegetables, suggesting that quantities of vegetable subgroups served may vary (IT_DS).

Food category sources that provide 5 percent or more of total Vegetable intake among toddlers include vegetables other than potatoes (35 percent), white potatoes (17 percent), grain-based mixed dishes (10 percent), baby foods (8 percent), meat and poultry and seafood mixed dishes (7 percent), soups (7 percent), and savory snacks (5 percent) (CAT_DS).

Grains

Although 99 percent of toddlers consume some type of food from the Grains food group on a daily basis, only 73 percent consume Whole Grains (IT_DS). The mean total Grain intake among toddlers is 3 oz eq/day. Only 0.5 oz eq/day of grains are consumed as whole grains, with intake higher among male compared to female toddlers.

The main category sources which provide 5 percent or more of total Grains include breads and rolls and tortillas (18 percent), grain-based mixed dishes (11 percent), sweet bakery

products (10 percent), crackers (9 percent), ready-to-eat cereals (6 percent), savory snacks (5 percent), baby foods (5 percent), and quick breads (5 percent) (CAT_DS). Pizza and Mexican dishes each provide 4 percent of total grains, with sandwiches providing 3 percent. Note that dietary intakes by whole grain source are not available.

Protein Foods

Almost all (95 percent) of those ages 12 to 24 months consumed Protein Foods on the day of assessment (IT_DS). Eggs are reported most commonly consumed (by 57 percent of toddlers), followed by Poultry (47 percent), Meats and cured meats (38 percent each), and peanuts and Nuts and Seeds (22 percent). Fifteen percent of infants are fed Legumes; 8 percent receive Soy (other than soy beverages); and only 6 percent are fed fish or Seafood.

The top food category sources of total Protein Foods include poultry (26 percent), cured meats and poultry (17 percent), eggs (14 percent), meat- and poultry- and seafood-based mixed dishes (10 percent), meats (7 percent), and plant-based protein foods (5 percent) (CAT_DS). Sandwiches provide about 4 percent of total Protein Foods, with seafood providing about 2 percent. Poultry is consumed in greater quantities than meat (0.7 oz eq/day compared to 0.3 oz eq/day) (IT_DS).

Dairy

Dairy foods are consumed by 99 percent of infants, with 96 percent consuming Milk, 66 percent consuming Cheese, and 22 percent consuming Yogurt (IT_DS). Total Dairy intake is about 2.5 cup eq/day among toddlers, with 2.1 cup eq/day coming from Milk, 0.4 cup eq/day from Cheese, and 0.1 cup eq/day from Yogurt (IT_DS). The top food categories that contribute to total Dairy intake include plain milk (73 percent), cheese (8 percent), yogurt (3 percent), mixed dishes (2 percent), dairy drinks and substitutes (2 percent), and flavored milk (2 percent) (CAT_DS).

Other Dietary Components

Toddlers consume a little more than 8 grams (g) of oils per day (IT_DS). Category sources of oils in the diets of toddlers are numerous, with the main contributors including savory snacks (12 percent), poultry (11 percent), crackers (10 percent), white potatoes (9 percent), grain-based mixed dishes (8 percent), plant-based protein foods (8 percent), and breads/rolls/tortillas (5 percent) (CAT_DS).

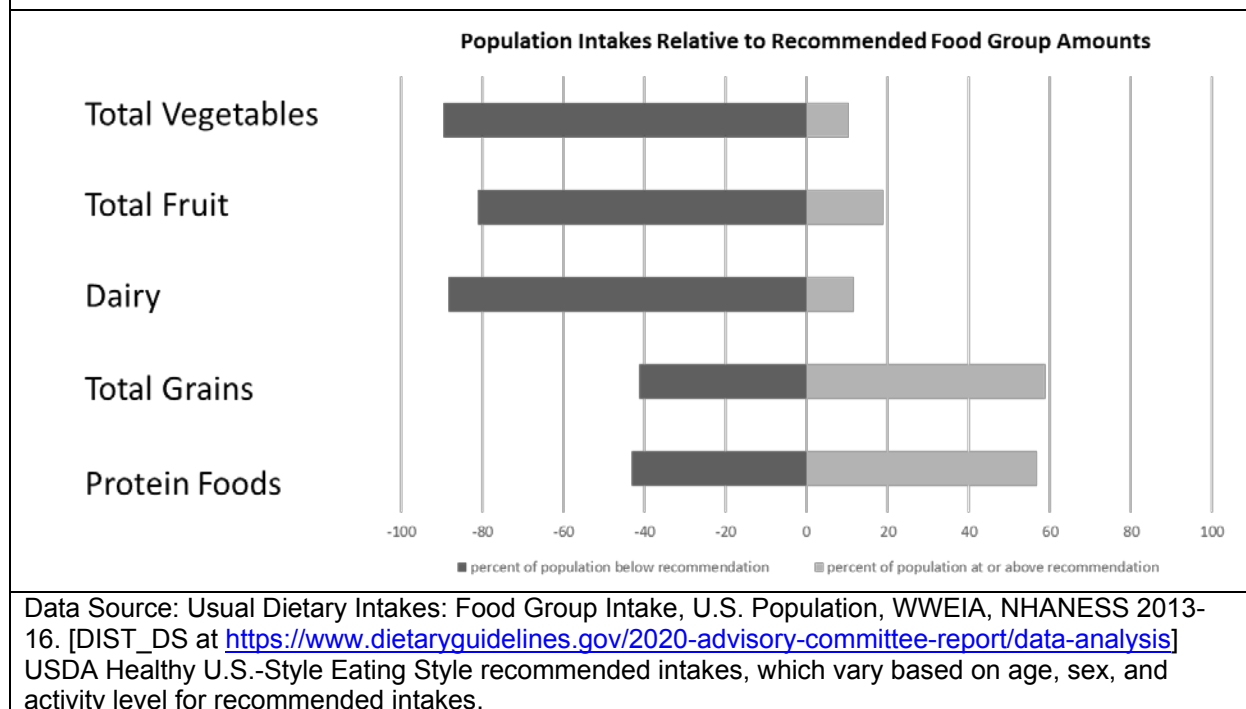
Toddlers consume almost 25 g of solid fats per day (IT_DS). The top food category sources of solid fats consumed by toddlers include plain milk (43 percent), sweet bakery products (8 percent), cheese (7 percent), cured meats and poultry (6 percent), and grain-based mixed dishes (5 percent). Pizza and Mexican dishes each provide about 3 percent of solid fats per day (CAT_DS).

Toddlers consume a little more than 6 tsp eq of added sugars each day (IT_DS). Food category sources of added sugars in the diets of toddlers ages 12 to 24 months include sweetened beverages (27 percent), sweet bakery products (15 percent), yogurt (7 percent), ready-to-eat cereals (6 percent), candy (6 percent), and other desserts (5 percent) (CAT_DS). Sugars and fruits each provide about 4 percent of added sugars, followed by flavored milk, and dairy drinks and substitutes at 3 percent each. Interestingly, from ages 12 to 24 months, patterns of food intake are similar to those among most Americans ages 2 years and older. Among toddlers, added sugars were primarily obtained through sweetened beverages (27 percent), sweet bakery products and other desserts (20 percent), and candy and sugars (10 percent) (CAT_DS).

Individuals Ages 2 Years and Older

Data analysis of NHANES 2015-2016 was first broadly examined as aggregated usual food group and subgroup data on foods and beverages using the USDA Food Patterns Equivalents Database and then refined further by characterizing foods and beverages “as consumed” through the WWEIA Food Categories. Finally, trends over time were examined comparing current intakes (2015-2016) of foods and beverages against a previous NHANES analysis (2003-2004). It is important to note that self-reported dietary patterns (e.g., vegetarian) were not collected in the survey years examined for this report. In this summary of the evidence, some differences and similarities between subgroups in the population are noted, but statistical testing between groups was not done.

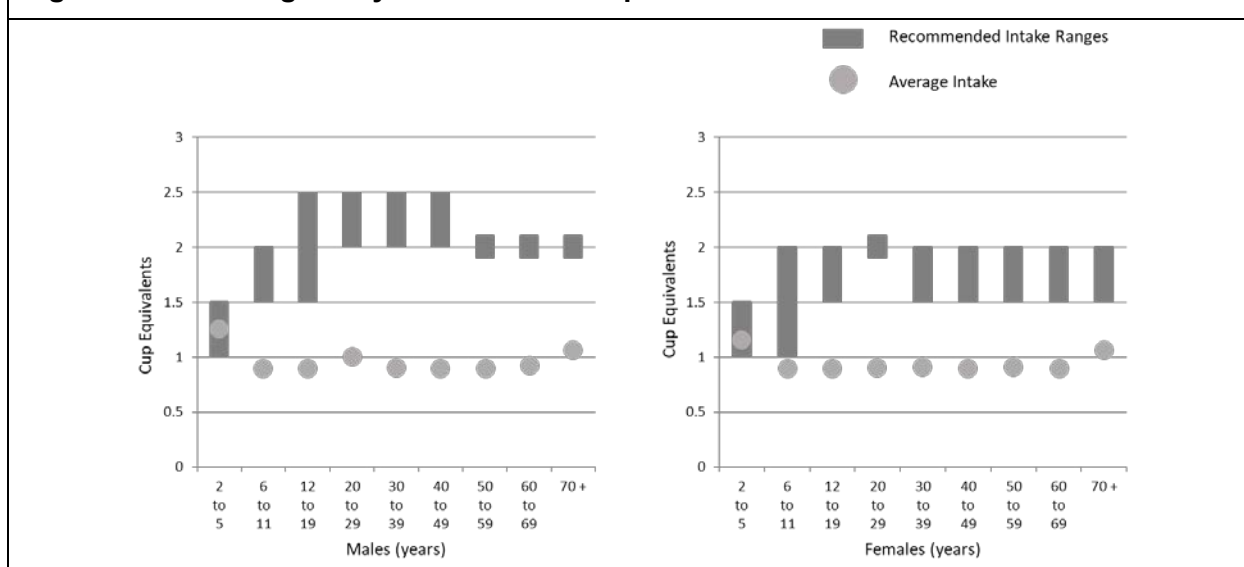
Intakes of most food groups have not changed over time.³⁹ A small increase in whole grains was seen between 2003-2004 and 2015-2016; however, intakes of whole grains are still well below recommended levels. Some changes in food intake were seen among youth, with total dairy intake decreasing among young children and total protein intakes decreasing among adolescents. The percentage of energy from solid fats and added sugars decreased somewhat during the same time period among all age groups.

Figure D1.4. Percent of population below, at, or above recommended food group amounts

Fruit

Recommended intakes of Fruit group foods range from 1 to 2.5 cup eq per day, based on the calorie level of the USDA Healthy U.S.-Style Food Pattern.⁶ Dietary intake of fruit is below recommended levels for the majority of the U.S. population (81 percent) (DIST_DS), with the exception of children ages 2 to 3 years, who primarily consume the additional fruit through fruit juice.⁴⁰ (See Figures D1.4 and D1.5.)

The mean total Fruit intake for individuals ages 2 years and older is 0.9 cup eq per day.⁴⁰ With the exception of preschool-aged children (1 cup eq/day), older adults (1.1 cup eq/day), and women who are pregnant or lactating (1.2 cup eq/day) (PL_DS). Americans on average consume less than 1 cup eq/day of total Fruit.⁴⁰ The majority of children ages 2 to 3 years (57 percent of females and 63 percent of males) consume fruit at levels that exceed recommendations (DIST_DS). Between the ages of 4 and 8 years, about half of children fall below recommended intakes, and 10 percent of male and 20 percent of female children exceed recommended intakes. Fruit intake plateaus during the elementary school years and remains at less than 1 cup eq/day through adulthood. Intake increases slightly among older adults to 1.1 cup eq/day.⁴⁰ Fruit intake does not vary substantially by sex.

Figure D1.5. Average daily Fruit intake compared to recommended intake

Data sources: What We Eat in America, NHANES 2015-2016 for average intakes by age-sex group. USDA Healthy U.S.-Style Eating Style recommended intake ranges, which vary based on age, sex, and activity level for recommended intakes. 2015-2020 Dietary Guidelines for Americans.

Approximately two-thirds of fruit consumption is whole fruit.⁴⁰ Other Fruits (e.g., apples, bananas, grapes) are consumed in larger amounts than Citrus, Melons, and Berries. Approximately one-third of Fruit intake is 100% fruit Juice. Mean fruit juice intake by children ages 2 to 5 years is 0.5 cup eq/day, decreasing with age throughout childhood and remaining consistently small during adulthood.

Food Category Sources of Fruit

Considering food category sources of fruit intakes, the top 4 subcategory sources of fruit intake among Americans of all ages are whole fruit, 100% fruit juice, sugar-sweetened and diet beverages, and desserts and sweet snacks (CAT_DS). Higher fat milk and yogurt is the fifth highest contributor of fruit for children (e.g., fruit in yogurts), while breakfast cereals and bars (e.g., dried fruit as part of a bar) rank fifth among adults.

A few differences in fruit intake by demographic factors are noted.⁴¹ Fruit intake is highest among Hispanic and non-Hispanic Black children between the ages of 2 and 5 years (1.3 cup eq/day) and among non-Hispanic Asian adults (1.3 cup eq/day) compared to other race-ethnic groups of children and adults (0.9 to 1 cup eq/day). Total Fruit intake was not associated with income; mean intakes are 0.9 cup eq/day among the lowest income group and 1.0 cup eq/day among the highest income group.⁴² However, fruit Juice consumption displayed an inverse

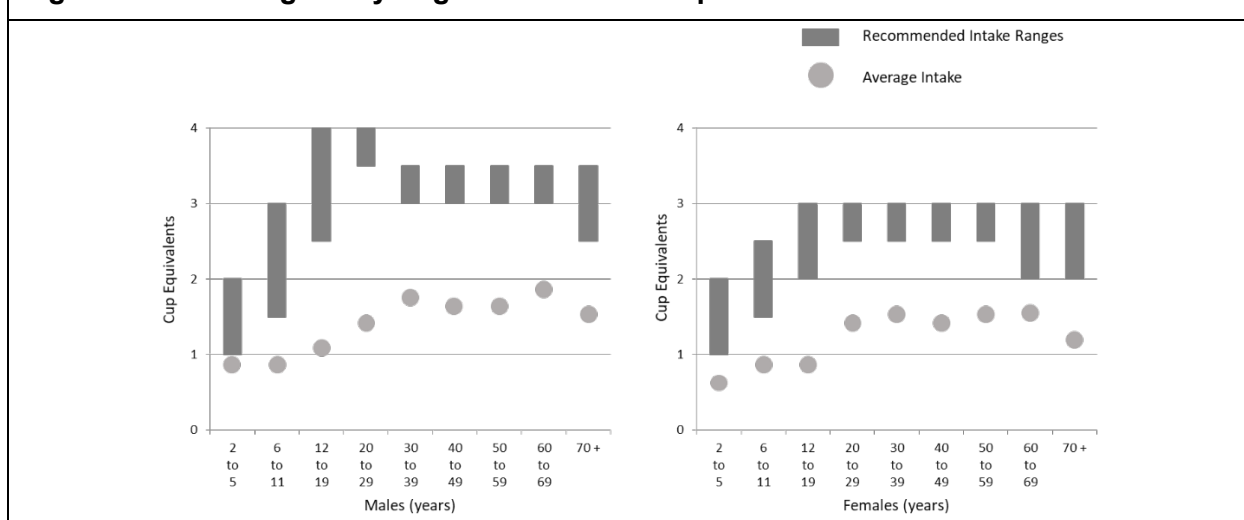
association with income, while Other Fruit and Citrus, Melons and Berries were positively associated with income.

Although the slight decreases in fruit intake over time (NHANES 2015-2016 compared with 2003-2004) are not statistically significant, they do signal dietary changes that bring Americans further away from recommended intakes. This trend should be monitored to see whether it persists over time.

Vegetables

Recommendations for Vegetable intakes range from 1 to 4 cups per day, based on energy level of the diet.⁶ The majority (about 90 percent) of Americans report a usual intake below the minimum recommendation for their age-sex group (DIST_DS), with a daily average across all age-sex groups of 1.5 cup eq/day.⁴⁰ (See Figures D1.4 and D1.6.) Children report a mean daily intake of less than 1.1 cup eq/day and adults report 1.4 to 1.7 cup eq/day, on average. The largest disparities between recommended and actual intakes of vegetables occur among children ages 4 to 8 years, adolescents, and young adults.

The majority of children (88 percent to 99 percent) and adolescents do not consume vegetables at recommended levels (DIST_DS), with a mean daily intake of total Vegetables of 0.9 cup eq/day.⁴⁰ The age group with the highest percentage of individuals with vegetable intakes at or above recommended amounts is children ages 2 to 3 years (DIST_DS). Ten percent of female and 15 percent of male children ages 2 to 3 years consume vegetables within or above recommended intakes. In adolescents, fewer than 2 percent of children ages 14 to 18 years meet or exceed recommend amounts of vegetables. Less than 3 percent of young adult males (ages 19 to 30 years) and less than 7 percent of young adult females meet or exceed recommended intakes of vegetables. Among adults ages 50 years and older, females are more likely than their male peers to meet or exceed recommended vegetable intakes (26 percent compared to 15 percent). The majority of Americans (up to 96 percent of youth and 99 percent of adults) consume too few Dark Green Vegetables and Red and Orange Vegetables relative to recommendations.

Figure D1.6. Average daily Vegetable intake compared to recommended intake

Data sources: What We Eat in America, NHANES 2015-2016 for average intakes by age-sex group. USDA Healthy U.S.-Style Eating Style recommended intake ranges, which vary based on age, sex, and activity level for recommended intakes. 2015-2020 Dietary Guidelines for Americans.

Food Category Sources of Vegetables

More than half of total vegetables are consumed as part of other foods rather than as discreet vegetables, by all age-sex groups, with the exception of older adults (CAT_DS). The top 3 food subcategories that contribute 10 percent or more to vegetable intake for all age groups are non-starchy and starchy vegetables; burgers and sandwiches; and rice, pasta, and other grain-based dishes. Chips, crackers, and savory snacks also provide more than 10 percent of vegetable intake in the diets of children. More than a quarter of total vegetable intake for Americans ages 2 years and older comes from white potatoes alone. Although absolute intake of potatoes is similar across age groups, the proportion of white potatoes to total vegetable intake is highest among children because their intakes of other vegetables are lower.⁴⁰ Beans, peas, and legumes are consumed in relatively small amounts, at an average of 0.1 cup eq/day.⁴⁰ Intakes of Dark Green and Red and Orange Vegetables are particularly low among all age-sex groups.

Demographic differences in vegetable consumption are seen among Americans. Non-Hispanic Asians report the highest intakes of total Vegetables (1.7 cup eq/day), with the majority of intake among non-Hispanic Asians coming from Other and Dark Green Vegetables.⁴¹ In comparison, the most common source of vegetables for non-Hispanic Black and Hispanic individuals are Starchy Vegetables. Total Vegetable intake is 1.4 cup eq/day in the highest income category and 1.27 cup eq/day in the lowest income group.⁴²

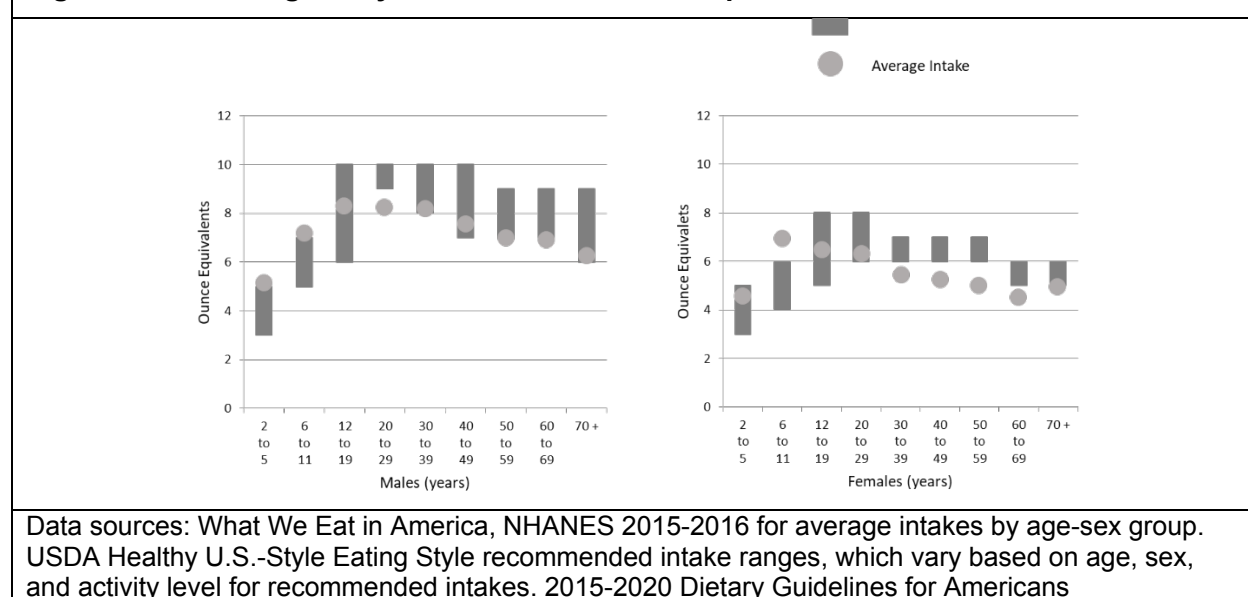
Total Vegetable intake among youth did not change significantly between the 2003-2004 and 2015-2016 NHANES cycles. However, a noticeable decline was seen among those ages 12 to 19 years.³⁹ Given that this change is contrary to evidence that suggests higher vegetable intakes are a critical component of a dietary pattern needed to promote health, this is a trend that should warrant monitoring.

Total and Whole Grains

The recommended range of total Grains ranges is from 3 to 8 oz eq per day and is based on energy intake.⁶ At least half of total Grains, or 1.5 to 4 oz eq/day, should come from whole grain sources. Mean total Grain intake among Americans ages 2 years and older is 6.4 oz eq/day,⁴⁰ which is within the recommended range. (See Figure D1.7)

More than 1 in 5 people exceeds recommended levels for total Grains (DIST_DS). However, only 0.9 oz eq/day are consumed from Whole Grains, which is well below recommended intakes.⁴⁰ Whole Grain intakes are well below recommended levels in all age-sex groups, with only 2 percent of the population meeting recommendations (DIST_DS).

Figure D1.7. Average daily total Grains intake compared to recommended intake



Youth ages 2 to 19 years reported a mean intake of 6.8 oz eq/day of total Grains, of which 0.9 oz eq/day were from Whole Grains;⁴⁰ 92 percent to 100 percent in this age group consume Whole Grains below recommended levels. Adults ages 20 years and older reported a mean consumption of 6.3 oz eq/day of total Grains, of which 0.9 oz eq/day were from Whole Grains.

With the exception of males ages 51 years and older, all other age-sex groups have mean usual intakes of Whole Grains less than 1.0 oz eq/day, although the range of the intake distribution among adults is wide (0.1 oz eq/day to 2.7 oz eq/day) (DIST_DS). The mean is higher than the median, suggesting a low intake among the majority of the population. About half of adults consume total Grains in amounts less than recommended levels; however, 16 percent of adult males and 20 percent of adult females exceed recommendations for total Grains. Nearly 75 percent of all Americans exceed recommendations for refined grains and Whole Grains are consumed at less than recommended levels by 98 percent of Americans. Intakes of Grains are higher among women than men.

Food Category Sources of Total and Whole Grains

The top food subcategory contributor to total Grain intake for all age-sex groups is burgers and sandwiches, providing a quarter or more of total Grain intake on an average day (CAT_DS). Among children ages 18 years and younger, rice, pasta, and other grain-based mixed dishes; chips, crackers, and savory snacks; and desserts and sweet snacks each provide more than 10 percent of total Grain intakes. Among adults, yeast breads and tortillas, and rice, pasta, and other grain-based dishes are among the top total Grain contributors.

Sources of Whole Grains tend to be from a narrow array of foods. The top food subcategories that contribute to Whole Grain intakes in the diets of U.S. children and adults include breakfast cereals and bars (33 percent to 42 percent); burgers and sandwiches (17 percent to 21 percent); and chips, crackers, and savory snacks (14 percent to 19 percent). Yeast breads and tortillas are a significant Whole Grain contributor among adults, but not among youth.

The highest intakes of total Grains (7 oz eq/day) are reported in the Hispanic and non-Hispanic Asian communities.⁴¹ The highest intake of Whole Grains occurs within the non-Hispanic Asian community (1.2 oz eq/day). Intakes of Whole Grains are higher among non-Hispanic Asian youth, particularly during adolescence, compared to other youth.

Total Grain intake is consistent across income levels.⁴² However, intake of Whole Grains is positively associated with increased income status among Americans ages 6 years and older.

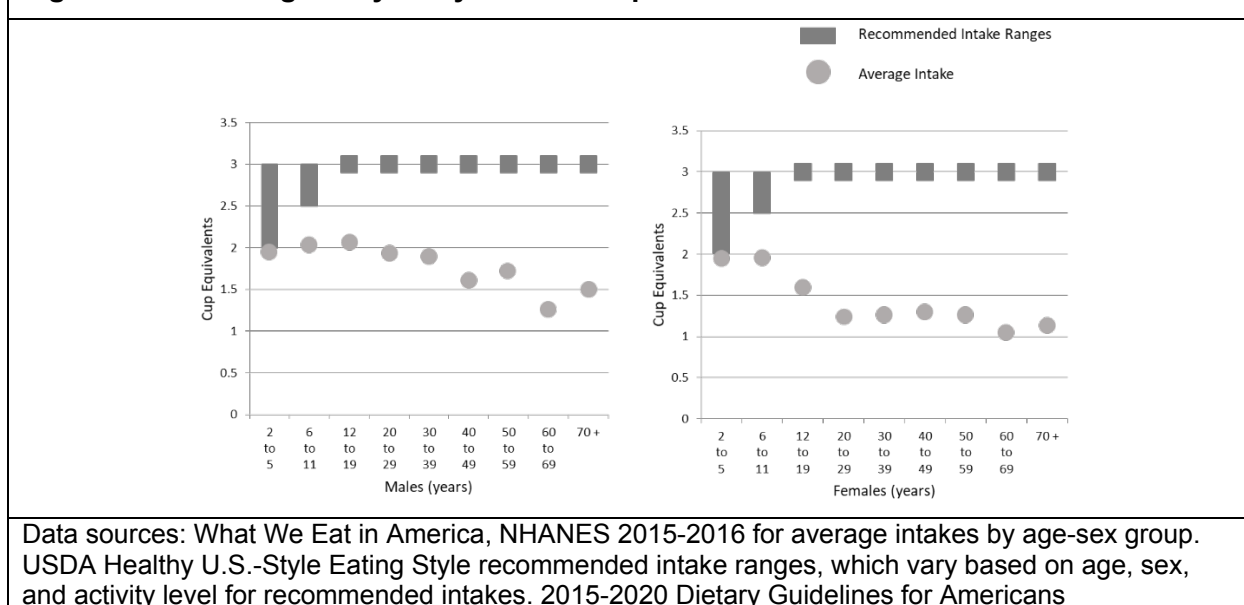
Although total Grain intakes remained steady between NHANES 2003-2004 and 2015-2016, Whole Grain intakes increased significantly among children ages 2 to 19 years but remain below recommended levels.³⁹

Dairy

Two to 3 cup eq of total Dairy foods are recommended for consumption each day; the recommendation is 3 cups for most age-sex groups, regardless of activity level. However, only 2 percent of the U.S. population meets the recommendation (DIST_DS). Although nearly 10 percent of Americans exceeded recommended intakes, 88 percent consume too little Dairy. Most children ages 2 to 3 years exceed recommended intakes. However, by adolescence, most youth have intakes below recommended amounts (see Figure D1.8).

Dairy intake is highest in young children (2.0 to 2.5 cup eq/day among those ages 1 to 3 years) and decreases with age.⁴⁰ The percentage of youth with Dairy intakes below recommended levels increases dramatically starting at age 9 years, with 79 percent or more between ages 9 and 13 years falling below recommended intakes (DIST_DS). However, nearly one-quarter of male teens exceed recommended Dairy intakes. Mean total Dairy intake is higher among youth ages 19 years and younger (1.9 cup eq/day) than among adults ages 20 years and older (1.5 cup eq/day).⁴⁰ Women who are pregnant (1.8 cup eq/day) and women who are lactating (1.6 cup eq/day) have somewhat higher total Dairy intakes compared to women who are not pregnant or lactating.⁴³ Males are more likely than females to exceed the recommendation in every age group (DIST_DS).

Dairy intake has decreased over time among youth, but the only statistically significant change has been among children ages 2 to 5 years.³⁹ Because Dairy foods (including calcium-fortified soy beverages and fortified cow's milk products) are a significant source of many nutrients, particularly calcium, phosphorous, and vitamin D, this downward trend among youth should be monitored.

Figure D1.8. Average daily Dairy intake compared to recommended intake

Food Category Sources of Dairy

Food subcategory sources of Dairy foods vary by age group (CAT_DS). Higher- and lower-fat milk and yogurt, specifically fluid milk (which includes calcium-fortified soy beverages but not other plant-based milk substitutes), are the primary contributors to Dairy intake in youth. Mean intakes are 1.1 cup eq/day of fluid Milk compared to 0.8 cup eq/day of Cheese and 0.05 cup eq/day of Yogurt.⁴⁰ The contribution of fluid Milk to Dairy intake decreases with age during childhood while the contribution of Cheese increases. The food subcategories of burgers and sandwiches and pizza also contribute significantly to total Dairy intake among children and adolescents (CAT_DS). Major food subcategories that contribute 10 percent or more to Dairy intake among adults ages 20 to 70 years include burgers and sandwiches followed by higher fat milk and yogurt and cheese. Among older adults, the top Dairy contributors include higher fat milk and yogurt, burgers and sandwiches, desserts and sweet snacks, and low-fat milk and yogurt. Overall, yogurt contributes only about 2 percent of dairy to the diets of Americans.

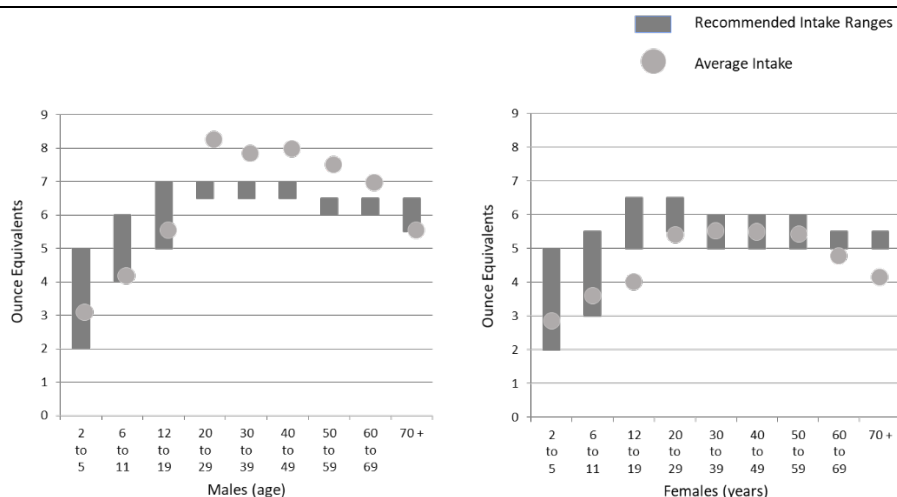
Some demographic differences are identified in Dairy intakes. Total Dairy intake is highest among non-Hispanic White and Hispanic individuals and lowest among non-Hispanic Black individuals of all ages.⁴¹ Dairy intake does not vary notably by income.⁴²

Protein Foods

Recommended intakes of Protein Foods range from 2 oz eq/day to 7 oz eq/day, depending upon calorie level.⁶ Mean total Protein Foods intake (including Seafood, Meat and Poultry, Nuts

and Seeds, and Soy Products, but excluding Legumes) by Americans ages 2 years and older is 5.8 oz eq/day, with average intake estimated at 4.1 oz eq/day among youth ages 2 to 19 years and 6.3 oz eq/day among adults.⁴⁰ The proportion of males ages 2 to 18 years with Protein Foods intakes below recommended levels increases with age from 23 percent (ages 2 to 3 years) to 64 percent (ages 9 to 13 years) (DIST_DS). The proportion of females ages 2 to 18 years with total Protein Foods intakes below recommended levels also increases with age from 32 percent (ages 2 to 3 years) to 79 percent (ages 14 to 18 years). A little more than half of adult males and one-quarter of adult females 19 years and older have Protein Foods intakes above recommended levels. Conversely, 50 percent of female adults ages 19 years and older consume Protein Foods below recommended levels compared to 31 percent of males. Mean intake of Protein Foods is within the range of recommended amounts for most groups except females ages 12 to 19 years and age 70 years and older (see Figure D1.9). Total Protein Foods intake is higher in males compared to females of all ages. Protein Foods intake has not changed significantly over time (2003-2004 to 2015-2016).³⁹

Figure D1.9. Average daily Protein Foods intake compared to recommended intake



Data sources: What We Eat in America, NHANES 2015-2016 for average intakes by age-sex group. USDA Healthy U.S.-Style Eating Style recommended intake ranges, which vary based on age, sex, and activity level for recommended intakes. 2015-2020 Dietary Guidelines for Americans.

Intakes of all Protein Foods subgroups increase with age among children ages 2 to 19 years in all race-ethnic groups.^{40,41} Poultry and Meat (i.e., beef, pork, and game meats) (1.2 and 1.0 oz eq/day, respectively), followed by cured meat (0.9 oz eq/day), are the predominant sources of total Protein Foods among youth ages 2 to 19 years.⁴⁰ Seafood contributes only 0.2 oz eq/day to Protein Foods intake in this age group. Eggs and Nuts and Seeds subcategories

contribute equal amounts to the diets of youth ages 2 to 19 years (0.4 oz eq/day for both). Meat and Poultry are the predominant contributors of Protein Foods among adults (1.6 oz eq/day for both), followed by cured meats (1.0 oz eq/day). Seafood contributes 0.6 oz eq/day of total Protein Foods to the diets of adults and is generally below recommended levels, with only 12 percent meeting or exceeding seafood recommendations. Approximately 20 percent of adults and 6 percent of children consume seafood twice per week.⁴⁴ Nuts and Seeds contribute more to Protein Foods in the diets of adults (0.8 oz eq/day) than do Eggs (0.6 oz eq/day), though statistical testing was not done. Animal-based and plant-based sources contribute 86 percent and 14 percent of total Protein Foods, respectively. These proportions do not include contribution from Legumes. However, mean daily intake of Legumes is small, 0.5 oz eq per day in the total population ages 2 and older.

Food Category Sources of Protein Foods

The food subcategories that provide 10 percent or more of Protein foods in the diets of Americans of all ages are burgers and sandwiches (15 percent to 30 percent) and poultry (11 percent to 20 percent) (CAT_DS). Meat, poultry, and seafood mixed dishes also are key sources of Protein Foods for U.S. adults.

Non-Hispanic Black youth have the highest intakes of poultry, while non-Hispanic White youth have the highest intakes of cured meats.⁴¹ Intakes of nuts and seeds and soybean products are higher among non-Hispanic White and non-Hispanic Asian youth than among other race-ethnic groups. A review of intakes of total Protein Foods shows similar findings among adults, with mean poultry consumption higher among non-Hispanic Black adults than other race-ethnic peers, while cured meat consumption is highest among non-Hispanic White adults. Seafood consumption is highest in the non-Hispanic Asian community (1 oz eq/day) and lowest among the non-Hispanic White community (0.5 oz eq/day). Intakes of nuts and seeds and eggs are highest among non-Hispanic White and non-Hispanic Asian groups (0.8 to 0.9 oz eq/day). Legume intake is highest among Hispanic individuals. As income level increases, total protein intake increases, primarily among seafood, nuts and seeds, and soybean products.

Calories from Solid Fats and Added Sugars

USDA Food Patterns do not specify intake recommendations for solid fats or added sugars; rather, to help consumers identify their total intake, a maximum limit in terms of calories from solid fats plus added sugars is provided.⁶ This allowance is small, ranging in the 2020 USDA Food Patterns from 137 calories (kcal) per day (for individuals whose total energy intake is only

1,000 kcal per day) to 596 kcal per day (for individuals whose total energy intake is 3,200 kcal or greater per day). The allowance does not include the solid fats that are inherent in food group and subgroup components; those are already calculated and used to determine the allowance for each pattern. For added sugars in particular, recommendations provide a quantitative limit of no more than 10 percent of total energy intake from added sugars. The majority of the population of all age-sex groups exceeds the maximum limit for energy intakes from solid fats and added sugars (DIST_DS).

Data on intakes of added sugars and saturated fats are described in the summary of evidence for Question 4, which addresses nutrients and food components of public health concern. Data on intakes of solid fats are described here.

Solid fat intakes rise with age in U.S. children.⁴⁰ Among male children and youth, mean intake is estimated at 28 g per day at ages 2 to 3 years, rising to 41 g/day by adolescence. Among females, estimated mean intake is 24 g/day at ages 2 to 3 years, rising to 32 g/day among those ages 9 to 13 years. Solid fats provide an average of 229 to 307 kcal/day among those ages 2 to 8 years and 288 to 367 kcal/day among those ages 9 to 18 years. Mean solid fat intakes decrease with age among adult males, from 43 g/day at ages 19 to 30 years to 40 g/day at ages 51 to 70 years. Among females, estimated mean intake remains stable at 30 to 31 g/day across adult age groups. Solid fats provide 360 to 384 kcal/day in the diets of adult males and 271 to 280 kcal/day in the diets of adult females. The estimated mean energy intake from solid fats and added sugars combined ranged from 611 kcal/day among older adult males and 481 kcal/day among older females, with a range of 194 to 1,101 kcal/day (DIST_DS).

Food Category Sources of Solid Fats and Added Sugars

The top subcategories of foods that provide solid fats among both adults and children include burgers and sandwiches (12 percent to 22 percent of total solid fat intakes) and desserts and sweet snacks (14 percent to 19 percent of total solid fats intakes) (CAT_DS). Higher fat milk and yogurt provide 19 percent of solid fats in the diets of those ages 2 to 5 years and 11 percent of solid fats among those ages 6 to 11 years.

The most significant food subcategories that provide added sugars among Americans is described in Question 4, which discusses nutrients that present a substantial public health concern.

Women Who Are Pregnant

Dietary intakes of women ages 20 to 44 years from WWEIA, NHANES 2013-2016 were used to assess food intakes of women who are pregnant. In some instances, comparisons to women who are not pregnant or lactating are noted; however, statistical comparison between groups was not made.

Fruit

Most women who are pregnant (64 percent) consume less fruit than is recommended on a given day (DIST_DS). Women who are pregnant report a mean consumption of 1.3 cup eq/day of total Fruit, with 0.3 cup eq/day coming from Citrus, Melons and Berries; 0.8 cup eq/day coming from other whole Fruit; and 0.3 cup eq/day from Juice (PL_DS).

Vegetables

Almost all women who are pregnant (90 percent) report consuming vegetables below recommended intakes (DIST_DS). About 65 percent consume less than recommended levels of Dark Green Vegetables, and 99 percent consume less than recommended levels of Red and Orange Vegetables on a given day. Women who are pregnant report a mean daily consumption of 1.6 cup eq of total Vegetables (excluding Legumes) (PL_DS). Women who are pregnant report a mean daily intake of 0.6 cup eq of Other Vegetables, 0.4 cup eq of potatoes, 0.3 cup eq of Dark Green Vegetables, and 0.2 cup eq of Red and Orange Vegetables (with tomatoes providing a large majority of this category). Legumes are not frequently consumed, with a mean daily reported intake of 0.09 cup eq.

Grains

About 1 in 3 women who are pregnant (31 percent) consumes less than the recommended intake of total Grains, with the remaining 69 percent meeting or exceeding recommended intakes (DIST_DS). Almost all women who are pregnant (95 percent) consume less than recommended intakes of Whole Grains. Mean total Grain intake among women who are pregnant is reported at 7.2 oz eq/day, and usual intakes of Whole Grains among women who are pregnant are 1.3 oz eq/day (PL_DS), which is significantly below the recommendation of 50 percent of total Grains coming from Whole Grain sources.

Dairy

Most women who are pregnant (90 percent) report Dairy intakes below recommended levels (DIST_DS). Mean daily intake of Dairy is estimated at 1.8 cup eq among women who are pregnant, of which 1 cup eq is from Milk and 0.8 cup eq is from Cheese (PL_DS). Yogurt is a small contributor to dairy at about 0.04 cup eq/day.

Protein Foods

Almost half of women who are pregnant (47 percent) consume less than recommended amounts of Protein Foods, and 24 percent consume greater than recommended levels of Protein Foods (DIST_DS). Mean daily total Protein Foods intake among women who are pregnant is estimated at 5.2 oz eq/day, with the majority of Protein Foods (3.9 oz eq/day) coming from Meat, Poultry, and Seafood; Poultry is the largest contributor (1.4 oz eq/day), followed by Meat (1.2 oz eq/day), and cured meat (0.7 oz eq/day) (PL_DS). Fish and Seafood provide 0.6 oz eq/day, with the majority of fish and Seafood coming from low omega-3 sources.² Other significant sources of Protein Foods include 0.5 oz eq/day obtained from Eggs, 0.7 oz eq/day coming from peanuts and Nuts and Seeds, 0.4 oz eq/day from Legumes, and 0.1 oz eq/day coming from Soy Products other than soy beverages.

Solid Fats, Added Sugars, and Oils

Virtually all women who are pregnant (99 percent) exceed the maximum limit of energy from solid fats and added sugars (DIST_DS). Mean energy intake from solid fats and added sugars combined is estimated to be 594 kcal/day among females who are pregnant, with a range of 254 to 1,031 kcal/day. Mean solid fat intakes among women who are pregnant are estimated at 36 g/day, with a range of 15 to 58 g/day. Solid fats provide an average of 306 kcal/day to the diets of women who are pregnant. Added sugar intakes among women who are pregnant are estimated at 20 tsp eq/day (range 5 to 37 tsp eq/day) (DIST_DS). Added sugars provide an estimated 288 kcal/day to the diets of women who are pregnant. Women who are pregnant report consuming 28 g of oils per day (PL_DS).

² Cooked seafood containing 500 mg or more of omega-3 fatty acids (eicosapentaenoic acid [EPA] and docosahexaenoic acid [DHA]) per 3 ounces was assigned as seafood high in omega-3 fatty acids. ars.usda.gov/ARSUserFiles/80400530/pdf/fped/FPED_1516.pdf

Women Who are Lactating

Dietary intakes of women ages 20 to 44 years from WWEIA, NHANES 2013-2016 were used to assess food intakes of women who are lactating. In some instances, comparisons to women who are not pregnant or lactating are noted; however, statistical comparison between groups was not made.

Fruit

The majority of women who are lactating (78 percent) consume less Fruit than is recommended (DIST_DS). Women who are lactating report a mean daily consumption of 1 cup eq/day of total Fruit, of which 0.2 cup eq are from Citrus, Melons, and Berries; 0.2 cup eq are from fruit Juice; and 0.6 cup eq are consumed as Other whole Fruit (PL_DS).

Vegetables

Most women who are lactating (88 percent) consume less than the recommended intakes of Vegetables, including 46 percent consuming less than the recommended levels of Dark Green Vegetables and 99 percent consuming less than recommended levels of Red and Orange Vegetables (DIST_DS). Women who are lactating report a mean daily consumption of 1.4 cup eq of total Vegetables (excluding Legumes), with 0.2 cup eq from Starchy Vegetables (mostly white potatoes), 0.3 cup eq from Dark Green Vegetables, 0.4 cup eq from Red and Orange Vegetables, and 0.5 cup eq from Other Vegetables (PL_DS). Legumes are infrequently consumed, with an estimated mean daily intake of 0.15 cup eq.

Grains

Most women who are lactating (79 percent) consume more than recommended levels of total Grains (DIST_DL). However, about 1 in 5 women who are lactating consumes less than recommended intakes. Almost all women who are lactating (95 percent) consume less than the recommended intakes of Whole Grains. Mean daily intake of total Grains among women who are lactating is reported at 7.8 oz eq, with usual intakes of Whole Grains among women who are lactating at 1.4 oz eq (PL_DS), which is well below the recommendation of 50 percent of total Grains coming from Whole Grain sources.

Dairy

Nearly all women who are lactating (95 percent) consume Dairy below recommended levels (DIST_DS). Mean daily intake of Dairy is estimated at 1.5 cup eq among women who are

lactating, of which 0.7 cup eq each are obtained by Milk and Cheese (PL_DS). Yogurt is infrequently consumed, providing only 0.04 cup eq/day.

Protein Foods

Approximately 16 percent of women who are lactating consume less than recommended amounts of Protein Foods, with the majority of women who are lactating meeting or exceeding recommended Protein Foods intakes (DIST_DS). Mean daily total Protein Foods intake among women who are lactating is estimated at 7.4 oz eq, with 5.0 oz eq coming from Meat, Poultry, and Seafood (PL_DS). Poultry contributes the most Protein Foods at 1.9 oz eq/day, followed by Meat (1.3 oz eq/day), fish and Seafood (1.0 oz eq/day), and cured meats (0.8 oz eq/day). Nearly half of fish and Seafood is from high omega-3 sources.³ Eggs contribute about 0.6 oz eq/day to Protein Foods intake. Peanuts and Nuts and Seeds provide about 1.2 oz eq/day of Protein Foods in the diets of women who are lactating, Legumes provide about 0.6 oz eq/day, and Soy Products (other than soy beverages) provide about 0.2 oz eq/day.

Solid Fats, Added Sugars, and Oils

Virtually all women who are lactating (99 percent) exceed the maximum limit of energy from solids fats and added sugars combined (DIST_DS). Mean energy intake from solid fats and added sugars combined is estimated at 583 kcal among lactating females, with a range of 236 to 1,069 kcal/day. Mean solid fats intakes among women who are lactating are estimated at 35 g/day, with a range of 17 to 62 g/day. Solid fats provide an estimated 362 kcal/day to the diets of women who are lactating. Mean added sugars intakes among women who are lactating are estimated to be 15 tsp eq/day (range 4 to 32 tsp eq/day), providing about 248 kcal/day. Women who are lactating consume about 33 g of oil in their diets daily (PL_DS).

To access the data analyses referenced above, visit:

<https://www.dietaryguidelines.gov/2020-advisory-committee-report/data-analysis>

³ Cooked seafood containing 500 mg or more of omega-3 fatty acids (eicosapentaenoic acid [EPA] and docosahexaenoic acid [DHA]) per 3 ounces was assigned as seafood high in omega-3 fatty acids.
[ars.usda.gov/ARSUserFiles/80400530/pdf/fped/FPED_1516.pdf](https://www.ars.usda.gov/ARSUserFiles/80400530/pdf/fped/FPED_1516.pdf)

Question 3. What are the current patterns of food and beverage intake?

Approach to Answering Question: Data analysis

Conclusion Statements

Dietary Patterns

For those younger than age 2 years, intake dietary patterns evolve substantially over this time period and vary to a large extent based on breastfeeding practices. Patterns of food group intakes and category sources of food groups among those ages 12 to 24 months are similar to those of the U.S. population ages 2 years and older, although intake of Dairy is higher than in older Americans.

For Americans ages 2 years and older, dietary quality, measured by the Healthy Eating Index-2015, is not consistent with the existing recommendations in the *Dietary Guidelines for Americans*. Average diet quality has slightly improved in the past 10 years. Differences in overall Healthy Eating Index scores are seen across age, sex, race-ethnic, and income subgroups and by pregnancy and lactation status, though differences are small and poor diet quality is observed across all groups. Healthy Eating Index scores suggest that intakes are notably misaligned with recommendations for Whole Grains, Fruits, Vegetables, fatty acids ratio,⁴ sodium, added sugars, and saturated fats across the population.

For those who are ages 2 years and older, foods and beverages consumed through mixed dishes (e.g., burgers and sandwiches, casseroles, pizza), snacks and sweets, and beverages (other than milk and 100% juice) contribute 50 to 60 percent of total energy intake. Food subcategory source contributions to energy vary by age, sex, race-ethnicity, and income. However, for the total population, the top 5 contributors to energy intakes include burgers and sandwiches; desserts and sweet snacks; rice, pasta and other grain-based mixed dishes; sweetened beverages; and chips, crackers, and savory snacks.

Comparisons of diet quality are not possible from birth to ages younger than 24 months because Healthy Eating Index recommendations do not exist for this age group.

⁴ Fatty acids ratio refers to the ratio of poly- and monounsaturated fatty acids to saturated fatty acids in the diet.

Beverages

Beverages account for approximately 15 to 18 percent of total energy intake for Americans ages 2 years and older and for 30 to 60 percent of total added sugars intake. Non-Hispanic Black and Hispanic children have the highest consumption of sweetened beverages and the lowest consumption of water. Non-Hispanic Black children have the lowest consumption of milk. Intake of fluid milk is highest in early childhood and is progressively lower in older age groups. Conversely, the intake of sweetened beverages is progressively higher among older age groups starting from early childhood. Among all adults, alcoholic beverages contribute 21 percent (females; third largest source) and 31 percent (males; second largest source) of total daily beverage calories.

Summary of the Evidence

Data analyses conducted for the Committee are found in the data analysis supplements and are referenced below as Food Category Sources of Food Groups and Nutrients (CAT_DS) and Beverages Data Supplement (Bev_DS).

Dietary Patterns

Infants and Toddlers Younger Than Age 24 Months

Data were examined by primary mode of feeding (i.e., human milk vs formula and mixed-fed infants). “Infant formula” reflects infant formula and mixed-fed for older infants (ages 6 to 12 months). The top food category source of energy from CFB among infants ages 6 to 11 months who consume infant formula is baby foods, which contributes 51 percent of energy (CAT_DS). This is followed by mixed dishes (11 percent); protein foods (7 percent); grains, snacks and sweets, and milk and dairy (6 percent each); and fruit, vegetables, and non-alcoholic beverages (4 percent each). The top food category sources of energy among infants who are fed human milk include baby foods (34 percent), fruit (12 percent), vegetables (11 percent), milk (i.e., cow’s milk) and dairy (10 percent), grains (9 percent), mixed dishes and protein foods (8 percent each), and snacks and sweets (7 percent). Differences between infants receiving human milk only and those receiving any infant formula are noted, but significance testing was not done for this analysis.

Among toddlers ages 12 to 23 months, milk is the largest contributor to energy intake, averaging 23 percent of energy consumed on a given day (CAT_DS). Mixed grain-based dishes provide 6 percent of energy, followed by fruit juice, whole fruit, and sweet bakery products (5

percent of energy, each). Poultry is the largest protein food contributor, with an average of 4 percent of energy, which is similar to the percentage of energy supplied by breads/rolls/tortillas. Baby foods, sweetened beverages, and crackers each supply about 3 percent of energy in the diets of toddlers.

Americans Ages 2 Years and Older

The top major food category of energy intake among all Americans ages 2 and older is mixed dishes, providing an average of 30 percent of total energy (range of 24 percent to 34 percent) (CAT_DS). The second largest category contributor to energy intakes differs by age. Among children ages 2 to 19 years and those 51 years and older snacks and sweets is the second largest contributor to energy intake. The second highest food category source of energy among adults ages 20 to 50 years is beverages (not including milk or 100% fruit juice).

The food subcategory that contributes the most energy to the diets of Americans ages 2 years and older is burgers and sandwiches (including tacos and burritos). This subcategory supplies an average of 15 percent of energy (range of 11 percent to 16 percent). Desserts and sweet snacks are the second highest energy contributing food subcategory for all ages, averaging 8 percent of energy contribution, except for adults ages 20 to 40 years, for which rice and pasta and other grain-based dishes is the second highest contributor to energy, at 7 percent of energy. Sweetened beverages, and rice and pasta and grain-based dishes both contribute about 6 percent of energy to the diets of Americans 2 years and older. Crackers, chips, and savory snacks are the fifth highest contributor of energy in the diets of Americans older than age 2 years.

The top major and subcategory food group sources of energy do not vary by sex. Sources of energy are similar among race-ethnic groups with the exception of non-Hispanic Asians, who consume less energy from burgers and sandwiches and more from rice/pasta/other grain-based mixed dishes.

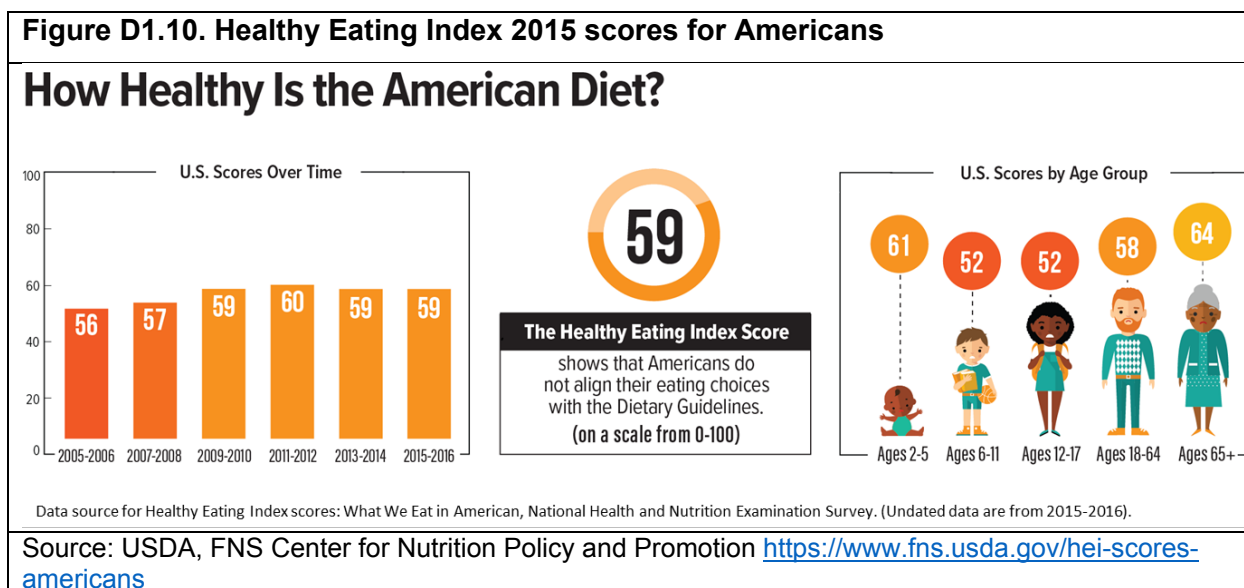
The population total and component HEI-2015 scores were estimated for Americans using NHANES 2015-2016.⁴⁵ Food category contributions to total energy intake also were examined to assess contemporary patterns of food and beverage intake. It is important to note that self-reported dietary patterns (e.g., vegetarian) are not collected in the survey years examined for this report. Thus, current patterns of intake can be summarized by adherence to the *2015-2020 Dietary Guidelines for Americans* using the HEI-2015, but the Committee does not have the data to identify other types of distinct dietary patterns (e.g., vegetarian dietary pattern).

The HEI-2015 is a measure of diet quality used to assess how well a set of foods aligns with the *2015-2020 Dietary Guidelines for Americans*.⁴⁶ The HEI-2015 includes 13 components⁵ that can be summed to a maximum total score of 100 points. The components capture the balance among food groups, subgroups, and dietary elements, including those to encourage, called adequacy components, and those for which there are limits, called moderation components. For the adequacy components, higher scores reflect higher intakes that meet or exceed the standards. For the moderation components, higher scores reflect lower intakes because lower intakes are more desirable. A higher total score indicates a diet that aligns better with the Dietary Guidelines. The HEI-2015 has been demonstrated to be a valid and reliable metric to evaluate compliance with the *2015-2020 Dietary Guidelines for Americans*.⁴⁶

In terms of the total population and by age groups in the United States, HEI scores indicate generally suboptimal diets, with ample opportunities to improve diet quality.⁴⁵ The mean HEI-2015 score for Americans ages 2 years and older is 58.7 out of 100 points, and scores have not changed substantially across time since the HEI was developed. Young children (score=61) and older adults (score=64) have slightly higher scores than children ages 6 to 17 years (score=52) and adults ages 18 to 64 years (score=58). All age groups have very low scores for Whole Grains, Fatty Acids, Sodium, and Saturated Fats. The youngest age group achieves at least 70 percent of the highest possible score in only 3 categories: Whole Fruits, Total Protein Foods, and Dairy. Young to middle-age adults, when compared to children, show improvements in intake, with at least 70 percent of the highest possible score in the additional categories of Total Vegetables, Greens and Beans, and Seafood and Plant Proteins. Those who are ages 65 years and older, when compared to young to middle-age adults, show further improvement in diet quality with the addition of higher scores in Total Fruit; they also have better scores for Refined Grains and Added Sugars. Notably, the Dairy score is highest for children (8.0 out of 10 possible points) and then is lower among adults ages 20 to 64 (5.4 out of 10) and older adults (5.6 out of 10).

Average diet quality has slightly improved in the past 10 years. Nevertheless, scores indicate that diet quality is not consistent with recommendations in the *2015-2020 Dietary Guidelines for Americans* (see Figure D1.10). Differences are seen across age groups, sex, race-ethnicity, and income, as well as pregnancy or lactation status, though differences are generally small.

⁵ **Adequacy components:** Total Fruits, Whole Fruits, Total Vegetables, Greens and Beans, Whole Grains, Dairy, Total Protein Foods, Seafood and Plant Proteins, Fatty Acids. **Moderation components:** Refined Grains, Sodium, Added Sugars, Saturated Fats.

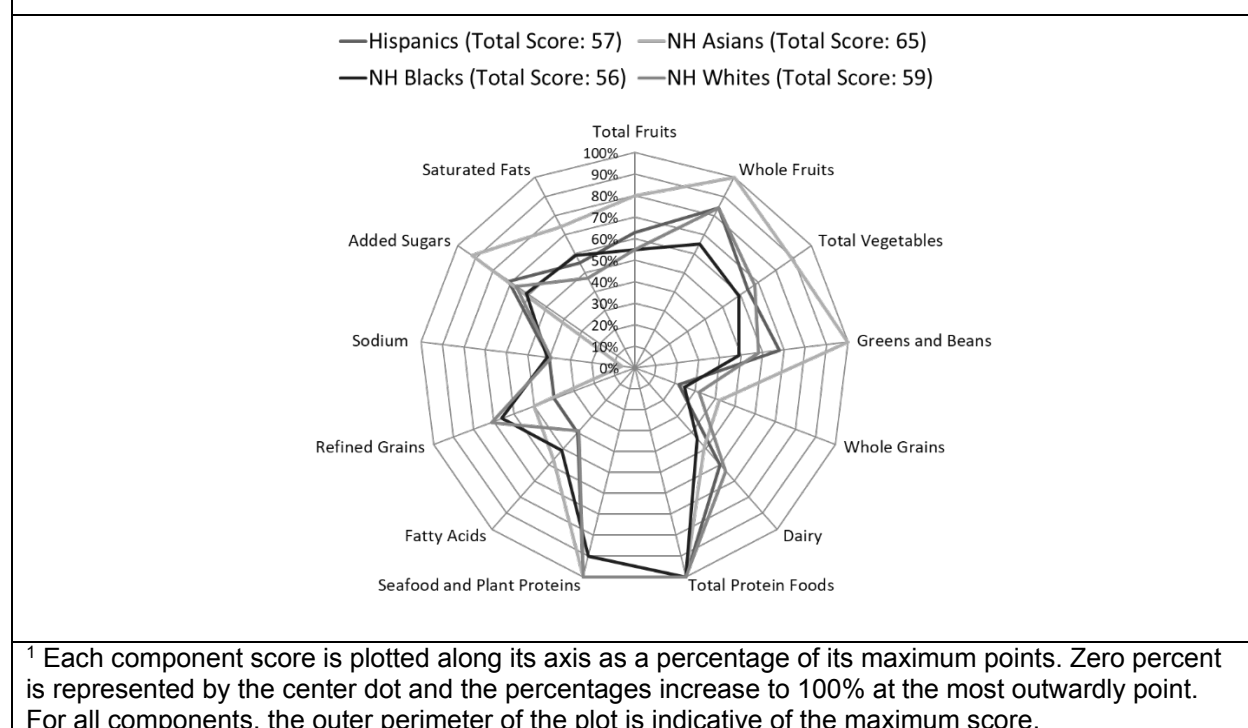


In general, females had a slightly higher average HEI-2015 score (61.0) than males (56.8) overall and in all age categories.⁴⁵ This difference was consistent by sex across all age groups. Both males and females had very low scores for Whole Grains, Fatty Acids, and Sodium. For both males and females, scores for Total Fruits and Whole Grains were lower for those ages 20 to 64 years but were higher for those ages 65 years and older, whereas scores for Total Vegetables and Greens and Beans were lower among older age groups. Dairy scores were higher in childhood and lower in older age groups. Males achieved at least 70 percent of the maximum quality score for the categories of Whole Fruits, Total Protein Foods, and Seafood and Plant Proteins. Males had 50 percent or less of the maximum quality score for Sodium and Whole Grains. Females achieved at least 70 percent of the maximum quality score for the additional categories of Total Vegetables and Greens and Beans. Females had 50 percent or less of the maximum quality score for Sodium and Saturated Fats.

When dietary quality is examined using the HEI-2015 by race-ethnic subgroups, it is clear that all groups fall short of meeting dietary guidance from the *2015-2020 Dietary Guidelines for Americans*.⁴⁵ Non-Hispanic Asians (score=65.4) and Hispanics (score=63.9) have slightly higher scores than do non-Hispanic Whites (score=59.0) and Non-Hispanic Blacks (score=55.6). However, all mean scores remain well below the recommendations. Total Protein Foods and Seafood and Plant Proteins are consumed in adequate quantities to meet HEI recommendations across all race-ethnic groups. The higher HEI scores among Asian Americans is largely driven by higher intakes of Total Fruits, Whole Fruits, Total Vegetables, Greens and Beans, combined with lower intakes of Added Sugars and Saturated Fats. Non-Hispanic Blacks do not achieve 70 percent or greater of the maximum score for any

components other than Protein Foods and have the lowest total HEI score, with especially low scores noted for Whole Fruits relative to other race-ethnic groups (see Figure D1.11).

Figure D1.11. Radar plot¹ of Total HEI-2015 scores by race/ethnicity, ages 2 years and older. What We Eat In America, National Health and Nutrition Examination Survey 2015-2016, day 1 recall.

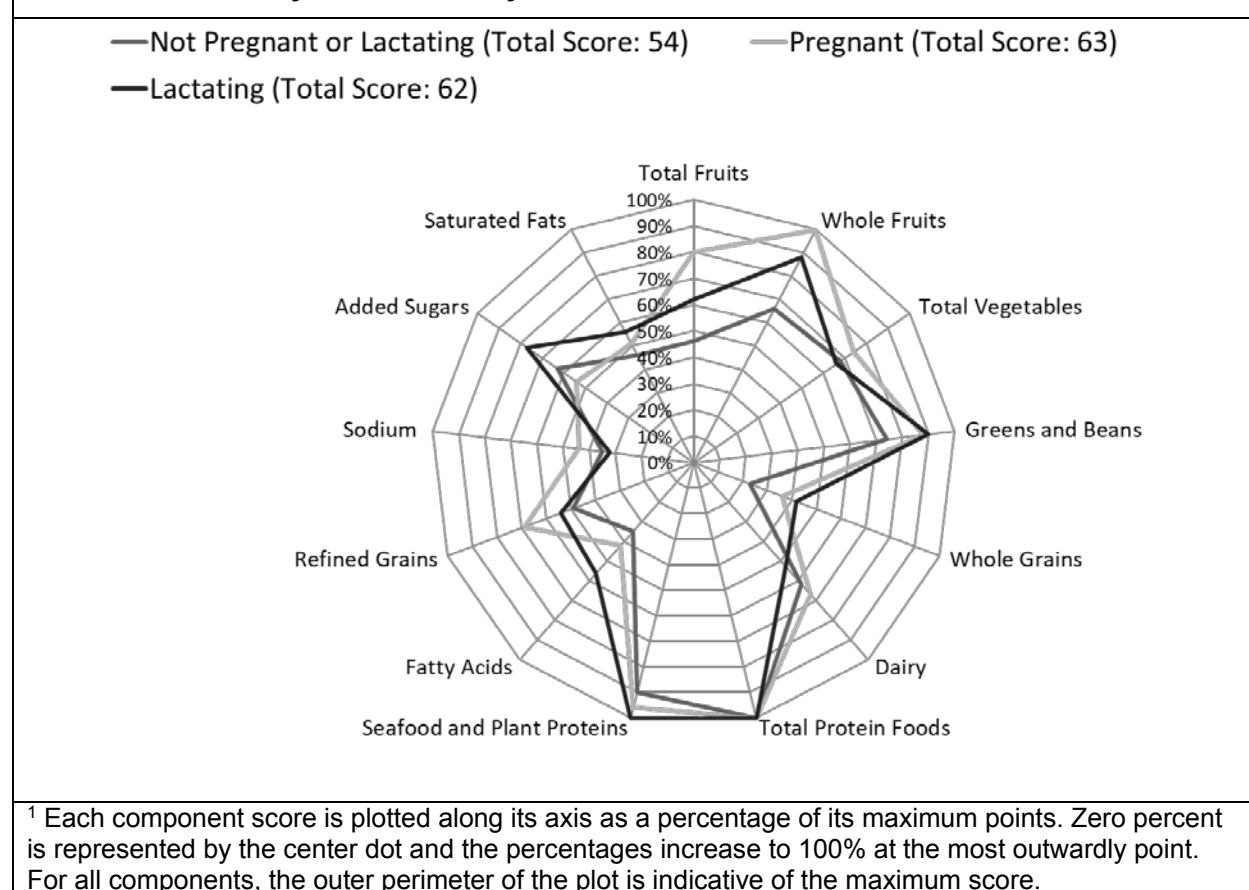


HEI-2015 scores were slightly higher among Americans in the highest poverty-to-income ratio (PIR) group (PIR ≥ 350 percent; score=61.3) when compared with the middle (PIR 131 to <350 percent; score=56.9) and lower income groups (PIR ≤ 130 percent; score=57.3).⁴⁵ All income levels have low scores for Whole Grains, Fatty Acids, and Sodium, whereas Americans in the highest income category tended to have higher scores for Total Vegetables, and Greens and Beans, Refined Grains and Added Sugars. In general, HEI component scores are higher with increasing age across all income groups, with the exception of a transient decrease in Total Fruits, Whole Grains, Dairy, and Sodium scores in the ages 20 to 64 age group.

Women who are pregnant (score=63) and women who are lactating (score=62) have slightly higher scores relative to women of the same age who are not pregnant or lactating (score=54) (see Figure D1.12). Higher dietary quality in these groups is driven by higher HEI component scores for Total Fruits, Greens and Beans, Whole Grains, Dairy, Fatty Acids, and Seafood and Plant Proteins (only women who are lactating), combined with higher HEI moderation

component scores for Refined Grains, Sodium, and Saturated Fats, when compared with those for women of similar ages who are neither pregnant nor lactating. Women who are pregnant have lower component scores than their peers (i.e., women who are neither pregnant nor lactating and women who are lactating) for Added Sugars and the highest HEI scores for Total Fruits, Total Vegetables, Dairy, Refined Grains, and Sodium among the 3 groups of women. Women who are lactating have lower component scores than their peers (i.e., women who are not pregnant or lactating and women who are pregnant) for Total Vegetables, Dairy, and Sodium.

Figure D1.12. Radar plot¹ of total HEI-2015 scores by pregnancy and lactation status, females ages 20-44 years. What We Eat In America, National Health and Nutrition Examination Survey 2013-2016, day 1 recall.



Beverages

Beverage intake patterns are described in the following section. Additional summary of evidence on intakes of beverages is described in **Part D. Chapter 10: Beverages** and **Part D. Chapter 11: Alcoholic Beverages**.

Infants and Toddlers Younger Than Age 24 Months

Aside from human milk and infant formula, plain water and 100% juice are the most frequently reported beverages among infants ages 6 to 11 months (BEV_DS). Beverages other than human milk and infant formula contribute 30 calories per day on average.

Among infants ages 12 to 23 months, 64 percent report whole milk, 23 percent report reduced or low or fat-free milk, 54 percent report 100% juice, 29 percent report sweetened beverages, and 75 percent report plain water (BEV_DS). Milk substitutes (e.g. almond beverage, calcium fortified soy beverage) are reported for 5 percent of toddlers. On average, beverages account for 371 calories per day. Mean estimated energy intakes from sweetened beverages is 60 calories per day.

Children Ages 2 to 19 Years

Beverages provide almost 1 out of every 7 calories consumed by U.S. youth ages 2 to 19 years.⁴⁷ Although some beverages can be a source of important nutrients (e.g., calcium, vitamin D, potassium, vitamin C, and magnesium), beverage intake represents more than 40 percent of energy from added sugars and is the chief source of caffeine in the diet. In particular, milk and sweetened beverages account for 75 percent of all calories from beverages. Milk is the predominant source of beverage calories for those ages 2 to 11 years, whereas sweetened beverages are the predominant source of beverage calories for those ages 12 to 19 years.

On any given day, most children (more than 80 percent) ages 2 to 19 years consume water, and by volume, water accounts for about 44 percent of total beverage consumption among U.S. youth, followed by milk (22 percent), soft drinks (20 percent), 100% juice (7 percent), and other beverages (8 percent).⁴⁸

Significant differences in beverage consumption exist by age group. As children grow older, the percent of children drinking milk and 100% juice decreases, while the contribution of water and sweetened beverages, including soft drinks, increases.⁴⁷ Sweetened beverages in this analysis include soft drinks, fruit drinks, sports and energy drinks, nutritional beverages, smoothies, and grain drinks. Calorically-sweetened milk, coffee, and tea are not a part of the sweetened beverages category.

Sweetened beverages are consumed on a given day by 44 percent of children ages 2 to 5 years and nearly 50 percent of children ages 6 to 11 years and those ages 12 to 19 years, accounting for about 20 percent of beverage calories among the younger children and 37 to 44 percent of beverage calories among children ages 6 to 19 years.⁴⁷ The mean intake in volume is 9 oz for the youngest children and 18 oz for children ages 12 to 19 years. A significantly larger

proportion of non-Hispanic Black children consume sweetened beverages than do non-Hispanic Asian and non-Hispanic White children. In particular, more non-Hispanic Black children drink fruit drinks than do any other race-ethnic group.

Adults Ages 20 Years and Older

Among adults, beverages provide approximately 1 out of every 6 calories of daily energy intake, more than half of added sugars intake, and nearly all of caffeine intake, but they also are a substantial source of vitamin C, vitamin D, calcium, and magnesium.⁴⁹

After water, coffee and tea (including sweetened coffee and tea) were the most frequently consumed beverage group on a given day (about 70 percent in both men and women), followed by sweetened beverages (46 percent in men and 38 percent in women).⁴⁹ For both men and women, sweetened beverages contribute about 32 percent of beverage calories. Compared with women, a larger proportion of men's total daily calorie intake came from sweetened beverages (i.e., 6.9 percent for men and 6.1 percent for women toward total daily calories) (CAT_DS).

Likewise, alcoholic beverages represent a significant source of beverage calories in adults.⁴⁹ Among men, alcoholic beverages rank second (31 percent) as a source of beverage calories, while among women, coffee and tea rank second (25 percent), and alcoholic beverages rank third (21 percent) in terms of beverage calories.⁴⁹ Alcoholic beverages contribute approximately 5 to 7 percent of total energy intake among adult males and 3 to 4 percent among adult females (CAT_DS).

Differences in beverage consumption between younger and middle-aged adults ages 20 to 64 years and adults ages 65 years and older were examined using data from NHANES 2013-2016 (BEV_DS). Older adults consume a smaller overall volume of beverages (66 oz per day) than did younger adults (88 oz per day). Fewer older adults consume alcohol than do younger adults, and mean consumption among alcohol consumers is significantly smaller among older adults. Similarly, a smaller percentage of older adults report sweetened beverages, and those who do report consuming them report smaller volumes than do younger adults.

Differences in sweetened beverage consumption by race-ethnicity and income were examined using data from NHANES 2011-2014. In this analysis, sweetened beverages were defined differently than other analyses described⁴⁹ and were specifically called "sugar-sweetened beverages." Despite differences in how beverages are categorized, considering differences in intakes by race-ethnicity and income is noteworthy. Asian adults consume the lowest amounts of sweetened beverages compared to other race-ethnic groups.⁵⁰ Hispanic men

and non-Hispanic Black women have the highest energy intakes from sweetened beverages when examining intakes by sex and race-ethnicity. For both children and adults, family income is strongly associated with prevalence of consumption and caloric intake from sweetened beverages.⁵¹ Mean intakes of alcoholic drink equivalents by race-ethnicity are 0.77 for non-Hispanic Whites, 0.70 for non-Hispanic Blacks, 0.31 for non-Hispanic Asians, and 0.57 for Hispanics.⁴¹

Women Who are Pregnant or Lactating

Beverage intakes differ by pregnancy and lactation status when compared to women who are neither pregnant nor lactating (BEV_DS). Women who are lactating have the highest total beverage volume intake (87 oz). Women who are pregnant and women who are neither pregnant nor lactating have mean daily reported intakes of 79 oz. Regardless of pregnancy and lactation status, a large majority of women report water consumption. Milk, milk drinks (e.g., kefir), and milk substitutes (e.g., almond milk) were reported by 33 percent of women who are pregnant and 26 percent of women who are lactating. Coffee and tea consumption are lowest among women who are pregnant. Sweetened beverage consumption is less common among women who are lactating (34 percent) than among other women, including women who are pregnant (50 percent). Alcohol consumption is low among women who are pregnant and women who are lactating. Differences are noted, but significance testing was not done for these analyses.

To access the data analyses referenced above, visit:

<https://www.dietaryguidelines.gov/2020-advisory-committee-report/data-analysis>

Question 4. Which nutrients present a substantial public health concern because of underconsumption or overconsumption?

Approach to Answering Question: Data analysis

Conclusion Statements

Food Components of Public Health Concern: Ages 1 Year and Older

For the population of Americans ages 1 year and older, dietary intake distributions, along with biological endpoints and prevalence of related clinical outcomes, suggest that vitamin D, calcium, dietary fiber, and potassium are underconsumed, and sodium, saturated fat, and added sugars are overconsumed and are of public health concern for all Americans.

Food Components of Public Health Concern: Specific Life Stages

Among **toddlers** (ages 12 to 24 months) vitamin D, calcium, dietary fiber, and potassium are underconsumed, and sodium, saturated fat, and added sugars are overconsumed and are of public health concern.

Based on dietary intake data and serum ferritin levels, iron is of public health concern among **older infants, adolescent females** (20 percent; ages 12 to 19 years), and **premenopausal females** (16 percent; ages 20 to 49 years).

Food components of public health concern among **women who are pregnant or lactating** include those for the entire population older than 1 year. Among women who are pregnant, low iron and iodine also are of public health concern, based on biomarker data that suggest low nutrient status.

Given the high prevalence of inadequate folic acid intakes observed in women who are or are capable of becoming pregnant and that nutrient's relationship to risk of neural tube defects, folate/folic acid should remain of concern among premenopausal **women** in the first trimester of pregnancy, when the neural tube is formed and closed. Folate status appears to be adequate based on biomarker data in women who are not pregnant or lactating.

Food Components that Pose Special Public Health Challenges: Ages 1 Year and Older

The following food components are underconsumed by all Americans ages 1 year and older but do not appear to pose a public health concern, given the present lack of adverse clinical and health outcome data: vitamins A, C, E, and K; magnesium; and choline.

Food Components that Pose Special Public Health Challenges: Specific Life Stages

Certain life stages have specific food components that may pose public health challenges. Proposed nutrients or food components that pose public health challenges for **all infants**, based on low estimated mean nutrient intakes compared to adequate intakes expected from complementary foods and beverages, include potassium, vitamin D, and choline.

Dietary intake data that capture both milk-based feeding sources (human milk or infant formula or mixed-fed) and complementary foods and beverages suggest that iron, zinc, and protein

intakes fall below the Estimated Average Requirements for **infants ages 6 to 12 months** whose milk-based feeding source is human milk.

Nutrients that pose public health challenges for **formula-fed infants ages 6 to 12 months**, with elevated mean intakes from formula and complementary foods compared to adequate intakes, include retinol and zinc. High intakes of these nutrients have not been linked directly to adverse health outcomes, so they are not considered nutrients of public health concern. However, they do warrant ongoing surveillance.

Nutrients or food components that pose public health challenges for **toddlers** between the ages of 12 and 24 months include choline and linoleic acid, given that dietary intakes do not approximate recommendations.

Young children ages 1 to 3 years overconsume retinol, zinc, selenium, and copper, relative to the Tolerable Upper Intake Levels. High intakes of these nutrients have not been linked directly to adverse health outcomes, so they are not considered nutrients of public health concern. However, they do warrant ongoing surveillance.

Adolescents ages 9 to 14 years have a constellation of potential nutritional risk factors that are considered a public health challenge. Girls have low intakes from foods and beverages of protein, iron, folate, vitamin B₆, and vitamin B₁₂, and girls and boys have low intakes of phosphorus, magnesium, and choline.

Older adults may be at risk for low intakes and resulting poor nutritional status related to protein and vitamin B₁₂.

Choline and magnesium are underconsumed in the diets of **women who are pregnant or lactating** and should be considered for further evaluation, given limited availability of biomarker, clinical, or health outcome data.

With the use of dietary supplements, **some women who are pregnant** have high intakes of folic acid and iron. Without the supplements these women would be at risk for inadequacy. With the use of supplements, **some women who are lactating** are exceeding recommendations for

iron and folic acid. Given that these high intakes have not been directly linked with clinical outcomes, these are not designated of public health concern but warrant monitoring.

Summary of the Evidence

Data analyses conducted for the Committee are found in the data analysis supplements and are referenced below as Food Group and Nutrient Intakes for Infants and Toddlers Data Supplement (IT_DS), Food Group and Nutrient Intakes for Women Who are Pregnant or Lactating Data Supplement (PL_DS), Intake Distributions Data Supplement (DIST_DS), Food Category Sources of Food Groups and Nutrients Data Supplement (CAT_DS), and Beverages Data Supplement (Bev_DS).

Infants Younger Than Age 6 Months

Given the specific nutritional needs of the birth to 24 months age group to support rapid growth and development, understanding current trends in dietary intakes is paramount. The Committee did not evaluate data on nutrient intakes for infants younger than age 6 months. Infants birth to younger than age 6 months rely on human milk and/or infant formula for a high proportion of energy and nutrient needs. Direct assessment of the volume and composition of human milk consumed is a challenge and imputed estimates have been published elsewhere.¹⁻³

Infants Ages 6 to 12 Months

Identifying food components of potential concern in infants and toddlers ages 6 to 24 months is challenging because little experimental research is available on nutrient requirements, biomarker data are not available in this population, and assessing dietary intakes is challenging, especially among infants younger than age 1 year. Estimated Average Requirement (EAR) values are needed to appropriately evaluate intakes for adequacy, but for infants ages 6 to 12 months, EARs are available only for protein, iron, and zinc. For other nutrients and food components, an Adequate Intake (AI) is generally available. For identifying nutrients of public health concern, the Committee focused on food components for which EARs have been established in this age group of infants. The macronutrient intakes as a proportion of reported energy are described, as are intakes of nutrients for which an EAR exists. Intakes of other nutrients are considered and described.

Macronutrient Intakes

The proportion of energy from dietary fats is higher in infants younger than age 12 months (approximately 40 to 50 percent) than among older ages (DIST_DS). Energy from carbohydrates is approximately 50 percent for infants ages 6 to 12 months, and energy from protein is approximately 10 percent of reported energy (DIST_DS).

Intakes of Micronutrients and Other Food Components

The proportion of nutrients required from CFB is different for infants receiving human milk vs infants receiving fortified infant formula. Therefore, for ages 6 to 12 months, data were examined by primary mode of feeding (i.e., human milk vs formula and mixed-fed infants; see Methodology).

Iron

Relevance of food component: Iron is relevant for infants, especially under circumstances where infant iron stores may be low.⁵² Previous conclusions from the USDA's Nutrition Evidence Systematic Review (NESR) determined "strong evidence suggests that CFB containing iron (e.g., meat, fortified cereal) help maintain adequate iron status or prevent deficiency in the first year among infants at risk of insufficient iron stores or low intake."⁵³

Dietary intake data summary: Less than 7 percent of infants in the formula and mixed-fed group have total dietary intakes of iron less than the EAR (all dietary sources, not including dietary supplements) (IT_DS). Infants who do not have compromised iron stores or who receive fortified infant formula with iron likely have adequate intakes or may have intakes that approach or exceed the Tolerable Upper Intake Level (UL).

For infants fed human milk, the proportion with intakes less than the EAR for iron is 77 percent (IT_DS).

Evidence on biomarkers and/or clinical health indicators: Serum ferritin is not measured as part of national nutrition monitoring for children younger than age 12 months. Around 4 percent of children ages 1 to 5 years have low serum ferritin (less than 12 nanograms per milliliter; NHANES 2015-2016).

Designation: Iron is considered a nutrient of public health concern for infants with human milk as the primary feeding mode.

Other Nutrients and Food Components

Slightly more than half (54 percent) of infants in the group fed human milk have dietary intakes from all food sources (human milk and CFB) below the EAR for zinc (IT_DS). No biomarker data or clinical health outcome related to low dietary intakes of zinc among infants ages 6 to 12 months who were fed human milk was available to the Committee. Zinc is considered a shortfall food component among infants fed human milk.

Less than 7 percent of infants in the formula and mixed-fed group have protein intakes below the EAR, however 27% of infants in the human milk fed group underconsumed protein relative to the EAR (IT_DS). No biomarker data or clinical health outcome related to low dietary intakes of protein among infants ages 6 to 12 months who were fed human milk was available to the Committee. Protein is considered a shortfall food component among infants fed human milk.

For all older infants ages 6 to 12 months, regardless of mode of feeding, most other food components are assumed to be adequate with the exception of potassium, vitamin D, vitamin E, and choline (IT_DS).

Retinol and zinc intakes from foods alone exceed the UL for infants older than age 6 months,¹ and these estimates are higher when dietary supplements also are considered.³ The ULs for infants and young children have been criticized as having been established with too little available data and are considered to be too low for many nutrients.⁵⁴

Nutrient-containing Dietary Supplements

The above summary focused on usual intake distributions of food components, foods, and beverages, but about 18 percent of infants and toddlers report use of dietary supplements.⁵⁵ Supplement use tended to be higher in toddlers (23 percent for ages 12 to 24 months) compared with younger infants (15 percent for birth to age 6 months) or older infants (12 percent for ages 6 to 12 months). Vitamin D and multivitamin infant drops were the most commonly reported supplement products for all infants, and multivitamin chewable products were most commonly reported among toddlers.⁵⁵ The use of vitamin D-containing supplements among infants may reflect higher breastfeeding rates over time and the American Academy of Pediatrics' (AAP) recommendation for vitamin D supplementation. Among users, the average daily intake of vitamin D from supplements was 7.4 µg per day for both infants (birth to age 12 months) and toddlers (ages 12 to 24 months).⁵⁵

Individuals Ages 1 Year and Older

Usual nutrient and food component intake distributions were examined among Americans ages 1 year and older with a primary emphasis on intakes from foods and beverages alone (i.e., without dietary supplements).⁵⁶ Because the emphasis of the *Dietary Guidelines for Americans* is food-based, the Committee focused predominantly on the acquisition of nutrients and food components from foods and beverages, including those that are fortified. However, it should be recognized that dietary supplements reduce the risk of inadequate intake but also increase the likelihood of potentially excessive intakes. A description of estimated energy intake and macronutrient intake distributions is described first. A summary of each nutrient or food component designated as either one of public health concern or of public health challenge follows. For each nutrient or dietary component, the relevance, dietary intake data, biomarker and/or chronic health end point data, and the designation are described.

Energy Intakes

The average caloric intake of U.S. adults is 2,463 and 1,814 calories (kcal) per day for males and females, respectively. Usual energy intakes increase with age in both sexes and are highest among adults ages 19 to 30 years and lowest among adults ages 71 years and older. Energy intakes are consistently higher in males than females in all age groups. Women who are pregnant (2,057 kcal per day) or lactating (2,192 kcal per day) have higher intakes compared to women of similar ages. For the U.S. population ages 1 year or older, average energy intakes are 2,056 kcal per day, with a distribution range of 1,171 to 3,237 kcal per day. Given extensive measurement error for energy intakes, these estimates likely reflect under-reporting. Nevertheless, the majority of the population ages 1 year and older exceeds recommended limits on percent of energy intakes from saturated fats and added sugars (DIST_DS).

Food Components with an Acceptable Macronutrient Distribution Range

For ages 1 year and older, more than 90 percent of children (ages 1 to 18 years) and 58 percent of adult males and 67 percent of adult females (ages 19 years and older) have carbohydrate intakes within the AMDR. For those without caloric intakes within the AMDR for carbohydrate, the proportion falls below the recommendation. Across all age groups, protein intake is within the AMDR. However, more than 10 percent of adults older than age 70 years and 20 percent of females ages 14 to 18 years have protein intakes (in grams) that fall below the EAR. The proportion of the population reporting total fat intakes within the AMDR is

approximately 60 percent for children and approximately 50 percent for adults. For those with fat intakes not within the AMDR, the proportion is above the recommendation.

Food Components with an Estimated Average Requirement or Adequate Intake

In general, the majority of Americans are meeting recommended intakes for a number of food components, including most B vitamins, iron (with the noted exception of females of reproductive age), copper, selenium, and zinc.⁵⁷ However, many food components are currently underconsumed from foods and beverages, either among all Americans or within certain population subgroups. Food components underconsumed by the entire population include dietary fiber, calcium, magnesium, potassium, choline, and vitamins A, C, D, E, and K. In addition to these underconsumed nutrients among all Americans, iron and folate (females of reproductive age), protein (adolescent girls and older adults), and vitamin B₁₂ (older adults) are underconsumed among these specific population subgroups.⁵⁷ Adolescents, especially girls, have particularly low intakes of multiple food components.

Several nutrients and food components with EARs or AIs may warrant special attention, as they are commonly underconsumed by Americans across age-sex groups. The public health significance of inadequate intakes, combined with biomarker data showing insufficient status and/or associated poor health outcomes, is discussed here and in specific chapters throughout this report.

Fiber

Relevance of food component: Fiber is defined as an “edible, non-digestible component of carbohydrates and lignin that is intrinsic and intact only in plants.”⁵⁸ The AI for fiber is based on the association between higher intakes of fiber and reduced risk of coronary heart disease.

Dietary intake data summary: Dietary fiber intake remains below recommendations for all population subgroups with an available AI. Intake of dietary fiber typically ranges from 15.6 to 18.9 grams (g) per day, with a mean of 16.4 g of fiber per day. Only 6 percent of Americans ages 1 year and older exceed the AI for dietary fiber. Females (12 percent) are more likely to exceed the AI for fiber than are males (4 percent). Certain subpopulations, such as non-Hispanic Blacks and those in the lowest income group, are at particular risk for having low dietary fiber intake, with less than 3 percent meeting or exceeding the AI.

Evidence on biomarkers and/or disease outcome: Data described previously in this chapter speak to the high prevalence rates of CVD intermediate outcomes and coronary heart disease. Additionally, the link between dietary fiber intake and colon cancer is considered.

Designation: Although no biomarker data exist to confirm low intakes, the association of fiber with CVD, which is prevalent in the population, provides evidence that low intakes of this food component is of public health concern.

Calcium

Relevance of food component: Calcium is the primary mineral found in the human body, with the vast majority located in bone (99 percent). Although calcium is important across the lifespan, as bone is in a constant state of dynamic remodeling, it is critically needed before and during the period when peak bone mass is achieved, from birth to around age 30 years.⁵⁹ Adequate calcium also is needed during periods of more rapid bone remodeling among post-menopausal women. Although the remaining extra-skeletal body reserve of calcium is small (approximately 1 percent), this pool of calcium also performs critical functions in cell signaling, muscle and nerve function, and regulated vasodilation and constriction.⁶⁰

Dietary intake data summary: Intakes of calcium generally range between 852 and 1,074 milligrams (mg) per day, with the average American consuming 972 mg of calcium per day. This level of intake places many Americans (44 percent) at risk of inadequacy, which is notably higher among girls of school age (68 percent below the EAR), adolescent girls (80 percent less than the EAR), and adult women ages 51 years and older (76 percent below the EAR). Non-Hispanic Blacks and Asians (approximately 60 percent below the EAR) have a higher risk of inadequacy than do non-Hispanic White or Hispanic Americans. About 50 percent of lower income Americans are at higher dietary risk for inadequate calcium intake compared to about 40 percent of those with higher incomes.

Evidence on biomarkers and/or disease outcome: No population-level biomarkers exist to reflect calcium status. Serum calcium is tightly regulated by a complex interchange of calcium from the bone to maintain a near-constant level of serum calcium.⁶⁰ Prevalence of low bone mass and osteoporosis are noted in the data described earlier in this chapter.

Designation: Calcium is a food component of public health concern based on low intakes and prevalence of low bone mass and osteoporosis in the U.S. population.

Vitamin D

Relevance of food component: Vitamin D is critical for optimal bone health and may have non-skeletal roles.⁶⁰

Dietary intake data summary: Intakes of vitamin D generally range from 4.1 to 5.3 micrograms (µg) per day, with the average American consuming 4.9 µg of vitamin D per day,

placing nearly all Americans (94 percent) with dietary intakes below the EAR. Although no differences in vitamin D intakes are observed by income, non-Hispanic Blacks have slightly higher prevalence of risk (97 percent) of inadequacy relative to other race-ethnic groups.

Evidence on biomarkers and/or disease outcome: It should be noted that serum 25-hydroxy vitamin D, a measure of vitamin D exposure, also indicates a large proportion (18 percent) of Americans are at risk for inadequacy.⁶¹ This is salient as vitamin D can be produced exogenously from ultraviolet (UV) exposure through sunlight. The vitamin D EAR is established with an assumed level of UV exposure.

Designation: Vitamin D is considered a nutrient of public health concern.

Potassium

Relevance of food component: Potassium is a mineral that plays a critical role in cellular function, regulation of intracellular fluid and electrolyte balance, and transmembrane electrochemical gradients.⁶² Potassium may counteract the impact of high sodium intakes, potentially helping to maintain normal blood pressure. Some data suggest that the dietary sodium to potassium ratio (Na:K) is more strongly associated with an increased risk of hypertension and CVD-related mortality than the risk associated from either elevated sodium or low potassium alone.⁶³⁻⁶⁵ Nevertheless, a moderate strength of evidence indicates a relationship between higher potassium intake (achieved by potassium supplementation) and lower blood pressure.⁶²

Dietary intake data summary: Intakes of potassium generally range from 2,323 to 2,988 mg per day, with the average American consuming 2,521 mg of potassium per day. Only 30 percent of Americans exceed the AI for potassium, with little variation in risk of inadequacy noted by sex, race-ethnicity, or income.

Evidence on biomarkers and/or disease outcome: Serum potassium is tightly regulated in individuals without kidney disease and is not assumed to be a good biomarker of status or tissue potassium stores. Urinary potassium is an additional tool to assess potassium intake but is not routinely measured. Thus, no practical population level biomarker of potassium intakes exists. Hypertension is prevalent in the U.S. population among adults and children (see Question 1, Summary of the Evidence).

Designation: Potassium is considered a food component of public health concern.

Food Components Assessed with Chronic Disease Risk Reduction

Sodium

Relevance of food component: Sodium intake is directly related to blood pressure across the lifespan. Hypertension, or high blood pressure, is a validated surrogate endpoint for CVD.⁶⁶ Elevated blood pressure contributes to the risk of CVD and stroke, which are both leading causes of morbidity and mortality in the United States.

Dietary intake data summary: Sodium is overconsumed except by infants. Intakes of sodium generally range from 3,001 to 4,100 mg per day, with the average American consuming 3,393 mg of sodium per day. The majority of Americans (approximately 90 percent) exceeds recommended intakes for disease risk reduction across all race-ethnic groups, with marginal differences observed by income. Males have higher intakes of sodium than do females, given their higher caloric intakes but the same CDRR level, resulting in 97 percent of males and 79 percent of females reporting intakes above recommendations.

Evidence on biomarkers and/or disease outcome: The prevalence of hypertension in the U.S. adult population is nearly 30 percent.⁹

Designation: Sodium is designated as a nutrient of public health concern.

Food Components with an Existing Dietary Guidelines Recommendation

The *2015-2020 Dietary Guidelines for Americans* recommends that no more than 10 percent of total energy intake come from saturated fats or added sugars.⁶ Solid fats contain more saturated fats than do liquid oils and have lower amounts of monounsaturated and polyunsaturated fatty acids. The intake of solid fats is considered here in the description of saturated fat intakes. The majority of the population of all age-sex groups exceeds recommended energy intakes from saturated fats and added sugars (DIST_DS). Thus, these food components were evaluated for their status of public health concern in the population.

Saturated Fat

Relevance of food component: No DRI values have been established for saturated fatty acids because, unlike unsaturated fatty acids, there is no biological requirement for their intake. However, because saturated fatty acids are consumed by the vast majority of Americans, the *2015-2020 Dietary Guidelines for Americans* provides a quantitative limit on saturated fats of no more than 10 percent of total energy intake.⁶

Dietary intake data summary: For Americans ages 1 year and older, the average amount of saturated fat in the diet is 26.6 g, with only 1 in 4 Americans (23 percent) achieving energy

intakes from saturated fat of less than 10 percent. Children younger than age 18 years have a lower prevalence of adherence with the energy recommendation compared to adults. Women who are pregnant (25 percent) or lactating (23 percent) tend to have lower prevalence of meeting saturated fatty acid energy goals than do women who are not pregnant or lactating (28 percent). The proportion of race-ethnic subgroups with energy intakes less than 10 percent from saturated fats varies substantially. Only 57 percent of non-Hispanic Asians, 30 percent of Hispanics, 31 percent of non-Hispanic Blacks, and 17 percent of non-Hispanic Whites report meeting saturated fat intake guidelines. Those with the lowest PIR (<131 percent) have higher compliance (27 percent meet guidelines) than do the middle PIR group (131 to <350 percent), with 20 percent meeting guidelines, while the highest PIR group (>350 percent) has about 25 percent meeting guidelines. The range of percent energy from saturated fat is rather narrow (i.e., within about 5 percent), contributing to differences in population prevalence by race and by income. However, most Americans do not have energy intakes aligned with current Dietary Guidelines guidance for saturated fat.

The top food subcategory sources of solid fats (e.g., animal fats, shortening, and coconut and palm oils) among American adults and children include burgers and sandwiches (12 percent to 22 percent) and desserts and sweet snacks (14 percent to 19 percent) (CAT_DS). Higher-fat milk and yogurt provide 19 percent of solid fats in the diets of children ages 2 to 5 years and 11 percent of solid fats among those ages 6 to 11 years. Concerted efforts to remove *trans* fats from the food supply to reduce LDL-C (a validated surrogate biomarker for CVD risk) have occurred.⁶⁷

Evidence on biomarkers and/or disease outcome: As described earlier in this chapter, the prevalence of cardiovascular intermediate outcomes as well as heart disease as a cause of death are of concern starting in adolescence. In adults ages 20 years and older, the overall prevalence of high total cholesterol is still more than 10 percent.¹³ Women ages 20 and older have a higher prevalence of high total cholesterol (17.7 percent) than do men (11.4 percent). The prevalence of low HDL-C in adults ages 20 years and older is nearly 20 percent.¹³ Among adolescents ages 12 to 19 years old, low serum HDL-C is about 16 percent.

Designation: Saturated fat remains of public health concern.

Added Sugars

Relevance of food component: The quantitative recommendation in the *2015-2020 Dietary Guidelines for Americans* for added sugars is to consume less than 10 percent of energy from added sugars.⁶ The 2015 Committee examined data from dietary intakes as well as

food pattern modeling to determine how much added sugars could be accommodated in a healthy diet while meeting food group and nutrient needs.⁶⁸ This 2020 Dietary Guidelines Advisory Committee is advising that the recommendation be decreased from 10 percent to 6 percent of energy from added sugars.

Dietary intake data summary: Added sugar in the U.S. diet is quantified in teaspoon equivalents, representing 4.2 grams⁶⁹ (see **Part D. Chapter 12: Added Sugars**, Question 1). The average usual intake of added sugars by Americans ages 2 year and older is nearly 17 tsp eq per day (about 267 kcal) (DIST_DS). For ages 1 year and older, 37 percent of the population have 10 percent or less of their energy intakes from added sugars; thus, 63 percent exceed the 10 percent recommendation (DIST_DS). Added sugar intake increases with increasing age among both boys and girls. Mean intake by males ranges from 11 tsp eq per day for ages 2 to 3 years (4 to 20 tsp eq per day) to 21 tsp eq per day for ages 14 to 18 years (6 to 45 tsp eq per day). Among females ages 2 to 3 years, mean intake is 9 tsp eq per day (3 to 18 tsp eq per day), rising to 17 tsp eq per day (5 to 34 tsp eq per day). Added sugars provide a mean intake of 148 to 168 kcal per day to the diets of children ages 2 and 3 years (49 to 318 kcal per day), rising to 267 to 344 kcal per day for ages 14 to 18 years (78 to 724 kcal per day). Added sugars intakes fall with age among adults of both sexes, with mean intake ranging from 18 to 21 tsp eq per day among males and 14 to 16 tsp eq per day among females. The range for adults is 5 to 44 g per day. Added sugars provide 284 to 334 kcal per day to the diets of adult males and 220 to 254 kcal per day among adult women. The mean percent energy contributed by added sugars was 12.7 percent for the population ages 1 year and older. Among children ages 4 to 18 years, energy from added sugars ranges from 13 to 15 percent. Among adults, the percent of energy is approximately 13 percent for those ages 50 years and younger and 12 percent for those older than age 50 years (DIST_DS). The percent of the population with 10 percent or less of energy from added sugars is 50 percent for ages 1 to 3 years. A smaller proportion of children ages 4 to 8 years achieve the goal: 21 percent of boys and 22 to 25 percent of girls. Nearly 30 percent of adolescent boys and 24 percent of adolescent girls achieve the goal. Among adults, approximately 40 percent achieve the goal.

Mean intake of added sugars is lowest among non-Hispanic Asian Americans (9.6 tsp eq) when compared with Hispanic (15.6 tsp eq), non-Hispanic White (16.6 tsp eq), and non-Hispanic Black (17.7 tsp eq) Americans, when all age groups (ages 2 years and older) are combined.⁷⁰ Differences were noted, though significance testing was not done for this analysis.

Designation: High intakes of added sugars is designated as a food component of public health concern.

Considerations for Specific Life Stages: Adolescents and Older Adults

In addition to the food components of public health concern noted for all Americans ages 1 year and older, adolescents and teenagers have dietary intakes that do not provide recommended intakes for several nutrients. This age group has a constellation of dietary risks, including low dietary intakes of protein (girls), iron (girls), folate (girls), vitamins B₆ and B₁₂ (girls), phosphorus, magnesium, and choline (both boys and girls). For adolescents and teenagers, there is a higher prevalence of risk of dietary inadequacy across multiple nutrients relative to younger and older age groups, and the use of dietary supplements is also lowest during this life stage.⁷¹ Although very few Americans are at risk of inadequate dietary intake of iron (6 percent are below the EAR), iron deficiency is especially problematic among adolescent girls and women of reproductive age, given that approximately 20 percent of this population subgroup is at risk of inadequate dietary iron based on biomarker data.

Older adults have low intakes of protein when compared with the EAR. Given the high prevalence of sarcopenia and reduced muscle strength (see Question 1, Summary of the Evidence), dietary protein should be further examined. Additional work may be needed to set optimal guidance for maintaining muscle strength.

About 1 in 4 older women (23 percent) has at-risk dietary intakes of vitamin B₆. Previous NHANES analyses identified 13 percent of older women with low pyridoxal 5'-phosphate, an indicator of vitamin B₆ status.⁷² Similarly, vitamin B₁₂ has been related to cognitive function. Although the Committee did not specifically address cognitive health data and biomarker data from NHANES, 8 percent of older women have low dietary intakes. Future Committees may wish to examine optimal nutrition for prevention of cognitive decline.

Considerations for Specific Life Stages: Pregnancy and Lactation

Although the HEI scores of women who are pregnant or lactating are slightly higher than for women of similar ages, food components of public health concern exist, in addition to those highlighted across all age groups. During pregnancy, increased requirements for some food components and energy exist.^{73,74} Although this increased nutrient intake should preferably come from food sources, even within countries ranked as high on the Human Development Index,⁷⁵ it is unlikely that women who are pregnant meet their needs through foods alone, especially for iron.⁷⁶ Indeed, more women who are pregnant or lactating use dietary supplements than do women of similar ages who are not pregnant or lactating.^{77,78}

The Committee reviewed NHANES 2013-2016 data on the dietary intakes of women who are pregnant.⁷⁹ The sample size was too small to estimate the proportion of the population with

intakes below the EAR. Thus, the Committee reviewed an analysis of U.S. women who are pregnant (n=1,003; ages 20 to 40 years) from the NHANES 2001-2014 that included estimates of intakes from food, beverages, and dietary supplements. More than 10 percent of women who are pregnant had total usual intakes, inclusive of dietary supplements, below the EAR for: calcium (13 percent), folate (16 percent), iron (36 percent), magnesium (48 percent), zinc (7 percent), and vitamins A (16 percent), B₆ (12 percent), C (12 percent), D (46 percent), and E (43 percent). Similarly, few women who are pregnant exceeded the AI for choline (8 percent), potassium (42 percent), and vitamin K (48 percent).⁷⁶

The requirements for iron increase during pregnancy to accommodate fetal requirement, the expansion of blood volume, and increased tissue and storage of iron.⁸⁰ Mean iron intake from food and beverages among women who are pregnant is 14.5 mg. However, the sample size using NHANES 2013-2016 was too small to estimate with confidence the proportion of women with intakes below the EAR. When using NHANES 2001-2014, 36 percent of women who are pregnant (and 95 percent without the use of a dietary supplement) have iron intakes from food, beverages, and dietary supplements below the EAR.⁷⁶ Biomarker data were not available for women who are pregnant, but the prevalence of low iron among women of similar ages who are not pregnant was considered. Biomarker data, together with dietary data, for women of similar ages who are not pregnant suggest that iron is of public health concern during pregnancy.

In addition, based on high risk of neural tube defects, folate/folic acid should remain of concern, given the high prevalence of dietary inadequacy among women who are pregnant (first trimester only).

Iodine needs increase by more than 50 percent during pregnancy to meet demands for neurological development and fetal growth.⁸¹ Inadequate iodine during pregnancy is related to impaired neurological and irreversible behavioral development. Although dietary data are not available for iodine, median urinary iodine concentrations of women who are pregnant remain below the WHO cut-off for “insufficiency” (less than 150 µg per liter [L]). Depending on survey years used, it is 144 µg/L⁸² or 148 µg/L.⁸³ Dairy consumption and use of dietary supplements containing iodine are among factors related to status; most prenatal products do not contain iodine.^{83,84} Urinary iodine concentrations and soy consumption (potential goitrogen) varies by race and ethnicity.⁸⁵ Given the severity of risk of low iodine during pregnancy, together with biomarker data, iodine should be considered as a potential area of public health concern, especially for women who are pregnant and not using iodine-containing prenatal supplements.

Choline and magnesium should be considered for further evaluation based on high estimates of inadequacy based on dietary data alone.

Most women who are pregnant or lactating exceed the UL for sodium (more than 90 percent). Given the role of sodium in blood pressure and the severity of risk of preeclampsia and hypertension, sodium remains of public health concern during pregnancy and lactation, respectively. Some women who are pregnant exceed the UL for calcium (3.0 percent), folic acid (33.4 percent), iron (27.9 percent), and zinc (7.1 percent), but this is mainly related to dietary supplement use.⁷⁶ However, without dietary supplements, nutrient goals are difficult to achieve. Thus, dietary supplements used in pregnancy should provide adequate but not excessive amounts of the critical food components discussed in this section (see **Part D. Chapter 2: Food, Beverage, and Nutrient Consumption During Pregnancy**).

Lactation is a life stage that requires higher energy intakes to support milk production, with increases in requirements for 8 nutrients. However, iron needs of women who are lactating are considerably lower than requirements in pregnancy. Some data suggest that women who are lactating continue to use dietary supplements that provide high amounts of iron. Thus, caution is warranted about continued use of prenatal supplements high in iron during lactation, but given higher requirements for other nutrients, it is not advised to discontinue use of multivitamin-minerals that do not provide prenatal levels of iron (see **Part D. Chapter 3: Food, Beverage, and Nutrient Consumption During Lactation**).

Other Population Subgroups

Marginal differences in intakes were observed for more than 10 different nutrients when examining intakes by race or Hispanic origin and/or family income status. Most notably, non-Hispanic Black Americans were at greater risk of inadequate intake of magnesium, phosphorous, and vitamins A and D when compared with other race or Hispanic origin groupings. Similar findings were apparent when evaluating the proportion of the population exceeding the AI by race-ethnic group. Less than 3 percent of non-Hispanic Blacks exceeded the AI for dietary fiber, while 7 percent or more of non-Hispanic Whites, non-Hispanic Asians, or Hispanic Americans did so. A higher prevalence of inadequate intakes was observed among Americans living in low income (<131 percent of the poverty level) than those living in households >350 percent of the poverty level, especially for calcium, magnesium, phosphorous, and vitamins A and C. Americans living in low income (<131 percent of the poverty level) households also had a lower prevalence of intakes exceeding the AI for dietary fiber and vitamin K when compared with those in households >350 percent of the poverty level.

To access the data analyses referenced above, visit:

<https://www.dietaryguidelines.gov/2020-advisory-committee-report/data-analysis>

Question 5. How does dietary intake, particularly dietary patterns, track across life stages from the introduction of foods, into childhood, and through older adulthood?

Approach to Answering Question: Data analysis

Conclusion Statement

Diet quality is higher among young children and older adults than other life stages but does not align with existing dietary guidance. Food category sources of food groups and nutrients differ across life-stage groups. Fluid milk as a beverage decreases starting in early childhood, while the intake of sweetened beverages increases. Fruit and vegetable intakes decline through adolescence and adulthood but increase among older adults. Intakes of burgers and sandwiches contribute to most food groups, nutrients, and food components that fall outside of recommended ranges.

Summary of the Evidence

Data described have been summarized for the questions “Describe/evaluate current dietary patterns and beverages.” The summary here describes how the data provide insight into differences and similarities in dietary patterns from infancy through older adulthood using cross-sectional data from the WWEIA, NHANES.

Data analyses conducted for the Committee are found in the data analysis supplements and are referenced below as Food Category Sources of Food Groups and Nutrients Data Supplement (CAT_DS) and Beverages Data Supplement (Bev_DS).

Dietary Intakes for Birth to Age 24 Months

The Committee’s analyses of existing NHANES 2007-2016 data suggest that infants who are exclusively fed human milk may be fed differently compared to their peers receiving infant formula. Differences are noted, though statistical testing between the groups was not done for the analysis described. Infants receiving infant formula are more likely to obtain Fruits, Vegetables, and Protein Foods from baby food, whereas infants fed human milk are more likely to receive these foods from non-baby food sources (CAT_DS).

By food pattern equivalent amounts, grains (likely infant cereals) are the primary contributor to CFB among younger infants (IT_DS) (see Table D1.3).

Table D1.3 Mean daily food group intakes among infants, toddlers, and young children				
	6 to 12 mo ¹	12 to 24 mo ¹	2 to 5 yrs males ²	2 to 5 yrs females ²
Fruit, cup eq	0.6	1.3	1.2	1.2
Vegetables, cup eq	0.4	0.6	0.7	0.7
Protein foods, oz eq	0.5	1.9	3.1	2.9
Grains, oz eq	1.1	3.1	5.3	4.5
Dairy, cup eq	0.3	2.6	2.0	1.9
Oil, grams	1.7	8.4	17.6	15.9
Solid fat, grams	3.3	24.7	27.5	25.1
Added sugars, tsp eq	1.0	6.2	11.3	9.8
¹ What We Eat In America (WWEIA), National Health and Nutrition Examination Survey (NHANES) 2007-2016, individuals ages 6 to 12 months and 12 to 24 months				
² WWEIA, NHANES 2015-2016, individuals ages 2 to 5 years				

The largest change in food group intakes occurs around age 12 months, generally when “table foods” or the food that caregivers consume are provided, with less intake of human milk and infant formula. Starting at age 12 months, intake of Fruits and solid fats are stable and consistent with intakes of older children ages 2 to 5 years. A marked increase is seen in both solid fats and added sugars between older infants and toddlers ages 12 months and older. The HEI applies only to those ages 2 years and older, so dietary patterns are examined using food category sources of energy, food groups, and nutrients (CAT_DS). The food subcategories that are significant sources of energy, food groups, and nutrient intakes among toddlers ages 12 to 24 months and preschool-aged children (ages 2 to 5 years) include high-fat dairy, burgers and sandwiches, starchy vegetables, sweetened beverages, desserts and sweet snacks, rice and pasta and grain-based dishes, chips and crackers and savory snacks, poultry, meat, and cured meats. Food group intakes that are notably small among this age group include Seafood, total Vegetables, Red and Orange Vegetables, Dark Green Vegetables, Whole Grains, and Legumes.

As children progress from the toddler years through the preschool years, diet quality is measured by the HEI-2015.⁴⁵ Diet quality is low across all life stages (see Figure D1.10). It appears that dietary intake of many food categories, particularly subcategory sources of energy and food components, tracks across life stages (CAT_DS). Examining food category sources of energy and food components gives context for how foods are consumed (e.g., added sugars as beverages; whole grains as breakfast cereals and bars). Trends of particular interest include the high intake of added sugars from sweetened beverages and sweets and desserts that begins

early in life, and the low intakes of fruit and vegetables that are seen from the introduction of solid foods throughout the lifespan. Food groups that show the most variation by age include Dairy (which decreases from early childhood onward), Protein Foods (which vary by age-sex group in terms of sources and total amount), and added sugars and solid fats (which increase from early childhood onward until a slight decrease occurs in later adulthood).

Although fruit is consumed at recommended levels by the majority of children ages 3 years and younger (DIST_DS), fruit consumption decreases during early childhood. By late childhood (ages 9 years and older) Fruit intake recommendations are met by less than 1 in 5 children, a pattern that continues throughout the lifespan, evidenced by food group intake distributions compared to food group recommendations. The majority of fruit is consumed as whole fruit (CAT_DS).

Vegetables are consumed at levels below recommendations starting in infancy and continuing throughout the lifespan (DIST_DS). Starchy Vegetables (mainly white potatoes) are the top source of vegetables for children and adolescents, with non-starchy vegetables becoming the most commonly consumed vegetables during adulthood (CAT_DS). Intakes of Red and Orange and Dark Green Vegetables are particularly low across all age-sex groups throughout the lifespan. Among those ages 2 and older, most vegetables in the diet are not consumed as distinct vegetables, as part of burgers and sandwiches, or as components of rice and pasta and other grain-based dishes (CAT_DS). This pattern is consistent across the rest of the lifespan.

Total Grains are consumed at or above recommended levels by youth (DIST_DS). However, about half of adults ages 20 years and older do not meet recommended intakes of total Grains, including one-third of women who are pregnant and 1 in 5 women who are lactating. Whole Grains are consumed at much lower than recommended levels by all age-sex groups throughout life. Burgers and sandwiches are the primary contributor of total Grains from early childhood throughout the rest of the lifespan (CAT_DS). Breakfast bars and cereals are the primary contributor of Whole Grains, followed by burgers and sandwiches, and chips and crackers and savory snacks across all life stages.

Protein Foods are consumed below recommended levels by more than one-third of infants, one-quarter of children, two-thirds of adolescent males, three-quarters of adolescent females, one-third of adult males, and half of adult females (including women who are pregnant) (DIST_DS). Burgers and sandwiches are the main category contributor to Protein Foods in the diets of all age-sex groups, followed by poultry, and meat and poultry and seafood mixed dishes (CAT_DS). Meat and poultry are the primary Protein Foods subgroups consumed by all age

groups. Mean intakes of Seafood are small among infants, children, and adolescents and larger during adulthood. Intake of seafood, particularly high omega-3 sources,⁶ is lowest among those with low income. Non-animal sources of protein, including Legumes and Nuts and Seeds, are not consumed in large quantities by any age group. Eggs contribute more protein to the diets of children than of adults. Though differences are noted, significance testing was not done.

Dairy intake is highest during early childhood. However, more than one-third of children younger than age 3 consume less than recommended levels (DIST_DS). Dairy intake drops significantly throughout childhood, with only 1 in 4 male and 1 in 10 female adolescents meeting recommendations. More than three-quarters of adults consume inadequate amounts of Dairy. Food sources of Dairy shift throughout the lifespan, with fluid milk providing the majority of intake in the first 3 years of life (CAT_DS). Cheese surpasses milk as the main source of dairy as people age. Burgers and sandwiches become a more significant source of Dairy during adolescence and adulthood. Yogurt contributes a small percentage of Dairy intake at all ages.

Intakes of solid fats and added sugars exceed recommended levels at all ages. Intakes increase with age, peaking during adolescence and young adulthood, then decreasing but remaining higher than recommended throughout the rest of the lifespan. Sweetened beverages are the largest contributor of added sugars at all ages, followed by desserts and sweet snacks, and sweetened coffee and tea among children and adults. Burgers and sandwiches are the most significant source of solid fats for ages 2 years and older, followed by desserts and sweet snacks. Higher-fat milk and yogurt are a significant source of solid fats for young children but decrease in other age categories concomitant with the decrease in Dairy intake.

Among older children and adolescents, the food subcategories that provide the majority of foods, energy, and nutrients include burgers and sandwiches, sweetened beverages, starchy vegetables, rice and pasta and grain-based dishes, chips and crackers and savory snacks, desserts and sweet snacks, poultry, meat, sweetened coffee and tea, and pizza (CAT_DS). Food subcategories that are notably low compared to recommendations include seafood, fruit, vegetables (particularly red and orange and dark green varieties), whole grains, legumes, and dairy.

The food subcategories that provide the majority of food, energy, and nutrients to the diets of adults include burgers and sandwiches, sweetened beverages, yeast breads and tortillas, meat, poultry, sweetened coffee and tea, rice and pasta and grain-based dishes, and snacks

⁶ Cooked seafood containing 500 mg or more of omega-3 fatty acids (eicosapentaenoic acid [EPA] and docosahexaenoic acid [DHA]) per 3 ounces was assigned as seafood high in omega-3 fatty acids. ars.usda.gov/ARSUserFiles/80400530/pdf/fped/FPED_1516.pdf

and sweets (CAT_DS). Among older adults, breakfast cereals and bars and meat and poultry and seafood mixed dishes also are significant contributors to energy and nutrient intakes. Food subcategories that are consumed in particularly low quantities include fruits, vegetables, dairy, whole grains, and legumes. Alcoholic beverages provide a significant amount of energy in the diet of many adults and contribute to intakes of added sugars without helping adults meet recommended intakes of food subcategories. Women who are pregnant and lactating consume diets that are somewhat closer to meeting recommendations for dairy, fruit, and vegetables intake. However, intakes of these foods are still below recommended levels for most women who are pregnant and lactating.

The food subcategory that is the most significant source of food, energy, and nutrients in the diets of Americans ages 2 years and older is burgers and sandwiches (CAT_DS). This category is the second highest source of energy and nutrients in the diets of toddlers and preschool-aged children, following high-fat dairy intake. Sweetened beverages are the second most common food subcategory source of energy in the diets of Americans ages 2 and older and is the fourth highest source of energy among toddlers and preschoolers. Sweetened coffee and tea are a notable contributor of energy among Americans ages 9 years and older, contributing as much as 10 percent of energy among adults. Starchy vegetables, desserts and sweet snacks, rice and pasta and grain-based dishes, chips and crackers and savory snacks, and poultry are other food subcategories that are common among all age groups. Food subcategories that are notably low among all age groups include seafood, total vegetables (especially red and orange and dark green vegetables), whole grains, and legumes. Dairy intake is low among all age groups except infants and toddlers.

To access the data analyses referenced above, visit:

<https://www.dietaryguidelines.gov/2020-advisory-committee-report/data-analysis>

DISCUSSION

Consistent and well-conducted Federal monitoring and surveillance have provided valuable insights into the health and nutritional status of Americans. Not surprisingly, most Americans have one or more chronic health conditions that are related to dietary intake across the life course, including overweight and obesity, heart disease, stroke, type 2 diabetes, hypertension, liver disease, certain types of cancer, dental caries, and/or metabolic syndrome. In many instances, overweight and obesity may be the earliest manifestation of energy imbalance and

poor nutritional status, and many of the chronic conditions that the Committee examined develop as a consequence of overweight and obesity. Given that most Americans and overweight or obese this is quite concerning. This Committee has taken a life-course approach to understand current patterns of dietary exposures, considering the data on existing chronic disease risk. Age has strong relationships with chronic disease. Although young children have the lowest incidence of all chronic diseases, children are not immune to chronic disease, with this report suggesting a high prevalence of cardio-metabolic disorders, dental caries, and a difficult-to-quantify but emerging concern about food allergy and related conditions (such as asthma). Older adults are at greater risk of all chronic diseases than are other age groups, and sarcopenia, osteoporosis, and cancer disproportionately affect this life stage. Unfortunately, the prevalence of chronic diseases in America has increased over time, often disproportionately among some subgroups, leading to health disparities and changes in life expectancy. Although some of the reduced life expectancy is driven by mid-life mortality⁸⁶ unrelated to chronic disease, chronic diseases remain the chief causes of mortality in the United States.

Racial and socioeconomic status disparities exist with regard to chronic diseases.⁸⁷ Racial variation exists for almost all the health conditions the Committee examined, including during pregnancy. Asian Americans have a relatively lower prevalence of most chronic health conditions examined, though pregnant Asian women have the highest prevalence of gestational diabetes. Low birth weight among non-Hispanic Blacks is at the highest level in more than 25 years. Chronic liver disease has increased in America, along with its associated mortality rates, and can result from obesity, alcohol misuse, metabolic syndrome, and hepatitis. Most U.S. adults report alcohol use, and among those who drink, about half report binge drinking (see **Part D. Chapter 11: Alcoholic Beverages**). Chronic liver disease is highest in American Indians and Alaska Natives. Across all age groups, non-Hispanic Asian Americans have higher diet quality than other race-ethnic groups and have lower risk for most chronic diseases.

Poverty and health inequalities are persistent and increasing within the U.S. population.⁸⁸ Understanding how dietary intake can reduce risk or aid in the treatment of chronic diseases is complex but never has the time to optimize the American diet to modify disease risk through primary and secondary prevention strategies been more salient.

Few Changes in the Dietary Landscape Over Time

The American dietary landscape has not changed appreciably in recent decades. Across the life course, it is characterized by a persistent overconsumption of total energy (i.e., calories), saturated fats, salt, added sugars, and alcoholic beverages among a high proportion of those

who choose to drink. Whole-grain intakes remain extremely low across most of the population; whole grains are mainly consumed as part of breakfast foods or in snack foods (chips, crackers). Intakes of fruits and vegetables are lower than current recommendations, with most Americans consuming less than 1 cup of whole fruit per day. Less than half of vegetables are consumed “alone” or as a distinct raw or cooked portion, meaning that they are largely being consumed when incorporated into another food type (i.e., as part of a sandwich or crackers). After early childhood, dairy intakes decrease over the life course, except for a small uptick in older adults. However, this increase is largely driven by ice cream and sweet desserts, which provide fewer key nutrients and more saturated fats relative to other foods in the dairy category. Though the diets of women who are pregnant or lactating are higher in key food groups, they still fall below recommendations.

These trends in food intake have ramifications on nutrient intakes and status throughout life for all Americans. Low intakes of fruits and vegetables contribute to the underconsumption of nutrients and food components such as vitamins A, C, and K; potassium; and fiber. Inadequate intakes of dairy may contribute to low intakes of protein, calcium, phosphorous, magnesium, and vitamins A and D. Intakes of fiber are also decreased when intakes of whole grains and legumes are low. Iron and vitamin B₁₂ status may be affected if intakes of poultry, meat, seafood, dairy, and eggs are low. Eggs also supply additional choline and vitamin D, two nutrients with notably low intakes relative to recommendations. Similarly, patterns of food group intakes across the life course contribute to higher than recommended intakes of food components of public health concern, such as added sugars, sodium, and saturated fats.

New Findings on Infants and Toddlers

For the first time, the Committee reviewed evidence on the diet and health of infants and toddlers. The period between the start of pregnancy until the infant reaches age 24 months, or the first 1,000 days of life, is thought to be the most critical window for optimizing nutritional exposures relative to neurocognitive development.⁸⁹ The data reviewed by the Committee suggest that while HEI scores were higher in pregnancy and lactation than in women of similar ages, many dietary deficits were noted. Iron deficiency is estimated to be present in 1 in 10 women who are pregnant in America, with estimates highest in the third trimester (approximately 25 percent), and being more prevalent in Hispanic, Mexican, and non-Hispanic Black women.⁹⁰ Very limited biomarker data are available that is national in scope to adequately describe the nutritional status of American women who are pregnant or lactating.

For some nutrients, human milk composition does not change based on maternal diet, though for other nutrients, the quality of human milk varies based on maternal status. Within this report, the Committee made many assumptions about the energy and nutrient composition of human milk. However, much more research is needed to develop an accurate database of representative values. The Committee's findings should be considered with that caveat in mind.

Among infants, breastfeeding initiation and duration have improved over time, and rates of exclusive breastfeeding differ substantially by race and ethnicity.⁹¹ From all data sources examined, breastfeeding rates are lowest among non-Hispanic Blacks. Baseline data suggest that breastfeeding rates are lower among low birth weight infants (less than 2,500 grams).⁹² The average dietary intake of younger infants (younger than age 6 months) is able to meet recommendations for most food components, with caution needed for vitamin D among those exclusively breast-fed.

Among infants who are fed formula, cow's milk (68.9 percent) formula is the predominant formula source, with lower percentages receiving soy (11.6 percent), specialty (6.3 percent), and "gentle/sensitive, or lactose-free/reduced formulas" (5.4 percent). Although it is not recommended by the AAP,⁹³ approximately 13 percent of U.S. infants were reported to consume cow's milk before age 12 months.⁹⁴ Cow's milk consumption before age 12 months varies by household education and income levels. Transition from sole consumption of human milk and/or infant formula to include nutrient-dense complementary foods is recommended at about age 6 months,⁹⁵ depending on the development of the child (see **Part D. Chapter 5: Foods and Beverages Consumed During Infancy and Toddlerhood**).

Most U.S. infants are introduced to CFB before age 6 months. After age 6 months, most children consume CFB. However, the primary mode of feeding is associated with the timing of introduction of CFB and the types of foods and beverages that are consumed. Formula-fed infants are more likely to be introduced to CFB at earlier ages; moreover, formula-fed infants are more likely to be consumers of various food components that could be perceived as lower in nutritional quality (i.e., added sugars, solid fats, oils), and are more likely to consume protein foods that are rich sources of iron and zinc. A higher percentage of fruit juice consumption was noted among formula-fed (45 percent) than in older infants fed human milk (20 percent). The AAP does not recommend fruit juice intake before age 12 months, at which point no more than 4 oz per day is recommended.

Notable differences are also observed in the sources of energy by primary feeding type (i.e., human milk, infant formula). Although the proportion of energy from protein foods and snacks and sweets is similar among infants who are fed human milk or formula, infants fed human milk

receive more energy from fruits, vegetables, milk and dairy and grains and less from mixed dishes. For older infants fed human milk, special considerations are warranted, given the limited set of EAR values for this age group, for iron, zinc, and protein. Though iron biomarker data are not available for older infants, prevalence of iron deficiency among U.S. toddlers ages 12 to 24 months in NHANES 2003-2010 was 15 percent.⁹⁰ Protein and zinc are also low relative to reference standards, but the dietary estimates are not supported by biochemical, clinical, or health consequences to date in older infants. Relative to the AI for older infants, potassium, vitamin D, and choline intakes were low and could be enhanced by inclusion of fruits, vegetables, yogurt, eggs, and legumes during the transition from milk-based to table-food feedings (see **Part D. Chapter 7: USDA Food Patterns for Children Younger than Age 24 Months**).

During the ages of 12 to 24 months, rapid devolution occurs in terms of meeting food component recommendations. This period of time generally is when the child is exposed to foods consumed by parents and caregivers. During this time between infancy and toddlerhood, large increases in added sugars and solid and saturated fats are observed. Patterns of food group intakes and sources of food groups among toddlers ages 12 to 24 months are similar to those of the U.S. population ages 2 years and older; however, it should be noted that dairy milk intake is higher in toddlers ages 12 to 24 months and represents about 43% of solid fat intake. Nutrients or food components that pose special challenges for children between the ages of 12 and 24 months include choline and linoleic acid. These nutrients are found in foods, including eggs, nuts, seeds, and meats, that are generally not consumed in high amounts by many infants and toddlers.

Dietary Patterns Through the Life Course

As children progress from the toddler years through the preschool years, dietary intakes change and HEI scores drop, indicating lower overall diet quality. The search for a sense of autonomy and desire for independence in many areas of life that occur during this developmental stage often manifest through selective or “picky” eating, food neophobia, or food “jags” (eating only 1 or a few foods for periods of time). Even though these behaviors usually resolve by the end of the preschool years, the dietary habits acquired during these years tend to persist throughout the life span.

Changes in dietary patterns in young children lead to decreases in dietary quality. These changes tend to have consistent themes for all children, but differences in patterns of intake for fruits and vegetables suggest that non-Hispanic Black children have the lowest intake of whole

fruit and highest intake of fruit juices.⁹⁶ Decreases in fluid milk as a beverage appear to be replaced with sweetened beverages as children age. These changes culminate to a constellation of dietary risk in adolescents. In addition to those shortfall food components notably low in all Americans, older children also have additional nutrients of concern, especially girls. Intakes of dairy, dark green vegetables, legumes, poultry, and eggs should be encouraged among pre-teens and adolescents, particularly girls.

Although older adults have higher relative HEI scores, additional concerns for vitamin B₁₂ and protein are observed and warrant consideration for tailoring specific guidance. About 1 in 4 older women (23 percent) have at-risk dietary intakes of vitamin B₆. Previous NHANES analyses identified 13 percent of older women with low pyridoxal 5'-phosphate, an indicator of vitamin B₆ status. Similarly, vitamin B₁₂ has been related to cognitive function. Though the Committee did not specifically address cognitive health data and biomarker data from NHANES, it noted that 8 percent of older women have low dietary intakes of food sources of vitamin B₁₂. Future Committees may wish to examine optimal nutrition for prevention of cognitive decline. Osteoporosis and sarcopenia are chief concerns for older Americans, especially women.

Race and ethnicity and income also were associated with differential intakes of food groups, nutrients, and food components. This report contains information on race-ethnic and income differences for food components of public health concern, but it should be noted that similar disparities in dietary intakes also exist across most of the shortfall nutrients (DIST_DS) and food components of public health concern (see Table D1.4).

Dietary Patterns and Food Security

The 2015 Committee described a need to understand how food security shapes dietary intakes. Data on dietary patterns and intakes of nutrients and food components by food security status were not available to this Committee. However, as reviewed by others outside this Committee, a food secure status has been associated with higher diet quality and nutrient intakes among adults^{97,98} and children^{99,100} when compared with those who are food insecure. Future work to understand how overall income and food security status interact to predict dietary intakes and the resulting diet quality is needed.

Ensuring Lifelong Healthy Dietary Choices

The work of Dietary Guidelines Advisory Committees since 2010 and present have clearly identified associations between dietary patterns and health outcomes, more so than with any

one nutrient or food component. The analytical framework the Committee used compared dietary intakes to the HEI. This strategy permitted the Committee to examine how well existing diets conform to recommendations. Dietary intakes have never aligned with recommendations. The Committee can identify areas in which Americans need to make improvements, but the charge of the committee does not extend to reviewing factors that impact our ability to change behaviors to improve dietary intakes. In the future, Committees may need to include a review of public health-based strategies that have been successful in promoting higher quality dietary intakes, especially in key populations that are at high risk and/or disadvantaged.

Even without systematic reviews on how to effectively shift the population at large to healthy dietary intakes, the Committee can identify opportunities within each life stage to provide specific advice about critical food components that provide key nutrients for individuals by age-sex subgroups at that particular stage of life. Opportunities also exist to think about healthy food intake patterns that should be carried forward into the next stage of life. Lastly, the Committee can easily identify substitutions of food components that can help improve diet quality while also being favorable to energy balance. This approach recognizes that nutrient needs vary over the life course and intakes at later life stages are likely influenced by intakes at earlier life stages.^{101,102} Although raising the general dietary quality is important, individuals and healthcare providers may be more attuned to small changes related to specific needs at a given life stage.

In addition to establishing optimal dietary patterns early in life, efforts should continue to ensure energy balance early in life and maintain energy balance over the life course. The Committee's review of the available data pointed to some major deficiencies in dietary intake for key demographic groups within the U.S. population. Using the life-course approach, the Committee recognized that pre-teens and adolescents may be at particular nutritional risk. Overweight and obesity are highly prevalent, and Americans need to make shifts in their diets that do not add calories but make substitutions with nutrient-dense foods or beverages with lower contributions to energy. For example, most adults consume 2 or more sweetened beverages each day. Replacing 1 or both of those per day with water or other beverages that do not contribute energy, all other dietary intakes being consistent, could reduce total energy intakes and help contribute to reduced energy balance (see **Part D. Chapter 14: USDA Food Patterns for Individuals Ages 2 Years and Older**, **Part D. Chapter 10: Beverages**, and **Part D. Chapter 12: Added Sugars**). Eating occasions should be viewed as opportunities to make better choices. Snacks, especially in young children, could be a way to promote intakes of fruit and vegetables, rather than foods high in sodium, added sugars, and saturated fats (see **Part D. Chapter 13: Frequency of Eating**). Ultimately, to improve diet quality, it is essential that

Americans eat more of key food groups and consistently displace other choices of lower dietary quality and higher energy density. Otherwise, efforts to improve dietary quality without displacement will lead to excess energy intakes and limited impact on chronic disease risk.

Among Americans ages 2 years and older, the top food categories and subcategories that contribute to energy intake remain remarkably stable across the life span. The majority of energy comes from burgers and sandwiches, snacks and sweets, and mixed dishes. The top sources of energy intake come from a limited number of food categories, with burgers and sandwiches dominating as a primary source of energy across most age groups. The consistent appearance of some food categories over the life course suggests that these foods are an integral part of the American food context and culture. As such, these key food categories make substantial contributions to shaping, either positively or negatively, the nutritional status of most Americans. Therefore, shifts in the nutritional composition of several food subcategories could have significant effects on the nutritional status of the population. For example, if changes in food choice, the food supply, and preparation techniques were strategically made, burgers and sandwiches could become a major way to increase the consumption of many food components and nutrients that are currently underconsumed, such as whole grains (fiber), vegetables, dairy, fish and seafood, and legumes. Changes in this food category could also decrease intakes of added sugars, saturated fats, and sodium. Small declines in added sugars and saturated fat intakes during the past decade suggest the needle has moved in positive ways. Leveraging the typical intake patterns of Americans to improve the quality of food components that make up usual choices in the diet could be the way to continue that progress across life stages.

Key Considerations

Beverages provide a considerable proportion of energy to the American diet, and high consumption of sweetened beverages has been related to lower diet quality and lower intakes of key food components. Given their extensive contribution toward added sugars intakes across all life stages, limited quantities of sweetened beverages, including not adding sugars to coffees and teas, should be encouraged. Excessive sodium is noted among all age-sex groups of Americans, primarily coming from “mixed dishes.” No one food is responsible for excessive sodium intake. Rather, it is the ubiquitous patterns of intakes from food subgroups high in sodium that are contributing to this issue. Sodium used in the processing of foods is the chief contributor to sodium, rather than sodium added by the consumer.

Understanding the context of eating is an important strategy to target behavior change. Most Americans consume 2 or 3 meals and 1 or 2 snacks on a given day (see **Part D. Chapter 13**).

The timing of these eating occasions appears to coincide with traditional mealtimes and affects diet quality, but a paucity of data exists relative to chrono-nutrition. Previous research has associated temporal dietary patterns, or the distribution of energy and intake of food components over time,⁹⁹ to also have associations with diet quality. Indeed, in the Committee's review, late night eating occasions appear to be associated with intakes of foods or beverages that should be limited, such as added sugars, saturated fats, sodium, and alcoholic beverages. Adolescents and teenagers have notable differences in the timing and frequency of eating occasions. Given that this population is a subgroup with a high proportion of low nutrient intakes, future work is needed to help understand the relationships between timing and frequency of eating and diet quality.

SUMMARY

Diet is a modifiable factor that is critically relevant to the primary and secondary prevention of most non-communicable chronic diseases that are the leading causes of disability and death affecting Americans. Dietary intake also is an important determinant of body weight and risk of overweight and obesity. Development of overweight and obesity begin early in life and trigger development of the risk factors that such as hypertension, elevated blood glucose, insulin resistance and dyslipidemia that remain public health problems in all age groups.^{101,102}

Overweight and obesity are both a health outcome and a contributor to risk for most of the health outcomes that the Committee examined. Although increases in adiposity may have stabilized in the United States, overweight and obesity remain highly prevalent and a pressing public health challenge. The diet is quite complex, and the implications of dietary intake on risk of disease in the moment or later in life can be difficult to quantify. To both encourage and facilitate a healthy diet, the focus needs to be not only on what Americans choose to eat, but also on the social, economic, and environmental contexts that determine dietary patterns. These contexts also drive dietary, and consequently, health disparities that exist in the United States.

The 2020 Committee has come to realize that each individual life stage also holds unique implications for dietary intake and the risk of disease. In terms of life stages, while young infants appear to be generally well-nourished, some gaps exist. The risk of chronic disease begins early in life, with important health consequences for the fetus based on the dietary intake of the mother and subsequent feeding behaviors. Early life nutritional exposures have emerged as an etiological risk factor associated with later-life chronic disease risk. For example, breastfeeding has been associated with various patterns of intake that differ from infants receiving formula,

and though infants appear to be generally well-nourished, these differences in feeding patterns leave room for improvement. Non-Hispanic Black infants are the least likely to be breastfed and have differential fruit and vegetable intake patterns starting early in life and continuing throughout the life course. This cumulative difference in feeding behavior for Black infants may set a course for higher risk of nutrition-related chronic disease that underpins many of the disparities seen today. Indeed, non-Hispanic Asian breastfeeding rates are higher and duration is longer; higher diet quality was observed among non-Hispanic Asians across all age groups examined. Differences in feeding are related to many factors that determine if or how long a woman breastfeeds a child. Data reviewed by the Committee did not include the context of such factors, but future research to better understand what drives the differences is of interest. Thus, concerted efforts to advance progress made in breastfeeding initiation and duration should continue, and culturally specific food recommendations are needed across the life course.

Diet quality is higher in young children but tends to decline with age throughout childhood and into adolescence. The poor diets of adolescent females are quite concerning, both at the individual level and for the potential intergenerational impacts. This life stage is associated with optimizing peak bone mass, which is one of the primary modifiable factors for risk of later life osteoporosis, which is highly prevalent in the United States. Moreover, as women transition into childbearing years, pre-pregnancy nutrition status relates to fetal health and nutrition. The interaction between the nutrition status of the mother and the health of the child is an important area for future research development. Risk of iron deficiency anemia among women who are pregnant and how that affects infant iron stores and cognitive development should be an area of priority, as most breastfed infants do not meet iron requirements from the diet alone and may depend on innate iron stores early in life. A noted lack of sample size from NHANES for women who are pregnant or lactating is an identified research need, as is the very limited availability of current biomarker data on women of reproductive age to address other food components that are of public health concern during pregnancy and lactation. Understanding how the diets of women who are pregnant or lactating shape dietary preferences of offspring is also an area for further investigation. Furthermore, a need exists for nationally-representative longitudinal data of mother-child dyads to fully understand the complexities of early life exposures to inform future editions of the *Dietary Guidelines for Americans*. More broadly, longitudinal data with multiple assessments of intake over time in the same population are needed to understand and characterize how patterns of intake at one stage of life influence or carry over into other stages. With this type of research, a better understanding could be gained of how to tailor initial dietary

patterns to foster acceptance of fruits, vegetables, and whole grains, echoing the *2015-2020 Dietary Guidelines for Americans* recommendations.

The Committee identified several life stages that are at increased risk for suboptimal dietary intakes. Several key themes in existing food patterns could be addressed to optimize healthy choices. First, given the limited set of foods that provide energy and food components to limit, specific guidance to consumers to help shift typical choices toward more nutrient-dense versions should be a starting point. Second, given the differential patterns within food groups by age, race-ethnicity, and income, messages could be tailored to “meet people where they are” to help them make small, positive shifts. Inherent in this is that there is no one diet, or food group, or individual food to consume or avoid, but rather that it is possible to make any number of changes to move toward a similar healthy end. The Committee also recommends that the *2020-2025 Dietary Guidelines for Americans* provide very specific messaging around beverage intakes, with a focus on sweetened beverages and alcoholic beverages. Current food pattern modeling exercises typically do not include or address beverages, and consumers may be confused by a lack of specific guidance surrounding beverage choices. Lastly, because of investments in research that provide data on dietary intakes of Americans across the life course, the Committee can identify opportunities to use typical intake patterns that are part of the American cultural food context to improve the nutritional intake of the population. Changing the production of commonly-consumed foods to improve diet quality and nutrient density while decreasing excess energy is a strategic path towards improving population nutrition. These and other efforts to enhance dietary adherence to the dietary pattern recommendations deserve careful, quantitative evidence-based investigation during these next 5 years.

Table D1.4 Food components of public health concern – summary by life stage					
<u>Food Component</u> (life stages)	Dietary Intake Metric	Biochemical or Clinical Indicator	Associated Health Condition	Major food categories contributing to intake¹	Food sources that are good sources²
Fiber (ages 1 yr and older, including pregnant or lactating women)	% <u>>AI</u>	No reliable biochemical marker exists	<u>Coronary heart disease</u>	Mixed dishes (burgers/sandwiches), vegetable (non-starchy, starchy), grains (breakfast cereals/bars)	Vegetables, fruits, whole grains
Vitamin D³ (ages 1 yr and older, including pregnant or lactating women)	% <u><EAR</u>	<u>Serum 25(OH) vitamin D concentrations</u>	<u>Impaired peak bone mass accrual; low bone mass and osteoporosis</u>	Dairy (milk, yogurt), mixed dishes (burgers/sandwiches), and protein foods (eggs)	Some seafood, UV exposed mushrooms, fortified milk
Calcium³ (ages 1 yr and older, including pregnant or lactating women)	% <u><EAR</u>	No reliable biochemical marker exists	<u>Impaired peak bone mass accrual; low bone mass and osteoporosis</u>	Mixed dishes (burgers and sandwiches), dairy (milk, yogurt), beverages other than milk or 100% juice (waters)	Yogurt, fortified orange juice, cheese, sardines, milk
Potassium³ (ages 1 yr and older, including pregnant or lactating women)	% <u>>AI</u>	<u>24-hour urinary excretion</u>	<u>Hypertension</u> and <u>cardiovascular disease</u>	Mixed dishes (burgers/sandwiches), vegetable (non-starchy, starchy), beverages (coffee/tea)	Apricots, lentils, prunes, squash, raisins
Sodium (ages 1 yr and older, including pregnant or lactating women)	% <u>>CDRR</u>	<u>24-hour urinary excretion</u>	<u>Hypertension</u> and <u>cardiovascular disease</u>	Mixed dishes (burgers/sandwiches), protein foods (poultry), vegetables (non-starchy)	
Saturated Fat (ages 2 yr and older, including pregnant or lactating women)	% <u>>10 % TE</u>	<u>Total cholesterol; LDL cholesterol</u>	<u>Cardiovascular disease</u>	Mixed dishes (burgers/sandwiches), desserts and sweet snacks, high fat dairy	
Added Sugars (ages 1 yr and older, including pregnant or lactating women)	% <u>>10 % TE</u>	No reliable biochemical marker exists	<u>Overweight and obesity</u> and <u>related comorbidities</u>	Sweetened beverages, desserts and sweet snacks, and coffee and tea	
Iron³ (Infants fed human milk; adolescent, pre-menopausal, pregnant women)	% <u><EAR</u>	Serum ferritin, soluble transferrin receptor, hemoglobin	<u>Iron deficiency</u> and <u>iron deficiency anemia</u>	Various heme and non-heme dietary sources of iron are consumed. <u>Iron requirements are higher for vegetarian diets.</u>	Meat, poultry, seafood, and fish, fortified breakfast cereal, legumes and pulses
Iodine (pregnant women)	% <u><EAR⁵</u>	<u>Urinary iodine concentrations</u>	Impaired neurocognitive development	<u>Goitrogens in the diet are relevant.</u>	Seaweed, cod, yogurt, iodized salt, milk
Folic Acid (pregnant women, 1 st trimester)	% <u><EAR</u>	<u>Serum and RBC folate</u>	Neural tube defects	Vegetables (dark green), grains,	Spinach, liver, asparagus, Brussels sprouts, enriched grains.

AI=Adequate Intake; CDRR=Chronic Disease Risk Reduction; EAR=Estimated Average Requirement; RAF=reproductive-aged females; TE=total energy intakes.
¹See Food Category Sources of Food Groups and Nutrients Data Supplement [<https://www.dietaryguidelines.gov/2020-advisory-committee-report/data-analysis>]²
Based on reference values provided in FoodData Central; values obtained at <https://fdc.nal.usda.gov/> and based on the percent DV per serving
³FDA's designation as a nutrient of "public health significance."
⁵Iodine dietary data are not currently available in FNDDS

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PART D. CHAPTER 2: FOOD, BEVERAGE, AND NUTRIENT CONSUMPTION DURING PREGNANCY

INTRODUCTION

Pregnancy is a critical period of life for both a mother and her child. Although each pregnancy can be viewed as a discrete 40-week stage in the lifespan with distinct nutritional needs, the outcome of that pregnancy is influenced by the woman's health status before conception and it can, in turn, influence her future health trajectory.¹ The physiological and metabolic changes that occur during pregnancy² can predispose some women to developing transient (and sometimes life-threatening) chronic health conditions, such as gestational diabetes mellitus (GDM) and hypertensive disorders. In addition, excessive gestational weight gain (GWG) is relatively common, particularly in women with a high prepregnancy body mass index (BMI),³ and retention of excess body weight postpartum places a woman at higher risk for chronic diseases in subsequent pregnancies⁴ and later in life.^{5,6} The Developmental Origins of Health and Disease (DOHaD) hypothesis posits that environmental exposures, including both under- and over-nutrition, during early developmental stages increase the risk of developing metabolic and neurodegenerative disorders during later life.^{7,8}

Thus, a mother's health and nutritional status during the first 1,000 days of an infant and child's life, beginning at conception and continuing through the second year of life, are crucial for ensuring optimal physical, social, and psychomotor growth and development and lifelong health.⁹ The intergenerational, or epigenetic, effects of intrauterine exposures⁷ highlight the potential for long-term benefits to be gained from optimizing nutrition during pregnancy. Accordingly, understanding the relationship between consuming a healthy diet and preconception, pregnancy, and postpartum outcomes was the top priority recommendation put forth by the Health in Preconception, Pregnancy, and Postpartum Global Alliance.¹⁰

For the first time, the *2020-2025 Dietary Guidelines for Americans* will take a life course approach, with a new focus on the first 1,000 days of life. To support this new focus, this chapter of the 2020 Dietary Guidelines Advisory Committee's report describes the findings of the systematic reviews conducted to examine the relationships between aspects of the maternal diet, including folate and omega-3 fatty acid supplements consumed before and/or during pregnancy on both maternal (micronutrient status, GDM, hypertensive disorders, and GWG) and infant perinatal outcomes (gestational age and birth weight at delivery), as well as longer-term child outcomes, including neurodevelopment and the risk of food allergies and atopic

allergic diseases. **Part D. Chapter 3: Food, Beverage, and Nutrient Consumption During Lactation** summarizes evidence on select topics pertaining to the dietary intake of women who are lactating and the associations with postpartum weight loss, human milk composition and quantity, and infant and child atopic and developmental outcomes. **Part D. Chapter 4: Duration, Frequency, and Volume of Exclusive Human Milk and/or Infant Formula Feeding**, **Part D. Chapter 5: Foods and Beverages Consumed during Infancy and Toddlerhood**, and **Part D. Chapter 6: Nutrients from Dietary Supplements During Infancy and Toddlerhood** describe evidence on the associations of consumption of human milk and infant formula, complementary foods and beverages, and iron and vitamin D supplements, respectively, with child outcomes. **Part D. Chapter 14: USDA Food Patterns for Individuals Ages 2 Years and Older** describes food patterns that provide sufficient nutrients to meet the Dietary Reference Intakes and *Dietary Guidelines for Americans* recommendations, while avoiding excessive energy intake, for all individuals ages 2 years and older, including those who are pregnant or lactating.

Background

In the United States, the health status of women of childbearing age falls short of recommendations for optimal pregnancy outcomes. Approximately, 50 percent of women ages 20 to 44 years have overweight or obesity.¹¹ Women are often motivated to improve their dietary intake during pregnancy to assure the best possible outcome for themselves and their child.¹² However, analysis of the nutrient intake of 1,003 women (ages 20 to 40 years) who were pregnant from the 2001-2014 National Health and Nutrition Examination Survey showed that many of these women did not meet the Estimated Average Requirement for key nutrients, including vitamins A, C, D, E, K, B₆, folate, choline, iron, potassium, calcium, magnesium, and zinc.¹³ Nutrient supplements were consumed by approximately 69 percent of women who were pregnant, which reduced the prevalence of those at risk for inadequate intakes of these nutrients. However, supplement use places some women at risk for exceeding the upper levels of intake for folate and iron.¹³

Making dietary changes only after a woman knows that she is pregnant is too late to achieve optimal pregnancy and postpartum outcomes¹ because crucial aspects of the development of the brain and spinal column of the infant occur within the first 3 to 4 weeks post-conception, generally before a woman knows that she has conceived.^{14,15} Because almost half of pregnancies in the United States are unplanned (with unplanned pregnancy rates as high as 75 percent among some age-race/ethnic groups), it is vital that all women, especially those of

reproductive age, maintain optimal nutritional status throughout their lifetime.¹⁶ This should include attention to both dietary quality and maintaining a healthy weight status.

A recent review of 60 studies representing nearly 1.4 million pregnancies demonstrated that high prepregnancy BMI is a key risk factor associated with adverse pregnancy outcomes for both the mother and the infant.¹⁷ Women who are obese before pregnancy were at increased risk for excessive GWG, GDM, hypertensive disorders, and cesarean section¹⁷ as well as perinatal complications, including infants who are large for gestational age at birth (LGA). Maternal obesity is both a risk factor for, and a consequence of, excessive GWG and/or excessive postpartum weight retention. The majority of women with overweight or obesity exceed GWG recommendations.^{18,19} Fewer than half of women revert to pregravid weights following pregnancy, with about half of women retaining 10 or more pounds and nearly 1 in 4 women retaining 20 pounds or more at 12 months postpartum.²⁰⁻²⁴ Weight status before pregnancy has been strongly associated with postpartum weight status²⁵ and may be more predictive of excessive postpartum weight retention than is total GWG.¹⁸ Postpartum weight retention results in about 1 in 7 women moving from a normal weight classification (pregnancy) to an overweight classification (postpartum).¹⁹ Therefore, interventions to normalize maternal prepregnancy BMI and prevent excess GWG could be an effective approach to break the trajectory of adverse pregnancy outcomes and long-term detrimental health outcomes for the mother and child.^{26,27}

Consistent with the DOHaD theory, children of women with high prepregnancy BMI, or who develop GDM or hypertensive disorders during pregnancy, are at greater risk of obesity and cardiometabolic diseases later in life.²⁸⁻³¹ Although mechanisms to explain these observations are still under investigation, recent studies have demonstrated associations between prepregnancy BMI and epigenetic changes in the child.^{32,33} More research is needed, but these findings provide biological plausibility linking maternal BMI to child health.

Both hypertensive disorders and GDM are serious pregnancy complications that are on the rise in the United States. Hypertensive disorders affect up to 15 percent of pregnancies and account for almost 10 percent of maternal deaths and 15 percent of premature births.^{34,35} Women who experience hypertensive disorders as well as their children are at increased risk of cardiometabolic disorders later in life.³⁶⁻³⁸ Given that pregnancy-related deaths in the United States nearly doubled between 1987 and 2016, preventing disorders that contribute to hypertensive disorders is imperative.³⁹ GDM affects approximately 6 percent of pregnancies among U.S. women⁴⁰ and is associated with an increased risk of future type 2 diabetes and cardiovascular disease among mothers,⁴¹ as well as increased risk of congenital anomalies,

stillbirth, and LGA newborn infants. Infants born to mothers with GDM are at increased risk of childhood obesity and associated chronic conditions during their lifetime.^{42,43}

Data available to describe relationships between diet during pregnancy and maternal and fetal outcomes focus on individual nutrients or classes of nutrients.^{44,45} Although such studies are important for examining physiological underpinnings of relationships between food and beverage intake and health outcomes, this approach does not capture the complexity of actual diets, particularly the diversity and innumerable combinations of nutrients and beverages and food components consumed by women.⁴⁵⁻⁴⁷ Accordingly, a systematic examination of the consequences of patterns of intake, both foods and beverages, before and during pregnancy, as well as the nutrient components of such patterns, is needed to create dietary guidance that is both meaningful and practical to the daily lives of women.⁴⁸

Patterns of dietary intake before and during pregnancy may affect the risk of poor maternal outcomes, including GDM and hypertensive disorders.⁴⁹⁻⁵² For example, adherence to a low carbohydrate dietary pattern before pregnancy that includes primarily animal-derived protein and fat has been associated with an increased risk of developing GDM.⁵³ Conversely, the consumption of a Mediterranean-style diet during pregnancy may reduce the odds of developing GDM, particularly among women with pre-existing cardiometabolic risk factors, and may moderate GWG.^{54,55} Furthermore, a Mediterranean-style diet during pregnancy may reduce the risk of metabolic syndrome postpartum.⁵⁶

Birth weight is a key indicator of infant health and wellbeing that is strongly influenced by gestational age and sex of the infant. Preterm birth and low birth weight affect 1 in 8 to 1 in 10 infants born each year in the United States⁵⁷ and account for about half of all hospitalizations among infants.⁵⁸ Prepregnancy weight status and weight gain during pregnancy are key factors influencing infant birth size.²⁶ Both low and high birth weight for gestational age and sex predispose mothers and their infants to health risks.¹⁷ Low birth weight (LBW) is defined as less than 2500 g (5.5 lbs) and very low birth weight as less than 1500g (3.3 lbs). Gestational age of less than 37 weeks is considered preterm.^{59,60} Small for gestational age (SGA) is a low birth weight and/or length at least 2 standard deviations below the mean, for gestational age and sex.⁶¹ High birth weight or LGA is defined as more than 4000g (8 lbs, 13 oz) at 40 weeks gestational age for both sexes.⁶²

Some evidence indicates that specific dietary patterns are associated with increased or decreased risk of preterm delivery^{28,46,63} and that supplemental nutrients may alter risk of fetal complications. For instance, supplementation with calcium (≥ 1 gram per day [g/d]), vitamin D (10 to 15 micrograms per day [μ g/d]), and a combination of the 2 nutrients during pregnancy

was associated with a reduced risk of pre-eclampsia and preterm birth, particularly among women who had poor nutritional status entering.⁶⁴⁻⁶⁶ Multi-micronutrient supplements containing iron and folic acid reduce the risk of LBW, SGA, and preterm birth.⁶⁷ Thus, the Committee sought to determine how dietary patterns, including frequency of eating and beverage intakes, are related to multiple components of pregnancy outcomes, including standardized birth weight, GWG, and gestational age at delivery. Although the influence of maternal dietary intake during pregnancy on birth weight has been considered in prior editions of the *Dietary Guidelines for Americans*, this is the first time that beverage intakes during pregnancy have been explicitly examined in relation to an infant outcome (birth weight standardized for gestational age and sex).

Neurodevelopment, which begins at conception, is often described as a scaffolding process characterized by the rapid evolution of increasingly complex neurologic circuits. Thus, optimal growth and development in the first 1,000 days demands that all obligatory components, including those provided by the diet, be available in sufficient quantities at the appropriate time.⁹ Both the timing and tempo of growth are important, as many aspects of development are sequential and continually build upon previous processes.^{9,68} Nutrients in commonly consumed foods that have a demonstrated time period of sensitivity that affect these developmental processes include protein, long-chain polyunsaturated fatty acids (LC-PUFA), zinc, copper, iodine, iron, folate, and choline.^{69,70}

Optimal nutrition during the prepregnancy years of a woman's life is crucial to support healthy pregnancy outcomes and child neurodevelopment. Suboptimal nutritional status of women entering pregnancy, particularly of folic acid, may increase the risk of congenital anomalies such as neural tube defects.⁷¹ Iron deficiency during pregnancy is associated with abnormal fetal development, and iron deficiency (in particular iron deficiency anemia) in early infancy is, in turn, associated with neurobehavioral deficits during infancy and early childhood, such as decreased attentiveness, slower speed of processing, and altered auditory and visual development. Many of these deficits may be irreversible with infant iron repletion,^{70,72} although this remains controversial. LC-PUFAs, produced endogenously or consumed from the diet, are particularly important for myelination and the development of vision during the perinatal period.^{9,69,70,73} Prenatal iodine deficiency may lead to irreversible neurocognitive defects and lower childhood IQ.^{9,69,70,73} The Committee evaluated the evidence regarding maternal seafood consumption as well as supplemental omega-3 fatty acids and folic acid related to select child neurodevelopmental outcomes.

The prevalence of food allergy and other atopic conditions has been steadily rising worldwide with the highest incidence noted among younger children,⁷⁴ and increasingly recognized as a growing public concern.⁷⁵ In infants, the first known ingestion of a food may cause an allergic reaction, suggesting that sensitization of offspring with food allergens may occur *in utero*.⁷⁶ However, the effects of maternal allergen exposure and maternal sensitization with allergens on development of allergies in offspring remain incompletely understood.⁷⁷ A more diverse maternal diet is postulated to favorably affect child atopic outcomes through both direct and indirect mechanisms.⁷⁸ A diverse maternal diet may lead to low dose exposure of different food antigens that could directly affect development of immune tolerance in the child. In addition, diet diversity may indirectly affect allergy outcomes by providing nutrients associated with prevention of allergic diseases such as omega-3 fatty acids and dietary fiber.^{79,80} Lastly, increased diet diversity leads to increased microbial diversity in infants during the introduction of solid food,⁸¹ and increased microbial diversity⁸² or abundance of certain bacteria⁸³ has been associated with reduced allergy outcomes. The Committee evaluated the association between maternal dietary intake including dietary patterns, and atopic diseases in the child.

Lastly, the Committee evaluated the effects of folic acid supplementation on both maternal and child outcomes. Folate is required as a one-carbon source for DNA and RNA synthesis, amino acid metabolism, and methylation. Folate is naturally present in some foods, added to others, and available as a dietary supplement. Food folates are in the tetrahydrofolate (THF) form and contain different numbers of glutamic acids depending on the type of food. Folic acid is the fully oxidized monoglutamate form of the vitamin that is used in fortified foods and most dietary supplements.⁸⁴

Women who are pregnant are at risk of folate deficiency due to the expansion of the maternal blood supply and the growth of fetal and maternal tissues.⁸⁵ The Recommended Dietary Allowance (RDA) for adult women is 400 µg/d, and 600 µg/d for women capable of becoming pregnant. To meet this higher requirement, the recommendation is that women take 400 µg of folic acid daily from fortified foods, supplements, or both, in addition to consuming food folate from a varied diet.⁸⁶ In 1998, fortification of enriched cereal-grain products (140 µg/100 g product) became mandatory in the United States.⁸⁴ This fortification is estimated to provide 100 to 200 µg of folic acid per day and has been associated with a significantly reduced incidence of neural tube defects.^{71,87} In April 2016, the Food and Drug Administration approved the voluntary addition of up to 154 µg folic acid/100 g to corn masa flour.⁸⁸ The Committee evaluated the evidence of associations between folic acid from supplements and fortified foods and maternal micronutrient status, risk of GDM and hypertensive disorders, and developmental

milestones in the child, but was unable to assess associations between folate from fortified foods and these outcomes due to insufficient evidence. A recent Cochrane Review provides some guidance on the health outcomes associated with fortification of grain products with folic acid.⁸⁹

Initially, the Committee was asked to investigate the relationships between 6 nutrients (folic acid, iodine, iron, vitamin B₁₂, vitamin D, and omega-3 fatty acids) from supplements and fortified foods and 5 potential maternal and fetal outcomes (micronutrient status, GDM, hypertensive disorders, human milk composition, and developmental milestones). Due to time constraints and, in some cases, existing systematic reviews or guidance that addressed some of the outcomes of interest, the scope of the Committee's reviews was reduced to focus on 2 of these nutrients, folic acid and omega-3 fatty acids. For folic acid, 5 outcomes were investigated, whereas for omega-3 fatty acids only the evidence for neurocognitive development of the child was reviewed. In addition, the Committee was not able to investigate the relationship between dietary patterns consumed during pregnancy and micronutrient status.

LIST OF QUESTIONS

1. What is the relationship between dietary patterns consumed during pregnancy and risk of gestational diabetes mellitus?
2. What is the relationship between dietary patterns consumed during pregnancy and risk of hypertensive disorders during pregnancy?
3. What is the relationship between dietary patterns consumed during pregnancy and gestational weight gain?
4. What is the relationship between frequency of eating during pregnancy and gestational weight gain?
5. What is the relationship between dietary patterns during pregnancy and gestational age at birth?
6. What is the relationship between dietary patterns consumed during pregnancy and birth weight standardized for gestational age and sex?
7. What is the relationship between beverage consumption during pregnancy and birth weight standardized for gestational age and sex?

8. What is the relationship between maternal diet during pregnancy and risk of child food allergies and atopic allergic diseases, including atopic dermatitis, allergic rhinitis, and asthma?
9. What is the relationship between seafood consumption during pregnancy and neurocognitive development of the infant?
10. What is the relationship between omega-3 fatty acids from supplements consumed before and during pregnancy and developmental milestones, including neurocognitive development in the child?
11. What is the relationship between folic acid from supplements and/or fortified foods consumed before and during pregnancy and 1) maternal micronutrient status, 2) gestational diabetes, 3) hypertensive disorders, 4) human milk composition, and 5) neurocognitive development in the child?

METHODOLOGY

All questions discussed in this chapter were answered using systematic reviews conducted with support from USDA's Nutrition Evidence Systematic Review (NESR) team. NESR's systematic review methodology provided a rigorous, consistent, and transparent process for the Committee to search for, evaluate, analyze, and synthesize evidence.

Questions 1, 2, 5, and 6 in this chapter were answered using existing NESR systematic reviews that were previously conducted as part of the Pregnancy and Birth to 24 Months Project, which was completed in 2019. The conclusion statements that answer these questions were taken directly from the existing systematic reviews and the wording reflects the findings of those reviews, which included articles published between 1980 and 2017. A description of the process the Committee used to determine that these existing systematic reviews were relevant to their questions and reflect the current state of the science is provided in **Part C.**

Methodology. In addition, detailed information about methodology used to complete these systematic reviews can be found at the following website: nesr.usda.gov/project-specific-overview-pb-24-0.

Questions 3, 4, and 7 through 11 in this chapter were answered using new NESR systematic reviews. The Committee developed a systematic review protocol for each question, which described how the Committee would apply NESR's methodology to answer the question. The protocol included an analytic framework and inclusion and exclusion criteria to guide

identification of the most relevant and appropriate bodies of evidence to use in answering each systematic review question. Each analytic framework outlined core elements of the systematic review question (i.e., population; intervention and/or exposure and comparator [i.e., the alternative being compared to the intervention or exposure]; and outcomes), and included definitions for key terms, key confounders, and other factors to be considered when reviewing the evidence. The inclusion and exclusion criteria were selected a priori to operationalize the elements of the analytic framework and specify what made a study relevant for each systematic review question.

Next, NESR conducted a literature search to identify all potentially relevant articles, and those articles were screened by two NESR analysts independently based on the criteria selected by the Committee. For each included article, data were extracted and risk of bias assessed. The Committee qualitatively synthesized the body of evidence to inform development of a conclusion statement(s) and graded the strength of evidence using pre-established criteria for risk of bias, consistency, directness, precision, and generalizability. Finally, recommendations for future research were identified. A detailed description of NESR's systematic review methodology is provided in **Part C. Methodology**, including standard inclusion and exclusion criteria applied in many of the Committee's systematic reviews. Complete documentation of each systematic review is available on the following website: nesr.usda.gov/2020-dietary-guidelines-advisory-committee-systematic-reviews. Below is a summary of the unique elements of the protocols developed to answer the questions addressed in this chapter.

For all questions discussed in this chapter, the population of interest for the intervention or exposure was women who are pregnant. For the questions that addressed supplements and/or fortified foods, the population of interest also included women before pregnancy. The population of interest for outcomes varied depending on the outcome examined, as described below.

For Question 3, consumption of and/or adherence to a dietary pattern during pregnancy was the primary intervention or exposure of interest. The comparators of interest were consumption of and/or adherence to a different dietary pattern or different levels of consumption of and/or adherence to a dietary pattern. Dietary patterns were defined as “the quantities, proportions, variety, or combination of different foods, drinks, and nutrients in diets, and the frequency with which they are habitually consumed.” To be included in the review on dietary patterns, studies needed to provide a description of the foods and beverages in the pattern. Dietary patterns considered in the review were measured or derived using a variety of approaches, such as

adherence to a priori patterns (indices/scores), data-driven patterns (factor or cluster analysis), reduced rank regression, or other methods, including clinical trials.

Question 3 also examined diets based on a macronutrient distribution outside of the Acceptable Macronutrient Distribution Range (AMDR), at any level above or below, as an intervention or exposure of interest. The comparator of interest was consumption of and/or adherence to a macronutrient distribution of carbohydrate, fat, and protein within the AMDR. To be included in the review, articles needed to describe the entire macronutrient distribution of the diet by reporting the proportion of energy from carbohydrate, fat, and protein, and have at least one macronutrient proportion outside of the AMDR.

The Committee established these criteria to take a holistic approach to answer the scientific questions, and thus needed to examine the entire distribution of macronutrients in the diet, and not one macronutrient in isolation. These criteria allowed the Committee to consider both the relationships with health outcomes of consuming a diet with one macronutrient outside of the AMDR, and also how consumption of that macronutrient displaces or replaces intake of other macronutrients within the distribution. A study did not need to report the foods/food groups consumed to be included. The criteria were designed to cast a wide, comprehensive net to capture any study that examined carbohydrate levels less than 45 percent or greater than 65 percent of energy, fat levels less than 20 percent or greater than 35 percent of energy, and/or protein levels less than 10 percent or greater than 35 percent of energy. Furthermore, when describing and categorizing studies included in these reviews, the Committee did not label the diets examined as “low” or “high,” because no universally accepted, standard definition is currently available, for example, for “low-carbohydrate” or “high-fat” diets. Instead, the Committee focused on whether, and the extent to which, the proportions of the macronutrients were below or above the AMDR.

The outcome examined in Question 3 was GWG, which was defined as the change in maternal body weight from baseline (before or during pregnancy) to a later time point during pregnancy and/or right before delivery; weight gain in relationship to weight gain recommendations, based on prepregnancy BMI.

Two literature searches were conducted to identify all potentially relevant articles for this question. The first search was designed to capture all potentially relevant articles on dietary patterns published from January 2000 to June 2019. The second search was designed to identify all potentially relevant articles on diets based on macronutrient distribution published from January 2000 to November 2019, and to capture any additional articles on dietary patterns published between June and November 2019. Articles for this question were searched for and

screened together with Question 1 on dietary patterns and postpartum weight loss in **Part D. Chapter 3: Food, Beverage, and Nutrient Consumption During Lactation**. This was done to leverage the overlap in topical areas and to improve efficiency. The Committee searched for and included studies that were published starting in 2000 because the field of dietary patterns research is relatively new, particularly for the populations and outcomes of interest in the questions being addressed in this chapter. Previous systematic reviews on dietary patterns searched for literature starting in 1980, but relevant studies published before the year 2000 were uncommon. Therefore, the Committee determined that the preponderance of evidence for these new reviews would be captured by searching literature starting in the year 2000.

For Question 4, frequency of eating during pregnancy was the intervention or exposure and GWG was the outcome (see **Part D. Chapter 13: Frequency of Eating** for details about the methodology used to answer this question).

For Question 7, beverage consumption during pregnancy was the intervention or exposure and birth weight standardized for gestational age and sex was the outcome (see **Part D. Chapter 10: Beverages** for details about the methodology used to answer this question).

For Question 8, maternal diet during pregnancy was the intervention or exposure, including consumption of foods that may be considered allergens (e.g., cow milk products, eggs, peanuts, tree nuts, soybean) and foods that are not considered allergens (including but not limited to meat, vegetables, fruits). The outcomes for this question were food allergies and atopic allergic diseases, including atopic dermatitis/eczema, allergic rhinitis and asthma, in infants and toddlers (birth to age 24 months) and children and adolescents (ages 2 to 18 years). Maternal diet during lactation and food allergies and atopic allergic diseases is discussed in **Part D. Chapter 3**, Question 4. Food allergy was defined as a diagnosis based on either the gold standard of a double-blind, placebo-controlled oral food challenge, or as parental report of clinical history together with blood immunoglobulin E (IgE) levels 0.35 or greater kilo unit per liter (kU/L) and/or skin prick test wheal 3 or greater millimeters (mm). Because of difficulty diagnosing asthma during infancy and toddlerhood, only those studies that assessed asthma in children who were at least age 2 years or older were included. A literature search was conducted to identify all potentially relevant articles published from January 1980 to January 2020 or older were included. A literature search was conducted to identify all potentially relevant articles published from January 1980 to January 2020.

For Question 9, seafood consumption during pregnancy was the intervention or exposure and neurocognitive development in the child was the outcome (see **Part D. Chapter 9: Dietary Fats and Seafood** for details about the methodology used to answer this question).

For Question 10, omega-3 fatty acids from supplements before and during pregnancy was the intervention or exposure. Fortified foods were not considered for this question because supplements are generally the major source of omega-3 fatty acids. The outcome for this question was developmental milestones, including neurocognitive development in infants and toddlers (birth to age 24 months) and children and adolescents (2 to 18 years). This included developmental domains (i.e., cognitive, language/communication, movement/physical, and social-emotional development), academic performance, attention deficit disorder (ADD) or attention deficit/hyperactivity disorder (ADHD), anxiety, depression, and autism spectrum disorder (ASD). Omega-3 fatty acids consumed as supplements during lactation and developmental milestones is discussed in **Part D. Chapter 3**, Question 7. A literature search was conducted to identify all potentially relevant articles published between January 1980 and February 2020.

For Question 11, folic acid from supplements and/or fortified foods during pregnancy was the intervention or exposure. The outcomes and their relevant intermediate risk factor levels considered were as follows:

- Gestational diabetes mellitus: Fasting glucose, hemoglobin A1C, glucose tolerance/insulin resistance, oral glucose tolerance test, gestational diabetes.
- Hypertensive disorders during pregnancy: Blood pressure (systolic and diastolic); protein in the urine (proteinuria); hypertensive disorders, including eclampsia, preeclampsia, and gestational hypertension.
- Micronutrient status in the mothers: Assessment of folate (including but not limited to serum folate, RBC folate), vitamin B₁₂, hemoglobin, mean corpuscular volume, red blood cell distribution width.
- Human milk composition: Folate in human milk, including but not limited to, total folate, reduced folates, unmetabolized folic acid. Human milk quantity was not considered as an outcome for this question.
- Developmental milestones, as described above in Question 10.

In order to capture fortification studies, this question also included uncontrolled before-and-after studies. In addition, cross-sectional studies were included for the human milk composition outcome alone, because of the dearth of longitudinal studies that addressed this outcome.

Folic acid from supplements and/or fortified foods during lactation and micronutrient status in mothers, as well as human milk composition and developmental milestones is discussed in

Part D. Chapter 3, Question 8. Three separate literature searches were conducted to identify all potentially relevant articles for Question 11. The first search was designed to identify articles on folic acid and micronutrient status or human milk composition, published from January 1980 to June 2019. The second search was designed to identify articles on folic acid and GDM or hypertensive disorders, published from January 1980 to July 2019. The third search was designed to identify articles on folic acid and developmental milestones, published from January 1980 to July 2019.

REVIEW OF THE SCIENCE

Question 1. What is the relationship between dietary patterns consumed during pregnancy and risk of gestational diabetes mellitus?

Approach to Answering Question: Existing NESR systematic review

Conclusion Statements and Grades

Limited but consistent evidence suggests that certain dietary patterns before pregnancy are associated with a reduced risk of gestational diabetes mellitus. These protective dietary patterns are higher in vegetables, fruits, whole grains, nuts, legumes, and fish, and lower in red and processed meats. Most of the research was conducted in healthy Caucasian women with access to health care. Grade: Limited

Evidence is insufficient to estimate the association between dietary patterns during pregnancy and risk of gestational diabetes mellitus. Grade: Grade Not Assignable

Summary of the Evidence

- This systematic review included 10 prospective cohort studies (PCSs) and 1 pilot randomized controlled trial (RCT), published between 1998 and 2016.⁹⁰
- The studies used multiple approaches to assess dietary patterns. Five studies used indices/scores to assess dietary patterns, 4 studies used factor or principal component analysis (PCA), and 1 study used both an index/score and PCA. In addition, 1 RCT assigned subjects to one of 2 experimental diets.
- Overall, 8 of the 11 included studies found statistically significant associations between dietary patterns and GDM risk among healthy White women with access to health care.

Greater adherence to a protective dietary pattern before and during pregnancy was associated with a decrease in GDM risk of 24 percent to 56 percent. Higher adherence to a detrimental pattern was associated with an increase in risk of 23 percent to 63 percent.

- The time points at which diet was assessed before or during pregnancy was heterogeneous across studies. Five studies measured diet before pregnancy while the rest (n=6) assessed diet during pregnancy:
 - o Greater adherence to a healthy diet assessed 2 to 10 years before pregnancy showed a consistent inverse association with the risk of GDM in all the studies. These findings are also in agreement with the evidence linking dietary patterns and type 2 diabetes mellitus risk in populations of women who were not pregnant.
 - o Studies that assessed diet during pregnancy had mixed findings: 1) 3 studies showed an association with GDM, 2) 1 showed an inverse association with blood glucose, only, and not with GDM, 3) 1 showed an effect on blood glucose and insulin response but did not study GDM, and 4) one other study showed no association with GDM.
- Generalizability of the studies is limited to healthy White women who have access to health care. Women of other races and ethnicities and those of lower socioeconomic status are underrepresented in this body of evidence. A major reason for grading this evidence as “limited” was the lack of adequately powered randomized controlled trials, few cohorts contributing to the observational studies, issues with risk of bias including self-reported exposure and outcome, and limited generalizability.

For additional details on this body of evidence, visit: [nesr.usda.gov/what-relationship-between-dietary-patterns-and-during-pregnancy-and-risk-gestational-diabetes#full-review](https://www.nesr.usda.gov/what-relationship-between-dietary-patterns-and-during-pregnancy-and-risk-gestational-diabetes#full-review)

Question 2. What is the relationship between dietary patterns consumed during pregnancy and risk of hypertensive disorders during pregnancy?

Approach to Answering Question: Existing NESR systematic review

Conclusion Statements and Grades

Limited evidence in healthy Caucasian women with access to health care suggests that dietary patterns before and during pregnancy higher in vegetables, fruits, whole grains, nuts, legumes, fish, and vegetable oils and lower in meat and refined grains are associated with a reduced risk of hypertensive disorders of pregnancy, including preeclampsia and gestational hypertension.

Not all components of the assessed dietary patterns were associated with all hypertensive disorders. Grade: Limited

Evidence is insufficient to estimate the association between dietary patterns before and during pregnancy and risk of hypertensive disorders of pregnancy in minority women and those of lower socioeconomic status. Grade: Grade Not Assignable

Summary of the Evidence

- This systematic review includes 8 studies (sample size ranging from 290 to 72,072) within 4 cohorts and 1 RCT, published between 2005 and 2016.⁹⁰
- The studies used multiple approaches to assess dietary patterns, which made it difficult to compare findings across studies. Three studies used indices/scores to assess dietary patterns, 4 studies used factor or PCA, and 1 RCT assigned participants to either an experimental or control diet.
- Despite this variability, 5 of the 8 included studies reported statistically significant associations between dietary patterns and hypertensive disorders risk among healthy White women with access to health care. An additional study showed an association between dietary patterns and blood pressure but not preeclampsia or gestational hypertension:
 - o Dietary patterns characterized by higher intakes of vegetables, fruits, whole grains, nuts, legumes, fish, and vegetable oils were associated with a 30 percent to 42 percent decreased risk of hypertensive disorders and a 14 percent to 29 percent decreased risk of preeclampsia.
 - o Two of the dietary patterns assessed were reported to be detrimental: traditional and processed food patterns, characterized by higher intakes of meats, potatoes, and processed foods. One was associated with a 21 percent increased risk of preeclampsia and the other was associated with an increased risk of high blood pressure during pregnancy.
- Generalizability of the included studies is limited to healthy White women who have access to health care. Women of other races and ethnicities and those of lower socioeconomic status are underrepresented in this body of evidence.
- The body of evidence had several limitations:
 - o The evidence base included 8 studies from only 4 unique cohorts and 1 RCT.

- o All but one of the studies were conducted outside the United States in samples that were predominantly White.
- o Dietary patterns varied considerably across studies, making it difficult to compare findings.
- o No adjustment was made for many key confounding factors.
- o The data were primarily observational, limiting the ability to draw any casual inferences. The RCT was conducted among 240 women and was not powered to examine hypertensive disorders (addressed by the authors as “hypertensive complications”). Additionally, the timing of the intervention in the RCT may have been too late in pregnancy for an effect to be seen.

For additional details on this body of evidence, visit: [nesr.usda.gov/what-relationship-between-dietary-patterns-and-during-pregnancy-and-risk-hypertensive-disorders#full-review](https://www.nesr.usda.gov/what-relationship-between-dietary-patterns-and-during-pregnancy-and-risk-hypertensive-disorders#full-review)

Question 3. What is the relationship between dietary patterns consumed during pregnancy and gestational weight gain?

Approach to Answering Question: NESR systematic review

Conclusion Statement and Grade

Limited evidence suggests that certain dietary patterns during pregnancy are associated with a lower risk of excessive gestational weight gain during pregnancy. These patterns are higher in vegetables, fruits, nuts, legumes, fish and lower in added sugar, and red and processed meat.
Grade: Limited

Summary of the Evidence

- This systematic review included 26 articles, including 5 articles from 4 RCTs and 21 articles from 19 PCSs published between 2009 and 2019.⁹¹⁻¹¹⁶
- Articles included in this review assessed one of the following interventions/exposures during pregnancy:
 - o Dietary patterns (24 studies).
 - o Diets based on a macronutrient distribution outside of the AMDR (2 studies).
- Eight of the 15 articles that assessed maternal dietary patterns using an index/score method

showed an association with GWG:

- Five of the 8 articles showed that greater adherence to a dietary pattern (identified as beneficial by the study) was associated with lower GWG.
- Three articles showed that greater adherence to a dietary pattern (identified as beneficial by the study) was associated with greater GWG in all participants or only women with obesity.
- Four of the 5 articles that assessed maternal dietary patterns using a factor or cluster analysis showed an association between adherence to dietary patterns and GWG.
 - One article showed that greater adherence to a dietary pattern (identified as beneficial by the study) was associated with lower GWG.
 - Four articles showed that greater adherence to a dietary pattern (identified as detrimental by the study) was associated with higher GWG.
- One study that assessed maternal dietary patterns using reduced rank regression showed that greater adherence to a dietary pattern was associated with higher GWG.
- Two RCTs showed that participants randomized to a dietary pattern (identified as beneficial by the study) had lower GWG.
- One RCT and one PCS showed no association between maternal consumption of a diet higher in fat (i.e., more than 35 percent of total energy from fat, which is greater than the AMDR) and GWG.
- Although the dietary patterns examined were characterized by combinations of different foods and beverages, the patterns that were consistently shown to be associated with lower risk of excessive GWG were: higher in vegetables, fruits, nuts, legumes, and fish and lower in added sugar and red and processed meat.
 - Not all foods were part of the same dietary pattern. The evidence did not show a consistent association between grains or dairy and GWG.
- The ability to draw strong conclusions was limited by the following issues:
 - There were few RCTs and thus data were primarily observational in nature, limiting the ability to determine causal effects of dietary patterns on GWG.
 - Key confounders were not consistently controlled for in most of the studies.
 - Studies had risk-of-bias issues, including exposure misclassification, self-reported outcomes, and selection bias.
 - Most of the studies were not designed to assess the association between dietary patterns and GWG.

- People with lower socioeconomic status (SES), adolescents, and racially and ethnically diverse populations were underrepresented in the body of evidence.

For additional details on this body of evidence, visit: nesr.usda.gov/2020-dietary-guidelines-advisory-committee-systematic-reviews/pregnancy-and-lactation-subcommittee/dietary-patterns-pregnancy-gestational-weight-gain

Question 4. What is the relationship between frequency of eating during pregnancy and gestational weight gain?

Approach to Answering Question: NESR systematic review

Conclusion Statement and Grade

No evidence is available to determine the relationship between the frequency of eating during pregnancy and gestational weight gain. Grade: Grade Not Assignable

Summary of the Evidence

- This systematic review was undertaken to examine the relationship between the frequency of eating during pregnancy and gestational weight gain.
- Frequency of eating was defined as the number of daily eating occasions. An eating occasion was defined as an ingestive event that is either energy yielding or non-energy yielding.
- Gestational weight gain was defined as weight a woman gains during pregnancy.
- This review identified 0 studies published between January 2000 and September 2019 that met the inclusion criteria for this systematic review.

For additional details on this body of evidence, visit: nesr.usda.gov/2020-dietary-guidelines-advisory-committee-systematic-reviews/frequency-eating-subcommittee/frequency-eating-gestational-weight-gain

Question 5. What is the relationship between dietary patterns consumed during pregnancy and gestational age at birth?

Approach to Answering Question: Existing NESR systematic review

Conclusion Statements and Grades

Limited but consistent evidence suggests that certain dietary patterns during pregnancy are associated with a lower risk of preterm birth and spontaneous preterm birth. These protective dietary patterns are higher in vegetables, fruits, whole grains, nuts, legumes and seeds; and seafood (preterm birth only), and lower in red and processed meats and fried foods. Most of the research was conducted in healthy, Caucasian women with access to health care. Grade: Limited

Evidence is insufficient to estimate the association between dietary patterns before pregnancy and gestational age at birth as well as the risk of preterm birth. Grade: Grade Not Assignable

Summary of the Evidence

- This systematic review included 10 PCSs and 1 RCT published between 2005 and 2016.¹¹⁷
- The studies used multiple approaches to assess dietary patterns:
 - Four studies used indices/scores to assess dietary patterns.
 - Four studies used factor analysis or (PCA).
 - One study used both indices/scores and PCA.
 - One RCT assigned subjects to 1 of 2 experimental diets.
 - One study did not use a formal method to arrive at a dietary pattern.
- Despite this variability, 5 of the 8 studies that assessed the relationship between dietary patterns during pregnancy and preterm birth found a statistically significant association. A sixth study found an association between dietary patterns during pregnancy and early preterm birth, but not preterm birth:
 - Highest adherence to a protective dietary pattern during pregnancy was associated with a preterm birth risk reduction of 9 percent to 90 percent.
 - Highest adherence to a detrimental dietary pattern during pregnancy was associated with an increase in preterm birth risk of 53 percent to 55 percent.

- Additionally, 4 of the 5 studies that assessed the relationship between dietary patterns during pregnancy and spontaneous preterm birth found a statistically significant association. The fifth study showed an effect modification by parity:
 - Highest adherence to a protective dietary pattern during pregnancy was associated with a spontaneous preterm birth risk reduction of 15 percent to 45 percent.
 - Highest adherence to a detrimental dietary pattern during pregnancy was associated with an increase in spontaneous preterm birth risk of 18 percent to 92 percent.
- The evidence was insufficient to estimate the association between dietary patterns during pregnancy and gestational age at birth when measured in days.
- Generalizability of the included studies was limited to healthy White women who have access to health care. Women of other races and ethnicities and those with lower socioeconomic status are underrepresented in this body of evidence.
- The ability to draw strong conclusions was limited by the following issues:
 - The data were primarily observational in nature, limiting the ability to determine causal effect of the dietary patterns.
 - The time points at which diet was assessed before or during pregnancy was heterogeneous across studies.
 - Outcome assessments were not uniform, and some studies used less robust methods than others.
 - Key confounding factors were not consistently controlled across studies.
 - Only 2 studies were conducted in the United States and 1 was primarily conducted in adolescent girls.
 - The study samples lacked diversity in terms of BMI, parity, age at conception, and smoking status

For additional details on this body of evidence, visit: [NESR.usda.gov
https://nesr.usda.gov/what-relationship-between-dietary-patterns-and-during-pregnancy-and-gestational-age-birth#full-review](https://nesr.usda.gov/what-relationship-between-dietary-patterns-and-during-pregnancy-and-gestational-age-birth#full-review)

Question 6. What is the relationship between dietary patterns consumed during pregnancy and birth weight standardized for gestational age and sex?

Approach to Answering Question: Existing NESR systematic review

Conclusion Statements and Grades

No conclusion can be drawn on the association between dietary patterns during pregnancy and birth weight outcomes. Although research is available, the ability to draw a conclusion is restricted by inconsistency in study findings, inadequate adjustment of birth weight for gestational age and sex, and variation in study design, dietary assessment methodology, and adjustment of key confounding factors. Grade: Grade Not Assignable

Insufficient evidence exists to estimate the association between dietary patterns before pregnancy and birth weight outcomes. There are not enough studies available to answer this question. Grade: Grade Not Assignable

Summary of the Evidence

- This systematic review included 18 PCSs, 1 retrospective cohort study, and 2 RCTs published between 1986 and 2016.¹¹⁷
- The studies used multiple approaches to assess dietary patterns:
 - Nine studies used an index or score to assess dietary patterns.
 - Eight studies used factor analysis or PCA.
 - Two RCTs trials assigned subjects to 1 of 2 experimental diets.
 - One study did not use a formal method to arrive at a dietary pattern.
 - One study used both logistic regression and PCA.
- Many studies did not standardize for gestational age and/or infant sex when assessing birth weight:
 - Just one-third of studies (n=7) used both gestational age- and sex-specific cut-off values when defining SGA, LGA, appropriate for gestational age (AGA), or intrauterine growth restriction (IUGR).
 - Nine out of 21 studies reported birth weight, alone, without standardizing for gestational age or sex using z-scores.

- Study findings were highly inconsistent across the body of evidence. About half of the studies (n=10) found no association between dietary patterns and birth weight outcomes. The studies that observed an association showed limited consistency in direction of effect and the dietary patterns generated.
- The generalizability of this review has serious limitations. People with lower SES, adolescents, and racially and ethnically diverse populations were underrepresented in the body of evidence.
- The ability to draw strong conclusions was limited by the following issues:
 - Study findings lacked consistency.
 - The data were primarily observational in nature, making it difficult to determine causal effect of the dietary patterns.
 - Many studies did not adjust birth weight for gestational age and sex, and the standardized measures that were used were heterogeneous.
 - The timing of exposure assessment and the duration of recall periods varied across studies.
 - Key confounding factors were not consistently accounted for.
 - None of the studies assessed effect modification between dietary patterns and maternal prepregnancy BMI in the context of birth weight outcomes.
 - Few included studies were conducted in the United States.

For additional details on this body of evidence, visit: [NESR.usda.gov](https://nesr.usda.gov/what-relationship-between-dietary-patterns-and-during-pregnancy-and-gestational-age-and-sex#full-review)
<https://nesr.usda.gov/what-relationship-between-dietary-patterns-and-during-pregnancy-and-gestational-age-and-sex#full-review>

Question 7. What is the relationship between beverage consumption during pregnancy and birth weight standardized for gestational age and sex?

Approach to Answering Question: NESR systematic review

Conclusion Statements and Grades

Insufficient evidence is available to determine the relationship between consumption of dairy milk during pregnancy and birth weight outcomes. Grade: Grade Not Assignable

Insufficient evidence is available to determine the relationship between consumption of tea during pregnancy and birth weight outcomes. Grade: Grade Not Assignable

Insufficient evidence is available to determine the relationship between consumption of coffee during pregnancy and birth weight outcomes. Grade: Grade Not Assignable

Insufficient evidence is available to determine the relationship between consumption of sugar-sweetened beverages or low- or no-calorie sweetened beverages during pregnancy and birth weight outcomes. Grade: Grade Not Assignable

Insufficient evidence is available to determine the relationship between consumption of water during pregnancy and birth weight outcomes. Grade: Grade Not Assignable

Summary of the Evidence

- Nineteen studies published between January 2000 and June 2019 met the criteria for inclusion in this systematic review, including 1 RCT and 18 PCSs.¹¹⁸⁻¹³⁶
- Many studies examined intake of multiple beverages.
- Evidence is summarized below by beverage type.

Dairy Milk

- Six studies examined the relationship between dairy milk consumption and birth weight outcomes. The body of evidence included 1 RCT and 5 PCSs.
- The search strategy focused on dairy milk, which included commercially available cow milk and soy beverages with varying fat and sweetener content. However, no studies examining soy beverages met the inclusion criteria.
- The body of evidence showed little consistency in the timing of exposure assessment (ranged from first through third trimesters) and the period of intake it represented (ranging from the previous 24 hours to average intake for the first half of pregnancy), which limited comparability across studies.
- Both continuous and categorical birth weight outcomes were examined:
 - Five studies assessed continuous birth weight.
 - Three studies assessed categorical birth weight outcomes.
- The 5 studies examining continuous birth weight found significant associations with milk intake, but in different directions. Four studies suggested that greater milk intake was related

to higher birth weight, but 1 study found the opposite.

- The 3 studies examining categorical birth weight outcomes had limited consistency in the outcomes measured and in findings:
 - Two of the 3 studies examined risk of SGA; 1 found greater milk intake was associated with lower risk, while the other did not find a significant relationship. One of those studies also evaluated risk of LGA and did not find a relationship with milk intake.
 - One study (the RCT) examined risk of LBW and found milk was related to lower risk.
- Overall, findings were inconsistent in both direction and statistical significance, limiting the ability to draw conclusions.
- This body of evidence had several limitations:
 - SES differed by geographic location, with the 2 studies conducted in Asia enrolling populations with substantially lower SES than did the European and Canadian studies, potentially limiting generalizability of those findings.
 - Two studies, including the RCT, had attrition rates of more than 25 percent, and neither provided information on the potential for selective attrition across intervention or exposure groups.
 - Outcomes examined, definitions used, and adjustment techniques varied across studies.
 - Many studies did not adjust for birth weight for gestational age and sex.
 - All studies failed to adjust for at least one key confounder.

Tea

- Eight PCSs examined the relationship between tea consumption and birth weight outcomes.
- Studies varied in the type of tea examined:
 - Three studies reported on overall tea intake.
 - Three studies reported on caffeinated tea only.
 - Three studies reported on specific types of tea (e.g., green, black, dark, oolong).
- Most studies examined tea intake in early pregnancy.
- Continuous birth weight was examined in 6 studies, and categorical birth weight outcomes were examined in 8.
- The 6 studies examining continuous birth weight reported mixed findings:
 - Three studies found tea intake at the highest amount related to lower birth weight.
 - Three studies found the relationship was not significant.
- The 8 studies examining categorical birth weight reported similarly mixed findings:
 - Of the 7 that examined risk of SGA or IUGR at birth, 3 found greater tea intake was

related to higher risk of SGA, while the relationship was non-significant for the remaining 4.

- LBW was examined in 2 studies, and greater risk of LBW was significantly associated with greater tea intake in 1 study and was non-significant in the other.
- This body of evidence had several limitations:
 - The majority of participants were White, well-educated, and higher SES, potentially limiting generalizability.
 - Three studies examined only caffeinated tea, which may not accurately represent total tea intake and limited the ability to draw independent conclusions about the beverage as compared to caffeine.
 - Outcomes examined and the definitions used varied across studies
 - Studies inconsistently adjusted birth weight for gestational age and sex.
 - Two studies had attrition rates of more than 20 percent, and neither provided information on the potential for selective attrition across exposure groups.
 - Seven of the 8 studies failed to adjust for at least one key confounder, most commonly prepregnancy BMI and diabetes diagnosis.

Coffee

- Seven PCSs examined the relationship between coffee consumption and birth weight outcomes.
- The timing of exposure assessment showed little consistency (ranging from 5 to 39 weeks gestation).
- Continuous birth weight was examined in 5 studies, and categorical birth weight outcomes were examined in 6.
- The 5 studies examining continuous birth weight reported mixed findings:
 - Three studies found greater coffee intake was related to lower birth weight
 - Two studies found the relationship was not significant.
- The 6 studies examining categorical birth weight reported similarly mixed findings:
 - Of the 5 that examined risk of SGA or IUGR at birth, 2 found greater coffee intake was related to higher risk of SGA, while the relationship was not significant for the remaining 3.
 - LBW was examined in 3 studies. One found greater coffee intake was related to greater risk of LBW, while the other 2 were not significant.
- This body of evidence had several limitations:

- The majority of participants were White, well-educated, and higher SES, potentially limiting generalizability.
- Three studies examined only caffeinated coffee, which may not accurately represent total coffee intake and limited the ability to draw conclusions about the beverage as compared to caffeine.
- Outcomes examined and the definitions used varied across studies.
- Studies inconsistently adjusted birth weight for gestational age and sex.
- Seven of the 8 studies failed to adjust for at least 1 key confounder, most commonly prepregnancy BMI and diabetes diagnosis.
- Two studies had attrition rates of more than 20 percent, and neither provided information on the potential for selective attrition across exposure groups.

Sugar-Sweetened Beverages and Low- or No-calorie Sweetened Beverages

- Seven studies examined the relationship between birth weight outcomes and intake of sugar-sweetened beverages (SSB), low- or no-calorie sweetened beverages (LNCSB), or both:
 - Three studies examined SSB independently.
 - Two examined LNCSB independently.
 - Two examined combined SSB and LNCSB.
 - Two did not specify whether the exposure represented SSB only or SSB plus LNCSB.
- The 3 studies examining SSB independently:
 - Measured intake across early, mid- and late-pregnancy.
 - Examined both continuous (n=3) and categorical (n=2) birth weight outcomes and were inconsistent in both the direction and statistical significance of their findings.
 - For continuous birth weight, 1 study found a positive relationship, 1 a negative relationship, and the third found no relationship with SSB intake.
 - No categorical outcomes were examined in more than 1 study.
- The 2 studies examining LNCSB independently:
 - Measured intake across early, mid- and late-pregnancy.
 - Examined continuous birth weight and found mixed results. One study showed greater LNCSB intake was related to lower birth weight, while the other did not find a significant association.
- The 2 studies that combined SSB and LNCSB intake looked specifically at caffeinated versions of the beverages:

- Both examined risk of SGA, with one finding a significant association between greater intake and greater risk of SGA while the other did not report a significant relationship.
- One study also examined continuous birth weight and found combined caffeinated SSB and LNCSB intake in early and mid-pregnancy was related to lower birth weight, but intake at 30 weeks was not.
- The 2 studies that did not clearly define the exposure variable and may have combined SSB and LNCSB intake defined the exposure as “cola” or “soda” and measured different outcomes.
 - One study found significant associations between greater intake and higher birth weight and higher risk of SGA, while the other found no relationship between intake and risk of IUGR.
- The body of evidence for SSB and LNCSB had several limitations:
 - The number of studies available for each beverage type was very small.
 - The exposure variable was poorly defined in multiple studies.
 - Three studies examined caffeinated versions of these beverages specifically, which may not represent complete intake of the beverage.
 - The studies showed little consistency in exposure assessment timing, outcome definitions, or direction of findings across studies.
 - Studies inconsistently adjusted birth weight for gestational age and sex.
 - Five studies had attrition rates of more than 20 percent for the full sample and did not include attrition rates by exposure group.

Plain Water

- Two PCSs assessed the relationship between water intake during pregnancy and birth weight outcomes.
- Exposure definitions made it difficult to determine whether the assessment included plain water intake only or also included water-based beverages, limiting the usefulness of the data.
- Both studies measured continuous birth weight and risk of SGA, and neither found a significant association with plain water intake for either outcome.
- This body of evidence had several limitations:
 - The number of studies available for this beverage type was very small.
 - Exposure definitions lacked clarity to confidently state they include plain water only.
 - Studies inconsistently adjusted birth weight for gestational age and sex.

For additional details on this body of evidence, visit: [nesr.usda.gov/2020-dietary-guidelines-advisory-committee-systematic-reviews/beverages-and-added-sugars-subcommittee/beverages-birth-weight](https://www.nesr.usda.gov/2020-dietary-guidelines-advisory-committee-systematic-reviews/beverages-and-added-sugars-subcommittee/beverages-birth-weight)

Question 8. What is the relationship between maternal diet during pregnancy and risk of child food allergies and atopic allergic diseases including atopic dermatitis, allergic rhinitis, and asthma?

Approach to Answering Question: NESR systematic review

Conclusion Statements and Grades

Food Allergy

Insufficient evidence is available to determine the relationship between lower or restricted consumption of cow milk products during pregnancy only, or during both pregnancy and lactation, and risk of food allergy in the child. Grade: Grade Not Assignable

Insufficient evidence is available to determine the relationship between peanuts, eggs, or wheat consumed during pregnancy and risk of food allergy in the child. Grade: Grade Not Assignable

Limited evidence suggests no relationship between soybean consumed during pregnancy and risk of food allergy in the child. Grade: Limited

No evidence is available to determine the relationship between dietary patterns or fish, tree nuts and seeds, and foods not commonly considered to be allergens such as meat, vegetables, and fruits consumed during pregnancy and risk of food allergy in the child. Grade: Grade Not Assignable

Atopic Dermatitis

Moderate evidence indicates that lower or restricted consumption of cow milk products during pregnancy does not reduce the risk of atopic dermatitis/eczema in the child. Grade: Moderate

Moderate evidence indicates that lower or restricted consumption of egg during pregnancy does not reduce the risk of atopic dermatitis/eczema in the child. Grade: Moderate

Insufficient evidence is available to determine the relationship between cow milk products and

eggs restricted during both pregnancy and lactation and risk of atopic dermatitis/eczema in the child. Grade: Grade Not Assignable

Limited evidence suggests that fish consumed during pregnancy does not increase the risk of atopic dermatitis/eczema in the child. Grade: Limited

Limited evidence suggests that dietary patterns during pregnancy are not associated with risk of atopic dermatitis/eczema in the child. Grade: Limited

Insufficient evidence is available to determine the relationship between peanuts, soybean, wheat/cereal, yogurt and probiotic milk products, and foods not commonly considered to be allergens, such as meat, vegetables, and fruits, consumed during pregnancy and risk of atopic dermatitis/eczema in the child. Grade: Grade Not Assignable

No evidence is available to determine the relationship between tree nuts and seeds consumed during pregnancy and risk of atopic dermatitis/eczema in the child. Grade: Grade Not Assignable

Allergic Rhinitis

Insufficient evidence is available to determine the relationship between cow milk products (fermented or non-fermented) consumed during pregnancy only, or during both pregnancy and lactation, and risk of allergic rhinitis in the child. Grade: Grade Not Assignable

Moderate evidence indicates that lower or restricted consumption of eggs during pregnancy does not reduce the risk of allergic rhinitis in the child. Grade: Moderate

Limited evidence suggests that dietary patterns during pregnancy are not associated with risk of allergic rhinitis in the child. Grade: Limited

Insufficient evidence is available to determine the relationship between fish, peanuts, tree nuts, soybean, wheat, and foods not commonly considered to be allergens, such as meat, vegetables, and fruits consumed during pregnancy and risk of allergic rhinitis in the child. Grade: Grade Not Assignable

No evidence is available to determine the relationship between seeds consumed during pregnancy and the risk of allergic rhinitis in the child. Grade: Grade Not Assignable

Asthma

Limited evidence suggests that a lower consumption of cow milk products during pregnancy does not reduce risk of asthma in the child. Grade: Limited

Insufficient evidence is available to determine the relationship between cow milk products consumed during both pregnancy and lactation and risk of asthma in the child. Grade: Grade Not Assignable

Limited evidence suggests no relationship between eggs consumed during pregnancy and risk of asthma in the child. Grade: Limited

Limited evidence suggests no relationship between fish consumed during pregnancy and risk of asthma in the child. Grade: Limited

Insufficient evidence is available to determine the relationship between maternal dietary patterns or peanuts, tree nuts, soybean, and other foods such as wheat/whole grains, vegetables, fruits, beverages, and margarine consumed during pregnancy and risk of asthma in the child. Grade: Grade Not Assignable

No evidence is available to determine the relationship between seeds consumed during pregnancy and risk of asthma in the child. Grade: Grade Not Assignable

Summary of the Evidence

- This systematic review included 36 articles from five RCTs, one non-RCT, and 13 PCSs that assessed the association between maternal diet and risk of food allergy, atopic dermatitis/eczema, allergic rhinitis, and asthma in the child occurring from birth through age 18 years.¹³⁷⁻¹⁷² The articles were published between 1987 and 2020 and consisted of:
 - Thirty articles from 15 studies that included only women who were pregnant.
 - Six articles from 4 studies that included women who were pregnant and women who were lactating.

- Six articles from 2 RCTs and 2 PCSs examined maternal avoidance and/or consumption of cow milk products, eggs, soybean, wheat, and peanuts during pregnancy alone, or during both pregnancy and lactation, in relation to risk of food allergy in the child from birth through age 18 years.
- Twenty-five articles from 5 RCTs, 1 non-RCT, and 10 PCSs examined maternal dietary patterns and consumption and/or avoidance of cow milk products, eggs, fish, soybean, wheat, peanuts, tree nuts, and other foods not commonly considered to be allergens during pregnancy alone, or during both pregnancy and lactation, in relation to risk of atopic dermatitis/eczema in the child from birth through age 18 years.
- Sixteen articles from 4 RCTs and 6 PCSs examined maternal dietary patterns and avoidance and/or consumption of cow milk products, eggs, fish, soybean, wheat, peanuts, tree nuts, and other foods not commonly considered to be allergens during pregnancy alone, or during both pregnancy and lactation, in relation to risk of allergic rhinitis in the child from birth through age 18 years.
- Nineteen articles from 2 RCTs and 8 PCSs examined maternal dietary patterns and avoidance and/or consumption of cow milk products, eggs, fish, soybean, peanuts, tree nuts, and other foods during pregnancy alone, or during both pregnancy and lactation, in relation to risk of asthma in the child from age 2 through 18 years.
- No articles were identified that examined maternal consumption of seeds during pregnancy in relation to risk of atopic outcomes in the child from birth through age 18 years.
- The ability to draw strong conclusions was limited by the following issues:
 - Few RCTs have been conducted and thus, data were primarily observational in nature, limiting the ability to determine causal effects of consumption or avoidance of different foods during pregnancy and risk of atopic dermatitis, food allergies, allergic rhinitis and asthma in the child.
 - Key confounders were not consistently controlled for in most of the studies.
 - Studies had risk-of-bias issues, such as self-reported outcomes and selection bias.
 - People with lower SES, adolescents, and racially and ethnically diverse populations were underrepresented in the body of evidence.

See **Part D. Chapter 3: Food, Beverage, and Nutrient Consumption During Lactation**, Question 4, for a review that addressed maternal diet during both pregnancy and lactation, and lactation only, and risk of child food allergies and atopic allergic diseases.

For additional details on this body of evidence, visit: [nesr.usda.gov/2020-dietary-guidelines-advisory-committee-systematic-reviews/pregnancy-and-lactation-subcommittee/maternal-diet-pregnancy-lactation-child-food-allergies-and-atopic-allergic-diseases](https://www.nesr.usda.gov/2020-dietary-guidelines-advisory-committee-systematic-reviews/pregnancy-and-lactation-subcommittee/maternal-diet-pregnancy-lactation-child-food-allergies-and-atopic-allergic-diseases)

Question 9. What is the relationship between seafood consumption during pregnancy and neurocognitive development in the child?

Approach to Answering Question: NESR systematic review

Conclusion Statements and Grades

Developmental Domains

Cognitive development: Moderate evidence indicates that seafood intake during pregnancy is associated favorably with measures of cognitive development in young children. Grade: Moderate

Language and communication development: Limited evidence suggests that seafood intake during pregnancy may be associated favorably with measures of language and communication development in the child. Grade: Limited

Movement and physical development: Insufficient evidence is available to determine the relationship between seafood intake during pregnancy and movement and physical development in the child. Grade: Grade Not Assignable

Social-emotional and behavioral development: Insufficient evidence is available to determine the relationship between seafood intake during pregnancy and social-emotional and behavioral development in the child. Grade: Grade Not Assignable

Attention deficit disorder or attention-deficit/hyperactivity disorder-like traits or behaviors: Insufficient evidence is available to determine the relationship between seafood consumption during pregnancy and attention deficit disorder or attention-deficit/hyperactivity disorder-like traits or behaviors in the child. Grade: Grade Not Assignable

Attention deficit disorder or attention-deficit/hyperactivity diagnosis: No evidence is available to determine the relationship between seafood consumption during pregnancy and

diagnosis of attention deficit disorder or attention-deficit/hyperactivity disorder in the child.

Grade: Grade Not Assignable

Autism spectrum disorder: Insufficient evidence is available to determine the relationship between seafood consumption during pregnancy and autism spectrum disorder-like traits or behaviors or autism spectrum disorder diagnosis in the child. Grade: Grade Not Assignable

Academic performance: No evidence is available to determine the relationship between seafood intake during pregnancy and academic performance in the child. Grade: Grade Not Assignable

Anxiety: No evidence is available to determine the relationship between seafood intake during pregnancy and anxiety in the child. Grade: Grade Not Assignable

Depression: No evidence is available to determine the relationship between seafood intake during pregnancy and depression in the child. Grade: Grade Not Assignable

Summary of the Evidence

- This review included 26 articles from 18 PCSs published between January 2000 and October 2019.¹⁷³⁻¹⁹⁸
- The 2020 Dietary Guidelines Advisory Committee used the following seafood definition: marine animals that live in the sea and in freshwater lakes and rivers. Seafood includes fish (e.g., salmon, tuna, trout, and tilapia) and shellfish (e.g., shrimp, crab, and oysters).
- Developmental domains
 - Evidence from 21 articles from 15 PCSs indicated predominantly beneficial associations between seafood intake during pregnancy and measures of cognitive development, including milestone achievement and intelligence, particularly in young children.
 - Evidence from 15 articles from 12 PCSs suggested beneficial associations between seafood intake during pregnancy and measures of language and communication development. However, results were less consistent than for cognitive development. Furthermore, 8 articles assessed measures of verbal intelligence or verbal intelligence quotient (IQ), which may be less specific assessments of language and communication development.
 - Few detrimental associations between seafood intake during pregnancy and measures

of child cognitive or language development were found.

- Heterogeneity in exposure and assessment methods, and ages of children at follow-up, made it difficult to determine a relationship between seafood intake during pregnancy and movement and physical development or social-emotional and behavioral development.
- Four articles, from 3 PCSs, found inconsistent results when examining the relationship between seafood intake during pregnancy and attention deficit disorder (ADD)-like or attention-deficit and hyperactivity disorder (ADHD)-like traits or behaviors in the child, with studies reporting either null or protective associations.
- Three PCSs assessed autism spectrum disorder (ASD)-like traits or behaviors or ASD diagnosis, but heterogeneity in outcome assessment methods and child age across the 3 PCSs made it difficult to determine a relationship between seafood intake during pregnancy and ASD-like traits or behaviors or ASD diagnosis.
- No studies that met inclusion criteria assessed the relationship between seafood intake during pregnancy and academic performance, anxiety, or depression in the child.
- Thirteen articles accounted for maternal mercury exposure and most found that controlling for mercury exposure strengthened or had little impact on the association between seafood intake during pregnancy and developmental outcomes.
- There were limitations in the evidence:
 - Heterogeneity in seafood intake categories used to compare seafood intake levels across studies made it difficult to assess precision and compare magnitude of associations.
 - Key confounders were not consistently accounted for and there was heterogeneity in exposures, outcomes and child age.

See **Part D. Chapter 3: Food, Beverage, and Nutrient Consumption During Lactation**, Question 6, for a review that addressed maternal seafood consumption during both pregnancy and lactation and neurocognitive developmental outcomes in the child.

For additional details on this body of evidence, visit: [nesr.usda.gov/2020-dietary-guidelines-advisory-committee-systematic-reviews/dietary-fats-and-seafood-subcommittee/seafood-pregnancy-lactation-infant-neurocognitive-development](https://www.nesr.usda.gov/2020-dietary-guidelines-advisory-committee-systematic-reviews/dietary-fats-and-seafood-subcommittee/seafood-pregnancy-lactation-infant-neurocognitive-development)

Question 10. What is the relationship between omega-3 fatty acids from supplements consumed before and during pregnancy and developmental milestones, including neurocognitive development in the child?

Approach to Answering Question: NESR systematic review

Conclusion Statements and Grades

Limited evidence suggests that omega-3 fatty acid supplementation during pregnancy may result in favorable cognitive development in the child. Grade: Limited

Insufficient evidence is available to determine the relationship between omega-3 fatty acid supplementation during both pregnancy and lactation, or during pregnancy only, and language and social emotional development in the child. Grade: Grade Not Assignable

Insufficient evidence is available to determine the relationship between omega-3 fatty acid supplementation during pregnancy and motor and visual development, academic performance, and the risk of attention-deficit disorder, attention-deficit/hyperactivity disorder, and autism spectrum disorder in the child. Grade: Grade Not Assignable

No evidence is available to determine the relationship between omega-3 fatty acid supplementation during both pregnancy and lactation, or during pregnancy only, and anxiety or depression in the child. Grade: Grade Not Assignable

Insufficient evidence is available to determine the relationship between omega-3 fatty acid supplementation during both pregnancy and lactation and cognitive development in the child. Grade: Grade Not Assignable

No evidence is available to determine the relationship between omega-3 fatty acid supplementation during both pregnancy and lactation and visual development, academic performance, or the risk of attention-deficit disorder, attention-deficit/hyperactivity disorder, or autism spectrum disorder in the child. Grade: Grade Not Assignable

Summary of the Evidence

Pregnancy Only, and Both Pregnancy and Lactation

- This systematic review included 31 articles from 14 RCTs and 1 PCS published between 1980 and 2020.¹⁹⁹⁻²²⁸

- Studies included in this review assessed interventions/exposures during:
 - Pregnancy only: 11 RCTs (24 articles); 1 PCS (1 article)
 - Both pregnancy and lactation: 3 RCTs (6 articles)
- 11 of the 14 RCTs assessed cognitive development
 - Eight RCTs delivered omega-3 fatty acid supplements during pregnancy alone. Of those 8 RCTs, 5 studies (11 articles) reported at least one statistically significant finding that supplementation resulted in favorable cognitive development in the child. One study reported at least one statistically significant finding that supplementation resulted in unfavorable measures of cognitive development in the child. All 8 studies reported at least one statistically non-significant result. Overall, results were inconsistent across different measures both within and between studies.
 - Three RCTs delivered omega-3 fatty acid supplements during both pregnancy and lactation. Of those 3 RCTs, 1 study reported at least one statistically significant finding that supplementation resulted in favorable cognitive development in the child. All 3 studies reported at least one statistically non-significant result.
- For language, motor, visual, and social-emotional development, findings were inconsistent and therefore a conclusion statement could not be drawn. Although all studies reported at least one statistically non-significant result, the number and direction of statistically significant findings varied across the body of evidence.
- Only 1 study examined academic performance; therefore, a conclusion could not be drawn.
- No evidence was available on omega-3 fatty acid supplementation and anxiety or depression.
- Only 1 study (2 articles) assessed the risk of ADD or ADHD; therefore a conclusion could not be drawn.
- Only 1 RCT and 1 PCS study assessed risk of ASD, and both had methodological limitations; therefore, the evidence was deemed insufficient to draw a conclusion.
- The ability to draw strong conclusions was limited by the following issues:
 - Wide variation in the developmental domains assessed, as well as in the measures used to evaluate child performance in each of those domains, which limited the ability to compare results across studies.
 - Potential risk of bias due to missing outcome data. Further, a lack of pre-registered data analysis plans potentially increased the risk of bias selectivity in results presented.
 - Findings were mixed both within and between studies, and these inconsistencies could

not be explained by methodological differences.

- Although some studies published results from multiple follow-up assessments, an insufficient number of studies were available to investigate the relationship between omega-3 fatty acid supplementation and developmental milestones in the child for many exposure-outcome pairs. Additionally, several studies did not provide evidence of sufficient sample size to detect effects, either because the study did not achieve the required sample size estimated by power calculations or because the study did not report a power calculation. This is particularly true for the long-term outcome assessments.
- People with lower-SES, adolescents, and racially and ethnically diverse populations were underrepresented in the body of evidence.

See **Part D. Chapter 3: Food, Beverage, and Nutrient Consumption During Lactation**, Question 7, for a review of omega-3 fatty acid supplementation during both pregnancy and lactation and neurocognitive outcomes in the child.

For additional details on this body of evidence, visit: [nesr.usda.gov/2020-dietary-guidelines-advisory-committee-systematic-reviews/pregnancy-and-lactation-subcommittee/omega-3-pregnancy-lactation-neurocognitive-development](https://www.nesr.usda.gov/2020-dietary-guidelines-advisory-committee-systematic-reviews/pregnancy-and-lactation-subcommittee/omega-3-pregnancy-lactation-neurocognitive-development)

Question 11. What is the relationship between folic acid from supplements and/or fortified foods consumed before and during pregnancy and 1) maternal micronutrient status, 2) gestational diabetes, 3) hypertensive disorders, 4) human milk composition, and 5) neurocognitive development in the child?

Approach to Answering Question: NESR systematic review

Conclusion Statements and Grades

Maternal Micronutrient Status

Strong evidence indicates that folic acid supplements consumed before and/or during pregnancy are positively associated with folate status (serum, plasma, and/or red blood cell folate). Grade: Strong

Insufficient evidence is available to determine the relationship between folic acid from supplements consumed before and/or during pregnancy and hemoglobin, mean corpuscular

volume, and serum vitamin B₁₂. Grade: Grade Not Assignable

No evidence is available to determine the relationship between folic acid from supplements consumed before and/or during pregnancy and red blood cell distribution width. Grade: Grade Not Assignable

No evidence is available to determine the relationship between folic acid from fortified foods consumed before and/or during pregnancy and micronutrient status. Grade: Grade Not Assignable

Gestational Diabetes

Insufficient evidence is available to determine the relationship between folic acid from supplements and/or fortified foods consumed before and during pregnancy and the risk of gestational diabetes. Grade: Grade Not Assignable

Hypertensive Disorders

Limited evidence suggests that folic acid supplements consumed during early pregnancy may have a beneficial effect on reducing the risk of hypertensive disorders during pregnancy among women at high-risk (e.g., history of preeclampsia or prepregnancy BMI ≥ 25 kg/m²) compared to no folic acid supplementation. Grade: Limited

Moderate evidence indicates that higher levels of folic acid supplements consumed during pregnancy compared to lower levels (including no folic acid supplementation) does not affect the risk of hypertensive disorders during pregnancy among women at low-risk. Grade: Moderate

No evidence is available to determine the relationship between folic acid from fortified foods consumed before and during pregnancy and the risk of hypertensive disorders during pregnancy. Grade: Grade Not Assignable

Human Milk Composition

No evidence is available to determine the relationship between folic acid from supplements or fortified foods consumed before and during pregnancy and human milk folate. Grade: Grade Not Assignable

Neurocognitive Development in the Child

Insufficient evidence is available to determine the relationship between folic acid supplementation before and/or during pregnancy and cognitive, language, and social-emotional development, and risk of autism spectrum disorder in the child. Grade: Grade Not Assignable

No evidence is available to determine the relationship between folic acid from supplements consumed before and during pregnancy and movement and physical development, academic performance, anxiety, depression, or the risk of attention-deficit disorder or attention-deficit/hyperactivity disorder in the child. Grade: Grade Not Assignable

No evidence is available to determine the relationship between folic acid from fortified foods consumed before and during pregnancy and developmental milestones, including neurobehavioral development, in the child. Grade: Grade Not Assignable

Summary of the Evidence

Maternal Micronutrient Status

- Nine studies were identified through a literature search from 1980 to 2019 which met the criteria for inclusion in this systematic review.²²⁹⁻²³⁷ Studies included in this review assessed interventions and exposures before and/or during pregnancy: 6 RCTs, 2 PCSs, and 1 retrospective cohort study.
- Studies varied in intervention details, including:
 - Folic acid supplement type (folic acid or 5-methyltetrahydrofolate).
 - Dose and comparator:
 - Three RCTs and 2 cohort studies compared no folic acid supplementation to folic acid supplementation (RCTs: 350 µg/d to 1.0 mg/d; cohorts: 400 µg/d or dose unknown).
 - Two RCTs compared different levels of folic acid supplementation (330 µg/d vs 730 µg/d; 1.1 mg/d vs 5.0 mg/d).
 - One RCT compared folic acid to 5-methyltetrahydrofolate (5-MTHF) supplementation at the same dose (1.0 mg/d).
 - Duration (2, 3, 5.5, 7, or 12 months).
- Of the 5 outcome measures defined in the analytic framework, all but red blood cell (RBC) distribution width were reported in the body of evidence.

- All but 1 study found a significant association between folic acid supplementation and at least one outcome measure.
- All 9 studies (6 RCTs; 3 PCSs) assessed plasma or serum folate.
 - Of those, 6 found that supplementation was associated with higher values on at least 1 measure of plasma or serum folate and 2 found no association. Another study compared supplementation with folic acid vs 5-MTHF and found that both groups increased over time.
- Six studies (4 RCTs; 2 PCSs) assessed RBC folate.
 - Five found that supplementation was associated with higher values on at least 1 measure of RBC folate and 1 found no association.
- Three studies (2 RCTs; 1 retrospective cohort) assessed hemoglobin. The findings were inconsistent; therefore a conclusion statement could not be drawn.
- Of the 2 RCTs that assessed mean corpuscular volume (MCV), neither found a significant effect on MCV, but study limitations and the small number of studies provided insufficient evidence to draw a conclusion.
- Only 1 RCT assessed the effect of supplementation on vitamin B₁₂; therefore, a conclusion could not be drawn.
- The body of evidence had important limitations:
 - None of the studies preregistered data analysis plans, indicating a risk of bias due to selectivity in results presented.
 - The cohort studies did not adequately account for potential confounding.
 - Risk of bias due to classification of exposures or deviations from intended exposures was a concern for the cohort studies.
 - The study populations did not fully represent the racial/ethnic or socioeconomic diversity of the U.S. population.
 - No studies met the inclusion criteria that examined the effect of intake of folic acid from fortified foods on the outcome of interest.

Gestational Diabetes

- One non-RCT that met the criteria for inclusion in this systematic review was identified through a literature search from 1980 to 2019.²³⁸
- This study found that women who consumed folic acid supplementation based on genotype and stage of pregnancy had significantly fewer cases of gestational diabetes compared to women who did not consume folic acid supplements before or during pregnancy.

- The evidence had several limitations:
 - No baseline data on study groups were provided for comparison.
 - Intervention methods and adherence were not clear.
 - Results by subgroup were not reported.
 - Consistency could not be assessed with only 1 study.

Hypertensive Disorders

- Eight studies, including 3 RCTs, 2 non-RCTs, and 3 PCSs, met the criteria for inclusion in this systematic review, which were identified through a literature search from 1980 to 2019.²³⁸⁻²⁴⁵
- The 3 RCTs compared 5.0 mg/d of folic acid supplementation to a lower-dose of either 0.5 mg/d (2 studies) or 1.0 mg/d (1 study) from early pregnancy through delivery. The folic acid supplementation dose had no effect on incidence of gestational hypertension, preeclampsia, or eclampsia. None of the studies compared folic acid supplementation to a control group with no folic acid supplementation.
- The 2 non-RCTs found a statistically significant association of folic acid supplementation (15 mg/d of 5-MTHF in one study; 400-800 µg/d in another study) from early pregnancy through delivery on risk of gestational hypertension or preeclampsia compared to a control group with no folic acid supplementation. One non-RCT was among a high-risk population (women who had preeclampsia in their preceding pregnancy); the other had methodological limitations related to exposure, outcome assessment, and analysis.
- The 3 PCSs reported mixed results. One study found an association between folic acid use in the first trimester and lower incidence of preeclampsia in the full study sample, and specifically among those with a BMI ≥ 25 kg/m²; another study found a statistically significant association between folic acid use at 12 to 20 weeks gestation and lower incidence of preeclampsia among high-risk women. A third study did not find a significant association between folic acid supplementation pre and/or post-conception (Four weeks before to 8 weeks after last menstrual period) and preeclampsia. In addition to problems related to confounding, these studies did not account for potential changes in folic acid supplementation during pregnancy.
- No articles were identified that met the inclusion criteria related to folic acid intake from fortified foods and risk of hypertensive disorders during pregnancy.

Human Milk Composition

- No studies related to folic acid intake from supplements during pregnancy which met the criteria for inclusion in this systematic review were identified through a literature search from 1980 to 2019.

Neurocognitive Development of the Child

- Six articles that met the criteria for inclusion in this systematic review were identified through a literature search from 1980 to 2019.^{200,202,246-249} The articles report findings from 4 studies representing 4 outcome domains:
 - Cognitive development: 1 RCT; 2 articles.
 - Language and communication development: 1 PCS; 2 articles.
 - Social-emotional development: 1 RCT; 1 article.
 - ASD: 1 nested case-control study; 1 article.
- Generally, folic acid supplementation before or during pregnancy was either not associated with or had a beneficial association with the included outcomes.
- For cognitive development, findings were inconsistent; therefore a conclusion statement could not be drawn.
- For social-emotional development, only 1 study was available and it had some limitations; therefore, a conclusion could not be drawn.
- For language development, 2 articles were included from the Norwegian Mother and Child (MoBa) cohort. These articles reported a lower risk of severe language delay in children age 3 years whose mothers had taken folic acid supplements during early pregnancy compared to children whose mothers either did not take folic acid during pregnancy or took folic acid supplements later in pregnancy.
- For ASD, 1 nested case-control found a significant association between folic acid supplementation before pregnancy and during pregnancy and lower risk of ASD in children ages 8-12 years, compared to no folic acid supplementation. This was true for a number of subgroups within the sample, including children without siblings, males, females, children with low SES, children with both parents with psychiatric diagnosis, and children without intellectual disabilities.
- No evidence was found on whether folic acid supplementation before and/or during pregnancy was associated with other included outcomes: movement and physical development, academic performance, ADD or ADHD, anxiety, or depression
- No evidence was found on folic acid from supplements or fortified foods consumed before

and during pregnancy and lactation and developmental milestones, including neurocognitive development.

See **Part D. Chapter 3: Food, Beverage, and Nutrient Consumption During Lactation**, Question 8, for a review that addressed maternal folic acid supplementation during lactation and selected health outcomes.

For additional details on this body of evidence, visit: [nesr.usda.gov/2020-dietary-guidelines-advisory-committee-systematic-reviews/pregnancy-and-lactation-subcommittee/folic-acid-pregnancy-lactation-health-outcomes](https://www.nesr.usda.gov/2020-dietary-guidelines-advisory-committee-systematic-reviews/pregnancy-and-lactation-subcommittee/folic-acid-pregnancy-lactation-health-outcomes)

DISCUSSION

Although the 2015 Dietary Guidelines Advisory Committee report²⁵⁰ included some discussion of nutrients of public health concern specific to women who are pregnant, and dietary patterns during pregnancy that are linked to risk of congenital anomalies, it did not include a substantial emphasis on food or beverage intake and maternal-fetal outcomes of pregnancy. The systematic reviews included in this report are the first to assess questions that specifically examine relationships between food and beverage patterns or micronutrients during pregnancy and maternal-fetal outcomes that affect large groups of women and their progeny. Four of the systematic reviews included in this body of evidence, specifically those that examined the impact of dietary patterns during pregnancy on maternal⁹⁰ and birth outcomes,¹¹⁷ were undertaken by the USDA and Department of Health and Human Services as part of the Pregnancy and Birth to 24 Months (P/B-24) Project (P/B-24 TEC).²⁵¹ These previously completed systematic reviews were adopted by the 2020 Dietary Guidelines Advisory Committee as they directly addressed the questions we were given.

Dietary Patterns and Risk of Gestational Diabetes Mellitus

These reviews found that several dietary patterns consumed before pregnancy were associated with a reduced risk of GDM.⁹⁰ These dietary patterns shared several characteristics, including higher intakes of fruits, vegetables, whole grains, fish, nuts, and legumes. In contrast, dietary patterns characterized by inclusion of red and processed meats were associated with an increased risk for development of GDM.⁹⁰ The time interval between dietary data collection and outcome measurement ranged from several weeks to 2 to 10 years. However, longitudinal

studies suggest that maternal dietary intake remains stable from prepregnancy throughout pregnancy.²⁵²⁻²⁵⁴

The Committee concluded that consistent evidence suggests that certain dietary patterns consumed before pregnancy are associated with reduced risk of GDM. This conclusion was graded as limited because much of the evidence was observational and only 7 distinct groups of women (6 PCSs of women who were pregnant and a pilot RCT with 1 group of women who were pregnant) were included. Only 2 PCSs were from the United States. These studies provided insufficient evidence to determine whether dietary intake during pregnancy was associated with GDM risk.

Dietary Patterns and Risk of Hypertensive Disorders During Pregnancy

Five of the 8 included studies showed significant associations between dietary patterns consumed before and during pregnancy and risk of hypertensive disorders.⁹⁰ The dietary patterns associated with reducing the risk of hypertensive disorders were characterized by food components similar to those related to lower risk of GDM (e.g., higher in vegetables, fruits, whole grains, nuts, legumes, and fish). Consumption of these patterns before and during pregnancy was associated with a 14 percent to 29 percent reduction in the risk of preeclampsia and a 30 percent to 42 percent decreased risk of hypertensive disorders, although not all components of the assessed dietary patterns were associated with all hypertensive disorders outcomes.⁹⁰ Although the associations between certain dietary patterns and reduced risk of hypertensive disorders were consistent, the strength of the evidence was judged to be limited and only applicable to healthy White women with access to health care. Evidence was insufficient for women of other races and ethnicities and those of lower SES. In addition, issues with methodology, measurement and limited representation of diverse groups of women hampered the ability to draw robust generalizable conclusions.

Dietary Patterns and Gestational Weight Gain

Weight gain during pregnancy can contribute both positively and negatively to maternal and fetal outcomes. The 2009 Institute of Medicine (IOM) report on weight gain during pregnancy outlined gestational weight gain (GWG) recommendations based on prepregnancy BMI.²⁶ However, 23 percent of women gain less, and 47 percent exceed recommended levels during pregnancy.²⁵⁵ GWG exhibits a U-shaped curve with regard to risk of poor fetal outcomes. Gaining less weight than recommended increases the risk of SGA and preterm birth.²⁵⁵

Excessive GWG increases the risk of GDM, hypertensive disorders, macrosomia in the infant, and cesarean delivery.²⁵⁵⁻²⁵⁷ Dietary interventions, with or without physical activity interventions, can modify GWG.²⁵⁸ However, most interventions have focused on restricting energy intake or modifying glycemic index, rather than on examining how dietary patterns affect GWG.

The systematic review for dietary patterns and GWG included 26 articles (4 RCTs and 19 PCSs from 23 distinct groups of women). Dietary patterns included in this review were assessed using a variety of methods including experimental diets (3 studies), macronutrient distribution (2 studies), index/score analysis (15 studies), factor analysis and principal component analysis (PCA) (5 studies), and reduced rank regression (1 study). Among the 15 studies that used an index or score to assess dietary patterns, 8 of the studies found an association with GWG; five of these studies found that greater adherence to a “beneficial” dietary pattern was associated with lower GWG, while 3 studies found that greater adherence to a “beneficial” dietary pattern was associated with higher GWG, particularly in women with obesity. Examples of beneficial dietary patterns were similar to those that were associated with reduced risk of hypertensive disorders and GDM, and included the Dietary Approaches to Stop Hypertension (DASH) diet and similar patterns. The patterns were higher in vegetables, fruits, nuts, legumes, and fish, while being lower in added sugars and red and processed meats. The DASH-style diet has been found to improve fasting blood glucose levels of women who are pregnant.²⁵⁹ The 7 studies using an index or score to assess dietary patterns that did not find an association between dietary patterns and GWG suffered from a variety of methodological issues including the lack of control for any key confounders, heterogeneity in timing of assessment of exposure, and/or they were not designed to assess the association between dietary patterns and GWG.

Among the studies using factor analysis or PCA to assess dietary pattern, one study found that greater adherence to a healthy dietary pattern was associated with lower GWG while four suggested that adherence to a less healthy dietary pattern was associated with greater GWG. The 3 RCTs using an experimental diet all found that adherence to Mediterranean or DASH dietary patterns was associated with lower GWG, with 2 showing effects throughout pregnancy and one showing a lower rate of GWG only through the end of the second trimester. The studies that examined macronutrient distributions outside the AMDR did not find associations between percent of energy derived from fat intake and GWG.

The evidence for the current review was graded as limited due to a small number of RCTs compared to observational studies, the lack of control for key confounders by many of the studies, and the lack of racial/ethnic and socioeconomic diversity in the study participants. In addition, many studies relied on self-reported data and were not specifically designed to

examine the relationship between dietary patterns and GWG. Moreover, not all studies stratified women by prepregnancy BMI status, which is a significant confounder in the relationship between GWG and prenatal diet quality.²⁶⁰ Despite these limitations, the evidence suggested that beneficial dietary patterns may help prevent excess or inadequate GWG, at least in some women.

Frequency of Eating and Gestational Weight Gain

Frequency of eating is a component of dietary patterns that may play a role in maternal-fetal outcomes of pregnancy. The 1992 Implementation Guide for the 1990 IOM GWG guidelines^{261,262} recommended that women who are pregnant eat 3 meals and 2 or more snacks each day, but this was not included in the more recent GWG recommendations.²⁶ This eating pattern aims to ensure that women are able to consume the extra nutrients needed during pregnancy, while minimizing common gastrointestinal complaints, namely nausea and indigestion. These recommendations also are consistent with the current typical eating pattern for Americans.

The Committee examined the association between frequency of eating and GWG (see **Part D. Chapter 13: Frequency of Eating**). However, no studies published between January 2000 and September 2019 met the inclusion criteria for this systematic review. Existing literature suggests that eating patterns change during pregnancy, moving from a main-meal focused pattern during the second trimester to a snack-dominant pattern by the beginning of the third trimester.²⁶³ Additionally, less frequent consumption of meals and/or snacks²⁶⁴ and differences in the timing of eating occasions during the day²⁶⁵ are associated with a higher risk of preterm birth. For example, consumption of a 3-meal a day pattern resulted in lower risk of preterm birth compared to a frequent “snack” meal pattern or an “evening meal” pattern characterized by large night-time meals and morning snacks.²⁶⁵ More research is needed to determine how frequency and content of eating and drinking occasions changes throughout pregnancy, and how these changes affect GWG, to further efforts to promote optimal maternal-fetal outcomes and to reduce poor outcomes such as preterm birth, SGA, and LGA. Food insecurity has been associated with higher GWG, so future studies must account for food insecurity as a potential underlying cause of reduced frequency of eating.²⁶⁶

Dietary Patterns and Gestational Age at Birth

Two systematic reviews undertaken by the Pregnancy and Birth to 24 Months Project examined the relationship between dietary patterns consumed before and during pregnancy and gestational age at birth, including preterm birth and birth weight, standardized for gestational age and sex.¹¹⁷ Ten percent of infants born in the United States are born prematurely⁵⁷ and 8 percent of infants are born at a low birth weight (<2500 g) each year⁵⁷; preterm birth is the leading cause of low birth weight. While the rate of LBW had dropped between 2006 and 2012, there has recently been a 4 percent increase in LBW rates in the United States.⁵⁷ It has been estimated that 47 percent of hospital stay costs for infants and 27 percent of total pediatric hospital stay costs are due to preterm birth and LBW.⁵⁸ Preterm birth accounts for 36 percent of all infant deaths, carries an annual societal economic cost of more than \$26 billion, and may result in immediate as well as lifelong disabilities.²⁶⁷

Ten PCSs and 1 RCT examined dietary patterns consumed during pregnancy and gestational age at birth and most found an association with altered risk of preterm birth and spontaneous preterm birth. Based on this evidence, the Pregnancy and Birth to 24 Months Project concluded that limited but consistent evidence suggests that certain dietary patterns during pregnancy are associated with a lower risk of preterm birth and spontaneous preterm birth. These protective dietary patterns are higher in vegetables, fruits, whole grains, nuts, legumes and seeds, and seafood (preterm birth, only), and lower in red and processed meats and fried foods.¹¹⁷ The range of risk reduction varied 10-fold (9 percent to 90 percent) for preterm birth, but was more moderate and consistent for spontaneous preterm birth (15 percent to 45 percent). The only RCT in the review found an increase of approximately 4 days in gestational age between controls and women consuming the healthier intervention diet.²⁶⁸ Dietary patterns characterized by high intakes of fried foods, red and processed meats, fats, and sugars (e.g., Western diet) were associated with a 53 percent to 55 percent increased risk of preterm birth (and a potentially higher risk of spontaneous preterm birth of 18 percent to 92 percent). Most of the research was conducted in healthy White women with access to health care, however. Therefore, the conclusion is limited in that it may not be generalizable to the entire population of U.S. women of reproductive age. It was not possible to draw conclusions about dietary patterns before pregnancy and preterm birth due to a lack of high-quality evidence. This is an area that requires further investigation.

Dietary Patterns and Birth Weight, Adjusted for Gestational Age and Sex

The systematic review examining dietary patterns before and during pregnancy and birth weight, adjusted for gestational age and sex, included 21 groups of women (19 cohorts and 2 groups of women enrolled in RCTs), with 7 studies conducted in the United States.¹¹⁷ The significant methodological limitations and inconsistency in study design and outcome measurements for age- and sex-specific birth weight resulted in an inability to draw a conclusion about how dietary patterns before or during pregnancy relate to these outcomes. The studies enrolled women with a lower prepregnancy BMI than is typical for pregnant women in the United States.²⁶⁹ Rates of smoking among participants, which is associated with reduced birth weight, varied substantially among studies in this systematic review and was not adequately accounted for in the analyses of the included studies. Of particular concern was the lack of adjustment of birth weight for gestational age or sex, and the timing of exposure and outcome assessments. Many studies did not use a standardized measure for outcomes such as SGA and LGA, and the definitions of these outcomes were quite heterogeneous. In addition, many of the studies included a relatively narrow range of birth weight.

Despite the limitations of the studies, the conclusions drawn from these systematic reviews are consistent with findings from other published systematic reviews and meta-analyses.^{28,270,271} However, although proposed physiological mechanisms support the associations found between dietary intake before and/or during pregnancy and risk of outcomes found in this body of evidence, the mechanistic evidence is still exploratory in nature.²⁷²⁻²⁷⁵

Beverages and Birth Weight, Adjusted for Gestational Age and Sex

Beverage intake is an important topic to consider during pregnancy as beverages contribute substantially to intakes of water, energy, and nutrients among pregnant women (see **Part D. Chapter 1: Current Intakes of Foods, Beverages, and Nutrients** and **Part D. Chapter 10: Beverages**) and have the potential to influence pregnancy outcomes. Women who are pregnant consume about the same volume of beverages as women who are not pregnant. However, they have a higher intake of water, milk, and diet beverages, a similar intake of sweetened beverages, and a lower intake of coffee and tea. The Committee reviewed the evidence for the relationship between beverage consumption during pregnancy and birth weight, standardized for gestational age and sex. Nineteen studies published between January 2000 and June 2019 met the criteria for inclusion in this systematic review, including 1 RCT and 18 PCSs. The studies examined milk, tea, coffee, SSB, LNCSB, or water during pregnancy in relationship to

infant birth weight, expressed in varying ways, and with varying adjustments for gestational age and sex. Many of the studies examined more than one beverage. The timing of beverage exposure assessment and the period of intake represented varied substantially, ranging from 5 to 39 weeks of pregnancy, although many studies focused on intake during the first and second trimesters. Overall, the lack of control for the rest of the (non-beverage) diet in this body of evidence was a limitation. The body of evidence available was insufficient in scope and breadth and encompassed too many methodological limitations to determine a relationship between beverage intake in pregnancy and infant birth weight (standardized for gestational age and sex).

Maternal Diet and Food Allergy and Atopic Allergic Outcomes in the Child

Atopic diseases are some of the most common chronic conditions affecting the United States population. The National Institute of Allergy and Infectious Diseases (NIAID) estimates that approximately 5 percent of children and approximately 4 percent of adults in the United States have 1 or more food allergies,²⁷⁶ which is similar to an overall prevalence of food allergy among U.S. infants and children ages 0 to 4 years of 6.6 percent reported by proxy using NHIS 2017 data.²⁷⁷ However, the NHIS data are based on parental self-report, and the degree to which reported food allergies were diagnosed by a health provider (and if so, based on an actual allergic reaction vs testing results), parental impression, or a combination of factors, cannot be determined from these data. In addition, the NIAID estimated that approximately 30 percent of the U.S. population has atopic dermatitis.²⁷⁸ The Centers for Disease Control and Prevention (CDC) estimates that approximately 8 percent of Americans have asthma,²⁷⁹ and an additional 8 percent have hay fever (allergic rhinitis).²⁸⁰ In this chapter and in **Part D. Chapter 3: Food, Beverage, and Nutrient Consumption During Lactation**, the Committee describes its investigation of the relationship of maternal diet during pregnancy and lactation and risk of food allergies and atopic allergic diseases in children.

The systematic review to determine the relationship between maternal diet during pregnancy, or pregnancy and lactation, and the risk of 4 atopic manifestations (food allergies, atopic dermatitis/eczema, asthma, and allergic rhinitis) in the child from birth through age 18 years included 36 articles from 5 RCTs, 1 non-RCT, and 13 PCSs published between 1987 and 2020. Five RCTs and 1 non-RCT focused on avoiding specific foods or food groups, 8 PCSs assessed dietary patterns, and 22 articles from 13 PCSs examined the association between different consumption levels of a variety of foods and beverages and risk of atopic outcomes. Most intervention studies were specifically designed to assess the relationship between avoiding a food product during pregnancy and/or lactation and the atopic outcome, whereas

observational studies compared different dietary patterns or intakes of the specific foods or food groups during pregnancy and/or lactation. The RCTs primarily recruited families who were at high risk of allergies. However, this was not the case with PCSs. The timing of study initiation and duration also varied between studies.

The Committee concluded that overall dietary patterns consumed during pregnancy are not associated with the risk of food allergies, allergic rhinitis, or atopic dermatitis/eczema in the child. The evidence pointed to a lack of association between restriction or avoidance of common food allergens in intervention trials or varying levels of intake in cohort studies and risk of various atopic diseases. For cow milk, moderate evidence indicated that lower or restricted consumption during pregnancy did not reduce the risk of atopic dermatitis/eczema and limited evidence suggested that that lower or restricted consumption did not reduce the risk of asthma. For egg, moderate evidence indicated that lower or restricted consumption during pregnancy did not reduce the risk of atopic dermatitis/eczema or allergic rhinitis, and limited evidence suggested that lower or restricted consumption did not reduce the risk of asthma. Limited evidence from cohort studies also suggested no relationship between fish and soybean consumption during pregnancy and the risk of asthma and food allergies, respectively, in the child.

The ability to draw strong conclusions was limited by the study designs (primarily the observational nature of the studies), which constrained the ability to determine causal effects of consumption or avoidance of different foods on risk of atopic diseases. These studies cannot discriminate between exposures of the mother during pregnancy and/or lactation, or those directly affecting the child. It also was not possible to attribute child atopic outcomes in these studies to the timing of the dietary (pattern) exposure. In most studies, key confounders were not consistently controlled for, study populations lacked racial and/or ethnic diversity and lower-SES, and adolescent populations were underrepresented.

Taken together these conclusions support the conclusions of the AAP²⁸¹ and the European Academy of Allergy and Clinical Immunology (EAACI)²⁸² that evidence to support maternal dietary restrictions either during pregnancy or pregnancy and lactation to prevent atopic disease in the child is lacking.

Maternal Seafood Consumption and Neurocognitive Development of the Child

Consumption of seafood during pregnancy is a topic of considerable scientific and public interest.²⁸³ The 2015-2020 Dietary Guidelines for Americans recommends that women who are

pregnant consume at least 8 and up to 12 ounces of a variety of seafood per week, from choices that are lower in methylmercury. Evaluating seafood consumption is inherently a “net effects” evaluation that implicitly “reflect[s] the sum of benefits and risks from all of the constituents in the fish”.²⁸⁴ In terms of neurocognitive development, fish is the primary dietary source of long-chain polyunsaturated omega-3 fatty acids,²⁸⁵ which are needed for brain development.²⁸⁶ Thus, the benefits of seafood need to be weighed against the potential for negative health consequences due to possible contamination with heavy metals, chiefly methylmercury. Exposure to methylmercury is considered especially dangerous during critical windows of neurocognitive development in the first 1,000 days of life, though the risks have not been entirely characterized.²⁸⁵

The Committee’s systematic review of seafood consumption during pregnancy and neurocognitive development of the infant and child yielded 26 PCSs from 18 cohorts published between January 2000 and October 2019 that addressed each neurocognitive component area. A majority of results suggested benefits in the area of cognitive development and language and communication development. Beneficial associations with cognitive development were observed across multiple cohorts, with the most consistent results observed among young children. Similarly, results were beneficial for language and communication, but were less consistent than for cognitive development. However, other domains, such as movement and physical development and social and behavioral development had a lower number of available studies and had considerable heterogeneity of outcome assessments or populations, rendering inconclusive findings that were unable to be graded. Additionally, insufficient data were available to grade evidence for the outcomes of academic performance, anxiety, and depression as well as ASD and ADD/ADHD.

Although the Committee’s questions did not specifically focus on safety, it noted isolated negative (i.e., increased risk) associations of seafood intake and neurocognitive outcomes in 3 studies. In one of the studies,¹⁸⁶ a negative association was observed primarily between maternal prenatal intake of squid and shellfish and child performance on perceptual performance and numeric subscales. No negative associations were observed between total seafood consumption or consumption of large fish with neurocognitive outcomes. In another study, a negative association was observed between maternal fish intake and child psychomotor development. However, maternal fish intake was assessed using a non-validated questionnaire, the negative association was observed only in female children, and no adjustment was made for maternal mercury exposure. Despite these isolated negative

associations, the overwhelming majority of studies showed a null or positive (i.e., favorable or beneficial) association.

Although the available scientific literature on the topic of seafood consumption during pregnancy and neurocognitive outcomes in the child has recently expanded, the totality of the evidence remains inconclusive due to several limitations. These limitations include: 1) lack of uniformity and usage of valid and reliable methods across studies to assess type, amount, frequency, source and preparation of seafood exposure at multiple time points during pregnancy, 2) the variety of measurement tools for neurocognitive development, as well as the wide range of outcomes included, 3) insufficient accounting for maternal methylmercury exposure in studies assessing child outcomes, and 4) lack of RCTs, primarily due to ethical considerations

These limitations made it difficult to draw firm conclusions about the relationships between seafood consumption during pregnancy and movement and physical development, social-emotional and behavioral development, attention deficit disorder/attention-deficit hyperactivity disorder-like traits or behaviors or diagnosis, and autism spectrum disorder in the child (see ***Part D. Chapter 9: Dietary Fats and Seafood*** for additional information about the methodology for this review).

This Committee's review could not address questions that differentiated the influence of maternal seafood intake during pregnancy on the child's neurocognitive development and the influences of direct seafood intake by the child after the introduction of complementary foods.

Omega-3 Fatty Acids from Supplements and Neurocognitive Development of the Child

In addition to considering seafood consumption, the Committee evaluated the impact of omega-3 fatty acid supplementation before and during pregnancy on neurocognitive outcomes of the child. Based on the evidence from 8 RCTs (17 articles) published between 2006 and 2019, the Committee concluded that omega-3 fatty acid supplementation during pregnancy may result in favorable cognitive development in the child. This conclusion statement was graded as "Limited." Overall, the studies had low risk of bias due to randomization, deviations from intended interventions, and outcome measurement for all studies. However, the results were mixed both within and between studies, which could have been due to the wide heterogeneity in the timing of the outcome assessment. Of the 8 trials with information on measures related to cognitive development, 2 conducted assessments only during infancy, 1 at age 1 week²¹⁰ and 1 at age 4 and age 6 months.²²² Thus, the results of those 2 trials could not be compared with

results of the other 6 trials. Among the other 6 trials,^{200-205,208,209,216,217,219-221,223,224,226} the maximum age at follow-up ranged from 5 to 12 years. Thus, the developmental domains assessed varied widely, as did the measures used to evaluate child performance in each of those domains. This variability limited the ability to compare results across studies. The dose and content of the supplements provided also varied; 3 trials^{203-205,208,209,216,217,219} included both docosahexaenoic acid (DHA) and eicosapentaenoic acid (EPA), with doses ranging from 500 to 2,200 mg for DHA and from 100 to 1,100 mg for EPA; 3 trials^{200-202,220,221,223,224,226} used only DHA, with doses of 400 to 600 mg. Most of the interventions began at 18 to 22 weeks gestation, but one began at 14.5 weeks^{203,204} and another at 16 weeks gestation.^{220,221} Two studies, one in Australia^{208,209,216,217} and one in Mexico,^{223,224,226} had sample sizes of approximately 700 to 900, whereas the other 4 trials had sample sizes ranging from 72^{205,219} to 161.^{203,204} The studies provided little information on baseline omega-3 status, but most trials excluded women taking DHA-containing supplements (except 1 trial).^{203,204} One of these 6 trials excluded women consuming more than 2 fish meals per week at enrollment (Perth).^{205,219} Three trials provided information indicating that women had low DHA intake^{223,224,226} or biochemical evidence from maternal or cord blood suggestive of low DHA status at baseline (DOMINO, KUDOS).^{203,204,208,209,216,217}

Of the 6 studies with follow-up beyond infancy, 4 identified at least 1 significant difference in outcomes in favor of the group receiving omega-3 supplements. In the DOMINO trial in Australia,^{208,209,216} these included: 1) being less likely to be rated as “delayed” on the Bayley Scores for Infant Development III (though not different in the average score) at age 18 months; 2) scoring better on one of the sustained attention tasks at age 27 months (though not on the other tasks); 3) scoring higher on training accuracy during the training trials for one of the assessments of working memory and inhibitory control (but not on the actual test trials); and 4) scoring higher for perceptual reasoning (but not other sub-scales) on the Wechsler Abbreviated Scale of other sub-scales on the Wechsler Abbreviated Scale of Intelligence) at age 7 years. On the other hand, children in the intervention group scored lower than those in the control group for assessments of executive function at age 4 years,^{209,217} although those were both based on parental report. No significant differences were found on the remainder of the assessments, including a distractibility task at age 27 months, the Differential Ability Scales at age 4 years, and the TEACH Sky search test at age 7 years.^{209,217}

In Mexico,²²³ children in the intervention group scored better on one of the sub-scales (omissions) on the Kiddie Continuous Performance Test at age 5 years, but did not differ in the overall score or the other 3 sub-scales, nor on the McCarthy Scales of Children’s Abilities.

These children also did not differ on the Bayley Scales of Infant Development at age 18 months.²²⁴ In the KUDOS trial in the United States,²⁰⁴ children in the intervention group scored higher on one of the tests of executive function at ages 24 and 30 months, but otherwise did not differ on the other tests performed at any of the ages (10, 18, 24, 30, 36, 42, 48, 60, and 72 months). In another study in Australia,²⁰⁵ children in the intervention group scored higher on eye-hand coordination at age 2.5 years, but not on the other sub-scales of the Griffiths Mental Development Scales. At age 12 years, no significant differences were seen in scores on the WISC or the Beery-Buktenica Developmental Test of Visual-Motor Integration, though only 48 children remained in the study.²¹⁹ In the other 2 trials, no significant differences by intervention group were detected at any age (6.5 to 8.5 years in the NUHEAL trial in Germany, Hungary, and Spain²⁰⁰⁻²⁰² and 9 months, 18 months and 5.75 years in a trial in Canada.^{220,221}

The ability to draw stronger conclusions was limited by the heterogeneity and inconsistencies of the findings described above. In addition, several studies did not provide evidence of sufficient sample size to detect effects, either because the study did not achieve the required sample size estimated by power calculations or because the study did not report a power calculation. This is particularly true for the longer-term outcome assessments. Lastly, the generalizability of this body of evidence to the United States was low because lower-SES and adolescent populations were underrepresented and the studies lacked racial and ethnic diversity.

Insufficient evidence was available for the other outcomes examined to draw a conclusion regarding the relationship of prenatal omega-3 supplementation with language, motor, visual, or socio-emotional development, academic performance, ADD, ADHD, or ASD. No evidence for the relationship with anxiety or depression in the child was found.

The Committee also examined 3 RCTs that evaluated omega-3 supplementation during *both* pregnancy and lactation. The findings of those trials did not alter the conclusions described above for supplementation during pregnancy only (see **Part D. Chapter 3**).

These conclusions are similar to those of a recent Cochrane review and meta-analysis,²⁸⁷ which stated that “very few differences between antenatal omega-3 LCPUFA supplementation and no omega-3 were observed in cognition, IQ, vision, other neurodevelopment and growth outcomes, language, and behavior.” The importance of an adequate supply of omega-3 fatty acids for brain development *in utero* is not disputed.^{286,287} Both omega-3 and omega-6 fatty acids are involved in numerous processes for central nervous system development. Accumulation of DHA in the brain occurs rapidly during the second half of gestation, suggesting that this is a critical period for an adequate supply from the diet, adipose stores, or through

synthesis from precursor fatty acids (e.g., alpha-linolenic acid). The effects of prenatal omega-3 supplements on neurocognitive development of the child thus likely depend on the adequacy of the maternal diet with respect to DHA and its precursors along with inherent synthetic capacity to generate LCPUFA from their precursors.^{288,289} Thus, further evidence is needed from RCTs that are adequately powered and targeted at populations with low intakes of omega-3 fatty acids.

Folic Acid from Supplements and Maternal and Child Health Outcomes

Women who are pregnant can obtain folate through food forms of folate, folic acid in fortified grains, or folic acid in supplements. The Committee examined the relationship between folic acid from supplements consumed before and during pregnancy and maternal and child outcomes. None of the identified articles that examined the relationship between folic acid from fortified foods consumed before and during pregnancy met inclusion and exclusion criteria. The outcomes investigated were: 1) maternal micronutrient status, 2) GDM, 3) hypertensive disorders, and 4) developmental milestones, including neurocognitive development in the child. Associations between folic acid from supplements and/or fortified foods consumed during lactation and maternal micronutrient status and human milk composition are discussed in **Part D. Chapter 3**.

Six RCTs, 2 PCSs, and 1 retrospective cohort study were included in the body of evidence. Micronutrient status was assessed by serum or plasma folate (which are short-term indicators of folate status), RBC folate (which is a longer-term and preferred biomarker of folate status⁸⁶) and various hematological markers. In addition, due to the risk of folate supplementation masking vitamin B₁₂ deficiency, serum or plasma B₁₂ concentrations also were assessed.

Although the studies varied in timing of initiation of supplementation, dose, and the form of folate provided, the Committee concluded that folic acid supplementation before and/or during pregnancy is positively associated with folate status (serum, plasma, and/or RBC folate). This conclusion was graded as “Strong” because the 6 RCTs had low risk of bias, and were consistent, direct, and precise in the measurements and outcomes. The 3 observational studies were moderately consistent, and the results of the cohort studies mostly aligned with those of the RCTs. The generalizability of the results from the RCTs was diminished because only 1 of the 6 was conducted in the United States, and it had limited racial/ethnicity and socioeconomic diversity. Of the cohort studies, none reported either race/ethnicity or socioeconomic status.

For hematologic markers of folate status, the evidence was either insufficient (hemoglobin, mean corpuscular volume) or nonexistent (red cell distribution width). In addition, insufficient

evidence was available to determine the relationship between folic acid from supplements consumed before and/or during pregnancy and serum/plasma vitamin B₁₂ concentrations.

For hypertensive disorders, the evidence reviewed by the Committee included 3 RCTs, 2 non-RCTs, and 3 PCS. For GDM, 1 non-RCT conducted in China was included in this body of evidence. This study found that women who consumed folic acid supplements, based on *MTHFR* and *MTRR* genotype and trimester of pregnancy, had significantly fewer cases of GDM compared to women who did not consume folic acid supplements before or during pregnancy (0.27 percent vs 3.24 percent; $p < 0.05$).²³⁸ However, the study raised serious concerns regarding risk of confounding and participant selection, missing data, and an unclear study protocol. Therefore, the Committee concluded that insufficient evidence was available to determine the relationship between folic acid from supplements consumed before and during pregnancy and lactation and the risk of GDM.

For hypertensive disorders, 3 RCTs compared a high dose of folic acid (5.0 mg/d) to doses close to the RDA (0.5 or 1.0 mg/d) in low-risk women. All were conducted in Iran, where flour fortification with folate was not routine, and all found no association with risk of gestational hypertension or pre-eclampsia. One non-RCT compared 15 mg/d 5-MTHF to aspirin and found lower incidence of preeclampsia compared to no 5-MTHF.²⁴¹ The other²³⁸ compared different doses of folic acid, but had serious methodologic limitations, as described above. The 3 PCSs compared no folate vs a folate supplement and showed no benefit²³⁹ or found benefit only for high-risk women.^{244,245}

The Committee concluded that the benefit of folic acid supplementation varied with maternal risk for hypertensive disorders. For women at high risk (e.g., prepregnancy BMI ≥ 35 kg/m², preeclampsia in a previous pregnancy), limited evidence showed that folic acid supplementation during early pregnancy reduced the risk of hypertensive disorders compared to no folic acid supplementation. However, for healthy women at low risk, moderate evidence supported no benefit of folic acid supplementation for hypertensive disorders. These studies have limitations regarding generalizability, as none were conducted in the United States and little data were provided on other participant characteristics.

Lastly, the Committee examined data on the relationship between folic acid supplementation before and during pregnancy and developmental milestones in the child, including neurocognitive development. Six articles from 4 studies were included in the body of evidence. In general, folic acid supplementation before or during pregnancy was either not associated with, or had a beneficial association with, the included outcomes. For cognitive development, findings were inconsistent and therefore a conclusion statement could not be drawn. For social-

emotional development, only 1 study was reviewed and it had limitations. Therefore, a conclusion could not be drawn. For language development, 2 articles were included from the Norwegian Mother and Child (MoBa) cohort. These articles reported a lower risk of severe language delay in children age 3 years whose mothers had taken folic acid supplements during early pregnancy compared to children whose mothers either did not take folic acid during pregnancy or took folic acid supplements later in pregnancy.

For ASD, 1 nested case-control study found a significant association between folic acid supplementation before pregnancy and during pregnancy and lower risk of ASD in children ages 8 to 12 years, compared to no folic acid supplementation. This was true for a number of subgroups within the sample, including children without siblings, males, females, children of low SES, children with both parents reporting a psychiatric diagnosis, and children without intellectual disabilities.²⁴⁸ Although these findings of reduced ASD with folic acid are promising, they are derived from single studies for each reported outcome. Therefore, the Committee concluded that insufficient evidence was available to determine the relationship between folic acid supplementation before and/or during pregnancy and cognitive, language, and social emotional development, and risk of ASD in the child. In addition, no evidence was available to determine the relationship between folic acid from supplements consumed before and during pregnancy and movement and physical development, academic performance, anxiety, depression, or the risk of ADD or ADHD in the child.

No studies that assessed the relationship between folic acid fortification before and/or during pregnancy and maternal and child outcomes were found. However, findings from a recent Cochrane systematic review showed improvements in folate status in women who were pregnant who consumed wheat and maize flour fortified with folic acid.⁸⁹ In 1 study, women who were pregnant (n=38) who received folic acid-fortified maize porridge had significantly higher erythrocyte and plasma folate concentrations compared to no intervention. However, in another study, women of reproductive age who were not pregnant (n=35) who consumed maize flour fortified with folic acid and other micronutrients did not have higher erythrocyte or plasma folate concentrations, compared to women consuming unfortified maize flour. In 2 non-RCTs, serum folate concentrations were significantly higher among women who consumed flour fortified with folic acid and other micronutrients compared to women who consumed unfortified flour. The authors concluded that fortification of wheat or maize flour with folic acid (i.e., alone or with other micronutrients) may increase erythrocyte and serum/plasma folate concentrations. Limitations of this review included the small number of available studies and low certainty of evidence due to how included studies were designed and reported.⁸⁹

SUMMARY

This is the first Dietary Guidelines Advisory Committee to conduct a series of reviews focused on women who are pregnant. The 3 most recent Dietary Guidelines Advisory Committees have examined relationships between specific foods, food components, or nutrients and pregnancy outcomes, including: alcohol,²⁹⁰⁻²⁹² caffeine,²⁹² calcium,²⁹² dairy,^{291,292} folate,²⁹⁰⁻²⁹² iron,²⁹⁰⁻²⁹² omega-3 fatty acids,^{290,292} total protein,²⁹² seafood,²⁹⁰⁻²⁹² and vegetable and/or soy protein.²⁹⁰ In addition, previous Committees examined relationships between pregnancy and maternal body weight,²⁹⁰⁻²⁹² physical activity,^{290,292} and food safety.²⁹⁰⁻²⁹² The 2020 Committee re-examined seafood consumption, omega-3 fatty acids, folic acid supplements, and beverages (including caffeinated choices), but did not specifically examine alcohol, protein intake, body weight, food safety, calcium, dairy products, iron, or physical activity. This Committee also examined several new relationships, including those between dietary patterns and maternal and child outcomes, frequency of eating and gestational weight gain, and beverage consumption and infant birth weight. In addition, for the first time, the Committee examined relationships between maternal consumption of dietary patterns and/or specific foods and atopic conditions in children, including food allergies, allergic rhinitis, atopic dermatitis/eczema, and asthma.

The evidence reviewed by the Committee reinforces the importance of nutrition for women of reproductive age and women who are pregnant for optimal maternal and fetal outcomes. Women who are pregnant have higher a mean Healthy Eating Index (HEI) score (i.e., 62 out of 100), than do their peers who are not pregnant (i.e., 54). Focusing on the components of the HEI, women who are pregnant have lower HEI scores than their peers (i.e., women who are neither pregnant nor lactating and women who are lactating) for Added Sugars and the highest HEI component scores for Total Fruits, Total Vegetables, Dairy, Refined Grains, and Sodium among the 3 groups of women (**see Part D. Chapter 1: Current Intakes of Foods, Beverages, and Nutrients**, Question 3 for additional information about the HEI).

Mean usual intakes of select underconsumed and overconsumed nutrients by pregnant and non-pregnant, non-lactating women in the United States, based on the What We Eat in America, NHANES 2013-2016 data, are summarized in Table D2.1. The definitions of underconsumed and overconsumed nutrients or food components can be found in **Part D. Chapter 1** and in the footnotes of Table D2.1. Nutrients or UL food components of public health concern are those that are underconsumed or overconsumed nutrients or food components with supporting evidence through biochemical indices or functional status indicators, if available, plus evidence

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that the inadequacy or excess is directly related to a specific health condition (**see Part D. Chapter**). Food components of public health concern among women who are pregnant include those for the entire population older than 1 year, including vitamin D, calcium, dietary fiber, and potassium, which are underconsumed and sodium, saturated fat, and added sugars, which are overconsumed. In addition, low iron intake is of public health concern among women who are pregnant, based on biomarker data that suggest low nutrient status.¹³ Given the high prevalence of inadequate folate intakes observed in women who are or are capable of becoming pregnant and that nutrient's relationship to risk of neural tube defects, folate/folic acid should remain of concern among premenopausal women during the first trimester of pregnancy, when the neural tube is formed and closed. Folate/folic acid and iron are unique in that with the use of dietary supplements, 27% and 14% of women who are pregnant will exceed the UL for folic acid and iron, respectively, but without the supplements these women would be at risk for inadequacy (Table D2.1). Choline and magnesium are also underconsumed in the diets of women who are pregnant and should be considered for further evaluation, given limited availability of biomarker, clinical, or health outcome data (Table D2.1) Low iodine intake is potentially of public health concern among women who are pregnant, based on biomarker data that suggest low nutrient status. Taken together, these data suggest that, while women apparently seek to improve their diets during pregnancy, further improvements are needed to better align with dietary recommendations.

Table D2.1 Mean usual intake of select underconsumed and overconsumed nutrients, by pregnancy status, in the United States, 2013-2016¹

		Pregnant		Non-Pregnant²	
		Food and Beverages (n=125)	Food, Beverages, and Dietary Supplements (n=119)	Food and Beverages (n=2060)	Food, Beverages, and Dietary Supplements (n=2019)
Potentially underconsumed:					
Choline (mg)	Mean (SE)	289 (12)	287 (13)	290 (4)	293 (4)
	% >AI (SE)	6† (1.7)	4† (1.8)	7 (1.1)	7 (1.0)
Dietary fiber (g)	Mean (SE)	18.1 (0.9)	n/a	15.4 (0.4)	n/a
	% >AI (SE)	11* (2.6)	n/a	7 (1.2)	n/a
Potassium (mg)	Mean (SE)	2457 (99)	n/a	2277 (42)	n/a
	% >AI (SE)	24 (5.1)	n/a	28 (2.6)	n/a
Vitamin D (µg)	Mean (SE)	5.0 (0.5)	15.1 (1.4)	4.0 (0.1)	13.2 (1.3)
	% <EAR (SE)	96† (1.8)	38 (5.5)	>97	73 (1.4)
Vitamin E (mg)	Mean (SE)	9.0 (0.6)	n/a	8.6 (0.2)	n/a
	% <EAR (SE)	82 (4.7)	n/a	85 (2.1)	n/a
Magnesium (mg)	Mean (SE)	291 (11)	308 (14)	270 (4)	284 (5)
	% <EAR (SE)	47 (5.5)	51 (5.2)	49 (2.2)	46 (2.1)
Vitamin C (mg)	Mean (SE)	93.6 (5.5)	158.1 (14.5)	72.5 (2.5)	122.3 (6.9)
	% <EAR (SE)	34 (3.9)	19 (3.9)	46 (2.5)	37 (1.9)
Vitamin A (ug RAE)	Mean (SE)	685 (53)	n/a	559 (15)	n/a
	% <EAR (SE)	32 (6.9)	n/a	46 (2.3)	n/a
Calcium (mg)	Mean (SE)	1018 (60)	1205 (75)	869 (11)	948 (13)
	% <EAR (SE)	25 (6.5)	17 (4.9)	44 (1.8)	38 (1.8)
Zinc (mg)	Mean (SE)	10.7 (0.6)	20.9 (1.7)	9.6 (0.1)	12.0 (0.3)
	% <EAR (SE)	21 (5.5)	17 (4.4)	14 (1.9)	12 (2.1)
Thiamin (mg)	Mean (SE)	1.56 (0.09)	2.57 (0.15)	1.41 (0.02)	3.01 (0.23)
	% <EAR (SE)	11† (4.3)	11† (3.9)	8 (1.6)	7 (1.3)
Copper (mg)	Mean (SE)	1.2 (0.05)	1.7 (0.12)	1.1 (0.02)	1.3 (0.03)
	% <EAR (SE)	9† (2.8)	11† (3.2)	11 (1.1)	10 (1.0)
Riboflavin (mg)	Mean (SE)	1.96 (0.10)	3.10 (0.20)	1.85 (0.03)	3.13 (0.15)

Part D. Chapter 2: Food, Beverage, and Nutrient Consumption During Pregnancy

	% <EAR (SE)	6† (1.9)	6† (2.4)	3 (0.7)	<3
Vitamin B12 (µg)	Mean (SE)	4.57 (0.33)	25.92† (15.36)	4.15 (0.09)	55.57 (13.93)
	% <EAR (SE)	6† (2.5)	<3	7 (1.5)	5 (1.1)
Potentially underconsumed and overconsumed:					
Iron (mg)	Mean (SE)	14.5 (0.9)	30.7 (2.4)	12.4 (0.2)	16.2 (0.5)
	% <EAR (SE) ³	n/a	n/a	n/a	n/a
	% >UL (SE)	<3	14† (3.5)	<3	<3
Folate (µg DFE)	Mean (SE)	527 (38)	1373 (97)	466 (8)	640 (15)
	% <EAR (SE)	31 (7.4)	22 (5.1)	18 (1.9)	14 (1.6)
Folic acid (µg)	Mean (SE)	193 (16)	691 (53)	158 (4)	261 (8)
	% >UL (SE)	<3	27 (5.4)	<3	<3
Potentially overconsumed:					
Sodium (mg)	Mean (SE)	3305 (134)	n/a	3191 (41)	n/a
	% >AI (SE)	>97	n/a	>97	n/a
	% >CDRR (SE)	88† (3.7)	n/a	85 (1.8)	n/a

AI=Adequate Intake; CDRR=Chronic Disease Risk Reduction; EAR=Estimated Average Requirement; UL=Tolerable Upper Intake Level

Underconsumed = A nutrient that is underconsumed by 5 percent or more of the population or specific groups relative to the EAR, AI, or other quantitative authoritative recommendations from the diet alone. Overconsumed = A nutrient that is consumed in potential excess of the UL, CDRR, or other quantitative authoritative recommendations by 5 percent or more of the population or in specific groups from the diet alone. For more information see: Table D 1.1 Framework to Begin the Process of Identifying Nutrients and Other Food Components as Underconsumed, Overconsumed, or of Potential Public Health Concern

¹Adapted from What We Eat in America, NHANES 2013-2016 Usual Nutrient Intake from Food and Beverages, and Total Usual Nutrient Intake from Food, Beverages, and Dietary Supplements, by Pregnancy and Lactation Status for Females 20 to 44 years of age^{293,294}

²Includes all women who are not pregnant and are not lactating.

³More than 35% of pregnant women had usual nutrient intake below the EAR for iron using data from WWEIA, NHANES 2001-2014¹³

†Estimate may be less reliable due to small sample size and/or large relative standard error

The evidence reviewed relating to healthy dietary patterns before and/or during pregnancy suggests a modest reduction in the risk of GDM, hypertensive disorders, excessive GWG, and preterm birth. There was remarkable consistency in the food components contained within these dietary patterns. These protective dietary patterns are generally higher in vegetables, fruits, whole grains, nuts, legumes and seeds, and seafood, and lower in red and processed meats. Thus, adherence to this dietary pattern has the potential to ameliorate the risk of the predominant complications of pregnancy, which result in adverse maternal and infant outcomes. Additionally, the food components of these beneficial dietary patterns are the same as the dietary components associated with overall chronic disease risk reduction (see **Part D. Chapter 1** and **Part D. Chapter 8: Dietary Patterns**), suggesting that consistent advice on components of a healthy diet can be communicated to women of reproductive age prior to and during pregnancy. Although the foods that are characteristic of healthy dietary patterns before and during pregnancy are similar, evidence to suggest how often during the day women should consume foods and beverages to achieve optimal GWG was lacking. More information is needed to develop guidance in this area, especially in light of previous *Dietary Guidelines for Americans* recommendations regarding achieving healthy weight before pregnancy and achieving GWG within the 2009 IOM recommendations.²⁶

Food Pattern Modeling exercises showed that each of the three Food Patterns styles (**Healthy U.S.**, **Healthy Vegetarian**, and **Healthy Mediterranean**) described in **Chapter 14: USDA Food Patterns for Individuals Ages 2 Years and Older** is expected to meet nutrient needs for women who are pregnant with the possible exception of iron, choline and vitamins D and E. Thus, these patterns will provide many of the nutrients that are commonly underconsumed by women who are pregnant. Therefore, the Committee recommends that women who are pregnant choose foods consistent with these dietary patterns. In addition, they should specifically incorporate foods that are rich in iron, folate, choline and vitamins D and E, such as red meat, seafood, eggs, green leafy vegetables, fortified grains and fortified milk, nuts, seed and vegetable oils (see **Part D. Chapter 1**).

This Committee's findings on folic acid supplements are consistent with those of previous Committees, namely that folic acid supplementation is associated with better maternal folate status during pregnancy and reduced risk of congenital anomalies in the child. The current review also suggests that folic acid supplementation may reduce the risk of hypertensive disorders among women at high-risk or with a previous history of these disorders. Given that preeclampsia is among the leading causes of maternal mortality, and both pre-eclampsia and congenital anomalies are linked to increased risk for preterm birth and infant mortality, folic acid

status during pregnancy has important public health ramifications. Supplementation with 400 µg/day of synthetic folic acid plus dietary intake of an additional 200 µg/day was recommended by previous Committees. The U.S. Preventive Services Task Force²⁹⁵ recommends that all women of reproductive age take a daily supplement containing 400 to 800 µg of folic acid, which is consistent with recommendations by the CDC and the IOM.^{86,296} However, as noted in **Part D. Chapter 1**, with the use of supplements, some women who are lactating are exceeding recommendations for folic acid intake. Given that this high intake has not been directly linked with clinical outcomes, it is not designated of public health concern, but warrants monitoring.

This Committee concurs with these recommendations and supports folic acid supplementation as the standard of care before and during pregnancy. The use of 5-MTHF (methylfolate) may be beneficial for some women who have the methylenetetrahydrofolate reductase polymorphism. However, not enough studies were available for review to make a recommendation specific to that supplemental form of the vitamin.^{297,298} Dietary intakes of folate are generally low and folate status may be compromised in some groups of women (see **Part D. Chapter 1**), so continued attention to intake is warranted. The Committee encourages all women of reproductive age to include foods high in folate, including those fortified with folic acid, as part of a healthy dietary pattern. These foods may include fortified whole grains, dark green and leafy vegetables, and legumes. However, in those women who are consuming substantial folic acid from fortified foods along with a supplement, the intake of folic acid may reach or exceed the Tolerable Upper Intake Level, as documented in **Part D. Chapter 1**.

The 2010 Dietary Guidelines Advisory Committee concluded that moderate evidence indicated that intake of omega-3 fatty acids, in particular DHA, from *at least* 8 ounces of seafood per week for women who are pregnant or breastfeeding is associated with improved infant health outcomes, such as visual and cognitive development. The 2020 Committee found limited evidence suggesting that omega-3 fatty acid supplementation during pregnancy may result in favorable cognitive development in children, and that seafood intake during pregnancy may be associated favorably with measures of cognitive development and language and communication development in young children. In addition, the systematic reviews on dietary patterns suggest that seafood intake as part of a healthy dietary pattern, particularly intake of fish high in omega-3 fatty acids, before pregnancy may be related to reduced risk of GDM and hypertensive disorders, and consumption during pregnancy may be related to reduced risk of hypertensive disorders and preterm birth and better cognitive development in children. Seafood intake is low among women who are pregnant (**Part D. Chapter 1**) and should be encouraged in accordance with recommendations by the *2015-2020 Dietary Guidelines for Americans*,²⁹² Food and Drug

Administration, and the Environmental Protection Agency,²⁹⁹ which are that women who are pregnant should consume at least 8 and up to 12 ounces of a variety of seafood per week, from choices that are lower in methylmercury and higher in omega-3 fatty acids. Additionally, women who are pregnant should limit intake of seafood choices that may be high in environmental contaminants.²⁸⁴ Supplementation with omega-3 fatty acids during pregnancy may be beneficial to cognitive development in children. However, the evidence reviewed was heterogeneous and was not clear on the specific amounts of various omega-3 fatty acids that may be responsible for the benefits. Thus, the Committee was unable to make a specific recommendation about routine supplementation with omega-3 fatty acids during pregnancy.

A lack of evidence prevented the Committee from examining relationships between beverage consumption during pregnancy and infant birth weight. National guidance on recommended beverage intakes during pregnancy are currently lacking. This is especially needed with regard to SSB, which have been linked to poor diet quality and higher energy intake during pregnancy.³⁰⁰ The American College of Obstetricians and Gynecologists (ACOG)³⁰¹ Committee on Obstetric Practice has stated that moderate caffeine intake (defined as up to 200 mg/day) appears to be safe during pregnancy. However, ACOG has no recommendations regarding SSB. Previous Dietary Guidelines Advisory Committees have examined caffeine intake specifically and recommended that women who are pregnant and consume caffeinated beverages do so in moderation and consult with their obstetric providers.

Systematic reviews performed by this Committee suggest that consumption of common allergenic foods (e.g., egg, cow milk) during pregnancy is not associated with an increased risk of food allergies, asthma, and related atopic disease outcomes in the child, nor is the restriction of these foods associated with a decreased risk of these conditions. These findings are similar to those of the AAP Committee on Nutrition and Section on Allergy and Immunology,²⁸¹ which published a clinical report that does not recommend maternal restriction as an atopy prevention strategy. Given current AAP recommendations and the systematic review results described in this chapter, the Committee does not support restriction of potential allergens in maternal diets before or during pregnancy, unless the woman is allergic to the foods. Rather, the findings of the Committee support the need for women to consume an overall healthy dietary pattern that includes these foods, as they are important sources of potential shortfall nutrients for women who are pregnant and lactating, such as protein, calcium, iron, vitamin D, magnesium, and choline.

Questions related to dietary supplements and/or fortified food sources of vitamins B₁₂ and D, iron, and iodine remain unstudied by this Committee. Three of these nutrients (vitamin D, iron

and iodine) are considered nutrients of public health concern (see **Part D. Chapter 1**), with iron and iodine of particular concern during pregnancy due to the potential neurocognitive deficits in children that are associated with low intake and/or inadequate nutrient status.^{9,69,70,73} Vitamin D deficiency has been associated with increased risk for GDM, preeclampsia,^{64,302,303} SGA, and preterm birth, while vitamin D supplementation is associated with lower risk of preeclampsia. Vitamin B₁₂ is a nutrient of potential concern among females of reproductive age because as many as 10 percent of adolescent girls and young women have inadequate intakes (see **Part D. Chapter 1**). Iodine and vitamin D are nutrients that have few dietary sources in the absence of fortification, so consumption of fortified foods and supplements may be the primary way to achieve adequate intakes of these nutrients. Although iron is present in a wide variety of foods, the increased need during pregnancy is difficult to achieve through dietary intake alone. Thus, the IOM and the CDC recommend iron supplementation during pregnancy.^{86,304} However, the U.S. Preventive Services Task Force and the ACOG recommended that only women who have iron deficiency should take iron supplements.^{305,306} Given the importance of these nutrients to achieve optimal pregnancy outcomes, and the fact that they are all nutrients of concern among females of reproductive age, additional attention should be given to these nutrients during development of dietary guidelines by future Dietary Guidelines Advisory Committees.

Strategies for Women of Reproductive Age

A variety of strategies may help women of reproductive age and women who are pregnant achieve food and nutrient intakes that promote optimal pregnancy outcomes. These strategies include:

1. Encourage women to achieve a healthy weight before pregnancy, and to strive for GWG within the 2009 IOM recommendations. Previous Committees have made this recommendation, and this Committee concurs. The increased energy needs during pregnancy can best be met through the consumption of a varied, nutrient-dense diet.
2. Encourage women before and during pregnancy to choose dietary patterns that are higher in vegetables, fruits, whole grains, nuts, legumes, seafood, and vegetable oils, and lower in added sugars, refined grains, and red and processed meats. These dietary patterns protect against poor maternal-fetal outcomes in pregnancy and are consistent with general healthy dietary advice that is given on a population-level to achieve healthy weight and prevent chronic disease risk.

3. Encourage women to consume foods and beverages that are good sources of iron, folate, calcium, choline, magnesium, protein, fiber, and other potential shortfall nutrients identified in **Part D. Chapter 1**.
4. Encourage women to not avoid potential allergenic foods during pregnancy unless it is medically warranted.
5. Encourage women to consume seafood in accordance with recommendations by the *2015-2020 Dietary Guidelines for Americans*,²⁹² the Food and Drug Administration, and the Environmental Protection Agency: at least 8 and up to 12 ounces of a variety of seafood per week, from choices that are lower in methylmercury and higher in omega-3 fatty acids.²⁹⁹
6. Encourage women who are or may be pregnant to follow guidance from the 2015 Committee²⁵⁰ that “Women who are or who may be pregnant should not drink. Drinking during pregnancy, especially in the first few months of pregnancy, may result in negative behavioral or neurological consequences in the children. No safe level of alcohol consumption during pregnancy has been established.”³⁰⁷ The Committee was not asked to review evidence regarding alcoholic beverage consumption in pregnancy because the Departments noted that they would continue the use of existing guidance specifying specifies that women who are pregnant or might be pregnant should not drink alcohol. The Committee supports the continued use of this existing guidance.
7. Encourage women who are pregnant to select foods in accordance with food safety recommendations outlined in previous scientific reports of the Dietary Guidelines Advisory Committee and editions of the *Dietary Guidelines for Americans*, including avoiding unpasteurized milk and soft cheeses, undercooked meats, and limiting processed meats. The Committee did not review evidence regarding food safety during pregnancy because the Departments noted that they would continue the use of existing guidance developed for pregnant women. The Committee supports the continued use of this existing guidance. These recommendations can be provided through one-on-one education and through social marketing campaigns and other population-level communication strategies.

Support for Federal Agencies

1. The Committee supports Federal programs, such as the Special Supplemental Nutrition Program for Women, Infants, and Children (WIC), that serve women who are pregnant should encourage participants to take advantage of available nutrition counseling services. In addition, policy, systems, and environmental change strategies and competitive pricing of healthy food and beverage choices can help ensure that women of all economic strata can benefit. Similar healthy foods and beverages should be routinely stocked and distributed by food pantries and other food assistance venues and recommended by food assistance programs.
2. The Committee supports further development of surveillance systems and databases to report dietary and beverage intakes of diverse subgroups of women who are pregnant. This should include dietary systems that can show how fortified foods and supplemental sources of nutrients contribute to overall nutrient intake and dietary quality during pregnancy. In addition, the ability to link maternal dietary intake data to that of their children would strengthen the ability to determine how maternal dietary practices influence child health and development. The Committee encourages implementation of surveillance systems to gather more information about the contextual aspects of food and beverage intake, such as the frequency and/or timing of consumption, food security, economic status, and culture. This information is important to fully understand how and why women consume specific foods and beverages before and during pregnancy.

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PART D. CHAPTER 3: FOOD, BEVERAGE, AND NUTRIENT CONSUMPTION DURING LACTATION

INTRODUCTION

Maternal nutrition is a key factor influencing the health of both the lactating woman and her child. For many nutrients, the requirements during lactation differ from those during pregnancy, so women who are lactating should adapt their dietary choices and supplement use to meet those needs. For example, requirements for energy, as well as for protein and several minerals and vitamins, increase substantially during the period of lactation, whereas the requirement for iron during lactation is one-third that of pregnancy.^{1,2} In well-nourished women, the energy requirements for lactation take into account energy released endogenously from mobilization of maternal fat stores,³ which may assist women in postpartum weight loss (PPWL).⁴

Lactation confers other short- and long-term health benefits to women's health as well. In the short-term, physiologic processes that accompany lactation during the early postpartum period facilitate uterine involution and enhance glucose tolerance and insulin sensitivity.⁵ Long-term benefits of lactation for women's health include reduction in risk of breast,⁶ ovarian, and endometrial cancers⁷; hypertension and cardiovascular disease⁸; non-alcoholic fatty liver disease⁹; and type 2 diabetes mellitus⁵ later in life. For some of these outcomes, the benefits are greater with longer durations of lactation.^{5,10} Surveillance data from the 2017-2018 National Immunization Survey¹¹ show that overall breastfeeding rates in the United States are meeting the Healthy People 2020 goals.¹² The percentage of infants who are "ever breastfed" (83.8 percent) now exceeds the Healthy People 2020 goal of 81.9 percent, and the objective for exclusive breastfeeding to 6 months (25.5 percent) has nearly been met (25.4 percent). In this survey, exclusive breastfeeding is defined as the infant being fed only human milk and no solids, water, or other fluids. Although these statistics are promising, they indicate that 75 percent of U.S. infants are not exclusively breastfed for 6 months, as recommended by the American Academy of Pediatrics (AAP)¹³ and the World Health Organization (WHO).¹⁴ Moreover, only 36 percent of infants in the United States are breastfed for at least 12 months,¹¹ as recommended by the AAP and WHO.

This chapter in the 2020 Dietary Guidelines Advisory Committee's report presents the evidence from a series of systematic reviews on associations of maternal diet, dietary patterns, and supplements consumed during lactation with maternal PPWL, micronutrient status, human milk composition and quantity, and selected health outcomes in the infant and child.

Subsequent chapters discuss the associations of consumption of human milk and/or infant formula and complementary foods with infant health outcomes, as well as an assessment of the ability of the USDA Food Patterns to meet nutrient needs during lactation (see ***Part D. Chapter 4: Duration, Frequency, and Volume of Exclusive Human Milk and/or Infant Formula Feeding*** and ***Part D. Chapter 5: Food, Beverage, and Nutrient Consumption During Infancy and Childhood*** and ***Part D. Chapter 14: USDA Food Patterns for Individuals Ages 2 Years and Older***).

Background

Lactation can be viewed along the continuum of the reproductive cycle from prepregnancy, through pregnancy and, finally, lactation. Just as pregnancy outcomes are influenced by maternal prepregnant body mass index (BMI) and metabolic status, lactation outcomes are affected by prepregnancy health status, gestational weight gain (GWG), and metabolic health during pregnancy. During pregnancy, physiological and metabolic changes occur in preparation for lactation, including growth and maturation of mammary tissue and deposition of adipose tissue. A number of these changes are influenced by the woman's dietary patterns and nutrient intake and were therefore included in the Committee's review.

Data from the WHO Collaborative Study showed that 3.7 kilograms (kg) of adipose tissue (range 3.1 to 4.4 kg or 6.8 to 9.7 pounds) was deposited in women with an average 12 kg GWG (approximately 26 pounds).¹⁵ During lactation, maternal energy requirements increase to support maternal metabolism, milk production, and tissue-specific growth. Lactation is energetically demanding; the energy in the milk secreted in the first 4 months of lactation is roughly equivalent to the total energy cost of pregnancy.^{1,16} However, energy from adipose tissue stores and many of the nutrients stored during pregnancy are available to support milk production. During the first 6 months of lactation, the Recommended Dietary Allowance (RDA) for women who are lactating is an additional 500 kcal per day from dietary intake, which assumes that an additional 170 kcal per day is mobilized from maternal adipose tissue.¹⁷ During the second 6 months of lactation, an additional 400 kcal per day from dietary intake is recommended, based on reduction in milk production from an average of 780 mL per day over the first 6 months of lactation to an estimated 600 mL per day thereafter.² Recommended intakes for several but not all vitamins and minerals also are higher during lactation than in pregnancy, with the notable exceptions of folate and iron. Because micronutrients are not evenly distributed among foods, women who are lactating should consume a varied, nutrient-

dense diet. Therefore, the Committee investigated how dietary patterns consumed by women who are lactating are related to maternal outcomes and human milk composition and quantity, as well as child neurocognitive development.

A review of NHANES 1999 to 2014 data showed that most (70 percent) women who are lactating use dietary supplements, compared to 45 percent of women who are not pregnant or lactating.¹⁸ More than half of the women surveyed continued to use prenatal supplements during lactation, often based on the recommendation of a health care provider.¹⁸ However, prenatal supplements are not designed to meet the needs of lactating women, and the folate and iron intakes from supplements alone exceed the RDA for these micronutrients by 2.4-fold and 3.7-fold, respectively.¹⁸ The Committee investigated how folate and omega-3 fatty acids from dietary supplements consumed by women who are lactating are related to various maternal and child outcomes and human milk composition.

Postpartum weight retention is common in women, particularly among women with high prepregnancy BMI or excessive GWG. The increased energy demands required to support lactation have the potential to contribute to PPWL and reduce the long-term risk of overweight or obesity.⁴ On average, women lose 0.6 to 0.8 kg (1.3 to 1.8 pounds) per month in the first 4 to 6 months of lactation. Women vary widely in the amount of weight they lose during lactation, and those who continue beyond 4 to 6 months postpartum ordinarily continue to lose weight.² Baker et al. (2008) showed that women from the Danish National Birth Cohort with a recommended GWG of approximately 12 kg (approximately 27 pounds) and who exclusively breastfed for 6 months, had no postpartum weight retention at 6 months.¹⁹ Because of the implications of PPWL for maternal health, the Committee investigated the association between dietary patterns consumed by women who are lactating and PPWL.

Human milk provides the biologic foundation for infant nutrient needs. Human milk has a unique array of nutrients and bioactive substances that support optimal infant growth and development.^{20,21} The amount of human milk produced varies in response to several factors, including demand by the infant, which may be related to the frequency of human milk removal from the breast, either by suckling or use of a breast pump, as well as other biological variables.²² The first milk produced following birth, colostrum, is a concentrated fluid, especially rich in nutrients and protective factors. By about 2 weeks postpartum, mature milk has been established.^{21,22} Specific nutrients and bioactive components in human milk vary throughout a single feeding, time of day of the feeding, and across time after delivery.^{21,22} The degree to which maternal nutrition influences human milk composition varies by the nutrient. The

components of human milk that are produced by the mammary gland are more likely influenced by maternal genetics than by dietary intake.²² Macronutrients produced by the mammary gland include casein and whey, the predominant proteins in human milk, and carbohydrates, including lactose and human milk oligosaccharides. Milk fat is comprised of fatty acids that are either synthesized *de novo* in the mammary gland or extracted from the maternal circulation. Thus, maternal diet affects the fat composition of human milk.²³ Accordingly, questions about how milk fatty acid composition varies with maternal diet have particular importance and were investigated by the Committee.

Concentrations of some micronutrients in human milk, but not all, are correlated with maternal nutrient status. These include vitamins A, D, E, K, B₁, B₂, B₆, B₁₂, choline, and the minerals iodine and selenium. Thus, the concentrations of these nutrients in human milk can be increased by maternal supplementation.²⁴ In contrast, concentrations of folate, calcium, copper, iron, and zinc are generally independent of maternal status, and maternal supplementation does not increase milk concentrations.²¹

Although at this time, no Acceptable Macronutrient Distribution Ranges (AMDR) have been established for infants,²⁵ the accretion of long-chain polyunsaturated fatty acids (LC-PUFA), such as docosahexaenoic acid (DHA), is critically important for the growth and development of the central and peripheral nervous systems and retina during infancy and childhood.^{26,27} Thus, an important question is whether maternal seafood consumption or dietary supplementation with DHA or other LC-PUFA during lactation further supports these developmental processes.

The Committee used systematic reviews to examine questions about the relationship between maternal dietary patterns during lactation (including seafood consumption and frequency of eating) and maternal PPWL, human milk composition and quantity, and child developmental milestones, including neurocognitive development. This chapter also examines the evidence for a relationship between the maternal diet consumed during lactation and the risk of food allergy and atopic diseases in the child. Atopic diseases cause significant morbidity and can be challenging to control. Therefore, there has been an emphasis on developing preventive strategies, which are particularly important for children at high risk of developing allergy due to family history.²⁸ Infancy offers a unique “window of opportunity” for allergy prevention.²⁹ Human milk contains nutrients and other bioactive components that could influence infant immune development and potentially atopic sensitization.³⁰ Some existing evidence suggests that modifying human milk composition via the maternal diet may prevent allergic diseases;

however, data are conflicting.³⁰ The Committee evaluated the association between maternal dietary intake during lactation and atopic diseases in the child.

Although the *Dietary Guidelines for Americans* focuses on food sources of nutrients, the Committee also examined the effect of some dietary supplements on maternal and child outcomes. Initially, six nutrients (folic acid, omega-3 fatty acids, iron, iodine, vitamin D, and vitamin B₁₂) from supplements and fortified foods were to be included in the review. Due to time constraints and, in some cases, existing systematic reviews or guidance that addressed some of the outcomes of interest, the scope of the Committee's reviews was prioritized to focus on 2 of these nutrients, folic acid and omega-3 fatty acids. For folic acid, the Committee investigated 3 outcomes (maternal micronutrient status, human milk composition, and neurocognitive development of the child), whereas for omega-3 fatty acids, the Committee reviewed only the evidence for neurocognitive development of the child.

LIST OF QUESTIONS

1. What is the relationship between dietary patterns consumed during lactation and postpartum weight loss?
2. What is the relationship between frequency of eating during lactation and postpartum weight loss?
3. What is the relationship between dietary patterns consumed during lactation and human milk composition and quantity?
4. What is the relationship between maternal diet during lactation and risk of child food allergies and atopic allergic diseases, including atopic dermatitis, allergic rhinitis, and asthma?
5. What is the relationship between dietary patterns consumed during lactation and developmental milestones, including neurocognitive development, in the child?
6. What is the relationship between seafood consumption during lactation and neurocognitive development in the child?
7. What is the relationship between omega-3 fatty acids from supplements consumed during lactation and developmental milestones, including neurocognitive development, in the child?
8. What is the relationship between folic acid from supplements and/or fortified foods consumed during lactation and 1) maternal micronutrient status, 2) human milk composition, and 3) developmental milestones, including neurocognitive development, in the child?

METHODOLOGY

All questions discussed in this chapter were answered using systematic reviews conducted with support from USDA's Nutrition Evidence Systematic Review (NESR) team. NESR's systematic review methodology provided a rigorous, consistent, and transparent process for the Committee to search for, evaluate, analyze, and synthesize evidence.

Questions 1 through 8 in this chapter were answered using new NESR systematic reviews. The Committee developed a systematic review protocol for each question, which described how the Committee would apply NESR's methodology to answer the question. The protocol included an analytic framework and inclusion and exclusion criteria to guide identification of the most relevant and appropriate bodies of evidence to use in answering each systematic review question. Each analytic framework outlined core elements of the systematic review question (i.e., population, intervention and/or exposure and comparator [i.e., the alternative being compared to the intervention or exposure], and outcomes), and included definitions for key terms, key confounders, and other factors to be considered when reviewing the evidence. The inclusion and exclusion criteria were selected a priori to operationalize the elements of the analytic framework and specify what made a study relevant for each systematic review question.

Next, NESR conducted a literature search to identify all potentially relevant articles, and those articles were screened by two NESR analysts independently based on the criteria selected by the Committee. For each included article, data were extracted, and risk of bias assessed. The Committee qualitatively synthesized the body of evidence to inform development of a conclusion statement(s) and graded the strength of evidence using pre-established criteria for risk of bias, consistency, directness, precision, and generalizability. Finally, recommendations for future research were identified. A detailed description of NESR's systematic review methodology is provided in **Part C. Methodology**, including standard inclusion and exclusion criteria applied in many of the Committee's systematic reviews. Complete documentation of each systematic review is available on the following website: nesr.usda.gov/2020-dietary-guidelines-advisory-committee-systematic-reviews. Below is a summary of the unique elements of the protocols developed to answer the questions addressed in this chapter.

For all questions discussed in this chapter, the population of interest for the intervention or exposure was women who are lactating. For Question 4 and the part of Question 3 that examined human milk quantity as the outcome, the Committee included only studies that

enrolled women who were exclusively or predominantly feeding human milk. The population of interest for outcomes varied depending on the outcome examined, as described below.

For Questions 1, 3, and 5, consumption of and/or adherence to a dietary pattern during lactation was the primary intervention or exposure of interest. The comparators of interest were consumption of and/or adherence to a different dietary pattern or different levels of consumption of and/or adherence to a dietary pattern. Dietary patterns were defined as “the quantities, proportions, variety, or combination of different foods, drinks, and nutrients in diets, and the frequency with which they are habitually consumed.” To be included in the review on dietary patterns, studies needed to provide a description of the foods and beverages in the pattern. Dietary patterns considered in the review were measured or derived using a variety of approaches, such as adherence to a priori patterns (indices/scores), data-driven patterns (factor or cluster analysis), reduced rank regression, or other methods, including clinical trials.

Questions 1, 3, and 5 also examined diets based on a macronutrient distribution outside of the AMDR, at any level above or below, as an intervention or exposure of interest. The comparator of interest was consumption of and/or adherence to a macronutrient distribution of carbohydrate, fat, and protein within the AMDR. To be included in the review, articles needed to describe the entire macronutrient distribution of the diet by reporting the proportion of energy from carbohydrate, fat, and protein, and have at least one macronutrient proportion outside of the AMDR.

The Committee established these criteria to take a holistic approach to answer the scientific questions, and thus needed to examine the entire distribution of macronutrients in the diet, and not one macronutrient in isolation. These criteria allowed the Committee to consider both the relationships with health outcomes of consuming a diet with one macronutrient outside of the AMDR, and also how consumption of that macronutrient displaces or replaces intake of other macronutrients within the distribution. A study did not need to report the foods/food groups consumed to be included. The criteria were designed to cast a wide, comprehensive net to capture any study that examined carbohydrate levels less than 45 percent or greater than 65 percent of energy, fat levels less than 20 percent or greater than 35 percent of energy, and/or protein levels less than 10 percent or greater than 35 percent of energy. Furthermore, when describing and categorizing studies included in these reviews, the Committee did not label the diets examined as “low” or “high,” because no universally accepted, standard definition is currently available, for example, for “low-carbohydrate” or “high-fat” diets. Instead, the

Committee focused on whether, and the extent to which, the proportions of the macronutrients were below or above the AMDR.

The outcome examined in Question 1 was PPWL, which was defined as the change in weight from baseline (postpartum) to a later time point during the postpartum period, or as postpartum weight retention, if GWG was controlled for. Two literature searches were conducted to identify all potentially relevant articles for this question. The first search was designed to capture all potentially relevant articles on dietary patterns published from January 2000 to June 2019. The second search was designed to identify all potentially relevant articles on diets based on macronutrient distribution published from January 2000 to November 2019, and to capture any additional articles on dietary patterns published between June and November 2019. Articles for this question were searched for and screened together with Question 3 in **Part D. Chapter 2: Food, Beverage, and Nutrient Consumption During Pregnancy** (dietary patterns and GWG). This was done to leverage the overlap in topical areas and to improve efficiency. For Questions 1, 3 and 5, the Committee searched for and included studies that were published starting in 2000 because the field of dietary patterns research is relatively new, particularly for the populations and outcomes of interest in the questions being addressed in this chapter. Previous systematic reviews on dietary patterns searched for literature starting in 1980, but relevant studies published before the year 2000 were uncommon. Therefore, the Committee determined that the preponderance of evidence for these new reviews would be captured by searching literature starting in the year 2000.

For Question 2, frequency of eating during lactation was the intervention or exposure and PPWL was the outcome (see **Part D. Chapter 13: Frequency of Eating** for details about the methodology used to answer this question).

For Question 3, dietary patterns during lactation, including diets based on macronutrient distribution (as defined above), was the intervention or exposure and human milk quantity and composition was the outcome. Human milk composition included macronutrients (fatty acids, total protein), water-soluble vitamins (vitamins B, C, and choline), fat-soluble vitamins (A, D, E, K), minerals (iodine and selenium), human milk oligosaccharides, and bioactive components. Due to the changes in human milk during the first weeks after delivery, the Committee required that only studies assessing milk composition and quantity in mature milk (defined as milk produced ≥ 14 days postpartum) be included. In addition, the Committee included cross-sectional studies for these outcomes because of the dearth of longitudinal studies that address

human milk composition and quantity. A literature search was conducted to identify all potentially relevant articles published from January 2000 to July 2019.

For Question 4, maternal diet during lactation was the intervention or exposure, including foods that may be considered allergens (e.g., cow milk products, eggs, peanuts, tree nuts, and soybean) and foods that are not considered allergens (including but not limited to meat, vegetables, and fruits). The outcomes for this question were food allergies and atopic allergic diseases, including atopic dermatitis/eczema, allergic rhinitis, and asthma, in infants and toddlers (birth to age 24 months) and children and adolescents (ages 2 to 18 years). Maternal diet during pregnancy and food allergies and atopic allergic diseases is discussed in **Part D. Chapter 2**, Question 8. Food allergy was defined as a diagnosis based on either the gold standard of a double-blind, placebo-controlled oral food challenge, or as parental report of clinical history together with blood immunoglobulin E (IgE) levels 0.35 kilo unit per liter (kU/L) or greater and/or skin prick test wheal 3 or greater millimeters (mm). Because of difficulty diagnosing asthma during infancy and toddlerhood, only those studies that assessed asthma in children who were age 2 years or older were included. A literature search was conducted to identify all potentially relevant articles published from January 1980 to January 2020.

For Question 5, dietary patterns during lactation (including diets based on macronutrient distribution, as defined above) was the intervention or exposure and the outcome was developmental milestones, including neurocognitive development in infants and toddlers (birth to age 24 months) and children and adolescents (ages 2 to 18 years). This included developmental domains (i.e., cognitive, language and communication, movement and physical and social-emotional development), academic performance, attention deficit disorder (ADD) or attention deficit/hyperactivity disorder (ADHD), anxiety, depression, and autism spectrum disorder (ASD). A literature search was conducted to identify all potentially relevant articles published from January 2000 to January 2020.

For Question 6, seafood consumption during lactation was the intervention or exposure and neurocognitive development was the outcome (see **Part D. Chapter 9: Dietary Fats and Seafood** for details about the methodology used to answer this question).

For Question 7, omega-3 fatty acids from supplements was the intervention or exposure. Fortified foods were not considered for this question because supplements are generally the major source of omega-3 fatty acids. The outcome for this question was developmental milestones (as described above for Question 5). Omega-3 fatty acids from supplements during pregnancy and child developmental milestones is discussed in **Part D. Chapter 2**, Question 10.

A literature search was conducted to identify all potentially relevant articles published from January 1980 to February 2020.

For Question 8, folic acid from supplements and/or fortified foods was the intervention or exposure. The outcomes considered were as follows:

- **Maternal micronutrient status:** Assessment of folate (including but not limited to serum folate, red blood cell [RBC] folate), vitamin B₁₂, hemoglobin, mean corpuscular volume (MCV), and RBC distribution width.
- **Human milk composition:** Folate in human milk, including but not limited to total folate, reduced folates, and unmetabolized folic acid. Human milk quantity was not considered as an outcome for this question.
- **Developmental milestones**, as described above for Question 5.

In order to capture fortification studies, this question also included uncontrolled before-and after studies. In addition, cross-sectional studies were included for the human milk composition outcome alone, because of the dearth of longitudinal studies that address this outcome. Folic acid from supplements and/or fortified foods before and during pregnancy and gestational diabetes mellitus (GDM), hypertensive disorders during pregnancy, micronutrient status in pregnant women, human milk composition and developmental milestones is discussed in **Part D. Chapter 2**, Question 11. Two separate literature searches were conducted to identify all potentially relevant articles for Question 8. The first search was designed to identify articles on folic acid and micronutrient status or human milk composition, published from January 1980 to June 2019. The second search was designed to identify articles on folic acid and developmental milestones, published from January 1980 to July 2019.

REVIEW OF THE SCIENCE

Question 1. What is the relationship between dietary patterns consumed during lactation and postpartum weight loss?

Approach to Answering Question: NESR systematic review

Conclusion Statement and Grade

Insufficient evidence is available to determine the relationship between dietary patterns during lactation and postpartum weight loss. Grade: Grade Not Assignable

Summary of the Evidence

- This systematic review includes 1 randomized controlled trial (RCT) conducted in the United States,³¹ which compared PPWL in women who were lactating between those who were randomized to a Mediterranean-style diet vs the USDA MyPyramid diet.
- The two groups showed no significant differences in PPWL.
- This study had notable limitations, including high attrition (approximately 21 percent), issues with implementation of the intervention, and lack of blinding of participants and investigators.

For additional details on this body of evidence, visit: nesr.usda.gov/2020-dietary-guidelines-advisory-committee-systematic-reviews/pregnancy-and-lactation-subcommittee/dietary-patterns-lactation-postpartum-weight-loss

Question 2. What is the relationship between frequency of eating during lactation and postpartum weight loss?

Approach to Answering Question: NESR systematic review

Conclusion Statement and Grade

Insufficient evidence is available to determine the relationship between the frequency of eating during lactation and postpartum weight loss. Grade: Grade Not Assignable

Summary of the Evidence

- Frequency of eating was defined as the number of daily eating occasions. An eating occasion was defined as an ingestive event (solid food or beverage, including water) that is either energy yielding or non-energy yielding.
- PPWL was defined as a change in weight from baseline (postpartum) to a later time point during the postpartum period. Additionally, it could be postpartum weight retention, if GWG was controlled for in the analysis.
- This review included 1 prospective cohort study (PCS) (using data from a multicomponent RCT) that met the inclusion criteria for this systematic review and was published within the date range of January 2000 and September 2019.³²
- The 1 included study did not report a significant association between a change in eating frequency and a change in weight from baseline over a 12-week follow-up.
- The study had several limitations, including:
 - Key confounders were not accounted for.
 - Data were from a multi-component RCT that was not designed to test frequency of eating.
 - One PCS with critical limitations was not sufficient to draw conclusions.

For additional details on this body of evidence, visit: [nesr.usda.gov/2020-dietary-guidelines-advisory-committee-systematic-reviews/frequency-eating-subcommittee/frequency-eating-postpartum-weight-loss](https://www.nesr.usda.gov/2020-dietary-guidelines-advisory-committee-systematic-reviews/frequency-eating-subcommittee/frequency-eating-postpartum-weight-loss)

Question 3. What is the relationship between dietary patterns consumed during lactation and human milk composition and quantity?

Approach to Answering Question: NESR systematic review

Conclusion Statements and Grades

No evidence is available to determine the relationship between maternal dietary patterns during lactation and human milk quantity. Grade: Grade Not Assignable

Insufficient evidence is available to determine the relationship between maternal diets differing in macronutrient distributions during lactation and human milk quantity. Grade: Grade Not Assignable

Insufficient evidence is available to determine the relationship between dietary patterns during lactation and total fat in human milk. Grade: Grade Not Assignable

Limited evidence suggests that maternal consumption of diets higher in fat (>35 percent fat) and lower in carbohydrate during lactation is related to higher total fat in human milk collected in the maternal postprandial period. Grade: Limited

Limited evidence suggests that certain maternal dietary patterns during lactation, including diets based on macronutrient distributions, are related to the relative proportions of saturated fat and monounsaturated fatty acids in human milk, and of polyunsaturated fatty acids in human milk collected in the maternal postprandial period. Grade: Limited

No evidence is available to determine the relationship between maternal dietary patterns during lactation and total protein concentration in human milk. Grade: Grade Not Assignable

Insufficient evidence is available to determine the relationship between maternal diets differing in macronutrient distribution during lactation and total protein concentration in human milk. Grade: Grade Not Assignable

No evidence is available to determine the relationship between maternal dietary patterns during lactation and bioactive proteins, including alpha-lactalbumin, lactoferrin, casein, alpha (1) antitrypsin, osteopontin, secretory immunoglobulin A, and lysozyme in human milk. Grade: Grade Not Assignable

No evidence is available to determine the relationship between maternal dietary patterns during lactation and human milk oligosaccharides. Grade: Grade Not Assignable

Insufficient evidence is available to determine the relationship between maternal dietary patterns during lactation and vitamin B₁₂ concentration in human milk. Grade: Grade Not Assignable

No evidence is available to determine the relationship between maternal dietary patterns during lactation and vitamin C, choline, and B vitamins (other than vitamin B₁₂) in human milk. Grade: Grade Not Assignable

No evidence is available to determine the relationship between maternal dietary patterns during lactation and vitamins A, D, E, and K in human milk. Grade: Grade Not Assignable

No evidence is available to determine the relationship between maternal dietary patterns during lactation and iodine and selenium in human milk. Grade: Grade Not Assignable

Summary of the Evidence

- This systematic review includes 3 RCTs (4 articles) and 2 cross-sectional studies (3 articles) published between 2009 and 2019.³³⁻³⁹
- Studies included in this review assessed one of the following maternal interventions or exposures during lactation:
 - Dietary patterns (2 studies)
 - Diets based on macronutrient distributions outside of the AMDR (3 studies)
- Two of the 3 RCTs reported that a maternal diet higher in fat during lactation (i.e., >35 percent of total energy from fat, which is greater than the AMDR) resulted in higher total fat in human milk.
- Some, but not all studies showed that maternal dietary patterns during lactation were related to the relative proportions of saturated fat, monounsaturated fatty acids, and polyunsaturated fatty acids in human milk, which differed depending on whether milk samples were collected in a fed or fasted state.
- This body of evidence had notable limitations:
 - All RCTs had a small sample size (<20 participants) and none reported power analyses.
 - The cross-sectional studies did not account for most of the confounders.
 - One cross-sectional study reported that the participants differed on supplement intake during lactation, in addition to differing on dietary patterns. However, this was not controlled for in the statistical analysis or accounted for in the interpretation of the study findings.
 - The timing and methods of human milk collection were heterogeneous.
 - The study populations did not represent the racial/ethnic or socioeconomic diversity of the U.S. population.

- Insufficient or no evidence was available to assess the association between dietary patterns and several other outcomes, including human milk quantity and human milk composition of total protein, water-soluble vitamins (B, C, and choline), fat-soluble vitamins (A, D, E, and K), minerals (iodine and selenium), human milk oligosaccharides, and bioactive proteins (alpha-lactalbumin, lactoferrin, casein, alpha (1) antitrypsin, osteopontin, secretory immunoglobulin A (sIgA), and lysozyme).

For additional details on this body of evidence, visit: [nesr.usda.gov/2020-dietary-guidelines-advisory-committee-systematic-reviews/pregnancy-and-lactation-subcommittee/dietary-patterns-lactation-human-milk](https://www.nesr.usda.gov/2020-dietary-guidelines-advisory-committee-systematic-reviews/pregnancy-and-lactation-subcommittee/dietary-patterns-lactation-human-milk)

Question 4. What is the relationship between maternal diet during lactation and risk of child food allergies and atopic allergic diseases including atopic dermatitis, allergic rhinitis, and asthma?

Approach to Answering Question: NESR systematic review

Conclusion Statements and Grades

Food Allergy

Insufficient evidence is available to determine the relationship between lower or restricted consumption of cow milk products during both pregnancy and lactation, and risk of food allergy in the child. Grade: Grade Not Assignable

No evidence is available to determine the relationship between maternal dietary patterns or cow milk products, eggs, peanuts, soybean, wheat, fish, tree nuts and seeds, and foods not commonly considered to be allergens, such as meat, vegetables, and fruits consumed during lactation and risk of food allergy in the child. Grade: Grade Not Assignable

Atopic Dermatitis

Insufficient evidence is available to determine the relationship between cow milk products restricted during both pregnancy and lactation, or during lactation only, and risk of atopic dermatitis/eczema in the child. Grade: Grade Not Assignable

Insufficient evidence is available to determine the relationship between egg consumption restricted during both pregnancy and lactation and risk of atopic dermatitis/eczema in the child. Grade: Grade Not Assignable

No evidence is available to determine the relationship between maternal dietary patterns or yogurt and probiotic milk products, eggs, fish, peanuts, tree nuts and seeds, soybean, wheat/cereal, and foods not commonly considered to be allergens, such as meat, vegetables, and fruits, consumed during lactation and risk of atopic dermatitis/eczema in the child. Grade: Grade Not Assignable

Allergic Rhinitis

Insufficient evidence is available to determine the relationship between cow milk products consumed during both pregnancy and lactation, and risk of allergic rhinitis in the child. Grade: Grade Not Assignable

No evidence is available to determine the relationship between maternal dietary patterns or cow milk products, eggs, fish, peanuts, tree nuts and seeds, soybean, wheat, and foods not commonly considered to be allergens, such as meat, vegetables, and fruits consumed during lactation and risk of allergic rhinitis in the child. Grade: Grade Not Assignable

Asthma

Insufficient evidence is available to determine the relationship between cow milk products consumed during both pregnancy and lactation, or during lactation only and risk of asthma in the child. Grade: Grade Not Assignable

Insufficient evidence is available to determine the relationship between fish, and other foods, such as margarine, oil, butter and butter-spreads, meat, and meat products consumed during lactation and risk of asthma in the child. Grade: Grade Not Assignable

No evidence is available to determine the relationship between maternal dietary patterns or eggs, peanuts, wheat, tree nuts and seeds, and soybean consumed during lactation and risk of asthma in the child. Grade: Grade Not Assignable

Summary of the Evidence

- This systematic review included 8 articles from 4 RCTs, one non-RCT, and 1 PCS that assessed the relationship between maternal diet during both pregnancy and lactation, or during lactation alone, and risk of food allergy, atopic dermatitis/eczema, allergic rhinitis, and asthma in the child occurring from birth through age 18 years.⁴⁰⁻⁴⁷ The articles were published between 1989 and 2013.
 - Six articles from 4 studies included women who were pregnant as well as those who were lactating.
 - Two studies included only women who were lactating.
- Four articles from 2 RCTs examined maternal avoidance of cow milk products, eggs, soybean, wheat, and peanuts, during both pregnancy and lactation, in relation to risk of food allergy, and allergic rhinitis in the child from birth through age 18 years. None of these studies was conducted exclusively in lactating women.
- Seven articles from 4 RCTs and 1 non-RCT examined maternal avoidance of cow milk products, eggs, soybean, wheat, and peanuts, during both pregnancy and lactation, or during lactation alone, in relation to the risk of atopic dermatitis/eczema in the child from birth through age 18 years. Of these, only 1 RCT was conducted exclusively in women who were lactating.
- Four articles from 2 RCTs and 1 PCS examined maternal avoidance and/or consumption of cow milk products, eggs, fish, soybean, peanuts, wheat, and other foods during both pregnancy and lactation, or during lactation alone, in relation to risk of asthma in the child from ages 2 through 18 years. Of these, 1 PCS was conducted exclusively in women who were lactating.
- No articles were identified that examined maternal avoidance or consumption of seeds during lactation in relation to the risk of atopic outcomes in the child from birth through age 18 years.
- The ability to draw strong conclusions was limited by the following issues:
 - Very few studies assessed the relationship between maternal diet during lactation alone and risk of atopic dermatitis, food allergy, allergic rhinitis and asthma.
 - Key confounders were not consistently controlled for in most of the studies.
 - Women with lower socioeconomic status (SES), adolescents, and racially and ethnically diverse populations were underrepresented in the body of evidence.

See **Part D. Chapter 2: Food, Beverage, and Nutrient Consumption During Pregnancy**, Question 8, for a review that addressed maternal diet during both pregnancy and lactation, and pregnancy only, and risk of child food allergy and atopic allergic diseases.

For additional details on this body of evidence, visit: [nesr.usda.gov/2020-dietary-guidelines-advisory-committee-systematic-reviews/pregnancy-and-lactation-subcommittee/maternal-diet-pregnancy-lactation-child-food-allergies-and-atopic-allergic-diseases](https://www.nesr.usda.gov/2020-dietary-guidelines-advisory-committee-systematic-reviews/pregnancy-and-lactation-subcommittee/maternal-diet-pregnancy-lactation-child-food-allergies-and-atopic-allergic-diseases)

Question 5. What is the relationship between dietary patterns consumed during lactation and developmental milestones, including neurocognitive development, in the child?

Approach to Answering Question: NESR systematic review

Conclusion Statement and Grade

No evidence is available to determine the relationship between maternal dietary patterns during lactation and developmental outcomes, including neurocognitive development, in the child.

Grade: Grade Not Assignable

Summary of the Evidence

- The outcomes for this systematic review included developmental domains (examined through milestone achievement and/or scales/indices, including cognitive, language and communication, movement and physical, and social-emotional), academic performance, ADD or ADHD, anxiety, depression, and ASD.
- This review identified 0 studies published between January 2000 and January 2020 that met the inclusion criteria for this systematic review.

For additional details on this body of evidence, visit: [nesr.usda.gov/2020-dietary-guidelines-advisory-committee-systematic-reviews/pregnancy-and-lactation-subcommittee/dietary-patterns-lactation-neurocognitive-development](https://www.nesr.usda.gov/2020-dietary-guidelines-advisory-committee-systematic-reviews/pregnancy-and-lactation-subcommittee/dietary-patterns-lactation-neurocognitive-development)

Question 6. What is the relationship between seafood consumption during lactation and neurocognitive development, in the child?

Approach to Answering Question: NESR systematic review

Conclusion Statement and Grade

No evidence is available to determine the relationship between maternal seafood intake during lactation and neurocognitive development in the child. Grade: Grade Not Assignable

Summary of the Evidence

- The Committee used the same seafood definition as that used in the *2015-2020 Dietary Guidelines for Americans*: Marine animals that live in the sea and in freshwater lakes and rivers. Seafood includes fish (e.g., salmon, tuna, trout, and tilapia) and shellfish (e.g., shrimp, crab, and oysters).⁴⁸
- Neurocognitive outcomes evaluated within this systematic review included developmental domains (i.e., cognitive, language and communication, movement and physical, social-emotional and behavioral development), academic performance, ADD or ADHD, anxiety, depression, and ASD.
- This review identified 0 studies published between January 2000 and October 2019 that met the inclusion criteria for this systematic review.

See **Part D. Chapter 2: Food, Beverage, and Nutrient Consumption During Pregnancy**, Question 9, for a review that addressed maternal seafood consumption during both pregnancy and lactation, and pregnancy only, and neurocognitive developmental outcomes in the child.

For additional details on this body of evidence, visit: [nesr.usda.gov/2020-dietary-guidelines-advisory-committee-systematic-reviews/dietary-fats-and-seafood-subcommittee/seafood-pregnancy-lactation-infant-neurocognitive-development](https://www.nesr.usda.gov/2020-dietary-guidelines-advisory-committee-systematic-reviews/dietary-fats-and-seafood-subcommittee/seafood-pregnancy-lactation-infant-neurocognitive-development)

Question 7. What is the relationship between omega-3 fatty acids from supplements consumed during lactation and developmental milestones, including neurocognitive development, in the child?

Approach to Answering Question: NESR systematic review

Conclusion Statements and Grades

Insufficient evidence is available to determine the relationship between omega-3 fatty acid supplementation during both pregnancy and lactation or during lactation alone, and cognitive, language, motor, and visual development in the child. Grade: Grade Not Assignable

No evidence is available to determine the relationship between omega-3 fatty acid supplementation during both pregnancy and lactation or during lactation alone and academic performance, anxiety, depression, or the risk of attention-deficit disorder, attention-deficit/hyperactivity disorder, or autism spectrum disorder in the child. Grade: Grade Not Assignable

No evidence is available to determine the relationship between omega-3 fatty acid supplementation during lactation and social-emotional development in the child. Grade: Grade Not Assignable

Summary of the Evidence

- This systematic review included 8 articles from 4 RCTs published between 1980 and 2020.⁴⁹⁻⁵⁶
- Studies included in this review assessed interventions and exposures during:
 - Both pregnancy and lactation: 3 RCTs (6 articles)
 - Lactation alone: 1 RCT (2 articles)
- All 4 RCTs assessed cognitive development:
 - Three RCTs delivered omega-3 fatty acid supplements during both pregnancy and lactation. Of those 3 RCTs, 1 study reported at least one statistically significant finding that supplementation resulted in favorable cognitive development in the child. All 3 studies reported at least one statistically non-significant result.
 - One RCT delivered omega-3 fatty acid supplements during lactation alone and showed a benefit of supplementation on one measure of cognitive development in the child. The

study also reported statistically non-significant results on other measures of cognitive development.

- For language, motor, and social-emotional development, findings were inconsistent and therefore a conclusion statement could not be drawn. Although all studies reported at least one statistically non-significant result, the number and direction of statistically significant findings varied across the body of evidence.
- No evidence was available on omega-3 fatty acid supplementation and visual development, academic performance, anxiety, depression or the risk of ADD, ADHD, or ASD.
- The ability to draw strong conclusions was limited by the following issues:
 - Wide variation in the developmental domains assessed, as well as in the measures used to evaluate child performance in each of those domains, limited the ability to compare results across studies.
 - Missing outcome data raised concerns about risk of bias. Further, a lack of preregistered data analysis plans potentially increased the risk of bias due to selectivity in the results presented.
 - Findings were mixed both within and between studies, and these inconsistencies could not be explained by methodological differences.
 - Although some studies published results from multiple follow-up assessments, an insufficient number of studies were available to investigate the relationship between omega-3 fatty acid supplementation and developmental milestones in the child for many exposure-outcome pairs. Additionally, multiple studies did not provide evidence of sufficient sample size to detect effects, either because the study did not achieve the required sample size estimated by power calculations or because the study did not report a power calculation. This is particularly true for the long-term outcome assessments.
 - People with lower-SES, adolescents, and racially and ethnically diverse populations were underrepresented in the body of evidence.

See *Part D. Chapter 2: Food, Beverage, and Nutrient Consumption During Pregnancy*, Question 10, for a review of omega-3 fatty acid supplementation during both pregnancy and lactation, and pregnancy only, and neurocognitive outcomes in the child.

For additional details on this body of evidence, visit: nesr.usda.gov/2020-dietary-guidelines-advisory-committee-systematic-reviews/pregnancy-and-lactation-subcommittee/omega-3-pregnancy-lactation-neurocognitive-development

Question 8. What is the relationship between folic acid from supplements and/or fortified foods consumed during lactation and: 1) maternal micronutrient status, 2) human milk composition, and 3) developmental milestones, including neurocognitive development, in the child?

Approach to Answering Question: NESR systematic review

Conclusion Statements and Grades

Maternal Micronutrient Status

Moderate evidence indicates that folic acid supplements consumed during lactation are positively associated with red blood cell folate, and may be positively associated with serum or plasma folate. Grade: Moderate

Insufficient evidence is available to determine the relationship between folic acid from supplements consumed during lactation and hemoglobin, mean corpuscular volume, and serum vitamin B₁₂. Grade: Grade Not Assignable

No evidence is available to determine the relationship between folic acid from supplements consumed during lactation and red blood cell distribution width. Grade: Grade Not Assignable

No evidence is available to determine the relationship between folic acid from fortified foods consumed during lactation and micronutrient status. Grade: Grade Not Assignable

Human Milk Composition

Moderate evidence indicates that folic acid supplements consumed during lactation does not influence folate levels in human milk. Grade: Moderate

No evidence is available to determine the relationship between folic acid from fortified foods consumed during lactation and human milk folate. Grade: Grade Not Assignable

Neurocognitive Development

No evidence is available to determine the relationship between folic acid from supplements or fortified foods consumed during lactation and developmental milestones, including neurobehavioral development, in the child. Grade: Grade Not Assignable

Summary of the Evidence

Maternal Micronutrient Status

- Five articles from 4 studies were identified through a literature search from 1980 to 2019 which met the criteria for inclusion in this systematic review.⁵⁷⁻⁶¹ Studies included in this review assessed interventions and exposures during lactation: 3 RCTs, 1 uncontrolled before-and-after study, and 1 PCS that was nested within one of the RCTs.
- Studies varied in intervention details. including:
 - Folic acid supplement type (folic acid or 5-methyltetrahydrofolate [5-MTHF])
 - Dose and comparator
 - Three RCTs and 1 PCS compared no folic acid supplementation to folic acid supplementation (300 µg/d to 1.0 mg/d)
 - One RCT also compared folic acid to 5-MTHF supplementation at the same dose (400 µg/d)
 - One uncontrolled before-and-after study compared folate levels before to after supplementation of 1.0 mg/d synthetic folic acid
 - Duration (1 month, 3 months, 4 months)
- Of the 5 outcome measures defined in the analytic framework, all but RBC distribution width were reported in the body of evidence.
- All studies found a significant association between folic acid supplementation and at least 1 outcome measure.
- All 4 studies assessed plasma or serum folate:
 - Four studies (5 articles: 3 RCTs; 1 PCS; 1 uncontrolled before-and-after study) assessed the relationship between folic acid from supplements during lactation. Two found that supplementation was associated with higher values on at least 1 measure of plasma/serum folate and two found no association.
- All 4 studies assessed RBC folate.

- All 4 studies (5 articles: 3 RCTs; 1 PCS; 1 uncontrolled before-and-after study) that assessed supplementation during lactation found that supplementation was associated with higher values on at least one measure of RBC folate.
- Two RCTs assessed hemoglobin. The findings were inconsistent and therefore a conclusion statement could not be drawn.
- One RCT each assessed the effect of supplementation on MCV or vitamin B₁₂ status; therefore, conclusions could not be drawn.
- This body of evidence had important limitations:
 - None of the studies preregistered data analysis plans, indicating a potential risk of bias due to selectivity in results presented.
 - Neither the PCS nor the uncontrolled before-and-after study adequately accounted for potential confounding.
 - Risk of bias due to classification of exposures or deviations from intended exposures was a concern for the cohort study and the uncontrolled before-and-after study.
 - The study populations did not fully represent the racial/ethnic or socioeconomic diversity of the U.S. population.
 - No studies that examined the effect of intake of folic acid from fortified foods on the outcome of interest met the inclusion criteria.

Human Milk Composition

- Four studies were identified through a literature search from 1980 to 2019 which met the criteria for inclusion in this systematic review: 3 RCTs and 1 uncontrolled before-and-after study.⁵⁹⁻⁶²
- Studies varied in intervention details, including folic acid supplement type (folic acid, 5-MTHF, or pteroylmonoglutamate), dose (300 µg/d, 400 µg/d, or 1 mg/d), time of initiation (1 to 25 weeks postpartum), duration (4 weeks, 12 weeks, or 16 weeks), and sample characteristics.
- As defined by the inclusion criteria, all studies took place in high or very high HDI countries⁶³; therefore, the participants were likely to be folate replete.
- None of the studies found an association between folic acid supplementation in women who were lactating and milk folate levels.
- This body of evidence had important limitations:

- In one of the 3 RCTs, the reference group was not recruited and randomized with the other 2 study groups. In another study, milk folate was significantly different between the control and intervention groups at baseline, and this was not controlled for in the analyses.
- Only 1 study reported a power calculation and that study did not reach the target sample size.
- The study populations did not fully represent the racial/ethnic or socioeconomic diversity of the U.S. population.

Neurocognitive Development

- The search identified 0 studies published between 1980 and 2019 that met the inclusion criteria.

See ***Part D. Chapter 2: Food, Beverage, and Nutrient Consumption During Pregnancy***, question 11 for a review that addressed maternal folic acid supplementation during pregnancy and select health outcomes.

For additional details on this body of evidence, visit: [nesr.usda.gov/2020-dietary-guidelines-advisory-committee-systematic-reviews/pregnancy-and-lactation-subcommittee/folic-acid-pregnancy-lactation-health-outcomes](https://www.nesr.usda.gov/2020-dietary-guidelines-advisory-committee-systematic-reviews/pregnancy-and-lactation-subcommittee/folic-acid-pregnancy-lactation-health-outcomes)

DISCUSSION

The 2020 Committee evaluated maternal dietary patterns during lactation, including frequency of eating, and their relationship to maternal PPWL. The Committee also examined the relationship between maternal folic acid supplementation and maternal micronutrient status. Maternal dietary patterns and folic acid supplementation also were considered in relation to human milk composition and quantity. In addition, maternal dietary patterns were examined in relation to child outcomes, including the risk of child food allergy and atopic allergic disease, and developmental milestones, such as neurocognitive development. The Committee also examined the relationship of maternal seafood consumption, omega-3 fatty acid supplementation, and folic acid supplementation during lactation with developmental milestones in the child. The following sections discuss the Committee's findings and in some cases highlight issues needing additional research; these research needs are articulated in ***Part E. Future Directions***.

Maternal Outcomes

Postpartum Weight Loss

Excess postpartum weight retention is common in the United States. For example, among 774 women in the National Institute of Child Health and Human Development Community Child Health Network, a national 5-site PCS in which the sample of women was predominantly low income, almost 50 percent had retained 10 or more pounds and about one-fourth had retained 20 or more pounds at 12 months postpartum compared to their prepregnancy weight.⁶⁴ Excess postpartum weight retention (≥ 20 pounds) was more likely among younger women, African-American women, and those who had gained more weight during pregnancy, whereas women who breastfed and exercised moderately lost more weight.

The determinants of PPWL are complex, as the period after childbirth is dynamic and includes potential changes in physical activity, appetite, sleep patterns, mental health status, and hormonal levels that influence eating behaviors and weight change.^{65,66} For example, maternal prolactin levels are very high during the first 2 to 3 months postpartum while lactation is being established, and this, together with other early postpartum hormonal changes may stimulate appetite.⁶⁷ Thereafter, the hormonal milieu shifts, including a decrease in prolactin levels, even though milk production (and thus energy output in milk) may be as high or higher than in early lactation; this is thought to help “reset” maternal appetite and metabolism and stimulate fat mobilization among women who continue to breastfeed.^{68,69}

Little information exists on dietary predictors of PPWL or weight retention.⁶⁵ Dietary patterns may play a role, but in its systematic review, the Committee identified only 1 study that examined dietary patterns during lactation in relation to PPWL.³¹ That study, an RCT of women who were lactating, was conducted in the United States and compared outcomes between those assigned to a Mediterranean-style diet, which emphasized nuts (especially walnuts), olive oil, and fruits and vegetables, or USDA’s MyPyramid diet. Women in both the MED (-251.2 kcal/d, $p=0.045$) and the MyPyramid (-437.5 kcal/d, $p=0.003$) diet groups reported reduced total energy intake compared to baseline. Participants in both diet groups demonstrated reductions ($p<0.001$) in body weight from baseline (-2.3 ± 3.4 kg and -3.1 ± 3.4 kg for the MED and comparison diets, respectively).³¹ However, PPWL between the two groups did not differ significantly, which is not surprising given that both diets would be considered “healthy” diets, and are composed of similar food groups.

Frequency of eating also may influence PPWL, though only 1 study on this question was identified. This study³² enrolled 60 lactating Swedish women who intended to breastfeed for 6 months. The study did not show a significant relationship between eating frequency and postpartum weight change in a 12-week intervention between 10 to 14 weeks and 22 to 26 weeks postpartum.

Future studies of PPWL during lactation should include careful assessment of dietary practices (using validated methods) and eating frequency (using the criteria described in **Part D. Chapter 13: Frequency of Eating**), and should take into account several potential confounders, including physical activity, eating away from home, exclusivity and duration of breastfeeding, sleep patterns, and psychosocial factors, including mental health status, race/ethnicity, maternal age, prepregnancy BMI, GWG, and SES. In addition, future studies should include information on food insecurity to distinguish between voluntary versus involuntary eating frequency behavior or restricted diets.

Maternal Micronutrient Status

The Committee evaluated the relationship between folic acid from supplements and/or fortified foods consumed before and during pregnancy and lactation and maternal health outcomes. No evidence was available to examine folic acid from fortified foods. The folate RDA is higher for women who are lactating than for women who are not, as the secretion of folate into breast milk increases the folate requirement.⁷⁰ The Committee did not evaluate any other supplement during lactation on maternal micronutrient status. Outcomes related to supplementation before and during pregnancy are summarized in **Part D. Chapter 2: Food, Beverage, and Nutrient Consumption During Pregnancy**. Four studies (5 articles) were included in the evidence portfolio for supplementation during lactation alone.

Three studies were RCTs conducted in the United States⁶⁰ and Canada,^{57,61} 1 PCS was conducted in Canada,⁵⁸ and 1 uncontrolled before-and-after study was conducted in Japan⁵⁹ with the primary outcomes of plasma or serum folate, hematological outcomes, and serum vitamin B₁₂. All studied folic acid supplements in the range of 300 to 1,000 µg/d and Houghton et al.⁵⁷ also included a group receiving 400 µg/d 5-MTHF. Duration of exposure varied (4 weeks, 12 weeks, or 16 weeks), and all were conducted within the first 25 weeks postpartum. Based on this evidence, the Committee concluded that moderate evidence indicated that folic acid supplementation during lactation is positively associated with maternal RBC folate and may be positively associated with maternal serum or plasma folate. The evidence was insufficient to

determine the relationship between folic acid from supplements consumed during lactation and maternal hemoglobin, MCV, and serum or plasma vitamin B₁₂. No evidence was available for the outcome of maternal red cell distribution width.

Human Milk Composition and Quantity

Maternal Dietary Patterns

As noted in the Introduction, only some of the components in human milk are affected by maternal dietary intake.²⁴ The Committee sought to determine the relationship between patterns of maternal dietary intake consumed during lactation and components of human milk. The evidence base included 3 RCTs that investigated maternal diets with a macronutrient distribution outside of the AMDR and 2 cross-sectional studies that investigated maternal dietary patterns.

Based on this body of evidence, the Committee drew two conclusions relative to fat and fatty acid composition of human milk. First, maternal consumption of diets higher in fat (>35 percent fat) and lower in carbohydrate during lactation is related to higher total fat in human milk collected in the maternal postprandial state, a conclusion supported by 3 RCTs. In addition, certain maternal dietary patterns during lactation, including maternal diets based on macronutrient distributions, may be related to the relative proportions of saturated fat and monounsaturated fat in human milk, and of polyunsaturated fat in human milk collected in the maternal postprandial period, a finding that was supported by 3 RCTs and 2 cross-sectional studies. These conclusions were graded as limited due to concerns about randomization (for RCTs), minimal information on maternal dietary intake and supplement use, variability in stage of lactation, and variability in timing of milk sample collection.

The 3 RCTs reported that total human milk fat was higher after the women consumed a higher fat diet or full-fat dairy diet. However, the specific fatty acids that differed depending upon whether the milk samples were collected in a fed or fasted state, which likely reflects differences in the physiological sources of milk fatty acids. For example, using stable isotopes, Hachey demonstrated that a delay of about 6 hours occurred between ingestion of a fat and its appearance in human milk.⁷¹ Medium-chain fatty acids (MCFA) (e.g., C:6 to C12:0) are synthesized in the mammary gland through *de novo* fatty acid synthesis,⁷² whereas *de novo* synthesis of long-chain fatty acids (LCFA) (e.g., C16:0 and C18:0) in the human mammary gland is limited, even on a low-fat diet.⁷³ The long chain polyunsaturated fatty acids, DHA,

eicosapentaenoic acid (EPA), and arachidonic acid (AA) in human milk, are acquired from the maternal diet.²³ Mohammed et al.³⁴ conducted a crossover study, and reported data from the same women in the fed and fasted state. They showed that primarily MCFA were higher in the milk when the women were fed a low-fat (25 percent of energy as fat) vs a high-fat (55 percent) diet, in both the fed and fasted state. These findings suggested enhanced *de novo* fatty acid synthesis of MCFAs when maternal dietary fat is restricted. For fatty acids with limited mammary synthesis (e.g., C16:0 to C18:3), milk concentrations were higher in the milk when women were consuming the high-fat diet, but only in the fed state.³⁴ Nasser et al.³⁶ compared the milk fatty acid composition of women fed low-fat (14 percent of energy as fat) vs high-fat (40.2 percent of energy as fat) diets, but did not report whether milk was collected when women were in a fed or fasted state. Consistent with Mohammed et al., milk monounsaturated fat (C:6 to C:12) concentrations were higher when women were on the low-fat diet. Some of the longer chain fatty acids, such as stearic acids (C18:0), α -linolenic acid (C18:3n:3), arachidic acid (C20:0) and eicosenoic acid (C20:1n-9), were higher in milk when women were consuming the high-fat diet.³⁶ Lastly, Yahvah³⁸ compared the human milk fat composition when women were consuming a lower fat (24 percent of energy as fat) vs a higher fat diet (36 percent of energy as fat) as a result of consuming low-fat vs high-fat dairy foods. Monounsaturated fat content was unaffected by the maternal diet, and some, but not all, fatty acids of chain length longer than C12 were higher during the high fat dairy diet, reflecting dietary fat intake.

Two cross-sectional studies assessed dietary patterns. Perrin et al.³³ compared human milk fat composition of U.S. women consuming vegan, vegetarian, or omnivore dietary patterns. The milk of vegan women had significantly higher unsaturated fatty acids and total omega-3 fatty acids, and lower saturated fats, trans fat, omega-6 to omega-3 fatty acid ratios, and linoleic acid to α -linoleic acid ratios than did milk produced by vegetarian or omnivore women. However, maternal DHA/EPA supplement usage differed between the groups (vegan: 26.9 percent, vegetarian: 9.1 percent, omnivore: 3.9 percent), which confounded the analysis. Tian³⁵ reported human milk fat concentration in Chinese women categorized into four dietary patterns using factor analysis. Differences in milk total saturated, total polyunsaturated fat, and n-6 content were observed among women in these groups, but these maternal dietary patterns may not be generalizable to diets consumed in the United States.

Insufficient or no evidence was available to assess the association between maternal dietary patterns and human milk quantity and human milk composition of total protein, water-soluble vitamins (B, C, and choline), fat-soluble vitamins (A, D, E, and K), minerals (iodine and

selenium), human milk oligosaccharides, and bioactive proteins. Pawlak³⁹ measured vitamin B₁₂ in the milk samples of U.S. omnivore, vegetarian, or vegan women studied by Perrin.³³ Although about 20 percent of human milk samples had low vitamin B₁₂ concentrations, they did not differ by maternal dietary pattern. These findings contrast older reports of reduced human milk vitamin B₁₂ content in vegan women and B₁₂ deficiency in infants of vegan women.^{74,75} However, vitamin B₁₂ supplement use was low at the time of those studies and analytical methods did not account for matrix effects of human milk on the measurement of B₁₂ concentrations. Similar to the situation regarding DHA/EPA supplementation, more vegan (46 percent) and vegetarian (27 percent) women who were lactating reported consuming a B₁₂ supplement than did omnivorous women (4 percent), which was not accounted for in the analysis. In addition, about 55 percent of the women in all 3 groups continued to take a prenatal supplement. Thus, the high prevalence of supplement use likely attenuated differences by maternal dietary pattern.

Maternal Folic Acid Supplementation

The Committee investigated the relationship between folic acid from supplements consumed before and during pregnancy and lactation and human milk composition. Three RCTs conducted in the United States⁶⁰ and Canada,^{57,61} and one uncontrolled before-and-after study conducted in Japan⁵⁹ reported human milk folate concentrations. All four studies reported human milk folate concentrations and Mackey also reported unmetabolized human milk folic acid and soluble human milk folate binding protein concentrations. None of the studies found an association between folic acid supplementation in women who were lactating and milk folate levels. Thus, the Committee concluded that consumption of folic acid supplements during lactation does not influence folate levels in human milk. This finding is consistent with the categorization of folate as one of the nutrients (i.e., calcium, copper, folate, iron, zinc) in human milk that are generally independent of maternal status and for which maternal supplementation does not increase milk concentrations.²⁴ The overall grade for the evidence was moderate. The RCTs were graded as strong for consistency, precision and directness, but generalizability was graded as limited, as 75 percent of the studies were in White females, a majority held college degrees, and most participants were of relatively high SES.

Child Health Outcomes

Maternal Diet and Child Food Allergy and Atopic Allergic Diseases

The Committee evaluated how maternal diet during pregnancy and/or lactation is related to the risk of child food allergy and atopic allergic diseases, including atopic dermatitis, allergic rhinitis, and asthma. Conclusion statements for exposures during pregnancy alone or both pregnancy and lactation are summarized in **Part D. Chapter 2**. Of the 8 articles included in the review that were conducted during both pregnancy and lactation, or lactation alone, only 1 RCT⁴⁴ and 1 PCS study⁴⁵ were identified that studied the lactation period alone.

The RCT randomized 62 Thai lactating women with a history of allergy to a diet that restricted dairy products (vs usual diet) from birth to 4 months postpartum. Infants in the intervention group had a significantly lower incidence of atopic dermatitis (6.67 percent) at age 4 months than did infants in the control group (25 percent).⁴⁴ Based on this single study, the Committee concluded that insufficient evidence was available to determine the relationship between maternal dietary patterns or maternal consumption of any of the food components studied and the risk of atopic dermatitis/eczema, food allergy, or allergic rhinitis in the child.

Lumia et al. explored the association between maternal dietary intake during month 3 of lactation and asthma risk in the child at age 5 years.⁴⁵ Of the 6 dietary components assessed, only 1, maternal use of margarines, was found to have a weak association with increased asthma risk in the child at age 5 years. Therefore, the Committee concluded evidence was insufficient to determine the relationship between maternal consumption of fish, cow milk products, meat, and meat products, and fats such as margarine, oil, and butter, with risk of asthma in the child. In addition, no evidence was available to assess maternal dietary patterns or consumption of eggs, peanuts, tree nuts, seeds, and soybeans on asthma risk. These findings support the conclusions of the AAP⁷⁶ and the European Academy of Allergy and Clinical Immunology⁷⁷ that maternal dietary restrictions during lactation do not prevent the development of atopic disease in the infant and child.

Maternal Diet and Neurocognitive Development

Maternal Dietary Patterns

No studies examining the relationship between maternal dietary patterns during lactation and neurocognitive development of the child met inclusion criteria. Further research is needed on maternal dietary patterns during lactation that emphasize foods rich in certain key nutrients, namely those that are important for brain development, and for which a relationship between maternal intake and human milk composition exists. Nutrients meeting both of these criteria include omega-3 polyunsaturated fatty acids, choline, iodine, and the B vitamins.^{21,78}

Maternal Seafood Consumption

No studies examining the relationship between seafood consumption during lactation and neurocognitive development in the child met inclusion criteria. All the seafood reviews by recent Dietary Guidelines Advisory Committees (see **Part D. Chapter 9: Dietary Fats and Seafood** for discussion on previous Committees' reviews of seafood) found a notable lack of data to inform decisions and recommendations for women who are lactating. Despite this, the totality of existing evidence supports consumption during lactation of fish and seafood that are known to be higher in DHA and EPA and lower in methylmercury as part of an overall healthy dietary pattern, as has been previously recommended in the *2015-2020 Dietary Guidelines for Americans*⁴⁸

Maternal Omega-3 Fatty Acid Supplementation

The Committee examined whether omega-3 fatty acid supplementation during pregnancy and/or lactation is related to neurocognitive development of the child. Much less evidence was available for lactation than for pregnancy (see **Part D. Chapter 2: Food, Beverage, and Nutrient Consumption During Pregnancy**, Question 10). The search revealed 4 eligible RCTs (7 articles) that included supplementation during lactation, conducted in Norway,^{49,54,55} the Netherlands,^{53,56} Germany,⁵² and the United States.^{50,51} In 3 of these, supplementation began at 15 to 19 weeks gestation and continued to 3 to 4 months postpartum.^{49,52-56} In the fourth trial, supplementation began at 5 days postpartum and continued to 4 months postpartum.^{50,51} Outcomes were assessed at various ages, from infancy to a maximum age of 18 months,⁵³ 5 years,^{50,52} or 7 years.⁴⁹ The types and dosages of supplements provided were heterogeneous: 1 trial provided cod liver oil,^{49,54,55} 1 provided 220 mg DHA plus 220 mg of AA,^{53,56} 1 provided

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1,020 mg of DHA, 180 mg of EPA, and 9 mg of vitamin E⁵² and 1 provided 200 mg of DHA.^{50,51} The number of women enrolled ranged from 119 to 149.

Cognitive development was assessed in all 4 trials. One study^{49,54} found a favorable effect of supplementation on one measure of intelligence at age 4 years, but no significant effect at age 7 years. Another study^{50,51} reported a favorable effect of supplementation on one measure of sustained attention at age 5 years, but no association with multiple measures of cognitive development at ages 12 months, 2.5 years, and 5 years. The other 2 trials found no significant effect of the intervention.^{52,53} Given the mixed results, the small number of studies, relatively small sample sizes, risk of bias due to several study limitations, and limited information on the generalizability of results to the general U.S. population, the Committee judged that evidence was insufficient to determine the relationship between omega-3 fatty acid supplementation during both pregnancy and lactation, or during lactation alone, and cognitive development in the child.

The evidence base was even more limited, and also mixed, for language development (2 trials), motor development (3 trials), visual development (1 trial), and socio-emotional development (1 trial). For several outcomes (academic performance, anxiety, depression, ADD, ADHD, and ASD), no evidence was available from these trials. Thus, the Committee concluded that either insufficient or no evidence was available to determine the relationship between omega-3 fatty acid supplementation during both pregnancy and lactation, or during lactation alone, and these outcomes.

These conclusions are consistent with those of a Cochrane systematic review and meta-analysis published in 2015,⁷⁹ which stated that “there is inconclusive evidence to support or refute the practice of giving LC-PUFA supplementation to breastfeeding mothers in order to improve neurodevelopment or visual acuity.” A review in 2016⁸⁰ came to a similar conclusion.

Despite the inconclusive nature of the evidence on this question, it is clear that an adequate supply of LC-PUFA, particularly DHA, to the infant is critical for brain development of the infant and child.^{80,81} Accumulation of DHA in the brain is most rapid during the second half of gestation and the first year after birth. As noted in the findings of the systematic review on maternal dietary patterns and human milk composition, the fatty acid content of the maternal diet affects the concentrations of fatty acids in human milk, including DHA. The effects of omega-3 fatty acid supplements provided to the lactating women on neurocognitive development of the child likely depends on the baseline omega-3 fatty acid adequacy of her diet as well as the ability of the infant and child to produce LC-PUFA from their precursor fatty acids in an amount sufficient to

support optimal development of the central nervous system.⁸² Thus, further evidence is needed from RCTs that are adequately powered and targeted at populations with low intakes of omega-3 fatty acids.

Maternal Folic Acid Supplementation

Folate is naturally present in some foods, added to others, and available as a dietary supplement. Food folates are in the tetrahydrofolate (THF) form and contain different numbers of glutamic acids depending on the type of food. Folic acid is the fully oxidized monoglutamate form of the vitamin that is used in fortified foods and most dietary supplements.⁸³ Folate plays a role in numerous biochemical pathways that affect brain development and function, including neural stem cell proliferation and differentiation, regulation of gene expression, neurotransmitter synthesis, and myelin synthesis and repair.⁸⁴ In particular, folate deficiency due to diet⁸⁵ or genetics⁸⁶ can disrupt myelination in the brain. Myelin is the supportive tissue that surrounds and protects the nerve cells and facilitates communication, and disruptions in myelination can have significant effects on central nervous system functioning by altering the speed of conduction in multiple systems. The acquisition of cognitive skills coincides with the pattern of central nervous system myelination. Therefore, retardation of myelination of the brain in infancy leads to delayed acquisition of cognitive skills.⁸⁷ Genetic polymorphisms in genes for enzymes in the folate-homocysteine pathway also have been associated with behavior in children with ADHD.⁸⁴ However, no studies examining the relationship between maternal folic acid supplementation during lactation and neurocognitive development of the child met inclusion criteria. Given that the systematic review undertaken by the Committee showed no effect of folic acid supplementation on human milk folate, further research in this area is not warranted. Instead, future research should focus on maternal dietary patterns during lactation that emphasize foods rich in certain key nutrients, namely, those that are important for brain development, and for which a relationship between maternal intake and human milk composition exists.

SUMMARY

This is the first Dietary Guidelines Advisory Committee to conduct a series of reviews focused on women who are lactating. However, the 3 most recent editions of the *Dietary Guidelines for Americans* have provided some guidance on specific foods, food components, or nutrients and lactation outcomes, including: alcohol (2005, 2010, 2015)^{48,88,89}; caffeine (2015)⁴⁸; and seafood (2010, 2015)^{48,88}; maintaining energy balance (2010)⁸⁸; healthy weight (2010)⁸⁸; and physical activity (2005)⁸⁹. The 2010 Committee examined several relationships that were not included in the final *Dietary Guidelines for Americans*; these included associations between specific foods, food components, or nutrients (including DHA) and lactation outcomes (including human milk composition), as well as the relationship between lactation and PPWL.

The 2020 Committee re-examined seafood consumption and omega-3 fatty acid supplements, but did not specifically examine alcohol, caffeine, or physical activity. This Committee examined several new relationships of maternal dietary patterns and frequency of eating with PPWL, and of maternal dietary patterns with human milk composition and quantity. In addition, for the first time, the Committee examined relationships between maternal dietary patterns and/or consumption of specific foods and dietary supplements during lactation and food allergy, atopic conditions, and neurodevelopment in children.

Nutrient requirements during lactation are intended to support the nutritional status of the woman and to provide the additional amounts of energy and nutrients associated with milk synthesis and the secretion of nutrients into human milk. A woman's nutritional and metabolic status before and during pregnancy is linked with lactation success and long-term metabolic health. Women who are lactating have a higher average Healthy Eating Index (HEI) Score (i.e., 62 out of 100) than do women of a similar age who are not pregnant or lactating (i.e., 54). The higher mean score is driven by higher HEI component scores for Total Fruits, Greens and Beans, Whole Grains, Fatty Acids, and Seafood and Plant Proteins, combined with higher HEI moderation component scores for Refined Grains, Added Sugars, and Saturated Fats. However, women who are lactating have lower component scores than their peers (women who are pregnant and those who are neither pregnant nor lactating) for Total Vegetables, Dairy, and Sodium. Additionally, nearly 1 in 6 women who are lactating consume Total Protein Foods in amounts less than those recommended in the USDA Food Patterns (**see Part D. Chapter 1: Current Intakes of Foods, Beverages, and Nutrients**, Question 3 for additional information about the HEI).

Mean usual intakes of select underconsumed and overconsumed nutrients by lactating and non-pregnant, non-lactating women in the U.S., based on the What We Eat in America, NHANES 2013-2016 data, are summarized in Table D3.1. The definitions of underconsumed and overconsumed nutrients or food components can be found in **Part D. Chapter 1** and in the footnotes of Table D3.1. Nutrients or food components of public health concern are those that are underconsumed or overconsumed nutrients or food components with supporting evidence through biochemical indices or functional status indicators, if available, plus evidence that the inadequacy or excess is directly related to a specific health condition (**see Part D. Chapter 1**). Food components of public health concern among women who are lactating include those for the entire population older than 1 year, including vitamin D, calcium, dietary fiber and potassium, which are underconsumed and sodium, saturated fat and added sugars, which are overconsumed (Table D3.1). In addition, diet analysis results showed that 5 percent or more of women who are lactating have intakes below the EAR for folate, magnesium, copper, thiamin, vitamin A, and zinc. Vitamin D, folate/folic acid and zinc are unique in that >5 percent of women are not meeting the EAR from foods alone, but the use of dietary supplements by women who are lactating can lead to some women exceeding the UL (Table D3.1). Iron may be overconsumed by women who are lactating, with 29 percent of those taking supplements exceeding the UL compared to <3 percent of women who are lactating who are not taking supplements (Table D3.1). Lastly, choline and magnesium are underconsumed in the diets of women who are lactating and should be considered for further evaluation, given limited availability of biomarker, clinical, or health outcome data (**see Part D. Chapter 1**). These data suggest that, while women apparently seek to improve their diets during lactation, further improvements are needed to better align with dietary recommendations and avoid under- or overconsuming nutrients and food components.

Table D3.1 Mean usual intake of select underconsumed and overconsumed nutrients, by lactation status, in the United States, 2013-2016¹

		Lactating		Non-Lactating²	
		Food and Beverages (n=78)	Food, Beverages, and Dietary Supplements (n=77)	Food and Beverages (n=2060)	Food, Beverages, and Dietary Supplements (n=2019)
<u>Potentially underconsumed:</u>					
Choline (mg)	Mean (SE)	366 (21)	370 (18)	290 (4)	293 (4)
	% >AI (SE)	14† (5.1)	6† (2.2)	7 (1.1)	7 (1.0)
Dietary fiber (g)	Mean (SE)	21.2 (1.0)	n/a	15.4 (0.4)	n/a
	% >AI (SE)	20* (4.2)	n/a	7 (1.2)	n/a
Potassium (mg)	Mean (SE)	2773 (135)	n/a	2277 (42)	n/a
	% >AI (SE)	46 (8.0)	n/a	28 (2.6)	n/a
Vitamin E (mg)	Mean (SE)	11.9 (1.0)	n/a	8.6 (0.2)	n/a
	% <EAR (SE)	71 (7.9)	n/a	85 (2.1)	n/a
Vitamin C (mg)	Mean (SE)	86.8 (7.6)	155.5 (12.6)	72.5 (2.5)	122.3 (6.9)
	% <EAR (SE)	53 (6.8)	34 (4.5)	46 (2.5)	37 (1.9)
Vitamin A (µg RAE)	Mean (SE)	845 (52)	n/a	559 (15)	n/a
	% <EAR (SE)	40 (8.0)	n/a	46 (2.3)	n/a
Magnesium (mg)	Mean (SE)	363 (14)	378 (18)	270 (4)	284 (5)
	% <EAR (SE)	14† (3.2)	13† (3.0)	49 (2.2)	46 (2.1)
Calcium (mg)	Mean (SE)	1163 (72)	1361 (84)	869 (11)	948 (13)
	% <EAR (SE)	13† (4.6)	8† (2.8)	44 (1.8)	38 (1.8)
Copper (mg)	Mean (SE)	1.5 (0.09)	1.9 (0.18)	1.1 (0.02)	1.3 (0.03)
	% <EAR (SE)	7† (2.9)	11† (3.3)	11 (1.1)	10 (1.0)
Thiamin (mg)	Mean (SE)	1.80 (0.10)	2.77 (0.16)	1.41 (0.02)	3.01 (0.23)
	% <EAR (SE)	5† (2.4)	4† (2.2)	8 (1.6)	7 (1.3)
<u>Potentially underconsumed and overconsumed:</u>					
Vitamin D (µg)	Mean (SE)	6.3 (0.8)	23.4† (9.0)	4.0 (0.1)	13.2 (1.3)

	% <EAR (SE)	89† (5.5)	38 (6.2)	>97	73 (1.4)
	% >UL (SE)	<3	7† (6.3)	<3	<3
Folate (µg DFE)	Mean (SE)	665 (61)	1408 (86)	466 (8)	640 (15)
	% <EAR (SE)	9† (4.4)	7† (2.8)	18 (1.9)	14 (1.6)
Folic acid (µg)	Mean (SE)	224 (27)	660 (51)	158 (4)	261 (8)
	% >UL (SE)	<3	24 (6.2)	<3	<3
Zinc (mg)	Mean (SE)	12.8 (0.9)	24.5 (1.8)	9.6 (0.1)	12.0 (0.3)
	% <EAR (SE)	13† (6.0)	12† (5.1)	14 (1.9)	12 (2.1)
	% >UL (SE)	<3	11† (4.5)	<3	<3
Potentially overconsumed:					
Iron (mg)	Mean (SE)	17.0 (1.2)	35.9 (2.5)	12.4 (0.2)	16.2 (0.5)
	% >UL (SE)	<3	29† (5.3)	<3	<3
Sodium (mg)	Mean (SE)	3880 (167)	n/a	3191 (41)	n/a
	% >AI (SE)	>97	n/a	>97	n/a
	% >CDRR (SE)	97† (2.1)	n/a	85 (1.8)	n/a

AI=Adequate Intake; CDRR=Chronic Disease Risk Reduction; EAR=Estimated Average Requirement; UL=Tolerable Upper Intake Level

Underconsumed=A nutrient that is underconsumed by 5 percent or more of the population or specific groups relative to the EAR, AI, or other quantitative authoritative recommendations from the diet alone. Overconsumed=A nutrient that is consumed in potential excess of the UL, CDRR, or other quantitative authoritative recommendations by 5 percent or more of the population or in specific groups from the diet alone. For more information see: Table D 1.1 Framework to Begin the Process of Identifying Nutrients and Other Food Components as Underconsumed, Overconsumed, or of Potential Public Health Concern

¹Adapted from What We Eat in America, NHANES 2013-2016 Usual Nutrient Intake from Food and Beverages, and Total Usual Nutrient Intake from Food, Beverages, and Dietary Supplements, by Pregnancy and Lactation Status for Females 20 to 44 years of age ^{90,91}

²Includes all women who are not lactating and are not pregnant

†Estimate may be less reliable due to small sample size and/or large relative standard error

Maternal Dietary Patterns and Frequency of Eating

As stated in the 2015 Committee report, “foods are generally not consumed in isolation, but rather in various combinations over time. In addition, dietary components of an eating pattern can have interactive, synergistic, and potentially cumulative relationships, such that the eating pattern may be more predictive of overall health status and disease risk than individual foods or nutrients”.⁹²

The 2020 Committee was unable to draw conclusions regarding maternal dietary patterns or frequency of eating during lactation and PPWL due to a lack of evidence. In addition, either insufficient or no evidence was available to determine the relationship between overall maternal dietary patterns and any component of human milk composition. Intervention studies that experimentally manipulated dietary fat content showed differences in milk fat content and composition. Diets containing more than 35 percent of energy from fat and that were lower in carbohydrate during lactation were related to higher total fat in human milk when milk was collected in the maternal postprandial period. In addition, diets based on different macronutrient distributions were related to the relative proportions of saturated fat and MCFA in human milk, and of polyunsaturated fatty acids in human milk collected in the maternal postprandial period. The 2010 Committee investigated the association between maternal dietary intake of omega-3 fatty acids from seafood and breast milk composition and health outcomes in infants.⁹³ They concluded that moderate evidence indicates that increased maternal dietary intake of long-chain omega-3 fatty acids, in particular DHA, from at least 2 servings of seafood per week during pregnancy and lactation is associated with increased DHA levels in human milk (results for infant outcomes will be described below). These findings are consistent with systematic reviews showing that human milk fat composition is related to maternal dietary intake⁹⁴ and that maternal fish consumption is associated with DHA concentration in human milk.⁹⁵ Taken together, evidence indicates that maternal diet influences human milk fat content and composition and that women who are lactating can increase the DHA content of their milk by consuming seafood.

In terms of infant outcomes, no evidence was available to determine a relationship between dietary patterns during lactation and child developmental outcomes. In addition, evidence was lacking or insufficient to determine whether dietary patterns or consumption or avoidance of specific foods, even common allergens, are related to any of the four outcomes investigated (food allergy, atopic dermatitis, allergic rhinitis, or asthma). These findings are similar to those of the AAP Committee on Nutrition and Section on Allergy and Immunology,⁷⁶ which published a

clinical report that does not recommend maternal restriction during lactation as an atopy prevention strategy. Given current AAP recommendations and the systematic review results of this report, the Committee does not support restriction of potential allergens in maternal diets during lactation, unless the woman is allergic to the foods. Rather, the findings of the Committee support the need for women who are lactating to consume an overall healthy dietary pattern that includes these foods, as they are important sources of potentially underconsumed nutrients, such as calcium, choline, magnesium, and vitamin D.

While the Committee was unable to establish relationships between maternal dietary patterns during lactation and the outcomes investigated, the Committee did find evidence to recommend certain dietary patterns during *pregnancy* (see **Part D. Chapter 2: Food, Beverage, and Nutrient Consumption During Pregnancy**). The beneficial dietary patterns were higher in vegetables, fruits, whole grains, nuts, legumes, fish, and vegetable oils, and lower in processed meat and refined grains. These foods are consistent with those present in dietary patterns associated with lower overall chronic disease risk in women who are *not pregnant or lactating* (see **Part D. Chapter 1: Current Intakes of Foods, Beverages, and Nutrients** and **Part D. Chapter 8: Dietary Patterns**). Taken together, these findings support relatively consistent dietary patterns associated with healthy outcomes in women of reproductive age.

Food Pattern Modeling exercises showed that each of the 3 Food Patterns styles (**Healthy U.S.; Healthy Vegetarian or Healthy Mediterranean**) described in **Chapter 14: USDA Food Patterns for Individuals Ages 2 Years and Older** is expected to meet nutrient needs for women who are lactating with the possible exception of choline and vitamins A, D and E. Thus, these patterns will provide many of the nutrients that are commonly underconsumed by women who are lactating. Therefore, the Committee recommends that women who are lactating choose foods consistent with these dietary patterns and specifically incorporate foods that are rich in choline and vitamins A, D and E, such as seafood, eggs, fortified milk, nuts, seeds and vegetable oils (see **Part D. Chapter 1: Current Intakes of Foods, Beverages, and Nutrients**).

Seafood and Omega-3 Fatty Acid Supplements

The 2020 Committee evaluated the evidence as to whether maternal seafood consumption or omega-3 fatty acid supplementation, are related to neurocognitive outcomes in the child. The Committee concluded that no evidence is available to determine relationships between seafood consumption during lactation and any measure of neurocognitive development the Committee

assessed. The Committee also concluded that moderate evidence suggested that seafood intake *during pregnancy* may be associated favorably with measures of cognitive, language, and communication development in the child (see **Part D. Chapter 2**, Question 9). Although the Committee's systematic review did not identify evidence for associations between seafood consumption during lactation and neurocognitive outcomes in the child, seafood choices, particularly those that are low in methylmercury content, are important components of a healthy dietary pattern for women who are not pregnant as well as for those who are pregnant. Seafood may increase the DHA content of human milk and provides potential underconsumed nutrients for women who are lactating. Therefore, the Committee concurs with recommendations from the *2015-2020 Dietary Guidelines for Americans*,⁴⁸ the Food and Drug Administration, and the Environmental Protection Agency,⁹⁶ which are that women who are lactating should consume at least 8 and up to 12 ounces of a variety of seafood per week, from choices that are lower in methylmercury and higher in omega-3 fatty acids. Women who are lactating should limit intake of seafood choices that may be high in environmental contaminants.⁹⁷

In terms of omega-3 fatty acids from supplements during both pregnancy and lactation, or lactation alone, and neurocognitive outcomes in the child, the Committee evaluated the evidence from a total of 4 RCTs and 1 PCS, but only 1 RCT investigated supplementation during lactation alone. Findings were mixed, both within and between studies, and an insufficient number of studies were available to investigate the relationship between omega-3 fatty acid supplementation and developmental milestones in the child for many exposure-outcome pairs. Therefore, the Committee concluded that evidence was insufficient for cognitive, language, motor, and visual development outcomes and evidence was lacking for any other outcome investigated. As a result, the Committee is unable to make a specific recommendation about routine supplementation with omega-3 fatty acids during lactation.

Folic Acid Supplements

The Committee evaluated the associations between maternal folic acid intake from supplements and maternal folate status, human milk composition, and child neurodevelopmental outcomes. Moderate evidence indicated that in women who are lactating, consuming folate supplements resulted in higher serum and RBC folate concentrations, but no difference in human milk folate concentrations, compared to non-supplement users. No evidence was available for effects of folic acid from supplements on child neurodevelopmental outcomes.

Dietary intakes of folate are generally low and folate status may be compromised in some groups of women (see **Part D. Chapter 1**), so continued attention to intake is warranted. However, the RDA for folate is lower during lactation than during pregnancy. Based on maternal dietary intake data, 9 percent of women who are lactating have folate intakes less than the Estimated Average Requirement (EAR), which is reduced to 7 percent in those taking supplements. Conversely, 24 percent of women who are lactating and taking folic acid supplements have folate intakes exceeding the Tolerable Upper Intake Level (UL) (see **Part D. Chapter 1**).

These findings are in agreement with the analysis of nutrient intakes of women who are pregnant or lactating using NHANES 1999-2014 data.¹⁸ Supplement use among women who are lactating was high (70 percent) and more than half continued to use prenatal supplements. The folate and iron intake from supplements alone exceeded the RDA for these micronutrients by 2.4-fold and 3.7-fold, respectively.¹⁸ The Committee encourages women who are lactating to consume foods high in folate, including those fortified with folic acid, as part of a healthy dietary pattern. These foods may include fortified foods, dark green and leafy vegetables, and legumes. However, caution is warranted about continued use of prenatal supplements during lactation due to their high levels of folic acid and iron.

Other Nutrients from Supplements and/or Fortified Foods

This Committee did not study questions related to dietary supplements and/or fortified food sources of vitamins B₁₂ and D, iron, and iodine. Vitamin D is considered a nutrient of public health concern for women who are lactating (see **Part D. Chapter 1**). Over supplementation with iron and folic acid is a potential concern for women who are lactating. Including nutrients from dietary supplements, 29 percent and 24 percent of women who are lactating are exceeding recommendations for iron and folic acid, respectively (see **Part D. Chapter 1**). Given that these high intakes have not been directly linked with clinical outcomes, these are not designated of public health concern but warrant monitoring.

Less than 3 percent of women in who are lactating have vitamin B₁₂ intakes below the EAR.⁹⁸ However, low concentrations of vitamin B₁₂ have been reported in the serum and human milk of mothers consuming vegan dietary patterns without B₁₂ supplementation.⁷⁵

Iodine and vitamin D are nutrients that have few dietary sources, in the absence of fortification. Thus, consumption of fortified foods and supplements may be the primary way to achieve adequate intakes of these nutrients, though the addition of seafood to the diet (for

iodine) and some sunlight exposure (for vitamin D) will also help meet requirements. The current EAR for vitamin D for women who are lactating is 400 IU (10 µg).⁹⁹ Currently 89 percent of women in this population are consuming less than the EAR from food. When food and supplements are both considered, 38 percent of women who are lactating are still consuming less than the EAR.⁹⁸ Vitamin D supplementation in the 400 to 2,000 IU (10 to 50 µg) range is not sufficient to produce human milk concentrations that are adequate to meet the vitamin requirement of an exclusively breastfed infant. Daily maternal vitamin D supplementation at 6,400 IU was required to achieve milk concentrations high enough to meet the infant AI of 400 IU (10 µg).¹⁰⁰ Given the importance of these nutrients to achieve optimal maternal nutrient status and human milk composition for the recipient infant, and the fact that they are all nutrients of concern among females of reproductive age, additional attention should be given to these nutrients during the development of future Dietary Guidelines.

Strategies for Women Who Are Lactating

A variety of strategies can help women who are lactating achieve food and nutrient intakes that promote optimal outcomes for them and their children. These strategies include:

1. Encourage women who are lactating to consume a wide variety of foods that are consistent with the dietary patterns described in **Chapter 14: USDA Food Patterns for Individuals Ages 2 Years and Older**
2. Encourage consumption of foods and beverages that are good sources of potentially underconsumed nutrients identified in **Part D. Chapter 1** or that are lower than recommended for women who are lactating in the USDA Food Patterns, including choline, magnesium, protein, fiber, and vitamins A, D, and E.
3. Encourage women to discontinue the use of prenatal high iron dose supplements during lactation unless they are medically indicated, as these supplements are usually formulated to meet the high iron requirements of pregnant women, not to meet the nutritional requirements for lactating women and can therefore result in iron intakes above the UL.
4. Encourage women to not avoid potential allergenic foods during lactation, unless it is medically indicated to protect the mother's health.
5. Encourage women to follow guidance from the 2015 Dietary Guidelines Advisory Committee⁹² and the AAP¹⁰¹ that, "women who are breastfeeding should consult with

their health care provider regarding alcohol consumption.” This Committee did not review evidence regarding alcoholic beverage consumption by lactating women, but supports this prior guidance.

6. Encourage women to follow guidance from the 2015 Dietary Guidelines Advisory Committee⁹² that “...those who are breastfeeding should consult their health care providers for advice concerning caffeine consumption.” This Committee did not review evidence regarding caffeine consumption. Insufficient high-quality data are available to make evidence-based recommendations on safe maternal caffeine consumption.¹⁰² Lactating women who are consuming caffeine in foods or beverages may want to monitor the behavior of their infant for fussiness, jitteriness, or poor sleep patterns and adjust their caffeine intake accordingly. The Committee supports this guidance.
7. Encourage women who are breastfeeding to consume seafood in accordance with recommendations by the *2015-2020 Dietary Guidelines for Americans*,⁴⁸ the Food and Drug Administration, and the Environmental Protection Agency: at least 8 and up to 12 ounces of a variety of seafood per week, from choices that are lower in methylmercury and higher in omega-3 fatty acids.
8. Encourage women to maintain a healthy pre-pregnancy weight, achieve appropriate weight gain during pregnancy, initiate and maintain breastfeeding throughout their child’s infancy, and return to a healthy weight during the postpartum period. This Committee did not review evidence regarding relationships of maternal BMI or GWG to lactation success; however, existing evidence shows that high prepregnancy BMI and excess GWG are risk factors for suboptimal breastfeeding outcomes.¹⁰³⁻¹⁰⁵ The *2010 Dietary Guidelines for Americans* stated⁸⁸: “The development of standardized approaches to promote healthy pre-pregnancy weight, appropriate weight gain during pregnancy, the initiation and maintenance of breastfeeding during infancy, and a return to healthy weight status postpartum can help prevent overweight and obesity throughout the life span.” This Committee supports these recommendations.

Support for Federal Programs

1. The Committee supports efforts by Federal programs, such as the Special Supplemental Nutrition Program for Women, Infants, and Children (WIC), that serve women who are lactating should encourage participants to take advantage of available nutrition

counseling services. In addition, policy, systems, and environmental change strategies and competitive pricing of healthy food and beverage choices can help ensure that women of all economic strata can afford them. Similar healthy foods and beverages should be routinely stocked and distributed by food pantries and other food assistance venues and recommended by food assistance programs.

2. Given the documented health benefits for the mother and infant, the Committee supports broader implementation of Federal programs that promote, protect and support breastfeeding.¹⁰ While this Committee did not review evidence regarding relationships of lactation to maternal health benefits, existing evidence shows that lactation confers short- and long-term maternal health benefits, which can be influenced by the duration of lactation.¹⁰ The 2010 Dietary Guidelines Advisory Committee investigated the relationship between breastfeeding and postpartum weight change and concluded that a moderate body of consistent evidence shows that breastfeeding may be associated with maternal PPWL.⁹³
3. The Committee supports further development of surveillance systems and databases to report food and beverage intakes of women who are lactating. These systems and databases should represent diverse subgroups of women. They also should include food and beverage composition and supplement data that can show how fortified foods and supplemental sources of nutrients contribute to overall nutrient intake and dietary quality during lactation, and should contain data on nutrient composition of human milk. In addition, the ability to link maternal dietary intake data to that of their children would strengthen the ability to determine how maternal dietary patterns and intakes affect child health and development. The Committee encourages implementation of surveillance systems to gather more information about the contextual aspects of diet, such as the frequency and/or timing of food and beverage consumption and the impacts of food security and economic status on food intake. This information is important to fully understand how and why women consume specific foods and beverages before and during lactation.

Need for Future Research

Despite the importance of the questions examined in this chapter for the long-term health of the mother and child, the available evidence for most questions was insufficient to form

conclusion statements. Many questions remain to be answered regarding the content and pattern of the diet of women during lactation and the influence on PPWL, human milk composition and quantity, and child outcomes, in addition to other questions that the Committee was not asked to address. The Committee supports ongoing Federal initiatives to fill these gaps in the literature. These initiatives began with a 2017 workshop on “Human Milk Composition: Biological, Environmental, Nutritional, and Methodological Considerations.” The consensus of the workshop attendees was that the “limited scope of Human Milk (HM) research initiatives has led to a lack of robust estimates of the composition and volume of HM consumed and, consequently, missed opportunities to improve maternal and infant health.¹⁰⁶” Additional research in this area is essential, and a number of recommendations for research on these important topics are discussed in **Part E. Future Directions**.

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PART D. CHAPTER 4: DURATION, FREQUENCY, AND VOLUME OF EXCLUSIVE HUMAN MILK AND/OR INFANT FORMULA FEEDING

INTRODUCTION

Birth to 24 months of postnatal life is a critical phase of the first 1,000 days of life, and how and what infants are fed contributes to developmental programming.¹ Breastfeeding is the biological norm and provides health benefits for both the mother and the infant.² Infants fed human milk have reduced risks of communicable diseases in infancy and non-communicable diseases later in life, including ear, gastrointestinal, and respiratory infections, asthma, and sudden infant death syndrome, compared to infants who were not breastfed or, in some cases, breastfed for shorter durations.³⁻⁶ Dissimilarities in growth trajectories have been documented in breast- vs formula-fed infants in the first year of life.^{7,8} Breastfeeding has been associated with a 12 percent to 14 percent reduction in the risk of childhood obesity,^{6,9} although associations are substantially attenuated in studies that have been able to control for important confounding factors (such as maternal socio-economic status) and in studies comparing siblings within the same family.¹⁰

The American Academy of Pediatrics (AAP) recommends exclusive breastfeeding for about the first 6 months of life and continued breastfeeding with complementary foods through at least the first year of life.^{3,11} The 2020 Healthy People breastfeeding goals are that 81.9 percent of infants will initiate breastfeeding at birth and 60.6 percent and 34.1 percent will continue any breastfeeding at 6 and 12 months, respectively.¹² Surveillance data from the 2017-2018 National Immunization Survey, for infants born in 2016, show that national breastfeeding rates are generally meeting these goals, with 83.8 percent initiation and 57.3 percent and 36.2 percent breastfeeding at 6 and 12 months, respectively.¹³ Likewise, exclusive breastfeeding rates of 47.5 percent and 25.4 percent at 3 and 6 months are meeting the 2020 Healthy People targets of 46.2 percent and 25.5 percent, respectively.¹² However, these percentages represent national data and marked disparities in infant feeding exist in the United States based on geography, income, education, and race and ethnicity.¹⁴

For infants who are not exclusively breastfed, the AAP recommends the use of iron-fortified infant formula for healthy infants for the first year of life.¹⁵ Approximately 75 percent of infants in the United States are receiving formula at age 6 months: 42.7 percent are exclusively formula-fed, and 31.9 percent receive human milk supplemented with infant formula (mixed-feeding).¹³

Thus, in the first year of life, infants may consume human milk and/or infant formula at varying levels of exclusivity, timing, and duration, which may influence growth and body composition, nutritional status, neurocognitive development, and both short-term and long-term health outcomes, including the risk of diabetes, cardiovascular disease (CVD), and food allergies and atopic diseases. This chapter describes the findings of the reviews conducted to examine these relationships.

Background

Previous editions of the *Dietary Guidelines for Americans*, since 1990, began at age 2 years. The systematic reviews included in this report of the 2020 Dietary Guidelines Advisory Committee are the first to examine questions that specifically explore relationships between feeding in the first 2 years of life and short and long-term health outcomes. This chapter focuses on the duration, frequency, and volume of exclusive human milk and/or infant formula consumption. Other chapters report evidence on the timing and composition of complementary feeding (**Part D. Chapter 5: Foods and Beverages Consumed during Infancy and Toddlerhood**) and iron and vitamin D supplements (**Part D. Chapter 6: Nutrients from Dietary Supplements During Infancy and Toddlerhood**) with respect to child outcomes.

The nutrient composition and biological context of human milk and infant formula are dramatically different. Human milk is a complex biological fluid that is the product of maternal genetics, physiological status, dietary intake (for some nutrients), and environmental exposures.¹⁶ The nutrient composition of human milk changes within a feeding and across the course of lactation, and transmits flavors from the maternal diet.¹⁷ In addition to providing nutrients to the infant, human milk provides a bridge from the intrauterine to extrauterine environment by immunological protection through bioactive proteins, antibodies, cytokines, immune cells, and human milk oligosaccharides (HMO).^{18,19} Human milk also contains microbes²⁰ and HMO that seed and feed the infant gut microbiota,^{21,22} which, in turn, educates the developing immune system.²¹⁻²⁴ Recent studies have shown associations between microbiome composition in early life and health outcomes that are also linked with human milk feeding, including growth and body composition^{25,26} and atopic diseases.^{27,28} Because the microbiome of breast and formula-fed infants differs,^{21,22} these observations suggest that the microbiome may be a mediator or modulator of the associations between human milk feeding and these health outcomes. For neurocognitive development, links are proposed through the microbiome-gut-brain axis,^{29,30} and compelling preclinical data support this hypothesis.³¹

However, human studies have not shown consistent associations between infant feeding, microbiome composition, and neurocognitive outcomes.³² Therefore, more research is needed in this area to determine causality.

Human milk meets all the nutritional requirements of the breastfed infant for the first 6 months of life, with the exception of vitamin D. As explained in **Part D. Chapter 6: Nutrients from Dietary Supplements During Infancy and Toddlerhood**, vitamin D supplements are recommended for breastfed infants.³³ Infant formulas are designed to meet the nutritional needs of human infants in the first year of life and their nutrient content is regulated by law.^{34,35} The nutrient content and composition of infant formula differs from that of human milk, which can lead to differences in nutrient absorption and nutrient status. For example, infant formulas contain higher protein content than does human milk³⁶ and most minerals and trace elements also are present in higher concentrations in formula than in human milk and in different forms (e.g., salts vs bound to carrier proteins).³⁷

Human milk consumption also has been associated with reduced risk of developing certain atopic diseases. Atopic diseases (atopic dermatitis, food allergies, allergic rhinitis, and asthma) occur due to environmental triggers in genetically susceptible individuals.³⁸ Over the past 2 decades, atopic diseases have emerged as among the most common chronic conditions in childhood. Skin sensitization presenting as atopic dermatitis is often the first manifestation of atopic disease and often appears to precede the subsequent development of the other allergic conditions.³⁹ For example, about 30 percent of all children with atopic dermatitis have a food allergy, and a child with moderate to severe atopic dermatitis has a 50 percent risk of developing asthma, either concomitantly or in later life.³⁹ Although induction of tolerance can be achieved for selected foods and other environmental antigens, for those who remain symptomatic, the management of symptoms can significantly reduce quality of life for the individuals and their families. Therefore, a major focus in control of allergic diseases has been on primary prevention.⁴⁰ Given that human milk contains immunomodulatory components, and that cow milk is one of the most common food allergens in infancy, it has been hypothesized that breastfed infants would have a lower incidence of atopic diseases than formula-fed infants. Evidence for associations between breastfeeding, components of human milk, and the development of atopic diseases has been conflicting, however,⁴¹ and previous reviews have not addressed exclusivity, timing, and duration of human milk exposure.

The 2020 Committee also investigated links between breastfeeding and risk of diabetes mellitus (DM) and CVD. Type 1 and type 2 diabetes are among the most common chronic diseases in people younger than age 20 years.⁴² From 2002 to 2012, type 1 and type 2 diabetes

incidence increased 1.4 percent and 7.1 percent, respectively, among U.S. youths. Onset of diabetes in childhood and adolescence is associated with numerous short- and long-term complications, including damage to the kidneys (nephropathy), eyes (retinopathy), and nerves (peripheral neuropathy).⁴² Type 1 diabetes results from the autoimmune destruction of the insulin-secreting pancreatic islets of Langerhans.⁴³ Environmental factors, including infant diet, are proposed to influence the risk of type 1 diabetes in genetically susceptible individuals.⁴⁴ A meta-analysis of data from approximately 10,000 individuals in 43 studies demonstrated that compared to never being breastfed, breastfeeding exclusively for more than the first 2 weeks of life reduced the risk of childhood onset type 1 diabetes by 14 percent (12 studies; odds ratio [OR]=0.86, 95% confidence interval [CI]: 0.75, 0.99), based upon the highest quality studies. Pooled analysis provided little evidence that being exclusively breastfed for less than 2 weeks or longer than 6 months or non-exclusive breastfeeding reduced the risk of type 1 diabetes.⁴⁵ Type 2 diabetes is a disorder of insulin resistance and its increased prevalence has tracked with the increase in childhood obesity.⁴⁶ Two systematic reviews^{47,48} have suggested that breastfeeding is associated with a lower risk of type 2 diabetes, but they lacked detailed investigations into duration and exclusivity of human milk feeding.

According to the World Health Organization,⁴⁹ CVD is the leading cause of death globally and an estimated 17.9 million lives are lost each year to CVD. In the United States, CVD accounts for 1 in every 4 deaths, resulting in 1 person dying every 37 seconds from CVD-related outcomes.⁵⁰ Four out of 5 CVD deaths are due to heart attacks and strokes, and one-third of these deaths occur prematurely in people younger than age 70 years.⁴⁹ Among younger individuals (ages 18 to 50 years), the incidence of CVD over the past 2 decades has either been steady or has increased.⁵¹ Although CVD outcomes typically affect adults, risk factors can begin as early as infancy⁵² and breastfeeding has been postulated to be protective against CVD outcomes.⁵³

Two new systematic reviews were conducted by the 2020 Committee to examine the evidence on overweight and obesity and on nutrient status. In addition, systematic reviews completed by the U.S. Departments of Agriculture and of Health and Human Services as part of the Pregnancy and Birth to 24 Months (P/B-24) Project^{54,55} that examined infant milk-feeding practices and risk of atopic outcomes,⁵⁶ diabetes,⁵⁷ and CVD⁵⁸ were adopted by the 2020 Committee. Due to time constraints, the Committee was unable to investigate the relationship between the duration, frequency, and volume of exclusive human milk and/or infant formula consumption and developmental outcomes.

LIST OF QUESTIONS

1. What is the relationship between the duration, frequency, and volume of exclusive human milk and/or infant formula consumption and overweight and obesity?
2. What is the relationship between the duration, frequency, and volume of exclusive human milk and/or infant formula consumption and long-term health outcomes?
3. What is the relationship between the duration, frequency, and volume of exclusive human milk and/or infant formula consumption and nutrient status?
4. What is the relationship between the duration, frequency, and volume of exclusive human milk and/or infant formula consumption and food allergies and atopic allergic diseases?

METHODOLOGY

All questions in this chapter were answered using systematic reviews conducted with support from USDA's Nutrition Evidence Systematic Review (NESR) team. NESR's systematic review methodology provided a rigorous, consistent, and transparent process for the Committee to search for, evaluate, analyze, and synthesize evidence.

Questions 1 and 3 in this chapter were answered using new NESR systematic reviews. The Committee developed a systematic review protocol for each question, which described how the Committee would apply NESR's methodology to answer the question. Each protocol included an analytic framework and inclusion and exclusion criteria that were used to guide identification of the most relevant body of evidence to use in answering each systematic review question. Each analytic framework outlined core elements of the systematic review question (i.e., population; intervention and/or exposure and comparator [i.e., the alternative being compared to the intervention or exposure]; and outcomes), and included definitions for key terms, key confounders, and other factors to be considered when reviewing the evidence. The inclusion and exclusion criteria were selected, up front, to operationalize the elements of the analytic framework, and specify what made a study relevant for each systematic review question. Next, a literature search was conducted to identify all potentially relevant articles, and those articles were screened by two NESR analysts independently based on the criteria selected by the Committee. For each included article, data were extracted and risk of bias assessed. The Committee qualitatively synthesized the body of evidence to inform development of a conclusion statement(s), and graded the strength of evidence using pre-established criteria

for risk of bias, consistency, directness, precision, and generalizability. Finally, recommendations for future research were identified. A detailed description of NESR's systematic review methodology is provided in **Part C. Methodology**, including standard inclusion and exclusion criteria applied in many of the Committee's systematic reviews. Complete documentation of each systematic review, including the protocol, is available on the following website: nesr.usda.gov/2020-dietary-guidelines-advisory-committee-systematic-reviews. Below is a summary of the unique elements of the protocols developed to answer Questions 1 and 3 on the duration, frequency, and volume of exclusive human milk and/or infant formula consumption.

For both Questions 1 and 3, the interventions or exposures were examined in healthy full-term infants (birth to 24 months). The interventions or exposures of interest, and their comparators, were:

- Ever consuming human milk (i.e., any amount of human milk feeding) compared with never consuming human milk,
- Different durations of any human milk consumption among infants fed human milk,
- Different durations of exclusive human milk consumption before the introduction of infant formula, and
- Different intensities/proportions/amounts of human milk consumed by mixed-fed infants.

These interventions or exposures and their comparators were selected to align with the first feeding decisions that caregivers make. First, caregivers must decide whether or not to feed human milk. For caregivers who feed human milk, the next decisions are how long to feed human milk at all and how long to feed human milk exclusively, which align with the second and third comparisons. In this Chapter, duration of exclusive human milk consumption before the introduction of infant formula (not complementary foods and beverages) was examined, to avoid overlap with systematic review Questions 1 and 3 in **Part D. Chapter 5: Foods and Beverages Consumed During Infancy and Toddlerhood**, which examined how the timing of the introduction of complementary foods is associated with various outcomes (growth, size, and body composition and nutrient status, respectively). The fourth comparison aligns with decisions about the supplementation of human milk with infant formula.

For Question 1, additional comparisons of interest were specified:

- Different intensities, proportions, or amounts of human milk consumed at the breast vs by bottle in infants fed human milk as their only source of milk, and

- Consuming human milk or infant formula (i.e., a single substance) compared with human milk and infant formula (i.e., both substances) during a single feeding session.

The first comparison aligns with decisions caregivers make about the feeding mode they use to feed human milk (i.e., breast, bottle, or both). The second comparison aligns with decisions caregivers may make about “topping up” a human milk feeding with infant formula.

In these systematic reviews, *human milk* refers to mother’s own milk provided at the breast (i.e., nursing) or expressed and fed fresh or after refrigeration or freezing. Examinations of donor milk were not included in these reviews. *Exclusive human milk consumption* refers to consuming human milk alone and not in combination with infant formula or complementary foods and beverages. This definition includes the WHO definitions of *exclusive* and *predominant breastfeeding*, which permit limited quantities of: a) drops or syrups containing vitamins, minerals, or medicines, b) water and water-based drinks, such as sweetened water and teas, c) fruit juice, d) oral rehydration salts solution, and e) ritual fluids.⁵⁹ *Infant formula* refers to commercially prepared infant formula meeting the FDA and/or Codex Alimentarius^{34,35} international food standards. *Mixed feeding* refers to feeding human milk and infant formula but not complementary foods or beverages such as cow milk. *Complementary foods and beverages* refers to foods and beverages other than human milk or infant formula (liquids, semisolids, and solids) provided to an infant or young child to provide nutrients and energy.

For Question 1, the outcomes of interest were divided into 2 groups:

- In all studies, the outcomes of interest were overweight and/or obesity from 2 years of age through adulthood.
- In a subset of studies, which conducted within-family analyses of siblings, additional outcomes of interest were specified: rapid weight gain from birth to 24 months and body mass index (BMI) and measures of body composition (e.g., percent fat mass, waist-to-hip ratio) from age 2 years through adulthood. The within-family analyses of siblings compared discordant siblings (i.e., siblings from the same family who were fed differently during infancy, or who had a different outcome status, or both). The Committee gave such studies special consideration because they reduce the risk of bias from confounding from genetic and environmental factors (i.e., factors that siblings share). Infant-feeding research can be prone to bias from confounding because infant feeding is strongly socially patterned. Therefore, analyses that reduce bias from confounding are important.

Initially, the outcomes of interest included measures of growth, size, and body composition from birth through adulthood for all studies. The outcomes of interest, however, were modified to focus only on overweight and obesity starting at 2 years of age, because the Committee determined that these outcomes were of the greatest public health importance. In addition, the Committee recognized that the relationship between infant feeding and growth and size outcomes was already examined by an expert panel for the CDC.⁶⁰ The additional outcomes of interest were still included for the within-family studies of discordant siblings (listed above), because it was thought that they could provide supporting evidence, from a set of studies with reduced risk of bias from confounding, for the conclusions drawn about overweight and obesity from the general body of evidence.

For Question 3, the outcomes of interest were iron status, iron deficiency and anemia, zinc status, iodine status, vitamin D status, vitamin B₁₂ status, and fatty acid status from birth to 24 months.

When establishing inclusion and exclusion criteria for the systematic reviews to address Questions 1 and 3, the Committee used standard NESR criteria for study design, publication status, language of publication, study participants, and health status of study participants and country. The Committee also established criteria for the size of study groups for both questions. The criterion on size of study groups required 30 participants per group, or a power analysis indicating that the study was appropriately powered for the outcome(s) of interest.

For Question 1, the Committee added a criterion for confounders that specified that studies would be excluded if they did not account for any of the key confounders selected by the Committee (listed in the analytic framework). Research examining the relationship between infant feeding and overweight and obesity is mostly observational and prone to bias from confounding. Therefore, this criterion was selected to help ensure that only the strongest studies that attempted to reduce the risk of confounding bias would be examined. For within-family studies of discordant siblings, cross-sectional studies were included because of the unique attributes of within-family analyses of siblings related to the reduced risk of confounding.

Two separate literature searches were conducted to identify all potentially relevant articles for Questions 1 and 3. The first search was from the P/B-24 Project (nesr.usda.gov/infant-milk-feeding-practices-technical-expert-collaborative). During the Project, a single literature search was conducted to identify potential studies published from January 1980 to March 2016 for the family of reviews on human milk and infant formula consumption and health outcomes. However, some of the intended reviews, including nutrient status and overweight and obesity, were not completed before the end of the Project. Therefore, the 2020 Committee was able to

use that search to identify studies for their reviews on those outcomes. The second search was done to update the first search and identify relevant articles published from January 2016 to September 2019.

Results of both literature searches were screened by NESR analysts using the inclusion and exclusion criteria established in the Committee's protocols for Questions 1 and 3, and described herein. Initially, the protocols for both Questions 1 and 3 specified that literature published between January 1980 and September 2019 would be included. The publication date criterion for Question 1 was subsequently modified to include studies published between January 2011 and September 2019. The Committee acknowledged that a number of systematic reviews have already been published on this topic.¹⁰ However, such reviews have not captured the most recently published studies. Therefore, the Committee selected their date range in order to fill that gap in evidence. Sibling studies published from January 1980 to September 2019 were included because these were considered to be a unique set of studies not previously examined as a cohesive unit.

Questions 2 and 4 in this chapter were answered using existing systematic reviews that were previously conducted by NESR as part of the P/B-24 Project, which was completed in 2019. The conclusion statements that answer these questions were taken directly from the existing systematic reviews and were not updated to match the slightly different phrasing conventions used by the Committee to write conclusion statements for the new systematic reviews (Questions 1 and 3), to prevent inadvertent changes to the meaning of the conclusion statements. A description of the process the Committee used to determine that these existing systematic reviews were relevant to their questions and timely enough to not require updating is provided in **Part C. Methodology**. In addition, detailed information about methodology used to complete these systematic reviews can be found at the following website:

nesr.usda.gov/project-specific-overview-pb-24-0.

REVIEW OF THE SCIENCE

Question 1. What is the relationship between the duration, frequency, and volume of exclusive human milk and/or infant formula consumption and overweight and obesity?

Approach to Answering Question: NESR systematic review

Conclusion Statements and Grades

Ever vs Never Consuming Human Milk

Moderate evidence from observational studies indicates that ever, compared with never, consuming human milk is associated with lower risk of overweight and obesity at ages 2 years and older, particularly if the duration of human milk consumption is 6 months or longer. Grade: Moderate

Duration of Any Human Milk Consumption Among Infants Fed Human Milk

Insufficient evidence is available to determine the relationship between the duration of any human milk consumption, among infants fed human milk, and overweight and obesity at ages 2 years and older; the available evidence was inconsistent. Grade: Grade Not Assignable

Duration of Exclusive Human Milk Consumption Before the Introduction of Infant Formula

Insufficient evidence is available to determine the relationship between the duration of exclusive human milk consumption before the introduction of infant formula and overweight and obesity at ages 2 years and older. Grade: Grade Not Assignable

Intensity, Proportion, or Amount of Human Milk Consumed by Mixed-Fed Infants

No evidence is available to determine the relationship between the intensity, proportion, or amount of human milk consumed by mixed-fed infants and overweight and obesity at ages 2 years and older. Grade: Grade Not Assignable

Intensity, Proportion, or Amount of Human Milk Consumed at the Breast vs by Bottle in Infants Fed Human Milk as their Only Source of Milk

No evidence is available to determine the relationship between the intensity, proportion, or amount of human milk consumed at the breast vs by bottle in infants fed human milk as their

only source of milk and overweight and obesity at ages 2 years and older. Grade: Grade Not Assignable

Consuming Human Milk or Infant Formula (i.e., a Single Substance) vs Human Milk and Infant Formula (i.e., Both Substances) During a Single Feeding Session

No evidence is available to determine the relationship between consuming human milk or infant formula (i.e., a single substance) vs human milk and infant formula (i.e., both substances, e.g., “topping up”) during a single feeding session and overweight and obesity at ages 2 years and older. Grade: Grade Not Assignable

Summary of the Evidence

- This systematic review examined the relationship between the duration, frequency, and volume of exclusive human milk and/or infant formula consumption and overweight and obesity. Specifically, this systematic review examined available evidence that compared:
 - Infants who ever consumed milk (i.e., any amount of human milk) with infants who never consumed human milk,
 - Infants who consumed human milk (i.e., any amount of human milk) for different durations,
 - Infants who consumed human milk exclusively for different durations before the introduction of infant formula,
 - Mixed-fed infants (i.e., consuming both human milk and infant formula, but not complementary foods and beverages) who consumed different intensities, proportions, or amounts of human milk,
 - Infants who consumed human milk as their only source of milk and who consumed different intensities, proportions, or amounts of human milk at the breast vs by bottle, and
 - Mixed-fed infants who consumed a single substance at a single feeding session (i.e., either human milk or infant formula) with mixed-fed infants who consumed both substances at a single feeding session (e.g., “topping up”).
- The outcomes of interest were overweight and obesity at ages 2 years and older. Available evidence about rapid weight gain from birth to 24 months and BMI and body composition at ages 2 years and older also were examined from studies that conducted within-family

analyses of discordant siblings (i.e., siblings fed differently during infancy, siblings with differences in outcome status, or both).

- This review identified 42 articles that met the inclusion criteria.⁶¹⁻¹⁰² Thirty of the 42 articles presented evidence about ever, compared with never, consuming human milk, and 21 of the 42 articles presented evidence about different durations of any human milk consumption (i.e., some articles presented evidence about both exposures).
- The 30 articles that examined the relationship between ever, compared with never, consuming human milk, and overweight and/or obesity at ages 2 years and older presented evidence from 21 independent cohorts.
 - The evidence had strong consistency. Fourteen of the 21 studies found significant associations and all of them showed that ever, compared with never, consuming human milk is associated with lower risk of overweight and/or obesity at ages 2 years and older. One study showed a marginal association in the same direction, and some of the remaining studies may have lacked statistically significant associations because they were underpowered.
 - The evidence available from 5 of 7 studies that compared infants who consumed human milk for different durations with infants who never consumed human milk suggested that a longer duration of human milk consumption (e.g., ≥ 6 months) is most likely to be associated with reduced risk of overweight or obesity, compared to never consuming human milk.
 - In 4 studies, the investigators conducted within-family analyses of siblings, which are designed to reduce bias due to confounding from genetic and environmental factors (i.e., because the siblings share these factors). Some of these analyses showed an attenuation of the significant associations found in full-sample analyses, suggesting that confounding may explain some of the association between ever, compared with never, consuming human milk and overweight and/or obesity at ages 2 years and older.
 - The ability to draw stronger conclusions was primarily limited by the potential for confounding in a body of evidence made up of observational studies, and some concerns about the generalizability of the evidence from the studies conducted outside the United States (because U.S. populations may have higher risk of overweight and obesity than do the populations sampled for the non-U.S. studies).
- The 21 articles that examined the relationship between the duration of any human milk consumption, among infants fed human milk, and overweight and/or obesity at ages 2 years

and older presented evidence from 1 cluster randomized controlled trial (RCT) and 18 independent cohorts.

- The evidence was inconclusive. Nine of the 19 studies reported significant associations, but they were inconsistent in direction. In addition, potential bias from confounding and the limited generalizability of the evidence from the non-U.S. studies raised concerns (in particular because the prevalence of obesity among the participants of the cluster RCT, conducted in Belarus, was much lower than the prevalence among youth in the United States).
- Evidence available from 2 studies was insufficient to determine the relationship between the duration of exclusive human milk consumption before the introduction of infant formula and overweight and/or obesity at ages 2 years and older.
- No studies were identified that examined the intensity, proportion, or amount of human milk consumed by mixed-fed infants, the intensity, proportion, or amount of human milk consumed at the breast vs by bottle, or the consumption of a single substance (i.e., either human milk or infant formula) vs both human milk and infant formula during a single feeding session.

For additional details on this body of evidence, visit: nesr.usda.gov/2020-dietary-guidelines-advisory-committee-systematic-reviews/birth-24-months-subcommittee/human-milk-infant-formula-overweight-obesity

Question 2. What is the relationship between the duration, frequency, and volume of exclusive human milk and/or infant formula consumption and long-term health outcomes?

Approach to Answering Question: Existing NESR systematic reviews

Conclusion Statements and Grades

Diabetes

Ever vs Never Consuming Human Milk

Limited evidence from observational studies suggests that never versus ever being fed human milk is associated with higher risk of type 1 diabetes. Grade: Limited

There is insufficient evidence to determine whether or not there is a relationship between never versus ever feeding human milk and type 2 diabetes, prediabetes, fasting glucose, HbA1c, insulin resistance, and glucose tolerance throughout the lifespan. Grade: Grade Not Assignable

Duration of Any Human Milk Consumption Among Infants Fed Human Milk

Moderate evidence from observational studies suggests that, among infants fed some amount of human milk, shorter versus longer durations of any human milk feeding are associated with higher risk of type 1 diabetes. Grade: Moderate

Limited but consistent evidence suggests that the duration of any human milk feeding is not associated with fasting glucose or insulin resistance in childhood or during the transition from childhood into adolescence. Grade: Limited

There is insufficient evidence to determine whether or not there is a relationship between shorter versus longer durations of any human milk feeding and type 2 diabetes, prediabetes, or HbA1C throughout the lifespan, and fasting glucose and insulin resistance in adulthood. Grade: Grade Not Assignable

Duration of Exclusive Human Milk Consumption

Limited evidence from observational studies suggests that shorter versus longer durations of exclusive human milk feeding are associated with higher risk of type 1 diabetes. Grade: Limited

Limited evidence, from a single study that used a strong design, also suggests that the duration of exclusive human milk feeding is not associated with fasting glucose or insulin resistance at 11.5 years of age. Grade: Limited

There is insufficient evidence to determine whether or not there is a relationship between shorter versus longer durations of exclusive human milk feeding and type 2 diabetes, prediabetes, and HbA1c throughout the lifespan, and fasting glucose and insulin resistance at ages other than 11.5 years. Grade: Grade Not Assignable

Intensity, Proportion, or Amount of Human Milk Consumed by Mixed-Fed Infants

There is insufficient evidence to determine whether or not there is a relationship between feeding a lower versus higher intensity, proportion, or amount of human milk to mixed-fed infants and diabetes outcomes in offspring. Grade: Grade Not Assignable

Cardiovascular Disease

Ever vs Never Consuming Human Milk

Limited evidence suggests that never versus ever being fed human milk is associated with higher blood pressure, within a normal range, at 6 to 7 years of age. Grade: Limited

Evidence about the relationship of never versus ever being fed human milk with blood lipids in childhood was inconclusive, and there was insufficient evidence to determine the relationship of never versus ever being fed human milk with endpoint cardiovascular disease outcomes, blood pressure and blood lipids in adolescence or adulthood, metabolic syndrome, and arterial stiffness. Grade: Grade Not Assignable

Duration of Any Human Milk Consumption Among Infants Fed Human Milk

Moderate evidence suggests that there is no association between the duration of any human milk feeding and blood pressure in childhood. Grade: Moderate

Evidence about the relationship of shorter versus longer durations of any human milk feeding with blood lipids in childhood and adulthood and with metabolic syndrome was inconclusive, and there was insufficient evidence to determine the relationship of shorter versus longer durations of any human milk feeding with endpoint cardiovascular disease outcomes, blood pressure in adolescence or adulthood, blood lipids in adolescence, and arterial stiffness. Grade: Grade Not Assignable

Duration of Exclusive Human Milk Consumption

Limited evidence suggests that there is no association between the duration of exclusive human milk feeding and blood pressure in childhood or metabolic syndrome at 11.5 years of age. Most of the evidence comes from just one non-U.S. sample assessed using a strong study design. Grade: Limited

There was insufficient evidence to determine the relationship of shorter versus longer durations of exclusive human milk feeding with endpoint cardiovascular disease outcomes, blood pressure in adolescence or adulthood, blood lipids, and metabolic syndrome at ages other than 11.5 years. Grade: Grade Not Assignable

Intensity, Proportion, or Amount of Human Milk Consumed by Mixed-Fed Infants

There is no evidence to determine whether or not there is a relationship between feeding a lower versus higher intensity, proportion, or amount of human milk to mixed-fed infants and cardiovascular disease outcomes in offspring. Grade: Grade Not Assignable

Summary of the Evidence

Diabetes

Ever vs Never Consuming Human Milk

- This systematic review examined comparisons of infants who were never fed human milk with infants who were ever fed human milk (i.e., any amount of human milk feeding).
- This systematic review examined available evidence related to diabetes outcomes in offspring, including fasting glucose, HbA1C, glucose tolerance/insulin resistance, and the incidence and prevalence of prediabetes, type 1 diabetes, and type 2 diabetes.
- Twenty-one articles met the inclusion criteria for this systematic review,⁵⁷ including 16 with evidence about type 1 diabetes, 2 with evidence about type 2 diabetes, and 3 with evidence about the intermediate diabetes outcomes of fasting glucose, HbA1C, and insulin resistance.
- Evidence about the association between never vs ever feeding human milk and higher risk of type 1 diabetes was limited. Across the 15 independent studies (16 articles) that examined type 1 diabetes, 6 found statistically significant associations. The primary difference between the studies that did and did not report significant associations was statistical power. With one exception, the statistically significant associations suggested that never vs ever being fed human milk is associated with higher risk of type 1 diabetes. The ability to draw stronger conclusions was primarily limited by insufficient sample sizes, risk of bias, such as the potential for confounding, and the retrospective collection of exposure data, which increased the risk of misclassification of the exposure.

- Evidence related to type 2 diabetes and intermediate diabetes outcomes (e.g., fasting glucose, HbA1C, and insulin resistance) was scant.

For additional details on this body of evidence, visit: [nesr.usda.gov/what-relationship-between-never-versus-ever-feeding-human-milk-and-diabetes-outcomes-offspring#full-review](https://www.nesr.usda.gov/what-relationship-between-never-versus-ever-feeding-human-milk-and-diabetes-outcomes-offspring#full-review)

Duration of Any Human Milk Consumption Among Infants Fed Human Milk

- This systematic review examined comparisons of infants who were fed human milk for shorter durations with infants who were fed human milk for longer durations.
- This systematic review examined available evidence related to diabetes outcomes in offspring, including fasting glucose, HbA1C, glucose tolerance/insulin resistance, and the incidence and prevalence of prediabetes, type 1 diabetes, and type 2 diabetes.
- Thirty-seven articles met the inclusion criteria for this systematic review,⁵⁷ including 30 with evidence about type 1 diabetes, 1 with evidence about type 2 diabetes, and 6 with evidence about intermediate diabetes outcomes (i.e., fasting glucose and insulin resistance).
- Evidence about the association between shorter vs longer durations of any human milk feeding and higher risk of type 1 diabetes was moderate. Across 22 independent observational studies (30 articles), 12 reported significant associations. With the exception of 1 study that had limited external validity, the significant associations between the duration of any human milk feeding and type 1 diabetes risk were inverse associations. The ability to draw stronger conclusions was primarily limited by insufficient sample sizes, risk of bias, such as the potential for confounding, and the retrospective collection of exposure data, which increased the risk of misclassification of the exposure.
- Evidence about the duration of any human milk feeding and fasting glucose and insulin resistance during childhood and the transition into adolescence was limited, and suggested no association. One cluster RCT and 3 prospective cohort studies (PCS) provided consistent evidence. The ability to draw stronger conclusions was primarily limited by the small number of studies and the limited evidence from the United States (where metabolic risk may be higher).
- Evidence related to type 2 diabetes, prediabetes, and HbA1C, and about fasting glucose and insulin resistance beyond early adolescence was scant.

For additional details on this body of evidence, visit: [nesr.usda.gov/what-relationship-between-shorter-versus-longer-durations-any-human-milk-feeding-and-diabetes#full-review](https://www.nesr.usda.gov/what-relationship-between-shorter-versus-longer-durations-any-human-milk-feeding-and-diabetes#full-review)

Duration of Exclusive Human Milk Consumption

- This systematic review examined comparisons of infants who were fed human milk exclusively for shorter durations with infants who were fed human milk exclusively for longer durations.
- This systematic review examined available evidence related to diabetes outcomes in offspring, including fasting glucose, HbA1C, glucose tolerance/insulin resistance, and the incidence and prevalence of prediabetes, type 1 diabetes, and type 2 diabetes.
- Eighteen articles met the inclusion criteria for this systematic review,⁵⁷ including 17 with evidence about type 1 diabetes, and 1 with evidence about fasting glucose and insulin resistance.
- Evidence about the association between shorter vs longer durations of exclusive human milk feeding and higher risk of type 1 diabetes was limited. Seven studies found significant associations, all of which were inverse associations between the duration of exclusive human milk feeding and type 1 diabetes risk. However, some of the studies that were most likely to have sufficient statistical power found nonsignificant associations. The ability to draw stronger conclusions was primarily limited by this inconsistency, insufficient sample sizes for some of the studies, risk of bias, such as the potential for confounding, and the retrospective collection of exposure data, which increased the risk of misclassification of the exposure.
- Evidence about the duration of exclusive human milk feeding and fasting glucose and insulin resistance at age 11.5 years was limited, and suggested no association. One cluster RCT provided strong evidence. The ability to draw stronger conclusions was limited by having only 1 study and because the study was not conducted in the United States (where metabolic risk may be higher).
- No evidence was identified that examined how the duration of exclusive human milk feeding was related to type 2 diabetes, prediabetes, and HbA1C, or fasting glucose and insulin resistance other than at age 11.5 years.

For additional details on this body of evidence, visit: [nesr.usda.gov/what-relationship-between-shorter-versus-longer-durations-exclusive-human-milk-feeding-and-diabetes#full-review](https://www.nesr.usda.gov/what-relationship-between-shorter-versus-longer-durations-exclusive-human-milk-feeding-and-diabetes#full-review)

Intensity, Proportion, or Amount of Human Milk Consumed by Mixed-Fed Infants

- This systematic review examined comparisons of mixed-fed infants fed different intensities, proportions, or amounts of human milk.
- This systematic review examined available evidence related to diabetes outcomes in offspring, including fasting glucose, HbA1C, glucose tolerance/insulin resistance, and the incidence and prevalence of prediabetes, type 1 diabetes, and type 2 diabetes.
- This review included 1 article,⁵⁷ which was not enough evidence to draw any conclusions about the relationship between the intensity, proportion, or amount of human milk fed to infants who are fed both human milk and infant formula and diabetes outcomes in offspring.

For additional details on this body of evidence, visit: [nesr.usda.gov/what-relationship-between-feeding-lower-versus-higher-intensity-proportion-or-amount-human-milk-2#full-review](https://www.nesr.usda.gov/what-relationship-between-feeding-lower-versus-higher-intensity-proportion-or-amount-human-milk-2#full-review)

Cardiovascular Disease

Ever vs Never Consuming Human Milk

- This systematic review examined comparisons of infants who were never fed human milk with infants who were ever fed human milk (i.e., any amount of human milk feeding).
- This systematic review examined available evidence related to CVD outcomes in offspring from childhood through adulthood, including blood lipids, blood pressure, arterial stiffness, metabolic syndrome, CVD, and CVD-related mortality.
- Thirteen articles met the inclusion criteria for this systematic review,⁵⁸ including 4 with evidence about blood lipids, 7 with evidence about blood pressure, 2 with evidence about arterial stiffness, and 1 with evidence about metabolic syndrome (1 article presented evidence for both blood pressure and arterial stiffness). None of the included articles presented evidence about CVD or CVD-related mortality.
- Evidence about the association between never vs ever feeding human milk and higher blood pressure, within a normal range, at age 6 to 7 years was limited. Across the 5 independent

studies (6 articles) that examined blood pressure in children, 3 found statistically significant associations, and all of them showed that never being fed human milk was associated with higher blood pressure within a normal range. The ability to draw stronger conclusions was primarily limited by the small number of studies, the lack of studies from the United States (where CVD risk may be higher), and risk of bias, such as the potential for confounding.

- Evidence about blood lipids in childhood was inconclusive. Across 3 independent studies, the only significant association was in a subsample of boys, no comparable analyses existed with which to compare the significant finding, and the nonsignificant associations were inconsistent in direction.
- Evidence related to outcomes beyond childhood was scant, and no studies examined endpoint health outcomes (i.e., CVD and CVD-related mortality).

For additional details on this body of evidence, visit: [nesr.usda.gov/what-relationship-between-never-versus-ever-feeding-human-milk-and-cardiovascular-disease-outcomes#full-review](https://www.nesr.usda.gov/what-relationship-between-never-versus-ever-feeding-human-milk-and-cardiovascular-disease-outcomes#full-review)

Duration of Any Human Milk Consumption Among Infants Fed Human Milk

- This systematic review examined comparisons of infants who were fed human milk for shorter durations with infants who were fed human milk for longer durations.
- This systematic review examined available evidence related to CVD outcomes in offspring from childhood through adulthood, including blood lipids, blood pressure, arterial stiffness, metabolic syndrome, CVD, and CVD-related mortality.
- Twenty-four articles met the inclusion criteria for this systematic review,⁵⁸ including 13 with evidence about blood pressure, 10 with evidence about blood lipids, 3 with evidence about metabolic syndrome, 3 with evidence about arterial stiffness, and 2 with evidence about CVD-related mortality (some articles included evidence for more than 1 outcome).
- Moderate evidence about shorter vs longer durations of any human milk feeding and blood pressure in childhood suggested no association. Compelling evidence from the Promotion of Breastfeeding Intervention Trial (PROBIT) showed no significant relationship between the duration of any human milk feeding and blood pressure at age 6.5 or 11.5 years, and inconsistent evidence across 6 independent PCSs did not suggest any discernable relationship between the duration of any human milk feeding and blood pressure in childhood. The ability to draw stronger conclusions was primarily limited by the small

number of studies and concern about generalizability of the evidence, because none of the evidence was from the United States and U.S. populations may be at higher risk for CVD than the populations examined by the studies included in the systematic review.

- Evidence about blood lipids in childhood and adulthood and about metabolic syndrome was inconclusive, primarily due to inconsistencies in the direction and statistical significance of the findings.
- Evidence related to outcomes beyond childhood was scant, and only 2 articles, with evidence from the same retrospective cohort study, examined endpoint CVD outcomes (CVD-related mortality in both articles).

For additional details on this body of evidence, visit: [nesr.usda.gov/what-relationship-between-shorter-versus-longer-durations-any-human-milk-feeding-and-cardiovascular#full-review](https://www.nesr.usda.gov/what-relationship-between-shorter-versus-longer-durations-any-human-milk-feeding-and-cardiovascular#full-review)

Duration of Exclusive Human Milk Consumption

- This systematic review examined comparisons of infants who were fed human milk exclusively for shorter durations with infants who were fed human milk exclusively for longer durations.
- This systematic review examined available evidence related to CVD outcomes in offspring from childhood through adulthood, including blood lipids, blood pressure, arterial stiffness, metabolic syndrome, CVD, and CVD-related mortality.
- Six articles met the inclusion criteria for this systematic review,⁵⁸ including 4 with evidence about blood pressure, 2 with evidence about blood lipids, and 1 with evidence about metabolic syndrome (1 article included evidence about both blood pressure and metabolic syndrome).
- Evidence about shorter vs longer durations of exclusive human milk feeding and blood pressure in childhood and metabolic syndrome at age 11.5 years was limited, and suggested no associations. Most of the evidence came from the PROBIT, which used a strong design to examine blood pressure and metabolic syndrome in children in Belarus. One additional study from Brazil provided supporting evidence about childhood blood pressure. The ability to draw stronger conclusions was primarily restricted by the limited number of studies and the lack of evidence from the United States (where the risk of CVD may be higher).

- Evidence related to other CVD outcomes was scant.

For additional details on this body of evidence, visit: [nesr.usda.gov/what-relationship-between-shorter-versus-longer-durations-exclusive-human-milk-feeding-and-0#full-review](https://www.nesr.usda.gov/what-relationship-between-shorter-versus-longer-durations-exclusive-human-milk-feeding-and-0#full-review)

Intensity, Proportion, or Amount of Human Milk Consumed by Mixed-Fed Infants

- This systematic review examined comparisons of mixed-fed infants fed different intensities, proportions, or amounts of human milk.
- This systematic review examined available evidence related to CVD outcomes in offspring from childhood through adulthood, including blood lipids, blood pressure, arterial stiffness, metabolic syndrome, CVD, and CVD-related mortality.
- No articles met the inclusion criteria for this systematic review.

For additional details on this body of evidence, visit: [nesr.usda.gov/what-relationship-between-feeding-lower-versus-higher-intensity-proportion-or-amount-human-milk-1#full-review](https://www.nesr.usda.gov/what-relationship-between-feeding-lower-versus-higher-intensity-proportion-or-amount-human-milk-1#full-review)

Question 3. What is the relationship between the duration, frequency, and volume of exclusive human milk and/or infant formula consumption and nutrient status?

Approach to Answering Question: NESR systematic review

Conclusion Statements and Grades

Ever vs Never Consuming Human Milk

Moderate evidence indicates that ever, compared with never, consuming human milk may be associated with fatty acid status from birth to 24 months. However, the difference in fatty acid status between infants fed human milk and infants fed infant formula is likely to depend on the composition of the human milk and infant formula consumed. Grade: Moderate

Insufficient evidence is available to determine the relationship between ever, compared with never, consuming human milk and iron and zinc status from birth to 24 months. No evidence is available to determine the relationship between ever, compared with never, consuming human

milk and iodine, vitamin B₁₂, and vitamin D status from birth to 24 months. Grade: Grade Not Assignable

Duration of Any Human Milk Consumption Among Infants Fed Human Milk

Insufficient evidence is available to determine the relationship between the duration of any human milk consumption, among infants fed human milk, and iron, zinc, vitamin D, and fatty acid status from birth to 24 months. No evidence is available to determine the relationship between the duration of any human milk consumption, among infants fed human milk, and iodine or vitamin B₁₂ status from birth to 24 months. Grade: Grade Not Assignable

Duration of Exclusive Human Milk Consumption Before the Introduction of Infant Formula

Insufficient evidence is available to determine the relationship between the duration of exclusive human milk consumption before the introduction of infant formula and fatty acid status. No evidence is available to determine the relationship between the duration of exclusive human milk consumption before the introduction of infant formula and iron, zinc, iodine, vitamin B₁₂, or vitamin D status from birth to 24 months. Grade: Grade Not Assignable

Intensity, Proportion, or Amount of Human Milk Consumed by Mixed-Fed Infants

No evidence is available to determine the relationship between the intensity, proportion, or amount of human milk consumed by mixed-fed infants and iron, zinc, iodine, vitamin B₁₂, vitamin D, or fatty acid status from birth to 24 months. Grade: Grade Not Assignable

Summary of the Evidence

- This systematic review examined the relationship between the duration, frequency, and volume of exclusive human milk and/or infant formula consumption and nutrient status. Specifically, this systematic review examined available evidence that compares:
 - Infants who ever consumed milk (i.e., any amount of human milk) with infants who never consumed human milk,
 - Infants who consumed human milk (i.e., any amount of human milk) for different durations,
 - Infants who consumed human milk exclusively for different durations before the introduction of infant formula, and

- Mixed-fed infants (i.e., consuming both human milk and infant formula, but not complementary foods and beverages) who consumed different intensities, proportions, or amounts of human milk.
- The outcomes of interest were iron status (including iron deficiency and anemia), zinc status, iodine status, vitamin B₁₂ status, vitamin D status, and fatty acid status.
- This review identified 23 articles.¹⁰³⁻¹²⁵
 - Iron status: Ten articles, published between 1990 and 2019, examined the relationships of: a) ever, compared with never, consuming human milk, and b) different durations of any human milk consumption, among infants fed human milk, with iron status from birth to 24 months.
 - The evidence available from 2 studies did not show a consistent association between ever, compared with never, consuming human milk and anemia. The evidence available from 5 studies did not show consistent associations between ever, compared with never, consuming human milk and hemoglobin, hematocrit, red blood cell count, mean corpuscular volume, red cell distribution width, serum ferritin, or serum iron.
 - The evidence available from 3 studies did not show a consistent association between the duration of any human milk consumption, among infants fed human milk, and iron deficiency or anemia. The evidence available from 4 studies did not show consistent associations between the duration of any human milk consumption, among infants fed human milk, and hemoglobin, hematocrit, serum ferritin, serum iron, mean corpuscular volume, transferrin receptor, or transferrin saturation.
 - Zinc status: Five articles, published between 1986 and 1994, examined the relationships of: a) ever, compared with never, consuming human milk, and b) different durations of any human milk consumption, among infants fed human milk, with zinc status from birth to 24 months.
 - The evidence available from 4 studies did not show a consistent association between ever, compared with never, consuming human milk and zinc status.
 - The evidence available from 2 studies was insufficient to determine whether an association exists between the duration of any human milk consumption, among infants fed human milk, and zinc status.

- Vitamin D status: One article, published in 2014, examined the relationship between the duration of any human milk consumption, among infants fed human milk, and vitamin D status from birth to 24 months. This evidence was insufficient to determine whether an association exists between the duration of any human milk consumption, among infants fed human milk, and vitamin D status.
- Fatty acid status: Nine articles, published between 1986 and 2016, examined the relationships of: a) ever, compared with never, consuming human milk, b) different durations of any human milk consumption, among infants fed human milk, and c) different durations of exclusive human milk consumption before the introduction of infant formula with fatty acid status from birth to 24 months.
 - The evidence available from 7 studies was moderately consistent in showing that ever, compared with never, consuming human milk is related to fatty acid status, but the direction and strength of associations varied depending on the composition of the infant formula fed to participants who never consumed human milk (and also likely due to the composition of human milk, although this could not be assessed), as well as the specific types of fatty acids examined in the blood.
 - The evidence available from 1 study was insufficient to determine whether an association exists between the duration of any human milk consumption, among infants fed human milk, and fatty acid status.
 - The evidence available from 1 study was insufficient to determine whether an association exists between the duration of exclusive human milk consumption before the introduction of infant formula and fatty acid status.
- No studies met the inclusion criteria that examined iodine status or vitamin B₁₂ status.
- The ability to draw stronger conclusions was primarily limited by:
 - The small number of studies that presented evidence on each topic,
 - The study designs, as most studies were designed to examine the effect of novel infant formula compositions rather than differences in outcomes between infants ever and never fed human milk,
 - Concerns about the generalizability of the evidence to U.S. infants consuming infant formulas currently on the market, and
 - Concerns about the potential for bias, especially bias due to confounding.

For additional details on this body of evidence, visit: [nesr.usda.gov/2020-dietary-guidelines-advisory-committee-systematic-reviews/birth-24-months-subcommittee/human-milk-infant-formula-nutrient-status](https://www.nesr.usda.gov/2020-dietary-guidelines-advisory-committee-systematic-reviews/birth-24-months-subcommittee/human-milk-infant-formula-nutrient-status)

Question 4. What is the relationship between the duration, frequency, and volume of exclusive human milk and/or infant formula consumption and food allergies and atopic allergic diseases?

Approach to Answering Question: Existing NESR systematic reviews

Conclusion Statements and Grades

Ever vs Never Consuming Human Milk

Moderate evidence suggests that never, in comparison to ever, being fed human milk is associated with higher risk of childhood asthma. Grade: Moderate

Limited evidence does not suggest a relationship between never versus ever being fed human milk and atopic dermatitis in childhood. Grade: Limited

Evidence about the relationship between never versus ever being fed human milk and atopic dermatitis from birth to 24 months is inconclusive, and there is insufficient evidence to determine the relationship of never versus ever being fed human milk with food allergies throughout the lifespan, allergic rhinitis throughout the lifespan, asthma in adolescence or in adulthood, and atopic dermatitis in adolescence or in adulthood. Grade: Grade Not Assignable

Duration of Any Human Milk Consumption Among Infants Fed Human Milk

Moderate evidence, mostly from observational studies, suggests that, among infants fed human milk, shorter versus longer durations of any human milk feeding are associated with higher risk of asthma in childhood and adolescence. Grade: Moderate

Limited evidence does not suggest a relationship between the duration of any human milk feeding and allergic rhinitis or atopic dermatitis in childhood. Grade: Limited

Evidence about the relationship between shorter versus longer durations of any human milk feeding and atopic dermatitis from birth to 24 months is inconclusive, and there is insufficient evidence to determine the relationship of shorter versus longer durations of any human milk

feeding with food allergies throughout the lifespan; allergic rhinitis from birth to 24 months, in adolescence, or in adulthood; asthma in adulthood; and atopic dermatitis in adolescence or in adulthood. Grade: Grade Not Assignable

Duration of Exclusive Human Milk Consumption Before the Introduction of Infant Formula

There is insufficient evidence to determine the relationship between shorter versus longer durations of exclusive human milk feeding prior to the introduction of infant formula and food allergies, allergic rhinitis, atopic dermatitis, and asthma throughout the lifespan. Grade: Grade Not Assignable

Intensity, Proportion, or Amount of Human Milk Consumed by Mixed-Fed Infants

There is no evidence to determine the relationship between feeding a lower versus higher intensity, proportion, or amount of human milk to mixed-fed infants and food allergies, allergic rhinitis, atopic dermatitis, and asthma throughout the lifespan. Grade: Grade Not Assignable

Intensity, Proportion, or Amount of Human Milk Consumed at the Breast vs by Bottle

There is no evidence to determine the relationship between feeding a higher intensity, proportion, or amount of human milk by bottle versus by breast and food allergies, allergic rhinitis, atopic dermatitis, and asthma throughout the lifespan. Grade: Grade Not Assignable

Summary of the Evidence

Ever vs Never Consuming Human Milk

- This systematic review examined comparisons of infants who were never fed human milk with infants who were ever fed human milk (i.e., any amount of human milk feeding).
- This systematic review examined available evidence related to food allergies, allergic rhinitis, and atopic dermatitis from birth through adulthood and asthma from childhood through adulthood (outcomes before childhood may represent transient recurrent wheeze).¹²⁶
- Forty-four articles met the inclusion criteria for this systematic review,⁵⁶ including 5 with evidence about food allergies, 2 with evidence about allergic rhinitis, 24 with evidence about atopic dermatitis, and 22 with evidence about asthma. Almost all of the evidence was from observational studies.

- Evidence about the association between never vs ever feeding human milk and higher childhood asthma risk was moderate. Across the 17 independent studies (19 articles) that examined asthma in children, 9 found statistically significant associations, and all of them showed that never being fed human milk was associated with higher risk. The majority of nonsignificant associations also were consistent in suggesting higher risk of childhood asthma with never vs ever feeding human milk, and some of the inconsistency in statistical significance may be explained by insufficient statistical power. The ability to draw stronger conclusions was primarily limited by the limited statistical power in some studies and concerns about internal validity, such as the potential for confounding in a body of evidence primarily made up of observational studies.
- Evidence about the lack of an association between never vs ever feeding human milk and atopic dermatitis in childhood was limited. Across the 9 studies that examined atopic dermatitis in children, the only significant association was from a study that used a sample in which about half of the participants were born small for gestational age (i.e., which raised concerns about generalizability). The ability to draw stronger conclusions was limited by the small number of studies, limited statistical power in some studies, a potential lack of generalizability of the samples to diverse U.S. populations, and the potential for reverse causality and confounding.
- Evidence about atopic dermatitis from birth to 24 months was inconclusive. Across 14 independent studies (16 articles), the associations were inconsistent in direction. In addition, the outcome assessment methods described by the studies raised concerns that the studies may have detected skin conditions similar to atopic dermatitis in addition to clinical atopic dermatitis.
- Evidence related to food allergies and allergic rhinitis throughout the lifespan and atopic dermatitis and asthma beyond childhood was scant.

For additional details on this body of evidence, visit: [nesr.usda.gov/what-relationship-between-never-versus-ever-feeding-human-milk-and-food-allergies-allergic-rhinitis#full-review](https://www.nesr.usda.gov/what-relationship-between-never-versus-ever-feeding-human-milk-and-food-allergies-allergic-rhinitis#full-review)

Duration of Any Human Milk Consumption Among Infants Fed Human Milk

- This systematic review examined comparisons of infants who were fed human milk for shorter durations with infants who were fed human milk for longer durations.

- This systematic review examined available evidence related to food allergies, allergic rhinitis, and atopic dermatitis from birth through adulthood and asthma from childhood through adulthood (outcomes before childhood may represent transient recurrent wheeze).¹²⁶
- Thirty-five articles met the inclusion criteria for this systematic review,⁵⁶ including 3 with evidence about food allergies, 7 with evidence about allergic rhinitis, 15 with evidence about atopic dermatitis, and 23 with evidence about asthma. Almost all of the evidence was from observational studies.
- Evidence about the association between shorter vs longer durations of any human milk feeding and higher risk of asthma in childhood and adolescence was moderate. Across the 20 independent studies (21 articles), 8 found statistically significant associations and, with 1 exception, they showed that shorter durations of any human milk feeding was associated with higher risk. The majority of nonsignificant associations were also consistent in suggesting higher risk of asthma in childhood and adolescence with shorter durations of any human milk feeding, and some of the inconsistency in statistical significance may be explained by insufficient statistical power. The ability to draw stronger conclusions was primarily limited by the limited statistical power in some studies, potential problems with reverse causality, and risk of bias, such as the potential for confounding in a body of evidence primarily made up of observational studies.
- Evidence about the lack of an association between shorter vs longer durations of any human milk feeding and allergic rhinitis and atopic dermatitis in childhood was limited. Across the 5 independent studies (6 articles) that examined allergic rhinitis in children, the only significant association was from a subsample analysis of African-American children, and no comparable analyses existed with which to compare the result. Likewise, across the 8 independent studies (9 articles) that examined atopic dermatitis in children, the only significant associations were reported by a study with risk of multiple comparison bias. The ability to draw stronger conclusions was primarily limited by the small number of studies, limited statistical power in some studies, limited generalizability of the samples to diverse U.S. populations, and the potential for confounding.
- Evidence about atopic dermatitis from birth to 24 months was inconclusive. Across 8 studies, the associations were inconsistent in direction. In addition, the outcome assessment methods described by the studies raised concerns that the studies may have detected skin conditions similar to atopic dermatitis in addition to clinical atopic dermatitis.

- Evidence related to food allergies throughout the lifespan, and outcomes beyond childhood, in general, was scant.

For additional details on this body of evidence, visit: [nesr.usda.gov/what-relationship-between-shorter-versus-longer-durations-any-human-milk-feeding-and-food-allergies#full-review](https://www.nesr.usda.gov/what-relationship-between-shorter-versus-longer-durations-any-human-milk-feeding-and-food-allergies#full-review)

Duration of Exclusive Human Milk Consumption Before the Introduction of Infant Formula

- This systematic review examined comparisons of infants who were fed human milk exclusively for shorter durations with infants who were fed human milk exclusively for longer durations before being introduced to infant formula. The question examined the duration of exclusive human milk feeding before the introduction of infant formula (not complementary foods and beverages) to avoid overlap with systematic review Question 5 in **Part D. Chapter 5: Foods and Beverages Consumed During Infancy and Toddlerhood**.
- This systematic review examined available evidence related to food allergies, allergic rhinitis, and atopic dermatitis from birth through adulthood and asthma from childhood through adulthood (outcomes before childhood may represent transient recurrent wheeze).¹²⁶
- This review included 1 article,⁵⁶ which provided insufficient evidence to draw any conclusions about the relationship between the duration of exclusive human milk feeding before the introduction of infant formula and food allergies, allergic rhinitis, atopic dermatitis, or asthma.
- A large degree of overlap may exist between current literature examining the duration of exclusive human milk feeding (which may terminate with complementary feeding) and the timing of the introduction of complementary foods and beverages (which may immediately follow a period of exclusive human milk feeding). Yet, the degree of overlap is difficult to ascertain; infant feeding research does not often specify whether exclusive human milk feeding is followed by complementary feeding or formula feeding or both, and complementary feeding research does not often specify whether complementary foods and beverages are introduced to infants fed human milk exclusively or fed infant formula in some amount. It would be beneficial for future researchers to be mindful about this potential ambiguity when designing and conducting research about the duration of exclusive human milk feeding or the timing of the introduction of complementary foods and beverages, and

strive to help clarify any unique contributions of each of the two feeding practices on atopic disease and other outcomes.

For additional details on this body of evidence, visit: [nesr.usda.gov/what-relationship-between-shorter-versus-longer-durations-exclusive-human-milk-feeding-prior#full-review](https://www.nesr.usda.gov/what-relationship-between-shorter-versus-longer-durations-exclusive-human-milk-feeding-prior#full-review)

Intensity, Proportion, or Amount of Human Milk Consumed by Mixed-Fed Infants

- This systematic review examined comparisons of mixed-fed infants fed different intensities, proportions, or amounts of human milk.
- This systematic review examined available evidence related to food allergies, allergic rhinitis, and atopic dermatitis from birth through adulthood and asthma from childhood through adulthood (outcomes before childhood may represent transient recurrent wheeze).¹²⁶
- No articles met the inclusion criteria for this systematic review.

For additional details on this body of evidence, visit: [nesr.usda.gov/what-relationship-between-feeding-lower-versus-higher-intensity-proportion-or-amount-human-milk-0#full-review](https://www.nesr.usda.gov/what-relationship-between-feeding-lower-versus-higher-intensity-proportion-or-amount-human-milk-0#full-review)

Intensity, Proportion, or Amount of Human Milk Consumed at the Breast vs by Bottle

- This systematic review examined comparisons of mixed-fed infants fed different intensities, proportions, or amounts of human milk by bottle and by breast.
- This systematic review examined available evidence related to food allergies, allergic rhinitis, and atopic dermatitis from birth through adulthood and asthma from childhood through adulthood (outcomes before childhood may represent transient recurrent wheeze).¹²⁶
- No articles met the inclusion criteria for this systematic review.

For additional details on this body of evidence, visit: [nesr.usda.gov/what-relationship-between-feeding-higher-intensity-proportion-or-amount-human-milk-bottle-versus#full-review](https://www.nesr.usda.gov/what-relationship-between-feeding-higher-intensity-proportion-or-amount-human-milk-bottle-versus#full-review)

DISCUSSION

Current infant-feeding practices in the United States encompass a spectrum of human milk exposures of differing durations, intensities, proportions, or amounts. The Committee sought to determine associations between these different levels, durations and intensities of exposure to human milk and infant formula and overweight and obesity, long-term health outcomes, nutrient status, and food allergy and atopic allergic diseases.

Overweight and Obesity

Ever vs Never Consuming Human Milk

Based on evidence from 17 observational cohort studies published between 2011 and 2019, and 4 sibling-pair studies published between 2003 and 2019 that also included cohorts of non-siblings, the Committee concluded that ever, compared with never, consuming human milk is associated with lower risk of overweight and obesity at ages 2 years and older, particularly if the duration of human milk consumption is 6 months or longer. This conclusion statement was graded as “Moderate.” The observational cohort studies were strongly consistent, but these studies were limited by potential confounding because none of them controlled for all of the key confounders identified in the analytical framework. In particular, few studies accounted for complementary feeding practices and childhood diet, which are likely to be correlated with whether the child was fed human milk and may also influence risk of overweight and obesity.

Sibling-pair studies greatly reduce the risk of confounding, because siblings share a common environment. The 4 sibling-pair analyses generally showed an attenuation of the significant associations that were found in full-sample analyses in those studies, which suggests that confounding may explain a substantial proportion of the association between ever vs never consuming human milk and subsequent overweight and obesity. Nonetheless, 1 of the sibling-pair analyses⁸⁷ did show a significant association between ever, compared with never, consuming human milk and lower odds of overweight or obesity at ages 9 to 19 years. In another sibling-pair analysis,⁷⁴ initiating human milk feeding was associated with a significantly lower BMI z-score at age 5 years, though not with risk of overweight or obesity. Sibling-pair studies are often limited by the smaller sample size available for within-family analyses, which makes it less likely to detect associations. Among these 4 studies, several risks of bias also were of concern. For example, in 2 of the cohorts,^{70,87,92} mothers were asked to recall how they fed their offspring during infancy when those offspring were between ages 4 and 18 years. In 1 cohort,^{63,66} some participants reported their own height and weight, and in another,^{70,92} the

methods used to collect outcome data were not reported. In addition, none of these studies had within-family analyses that compared infants who consumed human milk for different durations with infants who never consumed human milk. Therefore, it is not possible to comment on whether the trend described for the other observational studies (i.e., that longer durations of human milk consumption may be important) is observed in sibling-pair analyses.

Because of the risk of confounding in observational studies, and the limitations of the sibling-pair studies described above, it is difficult to determine whether a causal relationship exists between ever vs never consuming human milk and risk of overweight or obesity. Other systematic reviews and meta-analyses on this topic have generally come to similar conclusions. For example, a systematic review of systematic reviews¹⁰ concluded that breastfeeding is consistently associated with a reduction in the odds of overweight or obesity in childhood and adulthood, by about 13 percent in high-quality studies, but residual confounding could not be ruled out.

Duration of Any Human Milk Consumption Among Infants Fed Human Milk

With regard to the relationship between the duration of any human milk consumption, among infants fed human milk, and overweight and/or obesity at age 2 years and older, the Committee concluded that evidence was insufficient. This was based not on a lack of evidence (18 observational cohort studies, including 4 with sibling-pair analyses, and 1 RCT of a breastfeeding promotion intervention were included in the review), but rather on the inconsistency in the findings: Some studies showed inverse associations, some positive associations, and some no association between duration of human milk consumption and risk of overweight or obesity. Notably, all of the sibling-pair analyses showed no association. The systematic review of systematic reviews cited above¹⁰ stated that “there are some indications that breastfeeding of very short duration has a lesser protective effect than breastfeeding of longer duration on the later risk of overweight and obesity, although residential confounding cannot be excluded.”

Duration of Exclusive Human Milk Consumption Before the Introduction of Infant Formula

Only 2 studies^{93,98} examined the relationship between the duration of exclusive human milk consumption before the introduction of infant formula and overweight and/or obesity. Thus, the Committee concluded that evidence was insufficient to determine the relationship between the

duration of exclusive human milk consumption before the introduction of infant formula and overweight and obesity at age 2 years and older.

Intensity, Proportion, or Amount of Human Milk Consumed by Mixed-Fed Infants, by Breast vs Bottle, or During a Feeding

No studies were identified that examined whether overweight or obesity was related to: a) the intensity, proportion, or amount of human milk consumed by mixed-fed infants, b) the intensity, proportion, or amount of human milk consumed at the breast vs by bottle in infants fed human milk as their only source of milk, or c) consuming a single substance (i.e., either human milk or infant formula) vs both human milk and infant formula during a single feeding session.

Potential Mechanisms and Research Needs

Despite the challenges of establishing a causal relationship between human milk feeding exposures and risk of overweight or obesity, several lines of evidence suggest potential biological mechanisms for such a relationship. Rapid weight gain during infancy (particularly during the first 6 months) is consistently related to subsequent risk of overweight or obesity,¹²⁷⁻¹²⁹ and rapid weight gain is more likely among formula-fed than among breastfed infants.¹²⁸ Although the reasons for more rapid weight gain among formula-fed infants are not fully understood, infant self-regulation of energy intake may differ between breast- and formula-fed infants.¹³⁰ Additionally, higher protein intake among formula-fed infants drives hormonal differences that may stimulate greater weight gain and fat deposition,¹³¹ though the precise mechanisms are not yet clear and this is an active area of investigation. RCTs of reduced protein formulas have demonstrated less rapid infant weight gain and reduced obesity at school age.¹³²⁻¹³⁶ The concentrations of free amino acids in human milk vs formula also may be important. For example, free glutamate, which is much higher in human milk than in conventional infant formulas, is a key signal for satiation. An experimental study comparing extensively hydrolyzed formula, with higher free glutamate content, with a standard infant formula reported a significant difference in early rapid weight gain between the groups.¹³⁷

Overfeeding of formula-fed infants also is a possibility, as feeding by bottle may make it more difficult for the infant to communicate satiety signals, and in some cases the caregiver may urge the infant to finish the bottle so as to avoid wastage.^{138,139} The feeding dynamics of breast- and bottle-feeding mothers and their infants may differ. In a small pilot study using a within-subject approach, Whitfield and Ventura¹⁴⁰ assessed maternal responsiveness to infant cues during 2 human milk feeding sessions differing by feeding modality (breastfeeding vs bottle-

feeding). Mothers were more sensitive to infant cues during breastfeeding and the latency from feeding session midpoint to the first satiation cue was significantly longer during breastfeeding compared to bottle-feeding. Shloim et al¹⁴¹ investigated whether breastfed infants signal more to mothers to facilitate responsive feeding than do formula-fed infants, and, if so, what communication cues are important during the feeding interaction. Breastfeeding infants exhibited more engagement and disengagement cues than did formula-fed infants. The authors suggested that educating mothers to identify engagement and disengagement cues during a milk feed may promote more responsive feeding strategies. Differences in the dyadic approach of mothers and infants during feeding may have longer term implications for programming of appetite regulation. At ages 3 to 6 years, children who were fed human milk in a bottle as infants were less likely to have high satiety responsiveness compared to directly breastfed children, after controlling for child age, child weight status, maternal race/ethnicity, and maternal education.¹³⁹ All of the above studies were relatively small, so additional research on satiety signals and responsiveness is needed.

Future research studies on infant milk-feeding practices and health outcomes should be designed to reduce bias from confounding factors as much as possible. Sibling-pair studies are one example of this type of study design, but few such studies have been conducted and they tend to have much smaller sample sizes than do other types of observational studies. Larger sibling-pair studies are needed, and they need to examine siblings who differ in terms of the duration of human milk consumption (e.g., <6 months, ≥6 months), not just with respect to ever vs never consuming human milk.

Another way to approach these questions is with RCTs of breastfeeding promotion, as was done in the PROBIT trial in Belarus.¹⁴² If the trial achieves substantial differences in duration or exclusivity of breastfeeding between intervention groups, this provides an opportunity to examine effects on subsequent overweight or obesity (and many other outcomes).

Observational studies that make use of large datasets, especially those that follow participants longitudinally and, in particular, link children with siblings and parents, also would be very useful for robustly assessing associations and providing more confidence in conclusions regarding causality. This could be achieved by linking surveillance systems that collect data about infant feeding and health outcomes (including overweight and obesity), and making use of emerging electronic medical record data.

In general, observational studies need to take into account all of the key confounders in the analytical framework of this review, including aspects of the child's diet (complementary feeding and later dietary patterns). The use of instrumental variables, such as Mendelian randomization

approaches, also could be helpful in minimizing confounding.¹⁴³ In both observational and intervention studies, researchers should consider effect modification in their study design whenever possible (e.g., child sex, parental obesity, socioeconomic status, race or ethnicity, child diets, child activity levels) to examine the impact of infant feeding on these outcomes within key subgroups.

Long-term Health Outcomes

Diabetes Mellitus

The Committee included a systematic review that investigated the relationship between infant milk-feeding practices and the risk of diabetes outcomes in offspring.⁵⁷ A total of 53 articles met the inclusion criteria, although only 1 of the included articles examined lower vs higher intensities, proportions, or amounts of human milk fed to mixed-fed infants. Therefore, no conclusions could be drawn about these comparisons. Based on the available evidence the Committee was able to draw conclusions regarding type 1 diabetes and the comparisons of ever vs. never consuming human milk, different durations of any human milk consumption, and different durations of exclusive human milk consumption. Evidence was insufficient to determine whether or not a relationship exists between ever vs never feeding human milk or duration of exposure to human milk and type 2 diabetes, prediabetes, or intermediate outcomes throughout the lifespan.

Ever vs Never Consuming Human Milk

Limited evidence from observational studies suggests that never vs ever being fed human milk is associated with higher risk of type 1 diabetes and that the evidence is consistent and generalizable to the U.S. population. Although the prevalence of type 1 diabetes is low, small increases in the risk of type 1 diabetes may have public health implications.

Duration of Any Human Milk Consumption Among Infants Fed Human Milk

Moderate evidence from observational studies indicates that, among infants fed some amount of human milk, shorter vs longer durations of any human milk feeding are associated with higher risk of type 1 diabetes. Limited, but consistent, evidence suggests that the duration of any human milk feeding is not associated with fasting glucose or insulin resistance in childhood or during the transition from childhood into adolescence.

Duration of Exclusive Human Milk Consumption

Limited evidence from observational studies suggests that shorter vs longer durations of exclusive human milk feeding are associated with higher risk of type 1 diabetes. Limited evidence from long-term follow-up of children in the PROBIT cluster randomized trial also suggests that the duration of exclusive human milk feeding is not associated with fasting glucose or insulin resistance at age 11.5 years.

The research community has been keenly interested in infant feeding practices, including breastfeeding, in modulating the development of islet autoimmunity and type 1 diabetes.⁴⁴ The autoimmune destruction of insulin-producing beta cells in the pancreas that results in type 1 diabetes occurs in genetically susceptible individuals, but is likely triggered by environmental agents early in life and progresses over many months or years during which time the individual is asymptomatic.¹⁴⁴ Several disease-related autoantibodies have been identified that are predictive of clinical type 1 diabetes.¹⁴⁵ However, these autoantibodies may be biomarkers of the destructive process rather than being directly involved in beta-cell destruction. A number of mechanisms are proposed to be involved in the protective effect of breastfeeding against the development of type 1 diabetes. A delay in the introduction of cow milk proteins may be one important factor,¹⁴⁶ although recent results from the TRIGR RCT suggest that weaning to a hydrolyzed formula compared with a conventional formula does not reduce the incidence of type 1 diabetes at age 11.5 years.¹⁴⁷ However, that study was not designed to test the effect of exclusive breastfeeding on type 1 diabetes incidence. Recent evidence from 2 large Scandinavian birth cohorts^{148,149} and a meta-analysis⁴⁵ support a role of breastfeeding in reducing type 1 diabetes risk. Additional mechanisms that may be involved in the protective effect of breastfeeding include the presence of biologically active components in human milk that could play a role in reducing gut permeability and early enterovirus infections as well as promoting a healthier infant gut microbiota.⁴⁴

Breastfeeding has been proposed to reduce the risk of developing type 2 diabetes¹⁵⁰ through mechanisms that involve reduced circulating glucose and insulin concentrations in infancy⁴⁷ and reduced risk of obesity later in life.¹⁵¹ However, evidence to support this contention is sparse. Indeed, the one cluster RCT that has been conducted¹⁵² found no associations between the breastfeeding intervention and intermediate outcomes (related to type 2 diabetes) at age 11.5 years.

Cardiovascular Disease

A systematic review was conducted to investigate the relationship between infant milk-feeding practices and the risk of CVD outcomes and related intermediate outcomes in offspring.⁵⁸ A total of 35 articles met the inclusion criteria, none of which examined lower versus higher intensities, proportions, or amounts of human milk fed to mixed-fed infants. All of the studies were conducted in countries with high or very high Human Development Index (HDI) rankings,¹⁵³ but not the United States, thus reducing the generalizability to the U.S. population. Overall, the Committee concluded that evidence is inconclusive or insufficient to determine whether infant milk-feeding practices are associated with blood lipids or endpoint CVD outcomes. However, some conclusions could be made with regard to infant milk-feeding practices and blood pressure and metabolic syndrome.

Ever vs Never Consuming Human Milk

Limited evidence indicates that never vs ever being fed human milk is associated with higher blood pressure, within a normal range, at 6 to 7 years of age.

Duration of Any Human Milk Consumption Among Infants Fed Human Milk

Moderate evidence indicates no association between the duration of any human milk feeding and childhood blood pressure. However, evidence about the relationship of shorter vs longer durations of any human milk feeding with blood lipids in childhood and adulthood and with metabolic syndrome is inconclusive.

Duration of Exclusive Human Milk Consumption

Limited evidence suggests no association between the duration of exclusive human milk feeding and blood pressure in childhood or metabolic syndrome at age 11.5 years.

The biological plausibility of a protective effect of breastfeeding on CVD outcomes has as its underpinning the association between breastfeeding and reduced risk of overweight or obesity.⁶ The high content of long chain polyunsaturated fatty acids in human milk has been proposed as a potential mediator, as these fatty acids are incorporated into cell membranes of the vascular endothelium and supplementation with these fatty acids lowers blood pressure in hypertensive individuals.¹⁵⁴ Indeed, a non-RCT¹⁵⁵ and PCSs^{156,157} support an association between ever being fed human milk and lower blood pressure at ages 6 to 7 years, albeit within the normal range. However, evidence from the large cluster-randomized PROBIT study found no impact of

breastfeeding on blood pressure at ages 6.5, 11.5, or 16 years,^{84,152,158} as well as fasting insulin and glucose or metabolic syndrome at 11.5 years.¹⁵²

Nutrient Status

Due to the differences in the concentrations and bioavailability of some nutrients in human milk compared to infant formula, and changes in human milk composition over time as compared to the constant composition of formula (see **Part D. Chapter 3: Food, Beverage, and Nutrient Consumption During Lactation**), the Committee investigated associations between infant milk-feeding practices and nutrient status of the infant, which included iron, zinc, iodine, vitamin B₁₂, vitamin D, and fatty acids. Across all questions of human milk feeding and nutrient status, only 23 studies met inclusion and exclusion criteria. For most questions regarding human milk feeding and nutrient status, evidence was scant to nonexistent, leading to conclusions of insufficient evidence and grade not assignable. For questions where evidence was available to address a topic, the number of studies was typically small, did not show consistent associations, and most studies were prone to a substantial risk of bias.

Ever vs Never Consuming Human Milk

The only question for which moderate evidence existed was whether ever compared with never consuming human milk is associated with child fatty acid status. Human milk differs in fatty acid composition compared to infant formula. The evidence was consistent in showing that human milk feeding is likely related to fatty acid status but the direction and strength of associations differed as well as the specific types of fatty acids examined. In addition, fatty acid composition of breast milk is dependent on maternal diet, which was not reported in most studies.

The majority of evidence identified addressed the comparison of ever contrasted with never, consuming human milk and nutrient status outcome. Most studies compared infants who were fed human milk to infants who were fed an infant formula that had a novel composition at the time of the study (such as added DHA, or different levels of iron), and/or a control group who were fed a conventional infant formula. Because nutrient status outcomes in formula-fed infants can vary widely depending on the composition of the formula, which was quite different across studies, the synthesis of evidence was difficult. Other components of infants' diets varied and were often not reported clearly, including the exclusivity of human milk, types and amounts of formula fed in addition to human milk, types and amounts of complementary foods fed in addition to human milk or infant formula, and supplements. These other foods and factors that

could have influenced nutrient status were not described or accounted for in most of the literature identified. The inconsistency in findings may be due to differences between studies in consumption of human milk, infant formula, cow milk, complementary foods, and supplements.

The studies in this body of literature generally examined healthy full-term infants who were recruited at or close to birth and lived in the United States, Australia, Asia, or Europe. Race and ethnicity were not reported in most studies and cultural norms for infant feeding differ widely, leading to concern that the generalizability of the evidence to U.S. infants consuming commercial formulas currently available on the market is limited.

Food Allergy and Atopic Allergic Diseases

Five systematic reviews were completed to investigate the relationship between early infant feeding practices and the risk of atopic dermatitis, food allergies, allergic rhinitis, and asthma.⁵⁶ A total of 73 articles met the inclusion criteria. However, there was insufficient evidence to answer 3 of the systematic review questions, namely those comparing lower vs higher intensities, proportions, or amounts of human milk fed to mixed fed infants, or fed by bottle vs by breast. For the remaining 2 comparisons (ever vs. never being fed human milk and shorter vs. longer durations of any human milk feeding), evidence was found for 2 outcomes for specific age groups, but not across the life span.

Ever vs Never Consuming Human Milk

For asthma, moderate evidence indicated that never being fed human milk was associated with a higher risk of childhood asthma risk in childhood, but evidence was insufficient to determine if this relationship persisted into other life stages. Limited evidence did not suggest a relationship between never being fed human milk and atopic dermatitis in childhood. The evidence for birth to 24 months was inconclusive, however, diagnosis of atopic dermatitis can lack specificity in this age group. Evidence was insufficient to determine the relationship between duration of any human milk feeding with atopic dermatitis in adolescence or in adulthood. Insufficient evidence was available to determine a relationship between never vs ever being fed human milk and the risk of developing either allergic rhinitis or food allergy throughout the lifespan.

Duration of Any Human Milk Consumption Among Infants Fed Human Milk

Similar to the findings regarding any human milk feeding, moderate evidence indicated that being fed human milk for shorter durations was associated with higher risk of asthma in

childhood and adolescence, but the evidence was insufficient to determine if this relationship persisted into adulthood. Limited evidence did not suggest a relationship between shorter vs longer duration of any human milk feeding and atopic dermatitis in childhood. Evidence for a relationship between duration of any human milk feeding and atopic dermatitis from birth to 24 months was inconclusive and evidence was insufficient for adolescence or adulthood. In terms of allergic rhinitis in childhood, limited evidence suggested no relationship between the duration of any human milk feeding and evidence is insufficient to determine the relationship from birth to 24 months, in adolescence, or in adulthood. Lastly, evidence was insufficient to determine a relationship between the duration of any human milk feeding with food allergies throughout the lifespan.

Taken together, a protective association between any or longer durations of human milk consumption and lower risk of asthma in childhood was observed, while data for other atopic outcomes were limited or insufficient. These findings are consistent with the most recent conclusions from the American Academy of Pediatrics statement on the impact of breastfeeding on atopic disease.¹⁵⁹ However, a limitation is that nearly all of the evidence in this portfolio was from observational studies. Breastfeeding research may be subject to detection bias, because data are often collected through the use of parent reporting methods that may not be valid and reliable. However, for most studies in this set of evidence, feeding data were collected prospectively, which reduces recall bias. Confounding also can arise because sociodemographic differences between breastfed vs formula-fed groups are rarely mitigated by randomization (the exception is the PROBIT study, which is discussed below) and infant-feeding decisions can be strongly socially patterned. Most studies adjusted for confounding variables deemed important and feasible to control, although the specific adjustment variables varied between studies. Reverse causation can be a major concern for atopy outcomes, because parents may decide, or receive medical advice, to continue or discontinue feeding human milk based on infants' symptoms and because atopic disease in parents or older siblings may influence parents' feeding decisions as they try to prevent asthma. However, the majority of studies found no baseline differences in family history of atopic disease between groups or included family history of atopic disease as an adjustment variable.

The PROBIT cluster RCT was able to overcome many of the above limitations. In this trial,¹⁴² hospitals were randomized to breastfeeding promotion (intervention) or routine care (control). Infants from the intervention sites were significantly more likely than control infants to be breastfed to any degree at age 12 months (19.7 percent vs 11.4 percent) or exclusively breastfed at age 3 (43.3 percent vs 6.4 percent) or 6 (7.9 percent vs 0.6 percent) months.¹⁴² At

age 1 year, the infants in the intervention group were less likely to have atopic eczema than those in the control group (3.3 percent vs 6.3 percent; adjusted OR=0.54; 95% CI: 0.31, 0.95).¹⁴² However, by age 6.5 years, the groups did not differ in ever having atopic dermatitis/eczema, allergic rhinitis or asthma.¹⁶⁰ At age 16 years,¹⁶¹ adolescents in the intervention group had an approximately 54 percent lowered risk of flexural dermatitis (0.3 percent vs 0.7 percent), but no significant differences in lung function or questionnaire-derived measures of atopic eczema or asthma (note that atopic eczema is much less common at this age).¹⁶¹ Thus, this study provides evidence for longer-term protective effects of breastfeeding on flexural dermatitis, though the overall incidence in this population was very low.

The conclusion of our review that human milk is related to reduced risk of asthma is supported by previous meta-analyses.¹⁶²⁻¹⁶⁴ Gdalevich et al¹⁶² reported that the overall odds ratio for the protective effect of breastfeeding was 0.70 (95% CI: 0.60, 0.81). The importance of genetic susceptibility was evident in that the effect estimate was greater in studies of children with atopic first-degree relatives (OR=0.52; 95% CI: 0.35, 0.79) than in studies that combined children with and without atopic family history (OR=0.73; 95% CI: 0.62, 0.86) or those without a family history (OR=0.99; 95% CI: 0.48, 2.03).¹⁶² A more recent study confirmed that infants who were exclusively breastfed for 4 or more months had a reduced risk of asthma during the first 8 years of life (OR=0.63; 95% CI: 0.50, 0.78)] compared to infants breastfed for less than 4 months.¹⁶⁵ The biological plausibility for a role of breastfeeding in protecting against asthma development includes its demonstrated benefit in reducing the number of respiratory tract infections in infancy, especially among infants in middle- and low-income countries.¹⁶⁶ In addition, exclusive breastfeeding may be beneficial for lung function as evidenced by shorter duration of hospital admission, risk of respiratory failure, and the requirement for supplemental oxygen in infants hospitalized with bronchial inflammation.⁴¹ Indeed, infants exclusively breastfed for 4 months or more had better lung function at age 8 years, as measured by peak expiratory flow, than did infants breastfed less than 4 months.¹⁶⁵ Breastfeeding may mediate these effects through protecting the lungs from viral infections or by promoting maturation of the infant immune system and microbiome.¹⁶⁷

SUMMARY

The aim of these systematic reviews was to determine how various exposures to human milk are linked to selected outcomes in offspring. The comparisons were structured so as to align with the first feeding decisions that caregivers make: a) whether or not to feed human milk,

b) duration of human milk feeding, and c) feeding human milk exclusively or supplementing with infant formula. The strongest evidence found was in relation to the first of these comparisons. Specifically, the Committee concluded that ever being breastfed may reduce the risk of overweight or obesity, type 1 diabetes, and asthma, compared to never being breastfed. For the second issue, evidence suggested that a longer duration of any breastfeeding is associated with lower risk of type 1 diabetes and asthma, although the optimal duration of breastfeeding with respect to these outcomes is not well understood. For the third issue, exclusivity of breastfeeding was found to be associated with a lower risk of type 1 diabetes.

The outcomes included in these reviews were limited to overweight and obesity, long-term health outcomes (diabetes and CVD), nutrient status, and atopic or allergic diseases in the offspring, and did not include child infectious diseases (e.g., gastrointestinal, respiratory and ear infections), cancer, mortality, or development, nor any maternal outcomes that may be related to initiation or duration of lactation (see **Part D. Chapter 3: Food, Beverage, and Nutrient Consumption During Lactation**). Implications with regard to recommendations need to be considered in the context of all relevant outcomes, not just those reviewed herein. Nonetheless, the evidence summarized above supports existing recommendations for breastfeeding in the United States¹¹ and globally,¹⁶⁸ including many other high-income countries.^{154,169-173} Those recommendations generally advise exclusive breastfeeding until about age 6 months¹¹ and continued breastfeeding thereafter, together with appropriate complementary feeding, until at least 12 months¹¹ or 24 months of age.¹⁶⁸

Therefore, the Committee supports the following recommendations:

- Encourage exclusive breastfeeding, ideally for the first 6 months of life, with continued breastfeeding through the first year of life or longer as desired by the mother and infant.
- Encourage the broader implementation of policies and programs that promote, protect, and support breastfeeding to benefit both the health of the mother and the infant.

Given the evidence that human milk feeding may be related to infant fatty acid status, depending on maternal diet, the Committee also supports recommendations for lactating women to consume food sources of long-chain polyunsaturated fatty acids (see **Part D. Chapter 3**).

Despite the importance of the questions examined in this chapter for the long-term health of the child, the available evidence for many questions was insufficient to form conclusion statements, highlighting the critical need for additional research. Generally, much more evidence exists about shorter-term outcomes (e.g., in infancy and early childhood) than for long-

term outcomes (into adulthood), because studies of the latter require such a long timeframe. It also is important to note that no conclusions could be made regarding the effects of the intensity, proportion, or amount of human milk consumed by mixed-fed infants for any outcome investigated. Given the high prevalence of mixed-feeding in the U.S. population, additional research is needed to investigate how the patterns and proportions of human milk feeding across the day and night and within each feeding, in the context of mixed-feeding, are related to health outcomes. Similarly, very little evidence is available on the consequences of feeding human milk by bottle vs from the breast. The composition of human milk varies during the day and within a feeding, which may affect the infant's physiology¹⁷⁴; bottle-feeding human milk may modify these patterns. As mentioned previously, some evidence suggests that the feeding dynamics of breast- and formula-feeding mothers and their infants differ, which also deserves further investigation.

Specific research needs for the breastfeeding mother-infant dyad are discussed in **Part E. Future Directions**. However, as mentioned in **Part D. Chapter 3**, the Committee supports the on-going federal initiative to expand research on human milk composition and how it relates to maternal and infant health.¹⁷⁵

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PART D. CHAPTER 5: FOODS AND BEVERAGES CONSUMED DURING INFANCY AND TODDLERHOOD

INTRODUCTION

The age interval for complementary feeding, generally defined as ages 6 to 24 months, is a critical period for growth and development and is characterized by high nutrient needs in relation to the amount of food consumed.¹ For the purposes of this report, complementary feeding is defined as “the process that starts when human milk or infant formula is complemented by other foods or beverages and typically continues to 24 months of age as the child transitions fully to family foods”.² The timing of introduction and the types and amounts of complementary foods and beverages (CFB) provided to infants and toddlers may influence nutritional status, growth and body composition, neurocognitive development, and various health outcomes, both short-term and long-term, including bone health and risk of food allergies and atopic diseases. This chapter describes the findings of the reviews conducted to examine these relationships.

Importance and Relevance of this Topic

For infants fed human milk, nutrient needs can generally be met from human milk alone for approximately the first 6 months.³ Iron is a potential exception: The iron content of human milk is low and breastfed infants generally rely on iron stores present at birth to meet iron needs in early life.⁴ As a result, iron deficiency may occur before age 6 months among infants whose iron stores at birth are low due to low birth weight or gestational age, maternal prenatal iron deficiency, or immediate clamping of the umbilical cord, which prevents full placental transfusion of blood to the newborn.⁵ Vitamin D is another nutrient of concern because human milk vitamin D concentrations may not be sufficient to meet the needs of young infants in populations with inadequate exposure to sunlight and/or inadequate maternal vitamin D intake.⁶ For these reasons, **Part D. Chapter 6: Nutrients from Dietary Supplements During Infancy and Toddlerhood** addresses questions related to the use of iron and vitamin D supplements. For some of the other nutrients, concentrations in human milk may be low if the mother’s intake or nutrient status is deficient (e.g., some of the B vitamins, iodine, selenium),⁷ but this can be addressed by improving the mother’s diet. Most of the minerals in human milk (e.g., iron, zinc, calcium) are not affected by maternal diet.⁷

After age 6 months, complementary foods are needed to ensure adequate nutrition and growth, and to expose infants to varied flavors, textures, and types of foods as they make the

transition to family diets. Because the amounts of CFB consumed are generally small, yet nutrient requirements (per unit of body weight) are high due to the rapid rate of growth, infants need nutrient-dense CFB. For example, the CFB nutrient densities (per 100 kcal of food) required for breastfed infants at ages 6 to 8 months are 9 times higher for iron and 4 times higher for zinc compared to the nutrient densities required for an adult male.⁸

Brain development is most rapid during the first 1,000 days, from conception to age 24 months, and adequate nutrition is critical for this process.^{9,10} Key nutrients include fat (particularly long-chain polyunsaturated fatty acids, which can come from the diet or from endogenous fatty acid metabolism), protein, iron, iodine, zinc, copper, choline, and the B vitamins. As a result, the adequacy of complementary foods to provide some or all of these nutrients may have important effects on child development.

Atopic diseases, including food allergy and allergic skin disease, are relatively common in the United States, with an estimated 5 to 8 percent of children experiencing confirmed food allergies¹¹ and approximately 30 percent of the U.S. population with atopic dermatitis.¹² These outcomes may be influenced by both the timing and the types of complementary foods provided to infants and toddlers.^{13,14} Recent evidence from randomized controlled trials (RCT) suggests that infancy may be a critical period for the development of tolerance to food antigens.¹⁵⁻¹⁷ Thus, this topic is of considerable public health importance.

Children establish food patterns and preferences early in life, which, if they persist, may have a significant impact on certain health outcomes in childhood as well as later in life, such as overweight or obesity and cardiovascular disease (CVD) risk factors (e.g., blood lipids, blood pressure). For this reason, relationships of added sugars and seafood consumption during the period from birth to age 24 months to risk of CVD later in life were examined. These questions are discussed in **Part D. Chapter 9: Dietary Fats and Seafood** and **Part D. Chapter 12: Added Sugars**, respectively.

Finally, it is important to recognize that how infants and toddlers are fed, not just what they are fed, can influence health outcomes. For example, responsive feeding practices that are sensitive to the child's hunger and satiety cues may influence the risk of overweight or obesity and the ability to maintain self-regulation of energy intake later in life.¹⁸ In addition, repeated exposure to healthy foods such as vegetables and fruits may promote acceptance of these foods later in childhood.¹⁹ Although these questions of "how to feed" were not among the topics selected for this 2020 Dietary Guidelines Advisory Committee to address, other resources are available that provide background, evidence, and guidance.^{20,21}

LIST OF QUESTIONS

1. What is the relationship between complementary feeding and growth, size, and body composition?
2. What is the relationship between complementary feeding and developmental milestones, including neurocognitive development?
3. What is the relationship between complementary feeding and nutrient status?
4. What is the relationship between complementary feeding and bone health?
5. What is the relationship between complementary feeding and food allergies and atopic allergic diseases?
6. What is the relationship between added sugars consumption during infancy and toddlerhood and risk of cardiovascular disease?
7. What is the relationship between types of dietary fats consumed during infancy and toddlerhood and risk of cardiovascular disease?
8. What is the relationship between seafood consumption during infancy and toddlerhood and risk of cardiovascular disease and neurocognitive development?

METHODOLOGY

All questions discussed in this chapter were answered using systematic reviews conducted with support from USDA's Nutrition Evidence Systematic Review (NESR) team. NESR's systematic review methodology provided a rigorous, consistent, and transparent process for the Committee to search for, evaluate, analyze, and synthesize evidence.

Questions 1 through 5 in this chapter were answered using existing systematic reviews that were previously conducted by USDA's Nutrition Evidence Systematic Review (NESR) team as part of the Pregnancy and Birth to 24 Months Project, which was completed in 2019. The conclusion statements that answer these questions were taken directly from the existing systematic reviews and the wording reflects the findings of those reviews, which included articles published between 1980 and 2016 or 2017 depending on the review. A description of the process the Committee used to determine that these existing systematic reviews were relevant to their questions and timely enough to not require updating is provided in **Part C. Methodology**. In addition, detailed information about the methodology used to complete these systematic reviews can be found at the following website: nesr.usda.gov/project-specific-overview-pb-24-0.

Methodology specific to Question 6 is in **Part D. Chapter 12: Added Sugars** and methodology specific to Questions 7 and 8 is in **Part D. Chapter 9: Dietary Fats and Seafood**. These questions intended to examine the consumption of added sugars, dietary fats, and seafood in infants and toddlers as well as other age groups.

REVIEW OF THE SCIENCE

Question 1. What is the relationship between complementary feeding and growth, size, and body composition?

Approach to Answering Question: Existing NESR systematic reviews

Conclusion Statements and Grade

Timing of Introduction of Complementary Foods or Beverages

Moderate evidence suggests that first introduction of any complementary food or beverage between the ages of 4 and 5 months compared to approximately 6 months of age is not associated with weight status, body composition, body circumferences, weight, or length among generally healthy, full-term infants. Grade: Moderate

Limited evidence suggests that introducing complementary foods or beverages before age 4 months of age may be associated with higher odds of overweight or obesity. Grade: Limited

There is not enough evidence to determine the relationship between introduction of complementary foods or beverages at 7 months of age or older on growth, size, or body composition. Grade: Grade Not Assignable

Types and Amounts of Complementary Foods or Beverages

Moderate evidence indicates that higher vs lower meat intake or meat vs iron-fortified cereal intake over a short duration (about 3 months) during the complementary feeding period does not favorably or unfavorably influence growth, size, and/or body composition [Grade: Moderate].

There is insufficient evidence to determine a relationship between meat intake and prevalence/incidence of overweight or obesity.

Limited evidence suggests that type or amount of cereal given does not favorably or unfavorably influence growth, size, body composition, and/or prevalence/incidence of overweight or obesity. Grade: Grade Not Assignable¹

Moderate evidence suggests that consumption of complementary foods with different fats and/or fatty acid composition does not favorably or unfavorably influence growth, size, or body composition [Grade: Moderate]. There is not enough evidence to determine a relationship between consumption of complementary foods with different fats and/or fatty acid composition and prevalence/incidence of overweight or obesity.

Limited evidence suggests that sugar-sweetened beverage consumption during the complementary feeding period is associated with increased risk of obesity in childhood, but is not associated with other measures of growth, size, and body composition. Grade: Limited

Limited evidence showed a positive association between juice intake and infant weight-for-length and child body mass index z-scores. Grade: Limited

No conclusion could be made about the relationship between other complementary foods (vegetables, fruit, dairy products and/or cow milk, cereal-based products, milk-cereal drink, and/or categories such as “ready-made foods”) and growth, size, body composition, and/or prevalence/incidence of overweight or obesity. Grade: Grade Not Assignable

No conclusion could be made about the relationship between distinct dietary patterns during the complementary feeding period and growth, size, body composition, and/or prevalence/incidence of malnutrition, overweight or obesity. Grade: Grade Not Assignable

Summary of the Evidence

Timing of Introduction of Complementary Foods or Beverages

- This review included 81 articles that examined the association between timing of introduction of CFB and growth, size, and/or body composition across the lifespan.²²

¹ Grade not assigned due to inconsistency in types of cereal examined.

- Timing of CFB introduction is the age at which any or specific types of CFB were first consumed and was examined as early as age 1 month and as late as age 12 months.
- Timing of CFB introduction was not associated with growth, size, body composition, and/or weight status in the majority of included studies. A limited number of observational studies suggested that CFB introduction before age 4 months was associated with higher odds of overweight or obesity.
- Given the normal variation in healthy child growth patterns, caution should be used when interpreting results between timing, types, and/or amounts of CFB and outcomes for individuals based on findings at the population level.

For additional details on this body of evidence, visit: [nesr.usda.gov/what-relationship-between-timing-introduction-complementary-foods-and-beverages-and-growth-size-and#full-review](https://www.nesr.usda.gov/what-relationship-between-timing-introduction-complementary-foods-and-beverages-and-growth-size-and#full-review)

Types and Amounts of Complementary Foods or Beverages

- This review included 49 articles from 18 RCTs, 1 non-randomized controlled trial (non-RCT), and 30 prospective cohort studies (PCSs).²
- The studies varied in terms of the types and/or amounts of CFB examined. Studies examined meat, cereal, foods with different fatty acid composition, sugar-sweetened beverages (SSB), juice or 100% juice, and other individual CFB, as well as distinct dietary patterns consumed during the complementary feeding period.
- Gaps and limitations in the evidence included the need for RCTs and studies that examine a wider range of specific types and amounts of complementary foods and beverages, account for the rationale for type or amount of complementary foods and beverages given (e.g., reverse causality), and adjust for potential confounders (e.g., human milk and/or formula-feeding and baseline growth status).

For additional details on this body of evidence, visit: [nesr.usda.gov/what-relationship-between-types-and-amounts-complementary-foods-and-beverages-and-growth-size-and#full-review](https://www.nesr.usda.gov/what-relationship-between-types-and-amounts-complementary-foods-and-beverages-and-growth-size-and#full-review)

Question 2. What is the relationship between complementary feeding and developmental milestones, including neurocognitive development?

Approach to Answering Question: Existing NESR systematic reviews

Conclusion Statements and Grade

Timing of Introduction of Complementary Foods or Beverages

There was insufficient evidence to draw a conclusion about the relationships between timing of introduction of complementary foods and beverages and developmental milestones. Grade: Grade Not Assignable

Types and Amounts of Complementary Foods or Beverages

There was insufficient evidence to draw a conclusion about the relationships between types and amounts of complementary foods and beverages consumed and developmental milestones. Grade: Grade Not Assignable

Summary of the Evidence

Timing of Introduction of Complementary Foods or Beverages

- Three articles (1 RCT; 2 observational studies) met criteria for inclusion that examined timing of introduction of CFB and developmental milestones²³:
 - The RCT found no associations between timing of CFB and receptive or expressive language or fine- or gross-motor milestones at ages 30 to 35 months.
 - One observational study reported that earlier CFB introduction at age 4 months relative to at or after age 6 months was associated with earlier gross-motor milestone achievement (e.g., crawling, cruising, and walking) by age 18 months, as reported by mothers.
 - The other observational study found no associations between timing of CFB introduction and reading or math skills at age 4 years.
- The relationship between timing of introduction of CFB and developmental milestones may be influenced by a number of related factors, such as birth weight, current weight, type of early feeding (breast, formula, or mixed feedings), types and/or amount of human milk and CFB consumed, and the interval between exposure and outcome assessment.

- The ability to draw conclusions was restricted by an inadequate amount of evidence that was limited by the potential for reverse causality, and wide variation in study design, type and age of outcome assessment, exposure assessment, and reported results.

For additional details on this body of evidence, visit: [nesr.usda.gov/what-relationship-between-timing-introduction-complementary-foods-and-beverages-and-developmental#full-review](https://www.nesr.usda.gov/what-relationship-between-timing-introduction-complementary-foods-and-beverages-and-developmental#full-review)

Types and Amounts of Complementary Foods or Beverages

- This review included 8 studies, including 3 RCTs and 5 PCSs, that examined the relationship between consuming different types and/or amounts of CFB and developmental milestones during childhood through age 18 years.²³
- The studies varied in terms of the types and/or amounts of CFB examined, which included dietary patterns consumed during the complementary feeding period, meat and/or fortified-cereal intake, and foods with differing levels of docosahexaenoic acid (DHA) or phytate.
- Different types of developmental milestone outcomes were measured between ages 4 months and 8.5 years, including communication (e.g., sentence repetition), cognition (e.g., mental development index), motor (e.g., psychomotor development index), and neurological (e.g., cortical processing).
- Three articles from 2 observational studies identified positive associations between dietary patterns emphasizing vegetables and meats during the complementary feeding period, and intelligence quotient (IQ) between ages 4 and 8.5 years. However, a conclusion could not be drawn due to low generalizability and heterogeneity in exposures, observed effects, and potential confounding.
- One high-quality study found a positive association between DHA-enriched baby food and visual acuity (cortical processing). However, it was not possible to draw a conclusion with only 1 study.
- Because the study designs varied substantially, it was difficult to compare and contrast the reported results.
- No conclusion regarding the relationship between types and/or amounts of CFB and developmental milestones could be drawn due to an inadequate number of studies that were comparable in terms of design, the types of CFB examined, how and when developmental milestones outcomes were assessed, and reported results.

For additional details on this body of evidence, visit: [nesr.usda.gov/what-relationship-between-types-and-amounts-complementary-foods-and-beverages-consumed-and-0#full-review](https://www.nesr.usda.gov/what-relationship-between-types-and-amounts-complementary-foods-and-beverages-consumed-and-0#full-review)

Question 3. What is the relationship between complementary feeding and nutrient status?

Approach to Answering Question: Existing NESR systematic reviews

Conclusion Statements and Grade

Timing of Introduction of Complementary Foods or Beverages

Moderate evidence suggests that introducing complementary foods and beverages at 4 months of age compared to 6 months of age offers no long-term advantages or disadvantages in terms of iron status among healthy, full-term infants who are breastfed, fed iron-fortified formula, or both. Grade: Moderate

There is not enough evidence to determine the relationship between timing of introduction of complementary foods and beverages and zinc, vitamin D, vitamin B₁₂, folate, or fatty acid status. Grade: Grade Not Assignable

Types and Amounts of Complementary Foods or Beverages

Strong evidence suggests that consuming complementary foods and beverages that contain substantial amounts of iron, such as meats or iron-fortified cereal, helps maintain adequate iron status or prevent iron deficiency during the first year of life among infants with insufficient iron stores or breastfed infants who are not receiving adequate iron from another source [Grade: Strong]. However, the benefit of these types of complementary foods and beverages for infants with sufficient iron stores, such as those consuming iron-fortified infant formula, is less evident. There is not enough evidence to determine the relationship between other types/amounts of complementary foods and beverages containing lesser amounts of iron, such as fruits and vegetables, and iron status.

Limited evidence suggests that consuming complementary foods and beverages that contain substantial amounts of zinc, such as meats or cereals fortified with zinc, supports zinc status during the first year of life, particularly among breastfed infants who are not receiving adequate

zinc from another source. However, the benefit of these types of complementary foods for infants consuming fortified infant formula is less evident. Grade: Limited

Moderate evidence suggests that consuming complementary foods and beverages with differing fatty acid profiles, particularly long-chain polyunsaturated fatty acids, can influence fatty acid status. Grade: Moderate

During the second year of life, good sources of micronutrients are still needed, but there is limited evidence to indicate which types and amounts of complementary foods and beverages are associated with adequate micronutrient status.

There is not enough evidence to determine the relationship between types and amounts of complementary foods and beverages and vitamin B₁₂, vitamin D, or folate status. Grade: Grade Not Assignable

Summary of the Evidence

Timing of Introduction of Complementary Foods or Beverages

- Nine studies met the inclusion criteria for this systematic review, with most studies examining the relationship between timing of introduction of CFB and iron status. Few studies examined zinc, vitamin D, vitamin B₁₂, folate, and/or fatty acid status.²⁴
- The majority of studies reported no significant associations between timing of CFB introduction and nutrient status.
- Additional factors that need to be considered in examining the relationship between the age at which CFB are introduced and nutrient status include: birth weight, post-natal growth, type of feeding (i.e., breast, formula, or mixed feedings), iron stores at birth, and intake and absorption of iron from sources other than human milk, including types and amounts of CFB being consumed.

For additional details on this body of evidence, visit: [nesr.usda.gov/what-relationship-between-timing-introduction-complementary-foods-and-beverages-and-micronutrient#full-review](https://www.nesr.usda.gov/what-relationship-between-timing-introduction-complementary-foods-and-beverages-and-micronutrient#full-review)

Types and Amounts of Complementary Foods or Beverages

- Thirty-one studies met the inclusion criteria for this systematic review.²⁴
 - Most studies examined the relationship between types and/or amounts of CFB and iron status, and the CFB examined were largely limited to iron-fortified cereals and meats.
 - Several studies examined zinc and fatty acid status and few studies examined vitamin D, vitamin B₁₂, and folate.
- One RCT, conducted in both breastfed and formula fed infants, showed that consuming meats or iron- and/or zinc-fortified cereals as CFB generally protected against iron deficiency anemia and supported zinc status in the first year of life, though evidence is more limited in the second year of life.
 - Among breastfed infants, meat and iron- and zinc-fortified cereals supported iron and zinc status in later infancy. Meat provided a valuable source of trace minerals for breastfed infants who may not have been fed iron- and zinc-fortified products. In fact, the frequency of meat consumption was associated with iron status in the first and second years of life.
 - In infants and toddlers whose diets already contained other bioavailable iron and zinc sources (i.e., infant formulas and cereal fortified with iron and/or zinc), meat offered little additional benefit for iron or zinc status, though it is an important source of bioavailable iron and zinc.
- Dietary sources of fatty acids, particularly long-chain polyunsaturated fatty acids, in CFB (i.e., oils, fish, meats, and eggs) influenced the plasma fatty acid profile of infants and toddlers.
- A limitation of some of the studies included in this systematic review was lack of accounting for whether infants were fed breast milk and/or infant formula, and other aspects of the overall diet, including consumption of fortified products and bioavailability of nutrients consumed. Another limitation was a lack of studies that examined vitamin D, vitamin B₁₂, and folate.

For additional details on this body of evidence, visit: [nesr.usda.gov/what-relationship-between-types-and-amounts-complementary-foods-and-beverages-consumed-and#full-review](https://www.nesr.usda.gov/what-relationship-between-types-and-amounts-complementary-foods-and-beverages-consumed-and#full-review)

Question 4. What is the relationship between complementary feeding and bone health?

Approach to Answering Question: Existing NESR systematic reviews

Conclusion Statements and Grade

Timing of Introduction of Complementary Foods or Beverages

Insufficient evidence is available to draw conclusions about the relationship between the timing of introduction of complementary foods and beverages and bone health. Grade: Grade Not Assignable

Types and Amounts of Complementary Foods or Beverages

Insufficient evidence is available to draw conclusions about the relationship between the types and/or amounts of complementary foods and beverages consumed and bone health. Grade: Grade Not Assignable

Summary of the Evidence

Timing of Introduction of Complementary Foods or Beverages

- Three studies met the inclusion criteria for this systematic review, including 1 RCT, 1 PCS, and 1 case-control study.²⁵
- The RCT included a small sample of infants fed only vitamin D-fortified infant formula, and did not follow infants long enough to assess the impact of timing of introduction to CFB and bone health, as outcomes were assessed when infants were age 26 weeks.
- The observational studies did not measure and/or account for a number of confounding factors that could have influenced the relationship between timing of CFB introduction and bone health later in childhood.
- The ability to draw conclusions about the relationship between the timing of CFB introduction and bone health was limited by an overall lack of research, as well as heterogeneity in the 3 studies included in this systematic review with regard to methodology, subject populations, and results.

For additional details on this body of evidence, visit: [nesr.usda.gov/what-relationship-between-timing-introduction-complementary-foods-and-beverages-and-bone-health#full-review](https://www.nesr.usda.gov/what-relationship-between-timing-introduction-complementary-foods-and-beverages-and-bone-health#full-review)

Types and Amounts of Complementary Foods or Beverages

- Two PCSs met the inclusion criteria for this review, both of which examined the relationship between infants' and toddlers' dietary patterns and bone health.²⁵
- The ability to draw conclusions about the relationship between the types and/or amounts of CFB consumed and bone health was limited by an overall lack of research.
- Although both cohort studies included in this review assessed dietary patterns at ages 12 to 13 months in relationship to a single assessment of bone mineral content at ages 4 or 6 years, it was not possible to draw conclusions for types and/or amounts of CFB and bone health. This was due to the non-specific nature of the dietary patterns, as well as the long interval between the assessment of dietary pattern and radiological measurement of bone health.

For additional details on this body of evidence, visit: [nesr.usda.gov/what-relationship-between-types-and-amounts-complementary-foods-and-beverages-consumed-and-bone#full-review](https://www.nesr.usda.gov/what-relationship-between-types-and-amounts-complementary-foods-and-beverages-consumed-and-bone#full-review)

Question 5. What is the relationship between complementary feeding and food allergies and atopic allergic diseases?

Approach to Answering Question: Existing NESR systematic reviews

Conclusion Statements and Grades

Timing of Introduction of Complementary Foods or Beverages

Moderate evidence suggests that there is no relationship between the age at which complementary feeding first begins and risk of developing food allergy, atopic dermatitis/eczema, or asthma during childhood. Grade: Moderate

There is insufficient evidence to determine the relationship between the age at which complementary foods or beverages are first introduced and risk of developing allergic rhinitis during childhood. Grade: Grade Not Assignable

Types and Amounts of Complementary Foods or Beverages

Peanut, Tree Nuts, Seeds

Strong evidence suggests that introducing peanut in the first year of life (after 4 months of age) may reduce risk of food allergy to peanuts [Grade: Strong]. This evidence is strongest for introducing peanut in infants at the highest risk (with severe atopic dermatitis and/or egg allergy) to prevent peanut allergy, but is also applicable to infants at lower risk. However, the evidence for tree nuts and sesame seeds is limited. Limited evidence also suggests that there is no relationship between consumption of peanut, tree nuts, or sesame seeds during the complementary feeding period and risk of atopic dermatitis/eczema and asthma [Grade: Limited]. There is not enough evidence to determine the relationship between consuming peanut, tree nuts, or seeds as complementary foods and allergic rhinitis.

Egg

Moderate evidence suggests that introducing egg in the first year of life (after 4 months of age) may reduce risk of food allergy to egg [Grade: Moderate]. Limited evidence suggests that there is no relationship between the age of introduction to egg and risk of atopic dermatitis/eczema and asthma [Grade: Limited]. There is not enough evidence to determine if there is a relationship between consuming egg as a complementary food and allergic rhinitis.

Fish

Limited evidence suggests that introducing fish in the first year of life (after 4 months of age) may reduce risk of atopic dermatitis/eczema [Grade: Limited]. There is not enough evidence to determine if there is a relationship between consuming fish as a complementary food and risk of allergy to fish or other foods, asthma, or allergic rhinitis. There is also not enough evidence to determine if there is a relationship between consuming shellfish as a complementary food and risk of food allergy, atopic dermatitis/eczema, asthma, or allergic rhinitis.

Cow Milk Products

Limited evidence suggests there is no relationship between age of introduction of cow milk products, such as cheese and yogurt, and risk of food allergy and atopic dermatitis/eczema [Grade: Limited]. There is not enough evidence to determine if there is a relationship between consuming milk products during the complementary feeding period and risk of asthma or allergic rhinitis.

Other Foods

Wheat: There is not enough evidence to determine if there is a relationship between wheat consumption during the complementary feeding period and risk of food allergy, atopic dermatitis/eczema, asthma, or allergic rhinitis. Grade: Grade Not Assignable

Soy: There is not enough evidence to determine if there is a relationship between soybean consumption during the complementary feeding period and risk of food allergy, atopic dermatitis/eczema, asthma, or allergic rhinitis. Grade: Grade Not Assignable

Foods and beverages that are not common allergens: Limited evidence from observational studies suggests that introducing foods not commonly considered to be allergens, such as fruits, vegetables, and meat, in the first year of life (after 4 months of age) is not associated with risk of food allergy, atopic dermatitis/eczema, asthma, or allergic rhinitis. Grade: Limited

Diet diversity and dietary patterns: There is not enough evidence to determine a relationship between diet diversity or dietary patterns and risk of food allergy, atopic dermatitis/eczema, asthma, or allergic rhinitis. Grade: Grade Not Assignable

Summary of the Evidence

Timing of Introduction of Complementary Foods or Beverages

- The 31 observational studies included in this systematic review examined the relationship between the age of first introduction to a CFB and risk of food allergies, atopic dermatitis/eczema, asthma, or allergic rhinitis occurring during childhood through age 18 years.¹⁴
 - The studies included in this review examined the timing of introduction to CFB, or the age at which infants were first introduced to any foods or beverages other than human milk or infant formula. (Note: Studies that examined the timing of introduction of specific types of CFB, including common allergenic foods, such as peanuts, eggs, and fish, were addressed under Types and Amounts of Complementary Foods and Beverages below).
 - These studies did not specify what food or beverage was first introduced. However, highly allergenic foods are not typically the first CFB introduced into an infant's diet. Therefore, it is likely that the studies in this body of evidence reflected the first introduction of cereals, fruits, and vegetables.

- Nine studies examined risk of food allergy, 20 studies examined risk of eczema or atopic dermatitis, 8 studies examined risk of asthma, and 4 studies examined risk of allergic rhinitis.
- Most evidence reported no significant associations between age of first introduction to CFB and risk of food allergy. Although some evidence suggested that earlier first introduction of CFB may be associated with increased risk of developing food allergy, confidence in the results was restricted by methodological limitations.
- The inability to draw stronger conclusions about the relationship between the timing of first introduction to CFB and the risk of atopic disease is due to several limitations:
 - Use of non-validated or unreliable measures to assess risk of atopic disease (e.g., parent report of a physician diagnosis or the child's symptoms) and assessment of outcomes later in childhood (through age 10 years), when some atopic diseases, such as eczema, may have already resolved, or very early in childhood (age 3 to 4 months), before some atopic diseases may have occurred.
 - Lack of adjustment for key confounders, such as consumption of human milk and/or human milk substitutes (e.g., cow milk formula, hydrolyzed infant formula, or fluid cow milk), parental smoking, and exposure to household pets.
 - Potential for reverse causality due to baseline atopic disease risk status affecting both the timing and types and amounts of CFB introduced, and risk of developing atopic disease.

For additional details on this body of evidence, visit: [nesr.usda.gov/what-relationship-between-timing-introduction-complementary-foods-and-beverages-and-food-allergy#full-review](https://www.nesr.usda.gov/what-relationship-between-timing-introduction-complementary-foods-and-beverages-and-food-allergy#full-review)

Types and Amounts of Complementary Foods or Beverages

- The 39 studies included in this systematic review examined the relationship between consuming specific types of CFB (including amounts and the age at which the specific CFB were introduced) and risk of food allergies, atopic dermatitis/eczema, asthma, and allergic rhinitis occurring during childhood through age 18 years. An additional 12 studies examined diet diversity and 2 studies examined dietary patterns during the complementary feeding period in relation to these outcomes.¹⁴
- A number of studies examined consumption of the most common allergenic foods during the complementary feeding period and risk of atopic disease.

- Fourteen studies, including 2 RCTs, 6 PCSs, 4 nested case-control studies, and 2 case-control studies, examined the consumption of peanuts, tree nuts, or seeds during the complementary feeding period in relation to risk of developing atopic disease. Nine studies (2 RCTs) examined food allergy, 5 studies examined atopic dermatitis/eczema, and 2 studies examined asthma; no studies were identified that examined risk of allergic rhinitis.
- Twenty-eight studies, including 6 RCTs, 15 PCSs, 5 nested case-control studies, and 2 case-control studies, examined the consumption of eggs as a complementary food in relation to risk of developing any atopic disease. Thirteen studies (6 RCTs) examined food allergies, 15 studies (1 RCT) examined atopic dermatitis/eczema, 4 studies examined asthma, and 5 studies examined allergic rhinitis.
- Twenty-four studies, including 1 RCT, 18 PCSs, 3 nested case-control studies, and 2 case-control studies, examined the consumption of fish as a complementary food in relation to risk of developing atopic disease. Six studies (1 RCT) examined food allergies, 15 studies examined atopic dermatitis/eczema, 7 studies examined asthma, and 7 studies examined allergic rhinitis.
- Sixteen studies, including 1 RCT, 11 PCSs, 2 nested case-control studies, and 2 case-control studies, examined the consumption of cow milk products, such as cheese and yogurt, during the complementary feeding period in relation to risk of developing atopic disease. Four studies (1 RCT) examined food allergies, 9 studies examined atopic dermatitis/eczema, 3 studies examined asthma, and 3 studies examined allergic rhinitis.
- Eighteen studies, including 1 RCT, 11 PCSs, 5 nested case-control studies, and 1 case-control study, examined the consumption of wheat or cereals (including, but not limited to, wheat cereal) during the complementary feeding period in relation to risk of developing atopic disease. Eight studies examined food allergies, 9 studies examined atopic dermatitis/eczema, 3 studies examined asthma, and 2 studies examined allergic rhinitis.
- Four PCSs examined the relationship between age of introduction to soy and risk of developing atopic disease. One study examined food allergies, 3 studies examined atopic dermatitis/eczema, and 1 study examined asthma.
- A number of observational studies also examined the relationship between other types of CFB, not considered to be major allergens (e.g., fruit, vegetables, meat) and atopic diseases.

- The studies that examined diet diversity or dietary patterns were all observational, including 11 PCSs (from 6 cohorts) and 3 case-control studies.
- Many of the studies included in this review exclusively enrolled or primarily enrolled participants who were at greater risk of allergies and/or atopic disease than the general population on the basis of family history. However, despite the inclusion of higher risk populations in this body of evidence, the results are probably generalizable to infants and toddlers who are lower risk for atopic disease, but the benefit of early introduction on preventing allergy may not be as great.

For additional details on this body of evidence, visit: [nesr.usda.gov/what-relationship-between-types-and-amounts-complementary-foods-and-beverages-consumed-and-food#full-review](https://www.nesr.usda.gov/what-relationship-between-types-and-amounts-complementary-foods-and-beverages-consumed-and-food#full-review)

Question 6. What is the relationship between added sugars consumption during infancy and toddlerhood and risk of cardiovascular disease?

Approach to Answering Question: NESR systematic review

See *Part D. Chapter 12: Added Sugars*, Question 3, for a review that addressed added sugars and risk of CVD. This review included 1 study that examined the birth to age 24 months population.

Question 7. What is the relationship between types of dietary fats consumed during infancy and toddlerhood and risk of cardiovascular disease?

Approach to Answering Question: NESR systematic review

See *Part D. Chapter 9: Dietary Fats and Seafood*, Question 1, for a review that addressed dietary fat and risk of CVD. This review included 3 studies that examined the birth to age 24 months population.

Question 8. What is the relationship between seafood consumed during infancy and toddlerhood and risk of cardiovascular disease and neurocognitive development?

Approach to Answering Question: NESR systematic review

See *Part D. Chapter 9: Dietary Fats and Seafood*, Questions 2 and 3, for reviews that addressed seafood consumption and risk of cardiovascular disease and neurocognitive development, respectively. The reviews did not identify any studies that examined the birth to age 24 months population.

DISCUSSION

Timing of Introduction of Complementary Foods and Beverages

Growth, Size, and Body Composition

The Committee concluded that introducing CFB between ages 4 and 5 months, compared with age 6 months, offers no long-term advantages or disadvantages in terms of weight status, body composition, body circumferences, weight, or length of healthy, full-term infants. This conclusion was considered applicable to the U.S. population but was graded as “Moderate” because the evidence included only 2 RCTs and the observational studies were limited by lack of controlling for all of the key potential confounders and other methodological issues. The Committee concluded that introducing CFB before age 4 months may increase the odds of becoming overweight or obese, though this conclusion was graded as “Limited” because the evidence was scarce. Insufficient evidence was available to determine whether introducing CFB after age 7 months affects growth, size, or body composition.

The conclusions above regarding growth, size, and body composition are generally consistent with those of other recent reviews.^{26,27} For example, in a meta-analysis of PCSs, Wang et al²⁶ found that introducing CFB before age 4 months was associated with increased risk of overweight (relative risk (RR)=1.18; 95% confidence interval (CI): 1.06, 1.31) and obesity (RR=1.33; 95% CI: 1.07, 1.64) at ages 2 to 12 years. Grote et al²⁷ suggest that formula-fed infants may be at particular risk of excess energy intake when CFB are introduced early, as they appear to exhibit less self-regulation of energy intake than is observed among breastfed infants.

Developmental Milestones

The Committee was unable to draw a conclusion about the relationship between the timing of introduction of CFB and developmental milestones due to the limited number of studies, as well as variability in study design, type of developmental milestones, age of assessment, validity and reliability of assessment of milestones, and potential for reverse causality.

Nutrient Status

The Committee concluded that introducing CFB at age 4 months compared to age 6 months offers no long-term advantages or disadvantages in terms of iron status. This conclusion was graded as “Moderate” based mainly on the RCTs, as the observational studies available had several serious limitations, including lack of adjustment for potential confounders. Study populations were likely relevant to the U.S. population, but information for lower-income populations was lacking and racial/ethnic diversity was limited. Also, most of the studies included infants who were iron-replete at baseline, so effects among iron-deficient infants could differ. Evidence was insufficient to determine the relationship between timing of introduction of CFB and other biomarkers of nutrient status.

Bone Health

No conclusion could be drawn with regard to the relationship between the timing of introduction of CFB and bone health. Mixed findings were reported from the 3 studies that examined this relationship, and the age and methods of outcome assessment, as well as whether key confounders were taken into account varied widely across the studies.

Food Allergies and Atopic Allergic Diseases

The Committee examined whether the age at which infants are first introduced to any foods or beverages other than human milk or infant formula (i.e., not specific foods) is related to the risk of atopic diseases occurring during childhood through age 18 years. The conclusion, based on moderate evidence, was that no relationship exists between the age at which complementary feeding first begins and risk of developing food allergy, atopic dermatitis/eczema, or asthma. For allergic rhinitis, evidence was insufficient to determine a relationship. For most of the 31 studies in this evidence base, the majority of infants enrolled were at high risk of developing atopic disease based on family history (parent or sibling) of atopic disease. Some studies enrolled

exclusively breastfed infants, whereas other studies included infants who were breastfed, formula-fed, or mixed-fed. For food allergies, most of the 9 studies applied multiple valid and reliable methods to diagnose the condition, but a few studies relied on less valid methods, such as parent or physician report of either symptoms or the diagnosis. Five reported no significant associations between age of first introduction to CFB and risk of food allergy, whereas 4 reported that earlier introduction of CFB may be associated with increased risk of developing food allergy. Confidence in these results was restricted by methodological limitations. For other outcomes, the majority of studies showed no significant associations: 15 of 20 studies of atopic dermatitis, 7 of 8 studies of asthma, and 3 of 4 studies of allergic rhinitis.

Types and Amounts of Complementary Foods and Beverages

Growth, Size, and Body Composition

In general, the Committee found relatively little evidence with regard to whether the types and amounts of different CFB are related to growth, size, or body composition. Two conclusions were graded as “Moderate.” The first was that consuming different amounts of meat, or meat instead of iron-fortified cereal, during the complementary feeding period offers no long-term advantages or disadvantages in terms of growth, size, or body composition. Even though the majority of this evidence was from well-designed RCTs, these studies were not intended to ascertain the effects of sufficient versus insufficient meat consumption on growth, size, and body composition. Outcomes were measured before age 18 months, and thus the studies provided no evidence on outcomes later in childhood. The observational studies varied with respect to when meat intake was examined, how outcomes were assessed, and adjustment for key confounders. It should be noted that this conclusion does not apply to overweight or obesity outcomes, for which insufficient evidence was available.

The second conclusion graded as “Moderate” was that consuming complementary foods with different dietary fats or fatty acid composition does not influence growth, size, or body composition. The studies varied with regard to the types of fats and outcomes examined, and outcomes after age 24 months were not examined. Again, evidence was insufficient to determine a relationship with overweight or obesity.

Two conclusions were graded as “Limited.” First, consumption of SSB is associated with an increased risk of obesity in childhood but not with other measures of growth, size, or body composition. This body of evidence is from a small number of observational studies and they were inconsistent in how SSB were defined or examined. Second, juice intake is positively

associated with infant weight-for-length and child body mass index (BMI) z scores, but not enough evidence is available to determine a relationship with other outcome measures. Only a few observational studies were available, and most did not specify the type or percentage of fruit in the juice. In addition, the types of outcomes and ages of children in the studies varied.

Limited evidence suggested that type or amount of cereal given does not favorably or unfavorably influence growth, size, body composition, and/or prevalence/incidence of overweight or obesity, but a grade was not assigned because of inconsistency in the types of cereal and outcomes examined. Evidence was insufficient for the relationships of these outcomes to the types or amounts of other CFB, such as vegetables, fruit, dairy products and/or cow milk, cereal-based products, milk-cereal drinks, and/or categories such as “ready-made foods.” Study designs and types of CFB examined were heterogeneous and generalizability to the U.S. population was low. Similarly, evidence was insufficient as to whether different dietary patterns are related to growth, size, body composition, and/or prevalence of malnutrition, overweight, or obesity. The studies were difficult to compare due to variation in dietary patterns, health outcomes, and adjustment for confounding factors.

The findings that growth and body composition were generally unrelated to intakes of meat, cereal, or complementary foods differing in fat content or composition are consistent with the conclusions of a recent umbrella review,²⁸ which found no evidence to suggest associations between certain types or patterns of CFB and subsequent body composition, overweight, or obesity. The authors also found no relationship between total fat or polyunsaturated fatty acid intake in the first years of life and these outcomes.

The relationship between consumption of SSB by children younger than age 2 years and subsequent risk of overweight or obesity is of great interest, considering the high prevalence of overweight in the U.S. population, but relatively little evidence is available on this topic. For that reason, the conclusion statement from this review was graded as “Limited.” This uncertainty is echoed by the conclusion of the umbrella review by Patro-Golub et al²⁸, which stated that “there is inconsistent evidence to suggest an association between SSB intake in early childhood and long-term overweight and obesity; current diet is likely to be a major confounder.” Nonetheless, other evidence indicates that intake of SSB in early life is a strong predictor of SSB consumption later in life.²⁹

The relationship between juice intake in early life and risk of overweight also is of great interest. This NESR review suggested a positive association between juice intake and BMI z-score, but the conclusion was graded as “Limited.” In a recent meta-analysis,³⁰ consumption of 100% fruit juice was associated with a 0.087 (95% CI: 0.008, 0.167) unit increase in BMI z score

(4 percent increase in BMI percentile), which the authors judged to be not clinically meaningful. However, as for SSB, the consumption of juice in early life may be associated with consumption of juice and SSB later in childhood.³¹

Developmental Milestones, Including Neurocognitive Development

Evidence was insufficient to draw any conclusions about the relationship between the types or amounts of CFB and developmental milestones, due to an inadequate number of studies that were comparable in design, type of CFB consumed, how and when outcomes were assessed, and which results were reported.

The Committee examined associations between seafood consumption and neurocognitive development, but no studies were located for the birth to age 24 months population.

Nutrient Status

Strong evidence showed that iron-rich or iron-fortified CFB, such as meats or iron-fortified cereals, can help maintain adequate iron status or prevent iron deficiency during the first year of life, particularly among breastfed infants who are not receiving adequate iron from another source once iron stores present at birth are no longer sufficient (e.g., between ages 6 to 8 months).⁵ The benefit of these types of CFB for infants consuming iron-fortified infant formula is less evident. Not enough evidence was available to determine the relationship between other types and amounts of CFB containing lesser amounts of iron, such as fruits and vegetables, and iron status.

Some evidence, though limited, suggested that CFB that contain substantial amounts of zinc, such as meats or cereals fortified with zinc, can support zinc status during the first year of life, particularly among breastfed infants who are not receiving adequate zinc from another source. Again, the benefit of these types of CFB for infants consuming fortified infant formula is less evident. Plasma or serum zinc was the most common biomarker of zinc status used in the studies reviewed. This biomarker has several limitations²⁴ so the findings of studies using this zinc status outcome should be considered with caution. Only one study assessed zinc homeostasis by measuring total absorbed zinc from CFB and the exchangeable zinc pool. It showed lower zinc status in infants randomly assigned to receive infant cereal not fortified with zinc.

Moderate evidence indicated that CFB with differing fatty acid profiles, particularly long-chain polyunsaturated fatty acids, can influence fatty acid status. The studies reviewed varied in

terms of the CFB tested and the outcomes that were measured, but the results were generally consistent.

Not enough evidence was available to determine the relationship between types and amounts of CFB and vitamin B₁₂, vitamin D, or folate status. In addition, the Committee found only limited evidence to indicate which types and amounts of CFB are associated with adequate nutrient status in the second year of life, partly because only a few studies have gone beyond age 12 months.

The conclusion regarding the importance of iron-rich CFB is consistent with the findings of numerous authoritative organizations regarding the need for an adequate source of dietary iron after age 6 months,^{32,33} when iron stores at birth may become depleted. Iron is particularly important for normal neurological development and immune function.³²

The evidence showing that zinc-rich CFB are associated with the ability to maintain adequate zinc status is in agreement with the current understanding of zinc requirements during infancy.³⁴ The concentration of zinc in human milk declines sharply during lactation, such that by age 6 months, zinc intake from human milk is a very small proportion of estimated requirements. For this reason, both iron and zinc are considered “problem nutrients” for breastfed infants at ages 6 to 12 months, and complementary foods rich in these nutrients are needed to fill the gap.

As mentioned previously, polyunsaturated fatty acids are key nutrients for brain development. The evidence showing that CFB differing in fatty acid content can influence infant fatty acid status indicates that particular attention needs to be devoted to the fat content and composition of complementary foods. It has been recognized that intakes of DHA and arachidonic acid (ARA) from complementary foods are likely to be low in many low- and middle-income countries,³⁵ but the same may be true in higher-income countries if intakes of foods rich in these fatty acids are low.

Bone Health

Evidence was insufficient to determine whether the types and amounts of CFB consumed are related to bone health. Only 2 studies were included in the Committee’s review, both of which were PCSs that examined dietary patterns. It was difficult to compare the studies because the patterns examined differed with regard to the combinations of foods and food groups included. These studies assessed bone health outcomes at age 4 or 6 years and did not account for how dietary patterns may have shifted during the follow-up period.

Food Allergies and Atopic Allergic Diseases

Table D5.1 summarizes the findings with respect to food allergies, atopic dermatitis/eczema, asthma and allergic rhinitis. Strong evidence indicated that introducing peanut in the first year of life (after age 4 months) reduces the risk of food allergy to peanuts. This conclusion is consistent with other reviews. A meta-analysis of two high-quality RCTs^{15,16} revealed that peanut introduction at 4 to 11 months of age was associated with a 71 percent reduced risk of peanut allergy ($p=0.009$).³⁶ Historically, preventing food allergy in high-risk infants focused on allergen avoidance, with delayed introduction of potentially allergenic foods,³⁷ but the new evidence prompted a shift in the guidance from avoidance to early introduction of potentially allergenic foods. By 2017, the American Academy of Pediatrics (AAP)³⁸ and other professional and medical organizations³⁹⁻⁴¹ endorsed the introduction of peanut in the first year of life as an approach to prevent peanut allergy. Guidelines from the AAP for the timing of peanut exposure have been set based on an individual infant's risk of peanut allergy,¹³ although implementation of this guidance has been challenging.¹⁷

The evidence on whether the early introduction of other foods containing common dietary antigens can help prevent allergies and related atopic diseases is less strong, as shown in Table D5.1. However, the recent AAP document¹³ states that “there is no evidence that delaying the introduction of allergenic foods, including peanuts, eggs, and fish, beyond 4 to 6 months prevents atopic disease,” and the evidence from the Committee's review suggests that introduction of egg in the first year of life may be beneficial.

To better understand how specific types of foods consumed during infancy and toddlerhood influence risk of developing atopic disease, more research is needed that: a) uses RCT study designs, b) uses valid and reliable measures, c) uses consistent definitions of diet diversity and/or dietary patterns, and assesses these exposures at multiple time points across the complementary feeding period, d) adjusts for key confounders, e) takes into consideration the mechanisms by which specific types of foods may affect risk of developing atopic disease, and what analyses are appropriate, and f) accounts for the potential for reverse causality due to baseline atopic disease risk status affecting both complementary feeding behaviors and risk of developing atopic disease.

Table D5.1. Conclusion statements and grades from a systematic review examining the relationship between the types and amounts of complementary foods consumed and food allergy, atopic dermatitis/eczema, asthma, and allergic rhinitis

Peanut, tree nuts, seeds
- Strong evidence suggests that introducing peanut in the first year of life (after 4 months of age) may reduce risk of food allergy to peanuts [Grade: Strong]. This evidence is strongest for introducing peanut in infants at the highest risk (with severe atopic dermatitis and/or egg allergy) to prevent peanut allergy, but is also applicable to infants at lower risk. However, the evidence for tree nuts and sesame seeds is limited. - Limited evidence also suggests that there is no relationship between consumption of peanut, tree nuts, or sesame seeds during the complementary feeding period and risk of atopic dermatitis/eczema and asthma. Grade: Limited - There is not enough evidence to determine the relationship between consuming peanut, tree nuts, or seeds as complementary foods and allergic rhinitis.
Egg
- Moderate evidence suggests that introducing egg in the first year of life (after 4 months of age) may reduce risk of food allergy to egg. Grade: Moderate - Limited evidence suggests that there is no relationship between the age of introduction to egg and risk of atopic dermatitis/eczema and asthma. Grade: Limited - There is not enough evidence to determine if there is a relationship between consuming egg as a complementary food and allergic rhinitis.
Fish
- Limited evidence suggests that introducing fish in the first year of life (after 4 months of age) may reduce risk of atopic dermatitis/eczema. Grade: Limited - There is not enough evidence to determine if there is a relationship between consuming fish as a complementary food and risk of allergy to fish or other foods, asthma, or allergic rhinitis. - There is also not enough evidence to determine if there is a relationship between consuming shellfish as a complementary food and risk of food allergy, atopic dermatitis/eczema, asthma, or allergic rhinitis.
Cow milk products
- Limited evidence suggests there is no relationship between age of introduction of cow milk products, such as cheese and yogurt, and risk of food allergy and atopic dermatitis/eczema. Grade: Limited - There is not enough evidence to determine if there is a relationship between consuming milk products during the complementary feeding period and risk of asthma or allergic rhinitis.
Wheat
There is not enough evidence to determine if there is a relationship between wheat consumption during the complementary feeding period and risk of food allergy, atopic dermatitis/eczema, asthma, or allergic rhinitis. Grade: Grade Not Assignable
Soy
There is not enough evidence to determine if there is a relationship between soybean consumption during the complementary feeding period and risk of food allergy, atopic dermatitis/eczema, asthma, or allergic rhinitis. Grade: Grade Not Assignable
Foods and beverages that are not common allergens
Limited evidence from observational studies suggests that introducing foods not commonly considered to be allergens, such as fruits, vegetables, and meat, in the first year of life (after 4 months of age) is not associated with risk of food allergy, atopic dermatitis/eczema, asthma, or allergic rhinitis. Grade: Limited

Diet diversity and dietary patterns

- There is not enough evidence to determine a relationship between diet diversity or dietary patterns and risk of food allergy, atopic dermatitis/eczema, asthma, or allergic rhinitis. Grade: Grade Not Assignable

Cardiovascular Disease

Only 1 article⁴² examined the relationship between added sugars consumption during infancy and toddlerhood and risk of cardiovascular disease. That study found no significant associations between sugar-containing beverage intake at age 12 months and CVD-related outcomes (systolic blood pressure, diastolic blood pressure, total cholesterol, high-density lipoprotein cholesterol, low-density lipoprotein cholesterol, and triglycerides) at about age 6 years. However, the investigators found an association between higher intake of sugar-containing beverages and higher cardiometabolic risk factor score at age 6 years in boys (only). The study had limitations: not all key confounders were accounted for (gestational age, race/ethnicity, anthropometry at birth or baseline), several other important factors were not taken into account (maternal diet, parity, participation in a supplemental food program, family history of CVD, and complementary feeding practices), no information on non-completers was given, exposure data were measured only once, and the study provided no pre-registered data analysis plan.

The Committee examined associations between seafood consumption or dietary fat intake and later risk of CVD. For seafood consumption, no studies were located for the birth to age 24 months group. For fat intake and CVD, 3 studies included the birth to age 24 months group but the evidence provided was insufficient to generate separate conclusions for this population.

For these reasons, no conclusions could be drawn for the associations of interest described above for CVD.

SUMMARY

The evidence reviewed has several implications in terms of feeding guidelines for infants and children younger than age 2 years. The existing evidence suggests that CFB should not be introduced to infants before 4 months of age, and that introduction at age 4 to 5 months, as compared to 6 months, does not offer long-term advantages or disadvantages with regard to growth, size, body composition, overweight or obesity; iron status; or risk of developing food allergy, atopic dermatitis/eczema, or asthma during childhood. This recommendation is

consistent with infant feeding guidelines from authoritative sources in high-income countries. Several of these guidelines indicate that complementary foods should be introduced at “about” or “around” 6 months,^{33,43-47} although some recommend an age range of 4 to 6 months.⁴⁰ It should be noted that the outcomes included in the Committee’s reviews were limited to infant growth and body composition, nutrient status, developmental milestones, bone health, and atopic or allergic diseases, and did not include infant infectious diseases (e.g., gastrointestinal, respiratory and ear infections) nor any maternal outcomes that may be related to duration of exclusive breastfeeding (and, hence, age of introduction of complementary foods among breastfed infants). Recommendations regarding feeding of infants and children younger than age 2 years should ideally take into account the benefits and risks related to all relevant outcomes.

With regard to the types of CFB needed, the evidence supports guidance to provide foods that are rich in iron and zinc, either intrinsically (e.g., meats) or due to fortification (e.g., iron fortified infant cereal), particularly during the second 6 months of life among breastfed infants. As explained in the Introduction, after iron stores at birth are depleted, an external source of iron is needed to meet the very high requirements for iron to support growth and development. Results of data analysis and food pattern modeling confirm the challenges of meeting iron needs for breastfed infants at ages 6 to 12 months (see **Part D. Chapter 7: USDA Food Patterns in Infancy and Toddlerhood**). Iron requirements are lower in the second year of life than during infancy but a good source of iron is still needed. Foods that are rich in zinc can support zinc status in the first year of life. As is the case for iron in human milk, the zinc content of human milk after 6 months postpartum is relatively low, so breastfed infants who consume CFB that are high in zinc, such as meat or zinc-fortified foods, are better able to meet zinc requirements. Guidelines from several high-income countries emphasize the need for foods rich in iron and zinc,^{32,33,43,45-48} with some recommending that these foods be the first CFB introduced.

The evidence also supports the need to provide CFB that contain adequate amounts of polyunsaturated fatty acids, given their critical role in brain development and the link between dietary intake and the child’s fatty acid status. As described in **Part D. Chapter 1: Current Intakes of Foods, Beverages, and Nutrients**, intakes of omega-3 and omega-6 fatty acids from CFB among human milk-fed infants at ages 6 to 12 months are below the estimated needs. Although human milk is an important source of key fatty acids, milk concentrations are influenced by maternal dietary intake (see **Part D. Chapter 3: Food, Beverage, and Nutrient Consumption During Lactation**). Thus, both mother and child should consume diets adequate

in these nutrients. Canadian authorities emphasize that higher-fat CFB that are nutrient-dense are key components of a healthy diet for children younger than age 2 years.⁴⁴

The evidence indicates that introducing peanut and egg in the first year of life (after age 4 months) may reduce the risk of food allergy to peanuts and eggs. For other types of food allergy (to fish, shellfish, cow milk products, tree nuts, seeds, wheat, and soy), the evidence for such protective effects is less clear, but the Committee found no evidence that avoiding such foods in the first year of life is beneficial with regard to preventing food allergies or other atopic or allergic diseases. Recent guidelines from high-income countries are generally consistent in recommending that introduction of potentially allergenic foods should not be delayed beyond the first year of life.^{13,33,40}

Avoiding consumption of SSB by children younger than age 2 years is important for several reasons. First, the energy contributed by such beverages leaves less “room” for energy from nutritious CFB, leading to potential nutrient gaps (see **Part D. Chapter 7: USDA Food Patterns in Infancy and Toddlerhood**). Second, the evidence, though limited, suggests that SSB consumption by infants and young children is related to subsequent risk of child overweight. Lastly, intake of SSB in early life may set the stage for greater intake of SSB later in life, with adverse consequences with regard to overweight and obesity and risk of CVD. Consensus is widespread among authoritative bodies in high-income countries that SSB should not be consumed by children younger than 2 years of age.^{40,46,47,49}

The evidence for avoiding or limiting juice intake by the birth to age 24 months population is less clear. A consensus statement from four organizations⁴⁹ recommended that juice not be given in the first year of life, and that no more than 4 ounces per day of 100% fruit juice should be consumed at ages 1 to 3 years. That statement was based on the finding that fruit juice consumption in early life may influence consumption of juice and SSB later in childhood.

As mentioned in the Introduction, the Committee was asked to address several questions related to “what to feed” infants and young children. The topics reviewed represent only a portion of all the feeding questions that are relevant to infants and toddlers from birth to age 24 months. Questions of “how to feed” were not among the topics selected to be addressed by the 2020 Committee, but are of critical importance with regard to building healthy eating habits that can be maintained throughout life.^{20,21} These key issues should be taken up by the next Dietary Guidelines Advisory Committee.

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PART D. CHAPTER 6: NUTRIENTS FROM DIETARY SUPPLEMENTS DURING INFANCY AND TODDLERHOOD

INTRODUCTION

From birth to approximately 6 months of age, infants are generally expected to obtain all of their required nutrients from human milk or infant formula. Between ages 6 and 24 months, the combination of human milk (or infant formula, up to age 12 months) and nutrient-rich complementary foods and beverages is expected to meet nutrient needs. However, in some cases nutrients from dietary supplements may be recommended.

The original questions related to this topic were:

- What is the relationship between specific nutrients from supplements and/or fortified foods consumed during infancy and toddlerhood and nutrient status?
- What is the relationship between specific nutrients from supplements and/or fortified foods consumed during infancy and toddlerhood and growth, size, and body composition?
- What is the relationship between specific nutrients from supplements and/or fortified foods consumed during infancy and toddlerhood and bone health?

The specific nutrients identified for investigation were iron, vitamin D, vitamin B₁₂, and omega-3 fatty acids. Subsequently, the scope of these reviews was reduced to focus on 2 of these nutrients, iron and vitamin D, because of existing recommendations for use of iron and vitamin D supplements for breastfed infants.^{1,2} The Committee's reviews also were restricted to supplements only, not fortified foods, because existing reviews^{3,4} had already examined associations between types of complementary foods (inclusive of fortified foods) and the outcomes of interest (see **Part D. Chapter 5: Foods and Beverages Consumed During Infancy and Toddlerhood**). Finally, the reviews were restricted to examining relationships of: a) iron supplements to growth, size, and body composition, and b) vitamin D supplements to bone health.

Iron Supplements

An American Academy of Pediatrics (AAP) policy statement published in 2010¹ recommended iron supplementation for breastfed infants beginning at age 4 months and

continuing until iron-containing complementary foods are introduced in the diet. However, the issue of routine iron supplementation of breastfed infants has been controversial,⁵⁻⁷ and since that time, other authoritative organizations in Canada, the United Kingdom, Europe, and New Zealand have recommended against routine iron supplementation of all breastfed infants.⁸⁻¹¹ Instead, those organizations only recommend iron supplements for certain infants, such as those with a diagnosis of iron deficiency,¹⁰ or for high-risk groups (e.g., low socioeconomic status or living in areas with a high prevalence of iron-deficiency anemia).⁹ Some of these organizations^{8,9,11} noted the importance of delayed umbilical cord clamping to optimize iron stores at birth and reduce the risk of iron deficiency before age 6 months.¹²

Although providing iron supplements can be highly beneficial for iron-deficient infants, for those who are iron-replete, supplementation may have adverse consequences, such as reduced growth, alterations in absorption of other trace minerals, and gastrointestinal effects such as diarrhea, vomiting, and changes to the gut microflora.^{13,14} For this reason, it is important to understand the potential effects of routine iron supplementation on growth, size, and body composition.

Vitamin D Supplements

Adequate intake of vitamin D is important because of its role in the regulation of calcium and phosphorus metabolism and bone health. Vitamin D deficiency can result in rickets among infants and young children, particularly between the ages of 3 and 18 months.² Although vitamin D can be synthesized in the skin through exposure to sunlight, this is limited during the winter months in most of the United States and for most of the year in northern latitudes. Deficiency is most likely among those living at high latitudes, those with dark skin, and those with inadequate sunlight exposure. The Adequate Intake (AI) for infants is 400 International Units (IU) (10 mcg) per day and the Recommended Dietary Allowance (RDA) for children ages 1 year and older is 600 IU (15 mcg) per day.¹⁵ The average human milk vitamin D concentration is only about 20 IU per liter.²

Although maternal supplementation with high doses of vitamin D can increase milk vitamin D concentrations,¹⁶ the potential risks and benefits of this approach for ensuring adequate vitamin D status of breastfed infants have not been fully evaluated. For this reason, the AAP currently recommends vitamin D supplements for breastfed infants. The recommendation states: “Because human milk contains inadequate amounts of vitamin D (unless the lactating mother is taking supplements of approximately 6,000 IU/d), breastfed and partially breastfed infants should be supplemented with 400 IU of vitamin D per day beginning in the first few days of life

and continued until the infant has been weaned and is drinking at least 1 L/d of vitamin D-fortified infant formula or cow milk”.² Because bone development is the clinical outcome most likely to be influenced by vitamin D (due to its critical role in calcium absorption for bone mineralization), the Committee focused its review on the relationship between vitamin D supplements and outcomes related to bone health.

LIST OF QUESTIONS

1. What is the relationship between iron from supplements consumed during infancy and toddlerhood and growth, size, and body composition?
2. What is the relationship between vitamin D from supplements consumed during infancy and toddlerhood and bone health?

METHODOLOGY

Both questions discussed in this chapter were answered by conducting systematic reviews with support from USDA’s Nutrition Evidence Systematic Review (NESR) team.

NESR’s systematic review methodology provided a rigorous, consistent, and transparent process for the Committee to search for, evaluate, analyze, and synthesize evidence. The Committee developed a systematic review protocol for each question, which described how the Committee would apply NESR’s methodology to answer the question. Each protocol included an analytic framework and inclusion and exclusion criteria that were used to guide identification of the most relevant body of evidence to use in answering each systematic review question. Each analytic framework outlined core elements of the systematic review question (i.e., population; intervention and/or exposure and comparator [i.e., the alternative being compared to the intervention or exposure]; and outcomes), and included definitions for key terms, key confounders, and other factors to be considered when reviewing the evidence. The inclusion and exclusion criteria were selected, up front, to operationalize the elements of the analytic framework, and specify what made a study relevant for each systematic review question. Next, a literature search was conducted to identify all potentially relevant articles, and those articles were screened by two NESR analysts independently based on the criteria selected by the Committee. For each included article, data were extracted and risk of bias assessed. The Committee qualitatively synthesized the body of evidence to inform development of a conclusion

statement(s), and graded the strength of evidence using pre-established criteria for risk of bias, consistency, directness, precision, and generalizability. Finally, recommendations for future research were identified. A detailed description of NESR's systematic review methodology is provided in **Part C. Methodology**, including standard inclusion and exclusion criteria applied in many of the Committee's systematic reviews. Complete documentation of each systematic review is available on the following website: nesr.usda.gov/2020-dietary-guidelines-advisory-committee-systematic-reviews. Below is a summary of the unique elements of the protocols developed to answer the questions on nutrients from dietary supplements consumed during infancy and toddlerhood.

The intervention or exposure was the consumption of iron from dietary supplements for Question 1 and vitamin D from dietary supplements for Question 2. Dietary supplements are products that contain one or more dietary ingredients (in this case, iron or vitamin D) intended to be taken by mouth to supplement the diet.¹⁷ For both questions, the population of interest for the intervention or exposure was infants and toddlers (birth to age 24 months; in this report 0 to age 6 months refers to 0 to age 5.99 months, ages 6 to 12 months refers to ages 6 to 11.99 months, and ages 12 to 24 months refers to ages 12 to 23.99 months). Initially, the protocols for these questions specified an intervention or exposure of iron, vitamin D, vitamin B₁₂, and omega-3 fatty acids from supplements or fortified foods. However, the Committee modified their protocols to focus solely on iron and vitamin D from supplements, for a few reasons. First, iron and vitamin D are the nutrients of greatest public health concern in this age group with respect to the outcomes being examined (i.e., growth and bone health, respectively). Second, iron and vitamin D supplements are recommended for infants in the United States. Third, two existing NESR systematic reviews examined complementary foods, including fortified foods, and the outcomes of interest (see **Part D. Chapter 5: Foods and Beverages Consumed During Infancy and Toddlerhood**).^{3,4} The comparators were the consumption of iron for Question 1 and vitamin D for Question 2 at a different dosage or frequency from supplements or from fortified foods.

For Question 1, the outcomes of interest were measures of growth, size, and body composition at any age (e.g., weight, length/height, body mass index (BMI)/weight-for-length, body circumferences, body composition and distribution, incidence/prevalence of underweight, failure to thrive, stunting, wasting, healthy weight, overweight, and obesity). For Question 2, the outcomes of interest were measures of bone health from birth to age 18 years (i.e., bone mass, including bone

mineral density and bone mineral content; biomarkers of bone metabolism; rickets; and fracture).

When establishing inclusion and exclusion criteria, the Committee used standard NESR criteria for study design, publication status, language of publication, country, study participants, and health status of study participants. Studies were included if they were published from January 2000 to January 2020.

REVIEW OF THE SCIENCE

Question 1. What is the relationship between iron from supplements consumed during infancy and toddlerhood and growth, size, and body composition?

Approach to Answering Question: NESR systematic review

Conclusion Statements and Grades

Moderate evidence indicates that human milk-fed infants who are supplemented with iron do not have greater growth, and may have slower growth, than human milk-fed infants not supplemented with iron. Grade: Moderate

Insufficient evidence is available to determine the relationship between iron from supplements consumed during infancy and body composition during infancy. Grade: Grade Not Assignable

Insufficient evidence is available to determine the relationship between iron from supplements consumed during infancy and growth, size, and body composition beyond age 12 months. Grade: Grade Not Assignable

Insufficient evidence is available to determine the relationship between iron from supplements consumed after age 12 months and growth, size, and body composition. Grade: Grade Not Assignable

Summary of the Evidence

- Ten articles met the inclusion criteria for this systematic review, which presented evidence from 8 randomized controlled trials (RCTs), 1 non-RCT, and 1 study that did not clearly describe its prospective study design.¹⁸⁻²⁷
- The intervention or exposure of interest was iron from supplements consumed during infancy and toddlerhood. Nine studies¹⁹⁻²⁷ examined iron supplementation during infancy, and only 1 study¹⁸ examined iron supplementation during toddlerhood.
- The comparators of interest were different dosages of iron from supplements and iron from fortified foods.
- The outcomes of interest were measures of growth, size, and body composition at any age. However, no articles were identified that examined outcomes beyond 24 months. The articles presented evidence about growth (i.e., change in size between birth or baseline and follow-up) and size (i.e., attained size at follow-up). However, no articles presented evidence about body composition (e.g., percent fat mass, skinfold thickness).
- Moderate evidence, from 5 studies^{21,22,24,26,27} that compared iron from supplements with no iron from supplements, indicated that human milk-fed infants who are supplemented with iron do not have greater growth, and may have slower growth, than human milk-fed infants not supplemented with iron. Inconsistencies in the evidence may be explained by differences in the risk of iron deficiency between the populations studied, differences in participants' consumption of iron-fortified formula or iron-rich foods, and differences in the timing of iron supplementation. This heterogeneity, the small number of studies, and the small sample sizes were the primary factors limiting the ability to draw stronger conclusions.
- Evidence available from 3 studies^{18,20,21} was insufficient to determine whether a relationship exists between iron from supplements, compared with a different dosage or duration of iron from supplements, and growth or size because the studies used heterogeneous interventions that could not be compared.
- Evidence available from 2 studies^{25,26} was insufficient to determine whether a relationship exists between iron from supplements, compared with iron from fortified foods, and growth or size because the studies used heterogeneous interventions that could not be compared.

For additional details on this body of evidence, visit: [nesr.usda.gov/2020-dietary-guidelines-advisory-committee-systematic-reviews/birth-24-months-subcommittee/iron-supplements-infancy-toddlerhood-growth-size-body-composition](https://www.nesr.usda.gov/2020-dietary-guidelines-advisory-committee-systematic-reviews/birth-24-months-subcommittee/iron-supplements-infancy-toddlerhood-growth-size-body-composition)

Question 2. What is the relationship between vitamin D from supplements consumed during infancy and toddlerhood and bone health?

Approach to Answering Question: NESR systematic review

Conclusion Statements and Grades

Limited evidence suggests no relationship between consumption of 400 IU per day of vitamin D from supplements before age 12 months, compared with higher dosages of up to 1,600 IU per day, and biomarkers of bone metabolism in children up to age 36 months. Grade: Limited

Insufficient evidence is available to determine the relationship between 400 IU per day of vitamin D from supplements, compared with higher dosages, and bone mass, rickets, or fracture. Grade: Grade Not Assignable

Insufficient evidence is available to determine the relationship between 400 IU per day of vitamin D from supplements, compared with lower dosages, and bone mass, biomarkers of bone metabolism, rickets, or fracture. Grade: Grade Not Assignable

Insufficient evidence is available to determine the relationship between vitamin D from supplements, compared with no vitamin D from supplements, and bone mass, biomarkers of bone metabolism, rickets, or fracture. Grade: Grade Not Assignable

Insufficient evidence is available to determine the relationship between vitamin D from supplements, compared with vitamin D from fortified foods, and bone mass, biomarkers of bone metabolism, rickets, or fracture. Grade: Grade Not Assignable

Summary of the Evidence

- Six articles met the inclusion criteria for this systematic review,²⁸⁻³³ which presented evidence from 5 independent RCTs (1 research group published 2 articles about the same trial).
- The intervention of interest was vitamin D from supplements consumed during infancy or toddlerhood. In the United States, 400 IU of vitamin D per day is the AI for infants younger than age 12 months, whereas the RDA for ages 12 to 24 months is 600 IU per day. To meet this need, the AAP currently recommends a supplement of 400 IU per day for infants fed

human milk (with the possible exception of infants whose mothers are taking supplements of about 6,000 IU per day²; maternal vitamin D supplementation during lactation was outside of the scope of this systematic review).

- The comparators of interest were different dosages of vitamin D from supplements and vitamin D from fortified foods. However, no articles were identified that included fortified food comparators.
- The outcomes of interest were bone mass, biomarkers of bone metabolism, rickets, and fracture through adolescence (i.e., birth through age 18 years). However, no articles were identified that examined fracture or outcomes beyond age 36 months.
- Limited evidence from 3 studies^{29,30,33} suggests no relationship between 400 IU per day of vitamin D from supplements, compared with higher dosages, and biomarkers of bone metabolism in children up to age 36 months. The ability to draw a stronger conclusion was primarily limited by a small number of studies, small sample sizes, heterogeneous methods, and limited generalizability.
- Evidence available from 4 studies^{28-30,32,33} was insufficient to determine whether a relationship exists between 400 IU per day of vitamin D from supplements, compared with higher dosages, and bone mass. The ability to draw a conclusion was hindered by inconsistent findings from a small number of studies. No studies were available that examined the relationship between 400 IU per day of vitamin D from supplements, compared with higher dosages, and rickets or bone fracture.
- Evidence available from 1 study³³ was insufficient to determine whether a relationship exists between 400 IU per day of vitamin D from supplements, compared with lower dosages, and bone mass or biomarkers of bone metabolism. No studies were available that examined the relationship between 400 IU per day of vitamin D from supplements, compared with lower dosages, and rickets or fracture.
- Evidence available from 1 study³¹ was insufficient to determine whether a relationship exists between 200 IU per day of vitamin D from supplements for different durations, compared with no vitamin D from supplements, and biomarkers of bone metabolism or rickets. No studies were available that examined the relationship between 200 IU per day of vitamin D from supplements for different durations, compared with no vitamin D from supplements, and bone mass or fracture. No studies were available that compared other dosages of vitamin D from supplements with no supplementation. It is likely that the evidence that led to the current supplementation recommendation pre-dates our literature search date range of January 2000 to January 2020.

For additional details on this body of evidence, visit: [nesr.usda.gov/2020-dietary-guidelines-advisory-committee-systematic-reviews/birth-24-months-subcommittee/vitamin-d-supplements-infancy-toddlerhood-bone-health](https://www.nesr.usda.gov/2020-dietary-guidelines-advisory-committee-systematic-reviews/birth-24-months-subcommittee/vitamin-d-supplements-infancy-toddlerhood-bone-health)

DISCUSSION

Iron Supplements

This evidence from the Committee's review showed no positive effects, and possibly negative effects, on growth when iron supplements were given to breastfed infants younger than age 9 months, compared with infants not given iron or given a placebo. Of the 5 RCTs included in this comparison,^{21,22,24,26,27} 3 reported significant differences between intervention groups in one or more growth outcomes (all in the same direction, i.e., slower growth among infants given iron supplements)^{21,26,27} and 2 did not.^{22,24}

Several possible explanations may account for the differences in findings among these 5 studies. First, the study populations differed in several characteristics that may be related to risk of iron deficiency and therefore the potential impact of iron supplements on growth. Four studies were conducted among populations with medium to high average socio-economic or educational status,^{21,22,26,27} whereas the study by Lozoff et al²⁴ was conducted in rural China and only about one-third of mothers had a high school education or greater. Risk of iron deficiency appeared to be greater in the study by Lozoff et al²⁴ based on average hemoglobin and serum ferritin concentrations at age 9 months in the control or placebo groups.³⁴

Second, the studies differed in the extent to which the infants were supplemented with iron-fortified infant formula or iron-rich foods, which may have obscured effects of iron supplementation on growth. Although all studies enrolled infants who were initially breastfed, 3 studies reported that a substantial proportion of infants ceased breastfeeding and/or were supplemented with infant formula,^{22,26,27} whereas Dewey et al²¹ enrolled mothers who intended to exclusively breastfeed until 6 months (except for small "tastes" of low-iron foods) and to continue breastfeeding until at least 9 months. In the study by Lozoff et al,²⁴ investigators reported that more than 80 percent of infants were still breastfeeding at 9 months, and more than 50 percent received breast milk as the sole milk source. Lastly, the timing of iron supplementation differed among studies. Of the 3 studies that began iron supplementation at 1 month or 6 weeks, 2 did not report significant differences in growth between intervention groups,^{22,24} and the third reported significant group differences in growth among females but not

among male infants.²⁷ Both studies that began iron supplementation at about age 4 months demonstrated significant group differences in growth.^{21,26}

The potentially adverse effects of iron supplements on growth of infants and children younger than age 2 years are consistent with other findings. In a systematic review and meta-analysis focused on children ages 4 to 24 months,¹⁴ infants and children randomized to receive iron supplements had less length gain (SMD -0.83 cm, -1.53 to -0.12) and weight gain (-1.12 kg, -1.19 to -0.33) than those who did not receive iron. These analyses included children from both high-income (3 studies) and lower-income (5 studies) countries. In addition, among the trials with illness data, vomiting and fever were more prevalent among children receiving iron.¹⁴ For iron-deficient children, providing sufficient iron (from food, supplements, or fortified foods) is important for reducing iron-deficiency anemia and its consequences, including impaired neurobehavioral development.³⁵ However, iron is a “double-edged sword” in the sense that excess iron intake among iron-replete individuals may be harmful. In the meta-analysis described above,¹⁴ stratified analyses based on the initial iron status of the children were not possible. The potential mechanisms by which iron may adversely affect growth among iron-replete children include increased gastrointestinal illness, impaired zinc or copper status, pro-oxidative or pro-inflammatory effects, and disturbances in the gut microbiota.¹³ Among infants younger than age 6 months, iron homeostasis appears to be absent or limited, which has been attributed to lack of regulation of the iron transporters DMT1 and ferroportin.³⁶ As a result, supplemental iron is likely to be absorbed even if the infant is iron-replete and does not need it. After 6 months, infants appear to be able to downregulate iron absorption appropriately,³⁶ as is the case for older children and adults.

Vitamin D Supplements

All of the studies included in this review were RCTs. A single study³¹ compared vitamin D supplementation to placebo, while all other studies compared the impact of various doses of vitamin D supplementation on bone health indicators from birth to 36 months of age. The groups showed little to no evidence of statistically significant differences in bone health indicators based on dose of Vitamin D supplementation. Of the studies that examined bone health outcomes,^{29-31,33} 2 identified statistically significant differences,^{30,33} but these differences were small in magnitude while the number of comparisons conducted was large and sample sizes in each group were quite small. None of the studies that examined impact of vitamin D supplementation on biomarkers of bone metabolism identified any significant differences. Because only 1 study³¹

examined the impact of vitamin D supplementation on incidence of rickets, and not a single event was observed in that study, no conclusions could be drawn regarding that outcome.

Information on race and/or ethnicity of the participants was not provided in most of the studies. The countries of study origin were Canada, the United States, and Finland, but without knowing more about the characteristics of the participants, it is difficult to judge the potential risk factors for vitamin D deficiency that may have been present.

SUMMARY

The evidence suggesting slower growth among infants given iron supplements suggests that routine iron supplementation of all breastfed infants may not be advisable. An alternative could be to screen for iron deficiency among higher-risk infants younger than age 6 months, and provide iron supplements only to those with biomarkers indicating iron deficiency. However, screening for iron deficiency using appropriate biomarkers, such as serum ferritin, could be challenging because it is not as simple as measuring hemoglobin.³⁷ Iron supplementation is routinely advised for low birthweight and preterm infants beginning at age 1 month,¹ who are born with low iron stores. Apart from those subgroups, infants at higher risk for iron deficiency before age 6 months are those with birth weight less than 3,000 grams, male infants,³⁸ and those for whom the umbilical cord was clamped immediately.¹² After age 6 months, other sources of iron can be provided, such as iron-rich or iron-fortified complementary foods, so iron supplementation is generally not needed. Further research is needed to: a) evaluate how to best identify and treat infants who become iron deficient before age 6 months, including populations with racial and ethnic diversity, and b) investigate the biological mechanisms by which iron supplementation during infancy may affect growth, including potential effects on morbidity, the microbiome, zinc and copper status, and oxidative stress or lipid peroxidation.

Existing recommendations regarding vitamin D supplementation during infancy are based on a body of evidence compiled largely before 2000, the starting date for this review. The limited evidence available since 2000 suggests that doses higher than 400 IU per day (the current AAP recommendation for infants²) do not result in differences in biomarkers of bone metabolism in infancy or early childhood. Thus, at this time, the current body of evidence does not provide a basis for recommending vitamin D supplementation above 400 IU per day during infancy. Further research is needed to investigate how much (if any) vitamin D supplementation is needed for breastfed infants when the mother is taking high doses of vitamin D. Future studies

should be appropriately powered, include racially and ethnically diverse samples, and report baseline infant vitamin D status, human milk vitamin D content, and sun exposure.

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PART D. CHAPTER 7: USDA FOOD PATTERNS FOR CHILDREN YOUNGER THAN AGE 24 MONTHS

INTRODUCTION

Establishing healthy dietary patterns in early childhood is crucial to support immediate needs for growth and development and to promote lifelong health by helping to reduce the risk of obesity and associated cardiometabolic disorders later in life. However, developing evidence-based dietary guidelines for infants and toddlers is not a simple task, in part because the scientific evidence for many questions is relatively scant, as shown in the preceding 3 chapters (*Part D. Chapter 4: Duration, Frequency, and Volume of Exclusive Human Milk and/or Infant Formula Feeding*, *Part D. Chapter 5: Foods and Beverages Consumed During Infancy and Toddlerhood*, and *Part D. Chapter 6: Nutrients from Dietary Supplements During Infancy and Toddlerhood*). This is the first time a Dietary Guidelines Advisory Committee has been charged with developing food patterns for infants and children younger than age 24 months.

As described in *Part D. Chapter 14: USDA Food Patterns for Individuals Ages 2 Years and Older*, the USDA Food Patterns for ages 2 years and older are existing food patterns updated every 5 years. The USDA Food Patterns represent types and amounts of foods that aim to meet the Dietary Reference Intakes (DRI) and *Dietary Guidelines for Americans* recommendations, within energy needs, for each age-sex group. The foods in each of the food groups and subgroups are intended to be consumed in the indicated amounts, on average and over time, as an example of a healthy dietary pattern. Although some notable shifts are seen from ages 2 years to later into adulthood in consumption patterns of food groups and subgroups, as described in *Part D. Chapter 14*, the majority of foods that comprise a healthy dietary pattern are fairly consistent from age 2 years onward.

The time period between birth and 24 months, however, is characterized by major changes in feeding patterns and dietary intake. Exclusive breastfeeding is recommended for about the first 6 months¹ (see *Part D. Chapter 4*). For infants who are not fed human milk, or are mixed-fed (i.e., both human milk and infant formula), commercial infant formula is generally recommended until age 12 months.¹ The transition from sole consumption of human milk and/or infant formula to a varied diet that includes nutrient-dense complementary foods and beverages (CFB) is recommended around age 6 months.¹ Thus, the 2020 Dietary Guidelines Advisory Committee decided that USDA Food Patterns are not necessary for infants younger than age 6

months and began modeling exercises at age 6 months when CFB start to become an important part of the diet, even though they provide relatively limited energy at that age.^{2,3}

The main purpose of food pattern modeling is to exemplify approaches to meet nutrient recommendations. For this age group, this work must take into account differences in the nutritional composition of milk sources for infants and toddlers. Human milk differs from infant formula in several ways, including its nutritional composition, bioavailability of nutrients, and presence of bioactive substances. Furthermore, the composition of human milk changes across time, and the concentrations of some nutrients and even flavors⁴ are responsive to maternal diet (see **Part D. Chapter 3: Food, Beverage, and Nutrient Consumption During Lactation**). As described in **Part D. Chapter 1: Current Intakes of Foods, Beverages, and Nutrients**, nutrient intakes from milk sources (and CFB) differ substantially between infants fed only human milk and those who are fed infant formula (which is fortified with many nutrients⁵) or those who are fed both (i.e., mixed-fed). However, it must be recognized that provision of key nutrients is only one of the ways in which human milk influences infant health and development, as substances other than traditional nutrients in human milk also play a role, and breastfeeding is associated with many health benefits for the mother as well as the child (see **Part D. Chapter 3** and **Part D. Chapter 4**). Thus, the food pattern modeling exercises presented here should not be interpreted as an evaluation of the value of human milk compared to infant formula; they are exercises to demonstrate ways that nutritional goals can be met through CFB that *take into account* the milk source(s) in the child's diet.

For the period from ages 6 to 12 months, the Committee focused first on combinations of CFB aimed at meeting nutrient needs of infants whose milk source is human milk (i.e., no infant formula). The Committee then estimated nutrient intakes of infants fed infant formula if they consumed the same types and combinations of CFB that were developed for the infants fed human milk. The Committee considered the period from ages 12 to 24 months separately from ages 6 to 12 months for several reasons. First, ages 6 to 12 months is a time when infants are learning to eat new foods, so the variety, amounts, and textures of CFB increase and change substantially during those 6 months. Second, most of the DRI values between ages 6 and 12 months are Adequate Intake (AI) estimates, with Recommended Dietary Allowances (RDAs) established only for protein, iron, and zinc, whereas RDAs are established for most nutrients for ages 12 months and older.⁶⁻¹³ Third, infant formula is not recommended after a child is older than 12 months, and most infants in the United States (66 percent) are no longer receiving human milk after age 12 months.¹⁴ For that reason, the Committee focused on food patterns at ages 12 to less than 24 months that would meet nutrient needs of toddlers receiving neither

human milk nor infant formula, although potential combinations of foods for toddlers receiving human milk at ages 12 to 24 months also were examined.

The complementary feeding period is important not only for providing essential nutrients, but also for introducing infants and toddlers to various types and textures of CFB that can be beneficial to health and development. For example, certain foods should be introduced before age 12 months to reduce the risk of food allergies (e.g., peanut, egg; see **Part D. Chapter 5**). In addition, feeding experiences with foods provided in different textures and forms (such as “finger foods”) help to develop manual dexterity, hand-eye coordination, and dexterity of the tongue and other mechanical features involved in chewing and swallowing. The timely introduction and progression of textures helps to support the development of appropriate feeding and eating behaviors during childhood.¹⁵

The complementary feeding period also is a time for implementation of responsive feeding practices that can have positive effects on child health and development.¹⁶⁻¹⁸ Moreover, the interactions between the child and the caregivers and with the eating environment provide opportunities for modeling of healthy eating behaviors, bonding, and learning through food.¹⁹ The food pattern modeling exercises presented in this chapter focus on nutrient intake during this developmental period and are not designed to address these other important aspects of complementary feeding.

Nutrient Intakes and Systematic Review Findings that Informed Food Pattern Modeling for Ages 6 to 24 Months

The energy and nutrients needed from CFB vary by infant milk source. As described in **Part D. Chapter 1**, among infants ages 6 to 12 months, those who were fed infant formula or were mixed-fed typically met the Estimated Average Requirements (EAR) for iron, zinc, and protein (i.e., less than 7 percent had intakes less than the EAR). For infants fed human milk, the proportions with intakes less than the EAR were high for iron (77 percent), zinc (54 percent), and protein (27 percent). As described in **Part D. Chapter 5**, strong evidence shows that iron-rich sources, such as meats or iron-fortified CFB, including infant cereals, can help maintain adequate iron status or prevent iron deficiency during the first year of life among infants with insufficient iron stores or among infants fed human milk who are not receiving adequate iron from another source. In addition, evidence, though limited, suggests that CFB that contain substantial amounts of zinc, such as meats or cereals fortified with zinc, can support zinc status during the first year of life, particularly among infants fed human milk who are not receiving adequate zinc from another source. For most of the other nutrients (for which the DRI is an AI),

intakes appeared to be adequate regardless of milk source, with the exception of potassium, vitamin D, and choline (see **Part D. Chapter 1**). As explained in **Part D. Chapter 6**, vitamin D is a special case, and supplementation of infants is generally recommended unless their vitamin D intake from fortified products (including infant formula) is already sufficient.

After age 12 months, toddlers transition toward the typical foods and beverages consumed by most Americans ages 2 years and older, as described in **Part D. Chapter 1**. Thus, the food components of public health concern observed in toddlerhood are similar to those identified among ages 2 years and older, with low intakes of vitamin D, calcium, dietary fiber, and potassium and higher than recommended intakes of sodium, saturated fat, and added sugars. As described in **Part D. Chapter 1**, nutrients that pose special challenges among children between the ages of 12 and 24 months include choline and linoleic acid. As described in **Part D. Chapter 5**, moderate evidence indicates that CFB with differing fatty acid profiles, particularly long-chain polyunsaturated fatty acids, can influence fatty acid status. Although iron intake at ages 12 to 24 months appears to be adequate, National Health and Nutrition Examination Survey (NHANES) 2003-2010 data indicated that 15 percent of toddlers ages 12 to 24 months had iron deficiency.²⁰

Given the considerations above, achieving adequate iron and zinc intakes at ages 6 to 12 months for infants fed human milk was identified by the Committee as a major challenge and, hence, was a key focus of the Committee's work aimed at combinations of CFB during that age range. For both age intervals, the Committee was guided by the principle that CFB should be nutrient rich, particularly in nutrients for which potential risk of inadequacy exists, while also limiting exposures and intakes of other food components when they are of concern, such as added sugars.

LIST OF QUESTIONS

1. Can USDA Food Patterns be established based on the relationships identified in the systematic reviews? If so, how well do USDA Food Pattern variations meet nutrient recommendations for infants and toddlers? If nutrient needs are not met, is there evidence to support supplementation and/or consumption of fortified foods to meet nutrient adequacy?

(See **Part D. Chapters 3 through 6** for systematic reviews.)

METHODOLOGY

USDA food pattern modeling methodology for answering these questions involved aiming to establish food patterns that incorporate goals for nutrient adequacy for energy, nutrients, and other food components compared to the DRIs and potential recommendations of the 2020 Committee. The analyses used here were informed by the process to establish and model food patterns for ages 2 years and older. More information on this approach is available in **Part C. Methodology** and in **Part D. Chapter 14: USDA Food Patterns for Individuals Ages 2 Years and Older**. Nutrient profiles were developed from food groups and subgroups using data on foods consumed by infants and toddlers ages 6 to 24 months from NHANES, What We Eat in America (WWEIA) 2015-2016²¹ and corresponding food composition data from the USDA Food and Nutrient Database for Dietary Studies,²² USDA National Nutrient Database for Standard Reference,²³ and the USDA Food Patterns Equivalents Database.²⁴ Modifications of USDA Food Pattern elements were tested—for example, the proportions of intake from human milk or infant formula and the inclusion of fortified foods—where appropriate based on developmental age. The nutrient adequacy of variations of healthy eating patterns were then tested by comparing their nutrient content to the DRIs and potential recommendations of the 2020 Committee. The Committee then developed conclusion statements to summarize the answer to each food pattern modeling question and made research recommendations to inform future work on this topic.

Analytic Framework

The Committee developed a food pattern modeling protocol. The protocol included an analytic framework that described the scope of the food pattern modeling exercises. The analytic framework also described the population, data sources, and key terms used to answer this question. The patterns tested in these food pattern modeling exercises are intended to apply to the U.S. population ages 6 to 24 months old. The following are key definitions for the food pattern modeling exercises:

- **Essential Calories:** The energy associated with the foods and beverages ingested to meet nutritional goals through choices that align with the USDA Food Patterns in forms with the least amounts of saturated fat, added sugars, and sodium.
- **Food Groups and Subgroups:** USDA Food Patterns provide amounts from the 5 major food groups and subgroups, including:
 - Fruits

- Vegetables: Dark green, red and orange, beans and peas, starchy, and other
- Dairy, including calcium-fortified soy beverages
- Grains: Whole grains and refined grains
- Protein Foods: Meats, poultry, and eggs; seafood; nuts, seeds, and soy products
- **Food Pattern Components:** Oils, solid fats, added sugars.
- **Nutrient Profiles:** The anticipated nutrient content for each food group and subgroup that could be obtained by eating a variety of foods in each food group in nutrient-dense forms. The nutrient profiles are based on a weighted average of nutrient-dense forms of foods. The weighted average calculation considers a range of American food choices, but in nutrient-dense forms and results in a food pattern that can be tailored to fit an individual's preferences.
- **Nutrient-Dense Representative Foods:** For the purpose of USDA's Food Pattern modeling, nutrient-dense representative foods are those within each item cluster in forms with the least amounts of added sugars, sodium, and solid fats.
- **Added Sugars:** Sugars that are added during the processing of foods (such as sucrose or dextrose), foods packaged as sweeteners (such as table sugar), sugars from syrups and honey, and sugars from concentrated fruit or vegetable juices. They do not include naturally occurring sugars that are found in milk, fruits, and vegetables (see **Part F. Appendix F-1: Glossary**).
- **Solid Fats:** The food category called "solid fat" includes a variety of fats, but predominantly saturated fat and to a small extent, *trans* fat. This category includes the saturated fats naturally found in animal products (e.g., meats, dairy) as well as vegetable sources with high saturated fat content, like tropical oils, e.g., coconut oil and hydrogenated vegetable shortenings.

General Process for Developing and Updating the USDA Food Patterns

The overall food pattern modeling methodology used to develop and update the USDA Food Patterns includes: (1) identifying appropriate energy levels for the Patterns, (2) identifying nutritional goals for the Patterns, (3) establishing food groupings and food group amounts, (4) determining the amounts of nutrients that would be obtained by consuming various foods within each group, (5) evaluating nutrient levels in each Pattern against nutritional goals, and (6) adjusting and re-evaluating the Patterns to align with current or potential recommendations. The food pattern modeling exercises described in this chapter were informed by the process to

establish and model food patterns for ages 2 years and older (see **Part C. Methodology** and **Part D. Chapter 14: USDA Food Patterns for Individuals Ages 2 Years and Older**) with modifications reflecting the unique feeding aspects of the population ages 6 to 24 months.

1. Establish Energy Levels

The DRIs use formulas to calculate Estimated Energy Requirements (EER) for infants and toddlers that account for energy deposition for the growing child.¹⁰ Using these formulas, appropriate energy levels for each age-sex group for infants and toddlers were determined based on age in months, reference body lengths, median body weights, and sex of the child. Five energy levels from 600 to 1,000 kcal, at 100 kcal “step” intervals, were chosen to cover the energy needs for the majority of the population ages 6 to 24 months.

2. Establish Nutritional Goals

Specific nutritional goals for each modeling exercise were selected based on the age-sex group(s) being targeted. If more than one age-sex group was the target, the results were evaluated against the nutrient goals for all of those groups. Goals for energy, 3 macronutrients, 3 fatty acids, 12 vitamins, and 9 minerals were based on DRI reports released between 1997 and 2019.⁶⁻¹³ Other goals could include potential recommendations of the 2020 Committee. Because food patterns in general are designed as plans for individuals to follow, the goals were the RDA amounts for nutrients having an RDA. The AI was used when an RDA was not available. RDA or AI values for 2 age ranges, infants 6 to 12 months and toddlers 12 to 24 months, were used.

3. Establish Food Groupings and Food Group Amounts

Existing food groups and subgroups in the USDA Food Patterns for ages 2 years and older published in the *2015-2020 Dietary Guidelines for Americans* informed this exercise.²⁵

Before conducting food pattern modeling exercises, various options reflecting different proportions of energy coming from human milk or infant formula were created, so that the energy expected to come from CFB could be calculated. Infants and toddlers receiving human milk were the initial focus of the modeling exercises because the proportion of nutrients required from CFB is different for infants receiving infant formula, which is fortified. Energy from human milk was modeled at 3 levels (low, average, and high) (Table D7.1) and applied to each of 3 age intervals (6 to 9 months, 9 to 12 months, and 12 to 24 months). The average level was based on Scientific Report of the 2020 Dietary Guidelines Advisory Committee

the mean percentage of total energy from human milk at those ages in published studies from high-income countries,³ and the low and high levels were set at 15 percent lower and 15 percent higher than the mean, respectively, as shown in Table D7.1. For the modeling exercises for infants fed infant formula at ages 6 to 9 months and 9 to 12 months, the proportion of total energy expected to come from infant formula was the same as for human milk.

Table D7.1. Energy from human milk modeled at three levels (low, average, and high) applied to each of three age intervals (6 to 9, 9 to 12, and 12 to 24 months)¹ and the amount of energy available for complementary foods and beverages at 5 estimated energy needs from 600 to 1,000 kcal

Energy level (kcal)	600		700		800		900		1,000	
	CFB ² kcal	HM ² kcal	CFB kcal	HM kcal	CFB kcal	HM kcal	CFB kcal	HM kcal	CFB kcal	HM kcal
6 to 9 months										
HM level high (100% HM)	NA ²	600	NA	700	NA	800				
HM level average (80% HM)	120	480	140	560	160	640				
HM level low (65% HM)	210	390	245	455	280	520				
9 to 12 months										
HM level high (70% HM)	180	420	210	490	240	560	270	630		
HM level average (55% HM)	270	330	315	385	360	440	405	495		
HM level low (40% HM)	360	240	420	280	480	320	540	360		
12 to 24 months										
HM level high (50% HM)			350	350	400	400	450	450	500	500
HM level average (35% HM)			455	245	520	280	585	315	650	350
HM level low (20% HM)			560	140	640	160	720	180	800	200

1: Energy from human milk was modeled at 3 levels (low, average, and high) applied to each of 3 age intervals (6 to 9 months, 9 to 12 months, and 12 to 24 months). The average level was based on the mean percentage of total energy from human milk at those ages in published studies from high-income countries.³ and the low and high levels were set at 15 percent lower and 15 percent higher than the mean, respectively. For the modeling exercises for infants fed infant formula at ages 6 to 9 months and 9 to 12 months, the proportion of total energy expected to come from infant formula was the same as for human milk.

2: CFB=complementary foods and beverages; HM=human milk; NA=not applicable

The food group amounts for the 1,000 kcal Pattern established in the Healthy U.S.-Style Food Patterns in the *2015-2020 Dietary Guidelines for Americans*²⁵ were used in the first step in modeling the contributions to nutrient intakes from combinations of CFB for ages younger than 24 months. When the energy expected to come from CFB was less than 1,000 kcal, amounts of each food group were decreased such that the food group density (i.e., food group or subgroup amounts per 100 kcal) in the pattern remained similar to the food group density of the 1,000 kcal Pattern. Food group amounts were then compared to mean food group intakes in each age group. As part of the process to test the feasibility of combinations of CFB and human milk or

infant formula for infants and patterns for toddlers, amounts from each food group could be modified to reach all or most of the specified goals.

4. Determine the Amounts of Nutrients that Would be Obtained by Consuming Various Foods Within Each Group

A “composite” system was used to determine the anticipated nutrient content, or nutrient profile, of each food group. To create nutrient profiles, all foods reported for individuals ages 6 to 24 months as part of WWEIA, NHANES 2015-2016 were disaggregated into their ingredients. Similar ingredients were aggregated into food item clusters. A nutrient-dense form of the food specific to the life stage was selected as the representative food for each cluster. Unique considerations for this life stage were identified where relevant, such as the importance of adequate fat intake. Differences in the representative foods used, compared to those used for Food Patterns for children older than age 2 years, were the following:

- Whole milk was used instead of fat-free milk.
- Reduced-fat plain yogurt was used instead of fat-free yogurts (plain or flavored with non-caloric sweeteners).
- Reduced-fat cheeses were used as representative foods for *all* cheese item clusters, instead of using skim or fat-free cheese options when available.

A detailed list of the item clusters, the nutrient-dense representative foods, and the proportions of consumption is available as part of the online supplemental materials (available at <https://www.dietaryguidelines.gov/2020-advisory-committee-report/food-pattern-modeling/FPM-under-2>).

The proportional intake of each item cluster within each food group or subgroup was calculated from dietary intake data for this age group (i.e., infants and children younger than age 24 months) and used to compute a weighted average of nutrient-dense forms of foods representing each food item cluster. Using the nutrients in each representative food and the item cluster’s proportional intake, a nutrient profile was calculated for each food group or subgroup. Nutrient profiles also were calculated for oils and solid fats using food supply data to estimate proportional intakes. The nutrient amounts used for human milk were the mean concentrations of each nutrient published in the respective reports for the development of the DRIs for infants.⁶⁻¹³ (For the nutrient profile for human milk, see the online food pattern modeling report, available at <https://www.dietaryguidelines.gov/2020-advisory-committee-report/food->

[pattern-modeling/FPM-under-2](#)). The nutrient profile for infant formula comes from FNDDS 15-16, code 11710000 Infant Formula, NFS.²²

5. Evaluate Nutrient Level in Each Modeling Exercise Against Nutritional Goals

Using the updated nutrient profiles that apply to ages 6 to 24 months, the nutrients provided in each modeling exercise were compared to the goals, which in most cases aimed to meet at least 90 percent of the RDA or AI.

6. Adjust and Re-Evaluate to Align with Goals

After identifying any nutrient goals that were not met in the modeling exercises, the Committee used a step-wise iterative approach to make additional adjustments. Four modifiable elements were considered: (1) food group amounts could be increased or decreased, (2) goals and constraints could be adjusted, (3) food group nutrient profiles could be adjusted through selection of different representative foods or categorization of item clusters, and (4) certain foods could be included or excluded. Nutrient adequacy was reassessed after these modifications.

After all iterations were complete, energy contributions from all food groups and oils, termed “essential calories,” were summed and any remaining energy up to the kcal limit for each energy level was calculated. The uses for remaining energy were discussed, such as in relation to limits on added sugars.

REVIEW OF THE SCIENCE

Question 1. Can USDA Food Patterns be established based on the relationships identified in the systematic reviews? If so, how well do USDA Food Pattern variations meet nutrient recommendations for infants and toddlers? If nutrient needs are not met, is there evidence to support supplementation and/or consumption of fortified foods to meet nutrient adequacy?

Approach to Answering Question: Food Pattern Modeling

Conclusion Statements

Ages 6 to 12 Months

The Committee was not able to establish a recommended food pattern for infants ages 6 to 12 months because of uncertainty about nutrient requirements for this age range and challenges in meeting the Recommended Dietary Allowance for iron through complementary foods and beverages. However, examples of potential combinations of complementary foods and beverages that come close to meeting almost all nutrient recommendations are described for a variety of scenarios differing in the proportion of energy coming from human milk or infant formula versus complementary foods and beverages at ages 6 to 9 months and 9 to 12 months.

The example combinations of complementary foods and beverages described by the Committee support consumption of fortified infant foods to meet nutrient adequacy for infants whose milk source is human milk (i.e., no infant formula).

Infants fed infant formula who also consume iron-fortified infant cereals may consume up to 2 times the Recommended Dietary Allowance for iron (22 milligrams per day) at ages 6 to 12 months, although iron intakes are not likely to exceed the Tolerable Upper Intake Level of 40 milligrams per day.

Further work is needed to determine the feasibility of meeting all nutrient recommendations for infants fed human milk at ages 6 to 12 months from diets that do not include any fortified foods (e.g., fortified infant cereal, infant formula).

With the exception of vitamin D, supplementation should not be necessary if fortified foods with appropriate levels of fortification are included in the diet of infants whose milk source is human

milk. Vitamin D supplementation guidance from the American Academy of Pediatrics is provided in ***Part D. Chapter 6: Nutrients from Dietary Supplements During Infancy and Toddlerhood.***

Ages 12 to 24 Months

For toddlers fed neither human milk nor infant formula, the Committee developed a Food Pattern for ages 12 to 24 months that is consistent with the proportions of food groups and subgroups recommended for children ages 2 years and older. This Food Pattern requires careful choices of foods and beverages but does not require inclusion of fortified products specifically formulated for infants or toddlers to meet nutrient recommendations.

For toddlers who receive at least 20 percent of total energy from human milk at ages 12 to 24 months, the Committee was not able to establish a recommended food pattern because of uncertainty about nutrient requirements for this age range and challenges in meeting the Recommended Dietary Allowances. However, examples of potential combinations of complementary foods and beverages that come close to meeting almost all nutrient recommendations are described for a variety of scenarios differing in the proportions of energy coming from human milk and from complementary foods and beverages at ages 12 to 24 months.

For toddlers fed a lacto-ovo vegetarian diet and fed neither human milk nor infant formula at ages 12 to 24 months, the Committee developed a Healthy Vegetarian Pattern that includes regular consumption of eggs, dairy products, soy products, and nuts or seeds, in addition to fruits, vegetables, grains, and oils. This Food Pattern requires careful choices of foods and beverages but does not require inclusion of fortified products specifically formulated for infants or toddlers to meet nutrient recommendations.

Additional Considerations for Ages 6 to 24 Months Regarding Added Sugars

The combinations of foods needed to achieve recommended intakes of key nutrients for ages 6 to 24 months leave virtually no remaining dietary energy for added sugars, apart from the very small amounts (less than 3 grams per day) already inherent in the foods used in modeling.

Results of Food Pattern Modeling Exercises

Nutrient Profiles

The nutrient profiles for the foods included in the modeling exercises are shown in the online food pattern modeling report (available at <https://www.dietaryguidelines.gov/2020-advisory-committee-report/food-pattern-modeling>). These include energy and nutrients per cup equivalent (cup eq) or ounce equivalent (oz eq) of each food group or subgroup. In Table D7.2, the most nutrient-rich foods are listed with respect to the amounts of calcium, iron, potassium, and choline per 100 kcal.

Table D7.2. Nutrient-rich food sources of calcium, iron, potassium, and choline¹

Nutrient	Criteria for Selection	Food items	
Calcium	Calcium density ≥ 200 mg/100 kcal, except for fruits and vegetables for which 100 kcal is a large volume (i.e., energy/cup < 50 kcal); in those cases, food is selected if calcium content is ≥ 200 mg/cup.	<u>Dairy</u> Cheese Milk Yogurt <u>Fruits and Vegetables</u> Cooked turnip greens/ spinach	<u>Other</u> Tofu
Iron ²	Iron density ≥ 2 mg/100 kcal, except for fruits and vegetables for which 100 kcal is a large volume (i.e., energy/cup < 50 kcal); in those cases, food is selected if iron content is ≥ 2 mg/cup.	<u>Meats and Seafood</u> Octopus/squid Oysters/mussels/snails Liver Game meat Anchovy Ground beef <u>Other</u> Tofu	<u>Fruits and Vegetables</u> Bok choy Cauliflower Okra Asparagus Mushrooms Tomatoes (cooked) Edible-pod green peas Green peppers (cooked) Avocado
Potassium ³	Potassium density ≥ 400 mg/100 kcal, except for fruits and vegetables for which 100 kcal is a large volume (i.e., energy/cup < 50 kcal); in those cases, food is selected if potassium content is ≥ 400 mg/cup eq.	<u>Fruits and Vegetables</u> Bok choy Tomatoes Green pepper Cauliflower Mushrooms Asparagus Summer squash Okra Red pepper Eggplant Tomatoes (cooked) Carrots Edible-pod green peas Broccoli (cooked) Melon (cantaloupe/ honeydew) Apricot	Beets Pumpkin/ winter squash Kiwifruit Nectarines/ peaches Grapefruit Papaya Banana <u>Dairy</u> Milk Yogurt <u>Seafood</u> Fish Snails, clams
Choline ⁴	Choline density ≥ 50 mg/100 kcal, except for fruits and vegetables for which 100 kcal is a large volume (i.e., energy/cup < 50 kcal); in those cases, food is selected if choline content is ≥ 50 mg/cup.	<u>Protein foods</u> Liver Eggs Shrimp/scallops/crab/ lobster Fish Soy milk Beef/pork/lamb Turkey	<u>Fruits and Vegetables</u> Bok choy Mushrooms Cooked okra Edible-pod green peas

1: Excludes foods fortified with these nutrients

2: Excludes processed soy, tomatillos, spring onions and scallions, and cooked or canned fruits. Note that the bioavailability of iron from different sources is not taken into account in the ranking of these foods.

3: Excludes cooked and canned fruit, tomatillos, spring onions and scallions, cooked celery, and cooked onions

4: Excludes cooked celery and tomatillos

Modeling Exercises for Ages 6 to 12 Months

Infants Fed Human Milk

Based on energy allowances for human milk and CFB as shown in Table D7.1 (described in Methodology), the first step was to set up a model that included food group amounts in proportion to the amounts in the 1,000 kcal Pattern for ages 2 years and older. Numerous nutrient gaps were evident in this model for both ages 6 to 9 and 9 to 12 months. Gaps existed for iron and zinc, as expected, but also for magnesium, phosphorus, potassium, sodium, choline, niacin, and vitamins A, B₆, C, D, and E at ages 6 to 9 months, and magnesium, potassium, sodium, choline, and vitamins A, C, D and E at ages 9 to 12 months. Carbohydrate was also low at the lower energy levels. The iron content of this first model was only about 1 to 2 milligrams (mg) at ages 6 to 9 months and 1 to 4 mg at ages 9 to 12 months (far below the RDA of 11 mg) and zinc content was 1.4 to 2.5 mg at ages 6 to 9 months (below the RDA of 3 mg) and 2 to 4 mg at 9 to 12 months (closer to the RDA of 3 mg).

Therefore, the second step was to examine how replacing 56 kcal of grains with 56 kcal of fortified infant cereal (0.5 oz eq) would change iron and zinc intakes (see Table D7.3). For iron, this second model included about 8 to 9 mg at 6 to 9 months and about 8 to 11 mg at 9 to 12 months. These amounts were closer to the RDA, but still below it for most energy levels and human milk proportion options. For zinc, this second model included 3 to 5 mg, which was adequate.

Table D7.3. Summary of iron and zinc estimates in combinations of complementary foods and beverages without and with 0.5 ounce equivalents of fortified infant cereal for infants fed human milk at ages 6 to 9 months and 9 to 12 months

Energy and HM ¹ proportion ²	Iron (mg)				Zinc (mg)			
	6 to 9 months		9 to 12 months		6 to 9 months		9 to 12 months	
	No IC	IC ¹	No IC	IC ¹	No IC	IC ¹	No IC	IC ¹
600 H ^{1, 3}	---	---	1.4	8.4	---	---	1.7	2.9
600 A ¹	0.9	8.2	2.1	9.0	1.4	2.7	2.2	3.3
600 L ¹	1.6	8.5	2.8	9.7	1.9	3.0	2.7	3.8
700 H ³	---	---	1.6	8.4	---	---	2.0	3.1
700 A	1.1	8.2	2.5	9.4	1.6	2.9	2.6	3.7
700 L	1.9	8.8	3.3	10.2	2.2	3.3	3.1	4.3
800 H ³	---	---	1.9	8.8	---	---	2.3	3.4
800 A	1.3	8.3	2.8	9.7	1.9	3.1	2.9	4.0
800 L	2.2	9.1	3.7	10.6	2.5	3.6	3.6	4.7
900 H ⁴	---	---	2.1	9.0	---	---	2.6	3.7
900 A ⁴	---	---	3.2	10.1	---	---	3.3	4.4
900 L ⁴	---	---	4.2	11.1	---	---	4.0	5.1

1: H=high; A=average; L=low; HM=human milk; IC=fortified infant cereal; CFB=complementary foods and beverages

2: Energy from human milk was modeled at 3 levels (low, average, and high) applied to each of 3 age intervals. The average level was based on the mean percentage of total energy from human milk at those ages in published studies from high-income countries,³ and the low and high levels were set at 15 percent lower and 15 percent higher than the mean, respectively.

3: No combinations of CFB were developed at “high” human milk intakes for ages 6 to 9 months because all energy is allotted to HM.

4: No combinations of CFB were developed for 6 to 9 months at 900 kcal because it is above estimated energy needs.

The third step was to examine how much energy remained available for other CFB, after including 56 kcal (0.5 oz eq) of fortified infant cereal. Table D7.4. shows that the remaining energy for CFB was 0 to 224 kcal at 6 to 9 months and 124 to 484 kcal at 9 to 12 months. The lower amounts in these ranges correspond to options with high levels of human milk intake. At any given proportion of human milk, lower amounts were available at 600 to 700 kcal energy levels than at higher energy levels. This illustrates the energy constraints for CFB, particularly at the younger ages (6 to 9 months).

Table D7.4. Energy (kcal) provided by human milk or infant formula plus 0.5 ounce equivalents of fortified infant cereal and remaining energy available for other complementary foods and beverages for infants, by age and 3 levels of human milk or infant formula intake¹

Energy level (kcal)		600			700			800			900			1,000		
Age (months)	Energy Source	H ²	A ²	L ²	H	A	L	H	A	L	H	A	L	H	A	L
6 to 9	HM ² (or IF ²)	600	480	390	700	560	455	800	640	520						
	Total CFB ²	0	120	210	0	140	245	0	160	280						
	Infant Cereal	0	56	56	0	56	56	0	56	56						
	Remaining CFB	0	64	154	0	84	189	0	104	224						
9 to 12	HM (or IF)	420	330	240	490	385	280	560	440	320	630	495	360			
	Total CFB	180	270	360	210	315	420	240	360	480	270	405	540			
	Infant Cereal	56	56	56	56	56	56	56	56	56	56	56	56			
	Remaining CFB	124	214	304	154	259	364	184	304	424	214	349	484			
12 to 24	HM (or IF)				350	245	140	400	280	160	450	315	180	500	350	200
	Total CFB				350	455	560	400	520	640	450	585	720	500	650	800
	Infant Cereal				56	56	56	56	56	56	56	56	56	56	56	56
	Remaining CFB				294	399	504	344	464	584	394	529	664	444	594	744

1: Energy from human milk was modeled at 3 levels (low, average, and high) applied to each of 3 age intervals (6 to 9 months, 9 to 12 months, and 12 to 24 months). The average level was based on the mean percentage of total energy from human milk at those ages in published studies from high-income countries,³ and the low and high levels were set at 15 percent lower and 15 percent higher than the mean, respectively. For the modeling exercises for infants fed infant formula at ages 6 to 9 months and 9 to 12 months, the proportion of total energy expected to come from infant formula was the same as for human milk. This table represents a third step to examine how much energy remained available for other CFB, after including 56 kcal (0.5 oz eq) of fortified infant cereal.

2: H=high; A=average; L=low; HM=human milk; IF=infant formula; CFB=complementary foods and beverages

The fourth step was to examine how the remaining energy for CFB could be allocated across food groups and subgroups to move closer to nutrient adequacy for iron, zinc, potassium, and choline (the nutrients with the most critical gaps). Although gaps also existed for vitamins A and C, it should be noted that the AI values at ages 7 to 12 months (500 retinol activity equivalents [RAE] and 50 mg, respectively) are higher than the RDA values at ages 1 to 3 years (300 RAE and 15 mg, respectively), so the AI values may be overestimates. The recommended intakes issued by European Food Standards Authority²⁶ are 250 RAE of vitamin A and 20 mg of vitamin C during both of these age intervals. During this fourth step, the food combinations were set up so as to include a minimum amount of seafood, eggs, and nuts (weekly amounts of 3 oz eq, 1 oz eq, and 0.5 oz eq, respectively, by ages 9 to 12 months), in accordance with recommendations to introduce these foods during infancy. In addition, a maximum for Dairy (no more than 0.5 cup eq per day) was set, given that infants at this age are receiving human milk or infant formula. Remaining nutrient gaps were filled to the extent possible by prioritizing Protein Foods, particularly meat, because of the relatively high content and bioavailability of iron and zinc in red meats in particular. The approximate amounts of each of the food groups of CFB in the final models are shown in Table D7.5. When a range is shown, the lower amounts generally correspond to the lower energy levels and/or a higher proportion of energy from human milk, and the higher amounts correspond to the higher energy levels and/or a lower proportion of energy from human milk.

Table D7.5. Approximate amounts of food groups and subgroups in example combinations of complementary foods and beverages for ages 6 to 12 months¹

Food Groups	6 to 9 months		9 to 12 months	
	Daily amounts	Weekly amounts	Daily amounts	Weekly amounts
Total Fruits (cup eq)	$\frac{1}{8}$ to $\frac{1}{4}$	---	$\frac{1}{8}$ to $\frac{1}{2}$	---
Total Vegetables (cup eq)	$\frac{1}{8}$ to $\frac{1}{4}$	---	$\frac{1}{8}$ to $\frac{1}{2}$	---
Red and orange	---	$\frac{1}{4}$ to $\frac{2}{3}$	---	$\frac{1}{2}$ to $1\frac{1}{2}$
Starchy	---	$\frac{1}{4}$ to $\frac{1}{2}$	---	$\frac{1}{3}$ to 1
Dark green	---	Small amounts ²	---	$\frac{1}{4}$
Legumes	---	Small amounts ²	---	$\frac{1}{4}$
Other	---	$\frac{1}{4}$ to $\frac{1}{2}$	---	$\frac{1}{4}$ to $\frac{3}{4}$
Total Grains (oz eq) ²	$\frac{1}{2}$ to $\frac{3}{4}$	---	$\frac{1}{2}$ to 1	---
Fortified infant cereals	$\frac{1}{2}$	---	$\frac{1}{2}$	---
Other grains including whole and refined	0 to $\frac{1}{4}$	---	0 to 1 ³	---
Total Protein Foods (oz eq) ⁴	$\frac{3}{4}$ to $2\frac{2}{3}$	---	2 to 3	---
Meats	---	$4\frac{2}{3}$ to 16	---	$8\frac{1}{2}$ to $15\frac{1}{2}$
Poultry	---	$\frac{1}{2}$ to $1\frac{1}{4}$	---	1
Seafood	---	Modest amounts ⁵	---	≥ 3
Eggs	---	Modest amounts ⁵	---	≥ 1
Nuts and seeds	---	Modest amounts ⁵	---	$\geq \frac{1}{2}$
Total Dairy (cup eq)	$\frac{1}{4}$	---	$\frac{1}{2}$	---
Total added oils/fats (g)	0	---	0 to $7\frac{3}{4}$	---

1: The amounts shown represent the quantities of food items (cup or oz eq) that infants ages 6 to 12 months could consume as complementary foods and beverages from different food groups and subgroups to approach nutrient adequacy for iron, zinc, potassium, and choline (the nutrients with the most critical gaps) within the energy allocation for complementary foods and beverages for this age group (0 to 224 kcal at 6 to 9 months and 124 to 484 kcal at 9 to 12 months).

2: "Small amounts" refer to less than $\frac{1}{8}$ cup equivalent per week.

3: At least half of other grains as whole grains

4: Total protein foods includes a majority from meats rather than poultry because meat has higher iron content than poultry. The weekly amounts of seafood, eggs, and nuts and seeds represent minimum amounts; greater quantities from these subgroups may be accommodated within the quantities allocated to total protein foods and the energy allocation for complementary foods and beverages for this age group.

5: "Modest amounts" refer to less than 1 ounce equivalent per week.

These combinations come close to meeting almost all nutrient recommendations for a variety of scenarios differing in the proportion of energy coming from human milk and CFB at ages 6 to 9 months and 9 to 12 months. Projected iron intakes would range from 8.5 to 12 mg and projected zinc intakes from 3.1 to 6.5 mg per day for ages 6 to 12 months. However, projected potassium intakes fall short of 90 percent of the AI at several energy levels, which suggests the need to choose potassium-rich fruits and vegetables (see Table D7.2), as well as

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whole-grain products, which are generally higher in both potassium and iron than are refined grains. The amounts of dairy products that could be accommodated at ages 6 to 9 months were very small. In all of these models, no energy remained for added sugars (other than added sugars inherent from some of the foods in the nutrient profile) after aiming to achieve nutrient adequacy. In addition, little energy was available for oils or solid fats, but given that human milk is rich in fat, no added oils or fats are needed. The percentage of energy from fat in these models was 41 to 44 percent at ages 6 to 9 months and 35 to 42 percent at 9 to 12 months. The percentage of energy from protein was 11 to 16 percent at ages 6 to 9 months and 16 to 19 percent at ages 9 to 12 months.

Infants Fed Infant Formula

For infants fed infant formula at ages 6 to 12 months, the models developed above for infants fed human milk were modified to replace human milk with infant formula. Because these models included fortified infant cereal as well as infant formula, they had few shortfall nutrients, except for vitamin D and omega-3 fatty acids at some energy levels. However, the potential for excess intakes of certain nutrients exists. Table D7.6 shows the projected iron and zinc intakes when 0.5 oz eq of fortified infant cereal is included at ages 6 to 9 months and 9 to 12 months and at each energy level for infants fed infant formula. Iron reaches 142 to 181 percent (15.6 to 19.9 mg, respectively) of the RDA at 6 to 9 months and 123 to 176 percent (13.6 to 19.3 mg, respectively) of the RDA at 9 to 12 months, though none of these estimates exceeded the Tolerable Upper Intake Level (UL) for iron (40 mg). Zinc reaches 226 to 267 percent (7 to 8 mg, respectively) of the RDA at ages 6 to 9 months and 183 to 276 percent (5.5 to 8 mg, respectively) of the RDA at ages 9 to 12 months. These estimates all exceed the UL for zinc (5 mg), though this UL has been challenged as being too low.²⁷ In any case, infants fed infant formula do not need the extra iron and zinc contributed by fortified infant cereal if formula intake is greater than 760 milliliters (mL) at ages 6 to 9 months or 690 mL at ages 9 to 12 months. Thus, flexibility exists within the grains food group to substitute other grain products (preferably whole grain) for the 0.5 oz eq of fortified infant cereal shown in the example food group amounts described for infants fed human milk (Table D7.5). The percentage of energy from fat in these models was 44 to 46 percent at ages 6 to 9 months and 42 to 47 percent at ages 9 to 12 months. The percentage of energy from protein was 11 to 15 percent at ages 6 to 9 months and 15 to 19 percent at ages 9 to 12 months.

Table D7.6. Summary of iron and zinc estimates in combinations of complementary foods and beverages without and with 0.5 ounce equivalents of fortified infant cereal for infants fed infant formula at ages 6 to 9 months and 9 to 12 months

Energy and IF ¹ proportion ²	Iron (mg)				Zinc (mg)			
	6 to 9 months		9 to 12 months		6 to 9 months		9 to 12 months	
	No IC	IC ¹	No IC	IC ¹	No IC	IC ¹	No IC	IC ¹
600 H ^{1, 3}	---	---	9.0	15.2	---	---	5.0	5.7
600 A ¹	9.6	16.9	8.1	14.4	5.1	6.4	4.7	5.6
600 L ¹	8.7	15.6	7.1	13.6	4.9	6.0	4.5	5.5
700 H ³	---	---	10.5	16.5	---	---	5.8	6.4
700 A	11.2	18.3	9.4	15.7	5.9	7.2	5.5	6.3
700 L	10.1	17.0	8.3	14.8	5.7	6.8	5.3	6.2
800 H ³	---	---	12.0	17.9	---	---	6.6	7.3
800 A	12.8	19.9	10.7	16.9	6.8	8.0	6.3	7.1
800 L	11.6	18.5	9.5	15.9	6.5	7.6	6.1	6.9
900 H ⁴	---	---	13.5	19.3	---	---	7.4	8.0
900 A ⁴	---	---	12.1	18.2	---	---	7.1	7.8
900 L ⁴	---	---	10.7	17.0	---	---	6.8	7.6

1: H=high; A=average; L=low; IF=infant formula; IC=fortified infant cereal; CFB=complementary foods and beverages

2: For the modeling exercises, the proportion of total energy was the same for infant formula as for human milk. Energy from human milk was modeled at 3 levels (low, average, and high) applied to each of 3 age intervals. The average level was based on the mean percentage of total energy from human milk at those ages in published studies from high-income countries,³ and the low and high levels were set at 15 percent lower and 15 percent higher than the mean, respectively.

3: No combinations of CFB were developed at “high” human milk intakes for ages 6 to 9 months because all energy is allotted to HM.

4: No combinations of CFB were developed for 6 to 9 months at 900 kcal because it is above estimated energy needs.

Modeling Exercises for Ages 12 to 24 Months

Toddlers Fed Neither Human Milk Nor Infant Formula

These food pattern modeling exercises were conducted to identify a pattern of food groups and subgroups that resembles the Pattern established for ages 2 years and older. The first step was to set up a model that included food group amounts in proportion to the amounts in the 1,000 kcal Pattern for ages 2 years and older. Nutrients less than 90 percent of the RDA or AI were flagged. Carbohydrates were below the RDA, but above the EAR of 100 g and within the Acceptable Macronutrient Distribution Range (AMDR) for each energy level. Vitamins E and D were well below the RDA, as is true of the Healthy U.S.-Style Patterns applied to ages 2 years and older. Choline was at least 90 percent of the AI for all kcal levels. Potassium was less than 90 percent of the AI. In addition, calcium and iron were less than 90 percent of the RDA for the 800 and 700 kcal levels.

The next step was designed to increase iron and calcium to 90 percent of the RDA for the 700 and 800 kcal levels, through meats for iron and dairy for calcium. Seafood was adjusted such that 3 oz eq per week was included for all energy levels, as was done for the exercises for ages 9 to 12 months. Whole grains, a source of potassium, were set at 2 oz eq per day, with the remaining portion of grains allocated to refined grains (0.25 to 1 oz eq), with the exception of the 700 kcal level in which grains were adjusted such that 1.5 oz eq per day was provided through whole grains and 0.5 oz eq per day through refined grains. For all other food groups and subgroups, amounts were rounded to the nearest quarter measure (cup or oz eq) in daily or weekly amounts, where appropriate. These adjustments increased energy for the 700 kcal level to 736 kcal and iron at that level to 96 percent of the RDA, so the allocation to meats was reduced from 2.5 oz eq to 1.75 oz eq per day.

Omega-3 and omega-6 fatty acids were well below the AI in these models, which included negligible amounts of oils. To address this, fruit was reduced by a quarter cup eq at the 700 kcal level and refined grains were reduced by a quarter oz eq for the 700 and 800 kcal levels, with the remaining energy reallocated to oils. After these adjustments, iron was 87 percent of the RDA for the 700 kcal level.

In the final Patterns, total Protein Foods are approximately 2 oz eq in all kcal levels. The final Pattern amounts are summarized in Table D7.7.

Table D7.7. Amount from each food group or subgroup in the Healthy U.S.-Style Pattern developed for ages 12 to 24 months without any human milk or infant formula

ENERGY LEVEL (kcal)	1,000	900	800	700
FRUITS (cup eq ¹ /d ¹)	1.00	1.00	0.75	0.50
VEGETABLES				
Total Vegetables (cup eq/d)	1.00	1.00	0.75	0.65
<i>subgroup amounts in cup eq per week</i>				
Dark green (cup eq/wk ¹)	0.50	0.50	0.33	1.0
Red Orange (cup eq/wk)	2.50	2.50	1.75	1.00
Legumes (cup eq/wk)	0.50	0.50	0.33	0.75
Starchy (cup eq/wk)	2.00	2.00	1.50	1.00
Other (cup eq/wk)	1.50	1.50	1.25	0.75
GRAINS				
Total Grains (oz ¹ eq/d)	3.00	2.50	2.25	1.75
Whole grains (oz eq/d)	2.00	2.00	2.00	1.50
Refined grains (oz eq/d)	1.00	0.50	0.25	0.25
PROTEIN FOODS				
Total Protein Foods (oz eq/d)	2.00	2.00	2.00	2.00
<i>subgroup amounts in oz eq per week</i>				
Meats and Poultry (oz eq/wk)	7.70	7.00	7.00	8.75
Eggs (oz eq/wk)	2.25	2.25	2.75	2.00
Seafood (oz eq/wk)	3.00	3.00	3.00	3.00
Nuts, Seeds and Soy (oz eq/wk)	1.25	1.25	1.00	1.00
DAIRY (cup eq/d)	2.00	2.00	1.75	1.66
OILS (g ¹ /d)	13	8	9	9

1: eq=equivalents; d=day; wk=week; oz=ounce; g=gram

The macronutrient distribution for these Patterns is approximately 44 to 50 percent carbohydrate, 31 to 36 percent fat, and 17 to 20 percent protein (Table D7.8). Projected omega-6 fatty acid intake is 90 percent or more of the AI for the 800 to 1,000 kcal Patterns and 87 percent of the AI at the 700 kcal Pattern. Omega-3 fatty acid intake is at least 100 percent of the AI for all Patterns. Other nutrients that fall below 90 percent of the RDA or AI include iron at the 700 kcal level (88 percent of the RDA), potassium at the 700 to 900 kcal levels (ranging from 65 to 89 percent of the AI), vitamin E at all energy levels (ranging from 60 to 81 percent of the RDA), choline at 700 kcal level (87 percent of the AI), and vitamin D at all energy levels (approximately 40 percent of the RDA). To fill some of these gaps, caregivers could choose some of the nutrient-rich foods shown in Table D7.2. Apart from those exceptions, these Patterns achieve 90 percent of the RDA or AI for all other nutrients. In these Patterns, any energy remaining after meeting nutrient goals was allocated to oils, leaving no additional energy for added sugars apart from the 2 to 3 g of added sugars inherent in the Patterns from some of the foods in the nutrient profile (mostly refined grains).

Table D7.8. Summary of energy, macronutrient distributions, and select nutrient amounts and percent of RDA or AI for the Healthy U.S.-Style Pattern intended for infants ages 12 to 24 months without any human milk or infant formula

		Energy Level			
		1,000	900	800	700
Energy	kcal	1,001	907	804	704
Protein	% of kcal	17%	18%	19%	21%
Fat	% of kcal	33%	31%	34%	36%
Carbohydrate	% of kcal	50%	51%	48%	44%
Calcium	mg	782	772	675	612
	% RDA ¹	112%	110%	96%	87%
Iron	mg	8.4	7.9	7.2	6.2
	% RDA	120%	113%	102%	88%
Potassium	mg	1,797	1,772	1,488	1,299
	% AI ¹	90%	89%	74%	65%
Zinc	mg	7	7	7	6
	% RDA	243%	236%	220%	198%
Vitamin E	mg AT ¹	4.9	4.1	3.8	3.6
	% RDA	81%	69%	63%	60%
Vitamin D	IU ¹	260	258	235	214
	% RDA	43%	43%	39%	36%
Choline	mg	199	195	188	169
	% AI	100%	98%	94%	84%
Omega-3	g	1.2	0.9	0.9	0.9
	% AI	178%	135%	133%	130%
Omega-6	g	8.6	6.4	6.5	6.1
	% AI	123%	91%	93%	87%

1: RDA=Recommended Dietary Allowance; AI=Adequate Intake; AT=alpha tocopherol; IU=international units

As was true for ages 6 to 12 months, careful choices of CFB are required at ages 12 to 24 months, such as selecting potassium-rich fruits and vegetables (see Table D7.2), prioritizing seafood, prioritizing whole grains over refined grains, and choosing oils over solid fats.

Toddlers Fed Human Milk

Based on energy allowances for human milk and CFB as shown in Table D.7.1 (described in Methodology), the first step was to set up a model that included food group amounts in proportion to the amounts in the 1,000 kcal Pattern for ages 12 to 24 months with no human milk. Numerous nutrient gaps were evident in this model. Nutrients that fell short of the RDA or

AI for 1 to 3 year old children included calcium, iron, potassium, vitamin E, vitamin D, choline, omega-6 polyunsaturated fatty acids, and in some instances B vitamins.

Therefore, the second step was to examine how adjustments similar to those made for infants fed human milk at ages 9 to 12 months would increase the amount of iron and calcium in the combinations. Additionally, the nutrient profile for calcium in human milk was adjusted to account for the higher bioavailability of calcium in human milk (approximately 60 percent) when compared to cow milk (approximately 30 percent), by applying a factor of 2 to the human milk calcium concentration. Adjustments included the following: meat was increased (while keeping total Protein Foods at about 3 oz eq per day); poultry was set at no more than 1 oz eq per week; eggs were set at 1 oz eq per week (except for the 700 kcal level with an average proportion of human milk, in which eggs were set at 2 oz eq per week to achieve choline needs); nuts were set at 0.5 oz eq per week; and grains were adjusted to emphasize whole grains. These models generally met at least 90 percent of the RDA for iron (except for the 700, 800, and 900 kcal combinations with a high proportion of human milk), but projected calcium intakes were lower than the target for most of the combinations, and projected intake of omega-6 polyunsaturated fatty acids was also well below the AI.

The final step was to examine how further adjustments could increase omega-6 polyunsaturated fatty acids while maintaining iron and calcium to the extent possible, aiming for at least 450 mg of calcium (the amount recommended by the European Food Standards Authority.²⁶ Adjustments were made to vegetable subgroups to emphasize good sources of calcium and/or iron, including increases in dark green vegetables, legumes, red and orange vegetables, and other vegetables and a corresponding decrease in starchy vegetables. Refined grains were reduced to ¼ cup eq per day (except for the 1,000 and 900 kcal levels with a low proportion of human milk). To shift some energy to oils where needed, dairy was reduced in the combinations for which this would not reduce calcium to lower than 450 mg. Energy was then re-allocated to oils (2 to 11 grams per day) whenever possible to increase fatty acid adequacy.

The approximate amounts of each of the food groups of CFB in the final models are shown in Table D7.9. When a range is shown, the lower amounts generally correspond to the lower energy levels and/or a higher proportion of energy from human milk, and the higher amounts correspond to the higher energy levels and/or a lower proportion of energy from human milk.

Table D7.9. Approximate amounts of food groups and subgroups in example combinations of complementary foods and beverages for toddlers ages 12 to 24 months fed human milk¹

Food Groups	12 to 24 months	
	Daily amounts	Weekly amounts
Total Fruits (cup eq)	$\frac{1}{3}$ to $\frac{3}{4}$	---
Total Vegetables (cup eq)	$\frac{2}{3}$	---
Red and orange	---	$1\frac{1}{2}$
Starchy	---	$\frac{1}{2}$ to $\frac{3}{4}$
Dark green	---	1 to $1\frac{1}{2}$
Legumes	---	$\frac{1}{2}$
Other	---	$\frac{3}{4}$
Total Grains (oz eq) ²	$1\frac{1}{4}$ to $2\frac{1}{4}$	---
Total Protein Foods (oz eq) ³	$2\frac{1}{4}$ to 3	---
Meats	---	$9\frac{1}{4}$ to $15\frac{3}{4}$
Poultry	---	1 to 3
Seafood	---	≥ 3
Eggs	---	≥ 1
Nuts and seeds	---	$\geq \frac{1}{2}$
Total Dairy (cup eq) ⁴	$\frac{1}{4}$ to $1\frac{3}{4}$	---
Total added oils/fats (g) ⁵	2 to 11	---

1: The amounts shown represent the quantities of food items (cup or oz eq) that toddlers ages 12 to 24 months fed human milk could consume as complementary foods and beverages from different food groups and sub-groups to approach most nutrient recommendations for this age group for a variety of scenarios differing in the proportion of energy coming from human milk and complementary foods and beverages.

2: Emphasis on whole grains ranging from 1 to 2 oz eq

3: Total protein foods includes a majority from meats rather than poultry because meat has higher iron content than poultry. The weekly amounts of seafood, eggs, and nuts and seeds represent minimum amounts; greater quantities from these subgroups may be accommodated within the quantities allocated to total protein foods and the energy allocation for complementary foods and beverages for this age group.

4: Dairy is zero in combinations where the human milk proportion is high and energy for complementary foods and beverages is small.

5: Grams of oils are lower when proportions of human milk are high and energy for complementary foods and beverages is small.

The macronutrient distribution for these combinations is 44 to 48 percent carbohydrate, 35 to 40 percent fat, and 15 to 20 percent protein. These combinations come close to meeting most nutrient recommendations for a variety of scenarios differing in the proportion of energy coming from human milk and CFB. Projected omega-6 fatty acid intake is close to or greater than 90 percent of the AI for nearly all of the 800, 900, and 1,000 kcal level scenarios, and 66 to 89 percent at the 700 kcal level. Projected omega-3 fatty acid intake is greater than 100 percent of

the AI for all of the scenarios at the 800 to 1,000 kcal levels and the 700 kcal level with a “low” proportion of human milk, but 81 to 83 percent of the AI for the “high” and “average” human milk intake scenarios at the 700 kcal level. Other nutrients that fall below 90 percent of the RDA or AI include calcium at most energy levels (mostly above 70 percent of the RDA except at the 700 kcal level), iron at most energy levels (though nearly all had at least 80 percent of the RDA), potassium at all energy levels (50 percent to 82 percent of the AI), vitamin E at most energy levels (generally 60 to 83 percent of the RDA), and vitamin D at all energy levels (9 to 39 percent of the RDA). To fill some of these gaps, caregivers could choose some of the nutrient-rich foods shown in Table D7.2.

Toddlers Fed a Lacto-Ovo Vegetarian Diet, and Fed Neither Human Milk Nor Infant Formula

Descriptions of vegetarian dietary patterns in the literature often focus on foods that are not consumed, rather than on the foods that represent the pattern. The USDA Healthy Vegetarian Pattern intended for ages 2 and older was developed as part of the 2015 Committee’s work and described in detail in their report.²⁸ In brief, the Healthy Vegetarian Style Pattern was informed by reported dietary intakes of self-identified vegetarians using data from NHANES 2007-2010. Information on self-identified vegetarian status was not collected in more recent NHANES survey years, so this analysis was not undertaken by the Committee. In previous analysis, more than 90 percent of self-identified vegetarians consumed dairy products on the day of the NHANES survey, and 65 percent consumed eggs.²⁹ Thus, the Healthy Vegetarian Style Pattern was modeled as a lacto-ovo vegetarian pattern. Nutrient adequacy of the Healthy Vegetarian Patterns is calculated using the same nutrient standards as used for the Healthy U.S.-Style Patterns. The Healthy Vegetarian Style Pattern for ages 2 years and older is described in **Part D. Chapter 14: USDA Food Patterns for Individuals Ages 2 Years and Older.**

To adapt the Healthy Vegetarian Style Pattern for toddlers ages 12 to 24 months, the following steps were followed. First, the nutrient profiles based on proportions of foods reported for infants and toddlers were applied at the 1,000 kcal Pattern. This Pattern was evaluated against the nutrient goals for ages 12 to 24 months. Nutrients that did not align with the RDA or AI included choline, potassium, vitamin E, vitamin D, and omega-3 and omega-6 fatty acids.

Second, the 1,000 kcal pattern was adjusted to include 0.43 oz eq per day (3 eggs per week) to achieve more choline. Grains were shifted to emphasize whole grains as was done in the Patterns for non-vegetarians for ages 12 to 24 months. Of the 3 oz eq, 2 were applied to whole grains and 1 to refined grains. Then the proportions of energy from each food group were extrapolated down for the 900, 800, and 700 kcal levels.

Third, the following additional adjustments were made, mainly to achieve consistency. Amounts from Fruits were adjusted to correspond to the amounts in the Healthy U.S.-Style Pattern for ages 12 to 24 months, amounts from Vegetables in the 1,000 kcal level were carried across all levels, amounts from grains in the Healthy U.S.-Style for 12 to 24 months were adopted with emphasis on whole grains, amounts of Protein Foods in the 1,000 kcal level were carried across all levels with one adjustment to eggs across all energy levels (increased from 0.43 per day to 0.5 oz eq per day), and amounts from Dairy were adjusted to at least 1.75 cup eq per day to achieve the calcium goal.

In the final Patterns, total Protein Foods are approximately 1 oz eq per day for all energy levels. The final Pattern amounts are summarized in Table D7.10.

Table D7.10. Amount from each food group or subgroup in the Healthy Vegetarian Style Pattern developed for ages 12 to 24 months without any human milk or infant formula

Energy level (kcal)	1,000	900	800	700
FRUITS (cup eq ¹ /d ¹)	1	1	0.75	0.5
VEGETABLES				
Total Vegetables (cup eq/d)	1	1	1	1
<i>subgroup amounts in cup eq per week</i>				
Dark green (cup eq/wk ¹)	0.5	0.5	0.5	0.5
Red Orange (cup eq/wk)	2.5	2.5	2.5	2.5
Legumes (cup eq/wk)	0.75	0.75	0.75	0.75
Starchy (cup eq/wk)	2	2	2	2
Other (cup eq/wk)	1.5	1.5	1.5	1.5
GRAINS				
Total Grains (oz ¹ eq/d)	3	2.75	2.25	1.75
Whole grains (oz eq/d)	2	2	1.75	1.25
Refined grains (oz eq/d)	1	0.75	0.5	0.5
PROTEIN FOODS				
Total Protein Foods (oz eq/d)	1	1	1	1
<i>subgroup amounts in oz eq per week</i>				
Eggs (oz eq/wk)	3.5	3.5	3.5	3.5
Nuts, Seeds, and Soy (oz eq/wk)	4	4	4	4
DAIRY (cup eq/d)	2	1.75	1.75	1.5
OILS (g ¹ /d)	15	10	8.5	9

1: eq=equivalents; d=day; wk=week; oz=ounce; g=gram

The macronutrient distribution for these patterns is about 48 to 53 percent carbohydrate, 32 to 36 percent fat, and 16 to 17 percent protein (Table D7.11). Projected omega-3 and omega-6 fatty acid intakes are greater than 90 percent of the AI for all energy patterns. Nutrients that fall below 90 percent of the RDA or AI include iron at the 700 kcal level (89 percent of the RDA), potassium at all energy levels (66 to 87 percent of the AI), vitamin E at the 700 to 900 kcal levels (71 to 80 percent of the RDA), vitamin D at all energy levels (approximately 30 to 40 percent of the RDA), choline at the 700 kcal Pattern (88 percent of the AI), and calcium at the 700 kcal Pattern (86 percent of the RDA). To fill some of these gaps, caregivers could choose some of the nutrient-rich foods shown in Table D7.2. Apart from those exceptions, these Patterns achieve 90 percent of the RDA or AI for all other nutrients. However, it should be noted that most of the iron in this Pattern comes from whole grains, soy products, nuts/seeds and legumes, and that bioavailability of iron (and zinc) from these types of foods is low due to relatively high levels of phytate.⁹ If the RDA for iron is increased by a factor of 1.8 for vegetarian diets,⁹ these Patterns meet only 50 to 71 percent of the RDA for iron.

Table D7.11. Summary of energy, macronutrient distributions, and select nutrient amounts and percent of RDA or AI for the Healthy Vegetarian Pattern intended for infants ages 12 to 24 months without any human milk or infant formula

Energy level (kcal)		1,000	900	800	700
Energy	kcal	999	898	810	703
Protein	% of kcal	16%	16%	17%	17%
Fat	% of kcal	35%	32%	33%	36%
Carbohydrate	% of kcal	51%	53%	51%	48%
Calcium	mg	805	726	707	609
	% RDA ¹	115%	104%	101%	87%
Iron	mg	9.0	9.0	7.6	6.3
	% RDA ²	126% (71%)	122% (71%)	108% (60%)	89% (50%)
Potassium	mg	1732	1649	1537	1330
	% AI ¹	87%	82%	77%	66%
Zinc	mg	6.7	6.4	5.9	4.9
	% RDA	224%	213%	198%	163%
Vitamin E	mg AT ¹	5.6	4.8	4.5	4.3
	% RDA	93%	80%	74%	71%
Vitamin D	IU ¹	239	214	211	183
	% RDA	40%	36%	35%	31%
Choline	mg	204	195	190	175
	% AI	102%	98%	95%	88%
Omega-3	g	1.4	1.0	0.9	0.9
	% AI	196%	148%	133%	129%
Omega-6	g	9.6	7.3	6.5	6.3
	% AI	137%	105%	92%	90%

1: RDA=Recommended Dietary Allowance; AI=Adequate Intake; AT=alpha tocopherol; IU=international units

2: Taking into account the reduced bioavailability of iron in vegetarian diets (i.e., 10% rather than 18% for non-vegetarian diets), the requirement for iron is 1.8 times higher for individuals consuming vegetarian diets (i.e., $7 \times 1.8 = 12.6$ mg iron per day)⁹; percent of this requirement is shown in parentheses.

In these Patterns, any energy remaining after meeting nutrient goals was allocated to oils, leaving no additional energy for added sugars apart from the 2 to 3 g of added sugars inherent in the Patterns from some of the foods in the nutrient profile (mostly refined grains). Careful choices of foods and beverages within vegetarian diets are very important to meet nutrient needs.

For additional details on this body of evidence, visit:

<https://www.dietaryguidelines.gov/2020-advisory-committee-report/food-pattern-modeling/FPM-under-2>

DISCUSSION

Overview of Approach and Summary of Shortfall or Excess Nutrients

Developing recommended food patterns for infants and toddlers ages 6 to 24 months is challenging because nutrient needs are high relative to energy requirements at this age, and the amounts of CFB that can be consumed are relatively low, especially at the younger ages. The Committee opted to start with modeling the contributions of food groups in proportion to the amounts in the 1,000 kcal Pattern for ages 2 years and older, with adaptations as needed to correspond to estimated energy intakes and nutritional goals for infants and toddlers ages 6 to 24 months. This approach has the advantage of developing Patterns that are feasible with respect to the types of foods consumed in the United States, and that become consistent with the Patterns recommended for older age groups by age 24 months. However, the results do not necessarily represent the optimal combinations of foods and beverages for meeting nutritional goals, which requires a different modeling approach.

One strength of the approach taken herein was to model various scenarios with respect to the potential contribution from human milk or infant formula, as well as several options reflecting total energy needs at ages 6 to 12 months and 12 to 24 months. One key limitation of this approach is uncertainty regarding the nutrient composition of human milk. The models generally used the mean concentrations of each nutrient in human milk cited in the descriptions of the DRIs for infants as the nutrient profile (see the nutrient profile for human milk available at <https://www.dietaryguidelines.gov/2020-advisory-committee-report/data-analysis>), but in many cases these values are based on relatively few samples and/or outdated methods. Currently, no suitable approach or database is available that represents the variability of human milk composition in the United States. Several nutrients in human milk vary due to maternal nutritional status, diet and/or supplement intake, and other factors,³⁰ including total fat, fatty acids, most vitamins, choline, iodine, and selenium (see **Part D. Chapter 3: Food, Beverage, and Nutrient Consumption During Lactation**). This has implications for the modeling exercises. For example, because the 2011 DRI report for vitamin D¹² states that human milk is not a meaningful source of vitamin D, the nutrient profile for human milk used in modeling included no vitamin D. However, it is known that milk vitamin D levels can increase substantially

in response to maternal vitamin D supplementation and sun exposure^{30,31}; thus, infants are expected to get some vitamin D through human milk.

Another limitation is that the nutritional goals for the modeling exercises for ages 6 to 12 months were based mainly on AI values, because RDAs are available only for protein, iron, and zinc. The primary approach for setting the AIs for older infants was to sum the estimated mean content coming from reported CFB intakes and from 600 mL of human milk. However, when the value was judged to be unreasonable, the AI was set by extrapolating up from the AI for ages 0 to 6 months (for vitamins K, E, and B₁₂, selenium, and iodine), down from estimates of adult requirements (for thiamin and niacin), or a combination of the two (for riboflavin, vitamin B₆, folate, and choline). No DRI has been established for dietary fiber for older infants. The lack of RDAs made it difficult to evaluate risk of inadequacy for potential shortfall nutrients, such as potassium and choline, for which the AI may or may not represent the correct target. In addition, the potential for overconsumption was assessed in the models (particularly those with infant formula) based on ULs for older infants (and toddlers), but some ULs have been criticized as having been established with too little available data and are considered to be too low for certain nutrients,²⁷ specifically zinc and retinol. For both age intervals (6 to 12 months and 12 to 24 months), published nutrient reference values vary considerably across authoritative bodies,³² which suggests some uncertainty about nutrient requirements.

It also should be noted that these modeling exercises were based on energy requirements, but reported intakes among infants fed infant formula in this age group tend to exceed energy requirements (see **Part D. Chapter 1: Current Intakes of Foods, Beverages, and Nutrients**). In the various modeling scenarios presented, the volume of human milk or formula was calculated based on a given proportion of total energy requirements. The volumes of infant formula in these models may be an underestimate of actual intakes among infants fed infant formula. These modeling exercises did not attempt to model mixed-feeding scenarios, in which infants receive both human milk and infant formula. However, the example combinations that meet most nutrient recommendations for infants fed human milk also are likely to be nutritionally adequate for mixed-fed infants.

The first set of models for infants fed human milk at ages 6 to 12 months, in which the amounts of the various food groups and subgroups were proportional to the amounts in Patterns for children ages 2 years and older, there were numerous shortfall nutrients (i.e., those that did not meet at least 90 percent of the DRI value). Several of these food components were also reported as underconsumed in **Part D. Chapter 1**, including iron and zinc among infants fed human milk, and vitamin D, potassium, and choline among all infants at ages 6 to 12 months.

Although the intake data suggested that 27 percent of infants fed human milk at this age had protein intakes that were low enough to be at risk of inadequacy, protein was not a limiting nutrient in the modeling exercises in any of the scenarios, as a focus on iron naturally led to the inclusion of iron-rich foods, like meat, that also have a high protein content. Indeed, the percentage of energy from protein at ages 9 to 12 months (16 to 19 percent) was on the high side, and evidence suggests that protein intakes exceeding 15 percent of energy in early life may increase the risk of excess weight gain.³³ However, this is an area of active research and it is not clear which types of protein (e.g., dairy vs meat) may or may not be contributing to this association.

The modeling exercises for ages 6 to 12 months confirmed the challenges of meeting iron and zinc needs for infants fed human milk. For this reason, the second step for this age interval was to include 0.5 oz eq/d of fortified infant cereals. Fortified infant cereal helped to close some of the gap between the amount provided in the example combination of foods and the RDA for both iron and zinc. However, these models still had shortfalls for some nutrients, including iron, potassium, magnesium, and choline. In the final step of the modeling exercises, most of these gaps were filled by prioritizing protein foods, particularly meat. For infants fed infant formula at ages 6 to 12 months, the final step included fortified infant cereal as well as infant formula, so the final combinations of CFB had few shortfall nutrients except for vitamin D and omega-3 fatty acids at some energy levels.

For ages 12 to 24 months, the shortfall nutrients (for some or all of the energy levels) in the first set of models for toddlers fed neither human milk nor infant formula were calcium, iron, potassium, vitamin E, vitamin D, choline, and omega-3 and omega-6 fatty acids. Some of these food components also were reported as underconsumed at this age in **Part D. Chapter 1**, including potassium and vitamin D. Choline and linoleic acid were categorized as “special challenges.” Small increases in Protein Foods and Dairy and an emphasis on whole grains rather than refined grains closed some of these gaps, but potassium, vitamin E, and vitamin D were still consistently below the goals. As was the case at ages 9 to 12 months, the percentage of energy from protein was on the high side (17 to 21 percent), which warrants further consideration.

For toddlers fed human milk at ages 12 to 24 months, the modeling exercises revealed challenges in meeting nutrient goals for both calcium and iron simultaneously, given that: a) human milk has considerably less calcium than cow milk (though calcium absorption from human milk is high, approximately 60 percent,¹² and b) inclusion of sufficient amounts of dairy products to meet calcium needs meant that iron became a shortfall nutrient, because dairy

products contain very little iron. It should be noted that the RDA for calcium at ages 1 to 3 years (700 mg) is much higher than the AI for calcium at ages 7 to 12 months (270 mg), and that the recommended calcium intake for ages 1 to 3 years published by the European Food Standards Authority is only 450 mg.²⁶ As was true for toddlers fed neither human milk nor infant formula, other shortfall nutrients included potassium, vitamin E, and vitamin D. Further modeling work is needed that incorporates estimates of mineral absorption under various circumstances. Using tools such as linear programming would be helpful in addressing multiple nutritional constraints and food sources of nutrients simultaneously, to identify combinations of foods and beverages that meet all nutritional goals.

For toddlers fed lacto-ovo vegetarian diets, and fed neither human milk nor infant formula at ages 12 to 24 months, a pattern was developed, but most of the iron in this Vegetarian Style Pattern comes from whole grains, soy products, nuts and seeds, and legumes, from which bioavailability of iron is likely to be low due to relatively high levels of phytate and absence of heme iron.⁹ The projected percentage of the iron RDA provided in that Pattern is likely an overestimate of the amount that is physiologically available. If one assumes that iron requirements are 1.8 times higher for vegetarian diets than for non-vegetarian diets,⁹ the Vegetarian Style Pattern for toddlers would meet only 50 to 71 percent of the RDA for iron. Further work is needed to take this into account.

The percentage of energy from fat in these models was 41 to 44 percent at ages 6 to 9 months, 35 to 42 percent at 9 to 12 months, and 29 to 40 percent at ages 12 to 24 months, within recommended ranges capable of meeting the AI for infants and AMDR for toddlers. The AI is 30 g/d of fat at ages 7 to 12 months, which represents about 30 to 45 percent of energy for total energy intakes of 600 to 900 kcal/d. Projected intakes of omega-6 fatty acids in these models were more than adequate at ages 6 to 12 months but lower than the AI of 7 g/d for linoleic acid at ages 12 to 24 months for several scenarios. For omega-3 fatty acids, projected intakes in these models were greater than 90 percent of the AI for most energy levels (except the lowest, 600 kcal level) for the infants fed human milk or infant formula at ages 6 to 12 months. At ages 12 to 24 months they also were generally greater than 90 percent of the AI.

Iron as a Key Nutrient at Ages 6 to 12 Months

As expected, the most limiting nutrient for infants fed human milk at ages 6 to 12 months was iron. It was not possible to meet the RDA without the inclusion of iron-fortified infant foods. Because the iron concentration of human milk is low (approximately 0.3 mg/L after 5 months of lactation), the food pattern modeling exercises assumed zero iron coming from that source.

Absorption of iron from human milk is variable,³⁴ but even if 100 percent is absorbed, the amount of iron that an infant would receive from 600 mL would be less than 0.2 mg, a trivial amount relative to the RDA of 11 mg/d. This discrepancy may seem counter-intuitive, but it is likely that the iron content of complementary foods fed to infants during most of human evolution, when humans relied completely on hunting and gathering before the invention of agriculture, was much higher than it is today, and that iron deficiency was rare.³⁵ The estimated iron density of the pre-agricultural diet was 2.9 mg/100 kcal at age 9 months, whereas typical modern-day (unfortified) complementary food diets have an iron density of only 0.4 to 1.3 mg/100 kcal.

Fortified infant foods are not necessarily the only way for infants fed human milk to achieve the RDA, however. For example, certain animal-source foods (e.g., red meat) are good sources of iron, particularly when taking into account the fact that heme iron (as found in meat) is much better absorbed than non-heme iron (as found in plant-based foods). Assuming that infants at ages 6 to 12 months need 1.1 mg of absorbed iron (back-calculated from the RDA of 11 mg, which assumes 10 percent absorption), and 25 percent absorption of heme iron, infants would need 4.4 mg of iron from animal-source foods. Obtaining that amount solely from beef, which has about 1 mg of iron per 100 g (81 kcal of baby food beef), would require consuming 440 g of beef (356 kcal), which is not feasible. Organ meats such as liver have far more iron. For example, the iron content of chicken liver is about 11.5 mg per 100 g (166 kcal), so infants would need only 38 g (64 kcal) to meet the target of 4.4 mg. However, feeding liver to infants is not common in the United States. Other foods that are rich in iron are listed in Table D7.2. Further work is needed to estimate the quantities of iron-rich foods that would be needed by infants fed human milk, in the absence of fortified infant foods, to support adequate iron status between ages 6 and 12 months, recognizing that: a) the RDA is set to meet the needs of 97.5 percent of infants, and many infants require less than the RDA, b) iron absorption is up-regulated when iron stores begin to become depleted, and c) the Recommended Nutrient Intake for iron at this age set by WHO/FAO (i.e., 9.3 mg)³⁶ is lower than the RDA (i.e., 11 mg), both of which assume 10 percent absorption. In the meantime, it should be noted that iron-fortified infant foods have been an important strategy for reducing iron deficiency among infants in the United States for several decades.³⁷

On the other hand, infants fed infant formula have the potential for excess intakes of iron (and other nutrients), as the iron content of formulas most commonly used in the United States is relatively high (approximately 1.8 mg/100 kcal), about 40 times the iron content of human milk. In the food pattern modeling exercises for infants fed infant formula, inclusion of iron-

fortified infant cereal in addition to infant formula would result in total iron intakes that are 123 to 181 percent of the RDA, although it should be noted that the bioavailability of iron in fortified infant cereals is highly variable, depending on the type of cereal and form of iron that is added. As described in **Part D. Chapter 6: Nutrients from Dietary Supplements During Infancy and Toddlerhood**, iron is a “double-edged sword,” in that both deficient and excess intakes can be harmful. Although the estimated iron intakes in these scenarios did not exceed the UL of 40 mg, it is clear that iron-fortified infant foods are not necessary if infant formula intake is greater than 760 mL at ages 6 to 9 months or 690 mL at ages 9 to 12 months.

Potassium, Sodium, and Iodine

It was challenging to meet the AI for potassium (860 mg at ages 7 to 12 months; 2,000 mg at ages 1 to 3 years) in all of the modeling exercises. At ages 6 to 12 months, the predicted intakes were often less than 90 percent of the AI, especially at lower energy levels; at 12 to 24 months, predicted intakes were only 65 to 90 percent of the AI. Similarly, the Healthy U.S.-Style Pattern for the 1,000 kcal level intended for children ages 2 years or older does not achieve 90 percent of the AI. The AI for ages 7 to 12 months is based on 260 mg from human milk plus 600 mg from CFB, and it is possible that the latter is an overestimate of actual intakes. After 12 months, the AI is based on the highest median intakes at ages 1 to 3 years, and this may overestimate needs at ages 12 to 24 months. The recommended potassium intakes published by the European Food Standards Authority are lower than the AI values: 750 mg at ages 7 to 11 months and 800 mg at ages 1 to 3 years.³⁸ This suggests some uncertainty regarding potassium requirements for infants and children younger than age 24 months. Nonetheless, choosing potassium-rich foods is important at these ages (see Table D7.2 for a list of such foods).

The modeling exercises at ages 6 to 9 months provided relatively little sodium (179 to 400 mg), although by ages 9 to 12 months the estimates were adequate (384 to 566 mg in the models for infants fed human milk). The AI for sodium for infants ages 7 to 12 months is based on estimated sodium intake from human milk (70 mg, from 600 mL of human milk) plus CFB (300 mg/d), for a total of 370 mg/d. Physiological requirements for sodium during infancy^{39,40} correspond to an intake of about 300 to 460 mg/d at ages 6 to 12 months. Projected intakes at ages 6 to 9 months for “average” human milk intake models were less than 300 mg/d. Infant feeding guidance usually recommends not to add salt to foods for infants. This has implications not only for adequacy of sodium intake, but also adequacy of iodine intake, as iodized salt is a key contributor to the latter. If infants are fed some prepared foods to which salt has been

added, sodium intakes may not be low, but if the recommendation to avoid added salt were fully implemented, underconsumption may be a concern. The estimated sodium provided by the Patterns for 12 to 24 months (with no human milk or infant formula) was 613 to 729 mg, which is well below the AI of 800 (which is based on extrapolation down from adult values).

Iodine intakes could not be predicted because food composition data are not available for iodine. The AI for iodine at ages 6 to 12 months is 130 micrograms per day (mcg/d), extrapolated up from the AI of 110 mcg/d for ages 0 to 6 months. Estimated iodine intake at ages 6 to 12 months is about 141 mcg/d, based on Total Diet Study estimates of iodine in the U.S. food supply and predicted intakes based on food consumption data reported in WWEIA 2007-2008, 2009-2010, and 2011-2012.⁴¹ However, this estimate is based on 59 percent (83 mcg) from “baby food,” which includes infant formula, and 33 percent (46 mcg) from dairy products. It is not clear what the estimated intake would be among infants fed human milk. Infant formula generally has 15 mcg/100 kcal, which would provide the AI if energy intake from formula is 866 kcal or more, although the minimum content required is only 5 mcg of iodine per 100 kcal.⁵ The average estimated iodine concentration of human milk is similar, but maternal diet influences milk iodine concentration, and wide variability in iodine intakes of women who are lactating is likely. In situations in which neither the mother nor the infant consumes iodized salt or obtains adequate iodine from other sources (e.g., dairy products), iodine intakes of infants could be deficient. Only 53 percent of table salt sold at retail level in the United States in 2009 was iodized,⁴² and the iodine content of cow milk in the United States is highly variable.⁴³ Underconsumption of iodine during infancy has important potential consequences for brain development, especially if maternal intake was also low during pregnancy.⁴⁴

Added Sugars

In general, public health concern about sugars tends to focus on “added” sugars, rather than naturally occurring sugars that are intrinsic to fruits, vegetables, and milk.⁴⁵ The example combinations of foods developed for older infants contain a negligible amount of added sugars, with a range of 0.5 to 1.1 grams across all energy levels and models differing in proportions of energy from human milk. Similarly, low amounts of added sugars were estimated in the Patterns for toddlers (ages 12 to 24 months) with a range of approximately 2 to 3 grams, representing 1 percent of total energy intakes. This low amount of added sugars is logical given that the foods selected for the Patterns were in the most nutrient-dense forms, and would thus, by definition, be low in added sugars. For example, the food combinations and Patterns include only plain yogurt, whereas other types of yogurts with added sugars are more frequently consumed by this

age group. The observed intake patterns among infants and toddlers suggest that much higher amounts of added sugars are currently being consumed than the proposed combinations of foods in these modeling exercises. For older infants fed human milk, milk and dairy (28 percent of total added sugars), grains (17 percent), and fruits (16 percent) were the top 3 contributing sources of added sugars, whereas among infants fed infant formula or mixed-fed, the primary contributors were snacks and sweets (25 percent), baby foods (20 percent), and milk and dairy (19 percent). Nevertheless, the mean amounts of added sugars were quite similar despite different food sources, with both groups consuming about 1 tsp eq per day. The intake of added sugars precipitously increases in ages 12 to 24 months, with an average of about 6.2 tsp eq consumed on a given day. It should be noted that 100% fruit juice does not contribute toward added sugars, but rather toward fruit intakes. Fruit drinks and juice blends that are not 100% fruit juice do, however, contribute to intakes of added sugars. The Patterns developed for this age group consider only the nutrient contributions from 100% juice and fluid milk as beverages that contribute to the Fruits and Dairy groups, respectively. Most other beverages, such as fruit drinks, are not represented in those food groups. The modeling exercises described in this chapter illustrate that aiming to achieve recommended intakes of key nutrients for ages 6 to 24 months, including iron, leaves virtually no remaining energy for added sugars. Shifts in the dietary intakes of infants and toddlers are needed to ensure that nutrient-dense foods are provided.

SUMMARY

The results of modeling exercises for infants and children ages 6 to 24 months illustrate that simply extrapolating down from the patterns for children older than age 2 years is not sufficient to meet the unique nutrient needs during this life stage. During the complementary feeding period, human milk or other milk sources (such as infant formula until age 12 months, other milks thereafter) make up a substantial proportion of total energy intake such that the energy to be contributed by CFB is limited, especially at ages 6 to 12 months. At the same time, CFB need to provide nearly all of the iron and zinc and a substantial proportion of the amounts of several other key nutrients required by infants fed human milk at these ages, so the nutrient density of CFB has to be quite high. The nutrient gaps identified in ***Part D. Chapter 1: Current Intakes of Foods, Beverages, and Nutrients*** reflect this situation and confirm the need to provide sources high in these nutrients during the transition to the family diet.

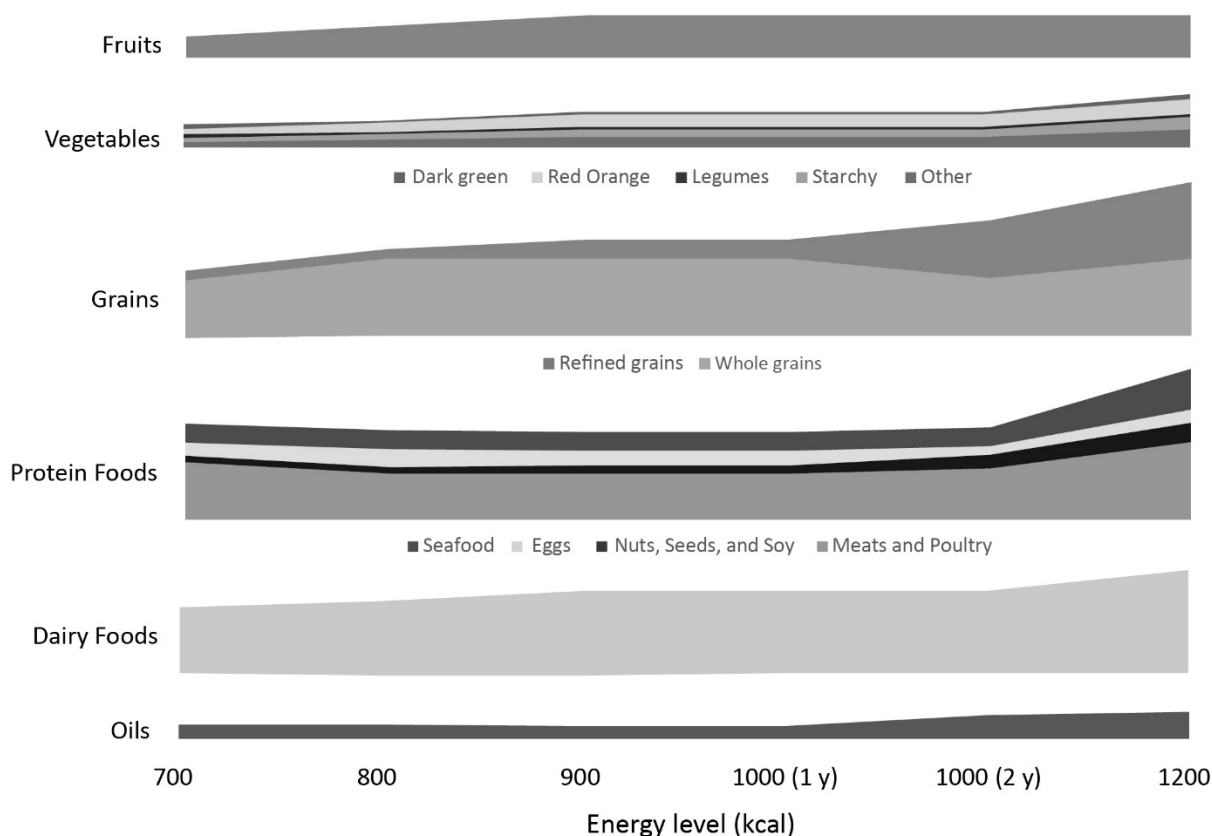
For infants ages 6 to 12 months, the Committee was not able to establish a recommended food pattern. Further work is needed to explore various options for meeting all nutrient recommendations during that age range, using tools such as linear programming and taking into account differences in iron bioavailability from different sources. In the meantime, the modeling exercises revealed the importance of prioritizing certain food groups and making careful food choices within food groups. For example, certain animal-source foods are important sources of key “shortfall” nutrients at this age, including iron, zinc, choline, and long-chain polyunsaturated fatty acids. Fortified infant cereals can contribute a substantial amount of some of these nutrients, particularly iron and zinc, but prioritizing consumption of meat, egg, and seafood is an important strategy for providing all of these crucial nutrients. By contrast, dairy products (such as yogurt and cheese) are less crucial than other types of animal-source foods at ages 6 to 12 months because infants are still receiving human milk or infant formula, and dairy products tend to have low amounts of iron. Prioritizing fruits and vegetables, particularly those that are rich in potassium, vitamin A, and vitamin C, is another key element of healthy complementary food diets at ages 6 to 12 months, not only to provide adequate nutrition but also to foster acceptance of these healthy foods. In addition, introduction of peanut products and egg in the first year of life is advised, to build tolerance to food antigens (i.e., help prevent food allergies) and to provide good sources of fatty acids and choline. Finally, the modeling exercises illustrated that CFB diets at this age include no remaining energy for added sugars and little energy for added oils or added solid fats.

For ages 12 to 24 months, the Committee was able to establish a recommended Food Pattern for toddlers fed neither human milk nor infant formula that resembles the Pattern established for ages 2 and older. The Pattern allows for a variety of nutrient-rich animal-source foods, including meat, poultry, seafood, eggs, and dairy products, as well as nuts and seeds, fruits, vegetables, and grain products. Key aspects to emphasize include choosing potassium-rich fruits and vegetables, prioritizing seafood, making whole grains the predominant type of grains offered, and choosing oils over solid fats. In these Patterns, energy allocated to oils is minimal (8 to 13 g/d) and no energy remains for added sugars not already inherent in the Patterns. For toddlers fed human milk at ages 12 to 24 months, the Committee was not able to establish a recommended food pattern but provides examples of potential combinations of CFB that come close to meeting almost all nutrient recommendations. Further work is needed to examine predicted nutrient intakes of toddlers fed human milk that take into account mineral bioavailability under various conditions. For toddlers fed lacto-ovo vegetarian diets and fed neither human milk nor infant formula at ages 12 to 24 months, a Pattern was established that

includes regular consumption of eggs, dairy products, soy products, and nuts or seeds, in addition to fruits, vegetables, grains, and oils. Because of concerns about iron bioavailability in the vegetarian pattern, the Committee recommends further modeling work that takes this into account. Careful choices of CFB within vegetarian diets are very important to meet nutrient needs. It should be noted that the Healthy Vegetarian Eating Pattern developed is not a vegan diet, as the former includes substantial amounts of animal-source foods (egg and dairy). Without supplements and/or fortified products, it is not possible to meet all nutrient goals with a vegan diet at this age.⁴⁶ In all of the Patterns for toddlers ages 12 to 24 months, any energy remaining after meeting nutrient goals was allocated to oils, leaving no additional energy for added sugars apart from the 2 to 3 g of added sugars inherent in the patterns from some of the foods in the nutrient profile (mostly refined grains).

These findings are not intended to provide a combination of CFB or food pattern that is right for every infant or toddler, because children develop at different rates, and many different circumstances influence feeding needs and decisions. In the Patterns developed for toddlers ages 12 to 24 months, the lowest energy level (700 kcal) presented challenges for meeting certain nutritional goals (e.g., iron and fatty acids). Toddlers with relatively low energy intakes may benefit from food combinations that resemble those for infants ages 6 to 12 months, with a gradual shift to the patterns presented for ages 12 to 24 months. A general principle is to view the period from ages 6 to 24 months as a continuous transition from diets appropriate for infants to diets that resemble family food patterns. Figure D7.1 illustrates this transition. For most of the food groups, amounts to be consumed gradually rise as energy from CFB increases, which is correlated with age. However, the energy from Protein Foods is relatively constant, and is a substantial proportion of total energy from CFB, at all energy levels between 700 and 1,000 kcal. This is a reflection of the need for nutrient-rich foods for children younger than age 24 months. Another important feature of Figure D7.1 is the high proportion of whole grains, relative to total Grains, until age 2 years.

Figure D7.1. Relative amounts of food groups and subgroups in Healthy U.S.-Style Patterns across energy levels for toddlers and young children¹: transition from diets appropriate for infants to diets that resemble family food patterns²



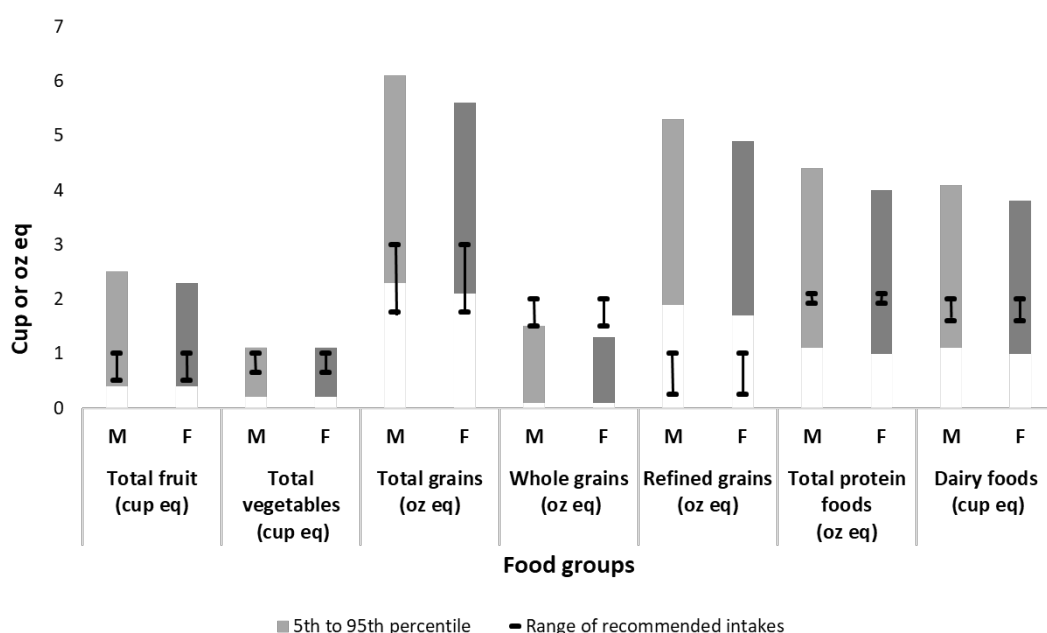
1: Inclusive of complementary foods and beverages (CFB) and not human milk or infant formula; modeled complementary food includes fluid milk, calcium fortified soy beverage, and 100% fruit and vegetable juice

2: For most of the food groups, amounts to be consumed gradually rise as energy from CFB increases, which is correlated with age. However, the energy from Protein Foods is relatively constant, and is a substantial proportion of total energy from CFB, at all energy levels between 700 and 1,000 kcal, and whole grains are a high proportion of total grains until age 2 years. These features reflect the need for nutrient-rich foods for children younger than age 24 months.

As described in **Part D. Chapter 14: USDA Food Patterns for Individuals Ages 2 Years and Older**, a strength of the USDA Food Patterns is that they provide examples of amounts of food groups and subgroups that could be consumed, but do not dictate the specific types of foods to be consumed, providing a large amount of flexibility for foods to be tailored to an individual's needs and preferences. This flexibility is very important during the CFB period, as it accommodates cultural preferences and cost considerations, and permits multiple approaches for the introduction of a wide variety of foods, flavors, and textures important in shaping healthy eating patterns. Figure D7.2 illustrates that the Healthy U.S.-Style Pattern for toddlers ages 12 to 24 months is an achievable pattern, with a few shifts from current consumption patterns

needed. The range of recommended intakes in the Pattern is well within the range (5th to 95th percentile) of current intakes of Fruits, Vegetables, total Protein Foods, and Dairy in this age group, though a shift toward greater intake of Vegetables is needed. By contrast, the recommended intakes of whole grains are well above current intakes, whereas the recommended intakes of refined grains are far below current intakes. Thus, a shift toward a higher proportion of total Grains as whole grains and a reduction in refined grains is needed.

Figure D7.2. Range of recommended food group amounts in the Healthy U.S.-Style Food Pattern compared to the 5th to 95th percentiles of intakes in the population for children ages 12 to 24 months not fed human milk¹



1: Illustrates that the Healthy U.S.-Style Pattern for toddlers ages 12 to 24 months (not fed human milk) is an achievable pattern, with a few shifts from current consumption patterns needed. The range of recommended intakes in the Pattern is well within the range (5th to 95th percentile) of current intakes of Fruits, Vegetables, total Protein Foods, and Dairy in this age group, though a shift toward greater intake of Vegetables is needed. By contrast, the recommended intakes of whole grains are well above current intakes, whereas the recommended intakes of refined grains are far below current intakes. Source: Food Group Intake Distributions, WWEIA NHANES 2013-2016, ages 12 to 24 months. Prepared by NCI, 2019

Although longitudinal studies tracking eating habits within the same individual across time are lacking, early dietary patterns may shape dietary choices later in life, as illustrated by the cross-sectional data spanning the NHANES data by age group in this report (see **Part D. Chapter 1**). Thus, establishing healthy eating habits during the first 2 years of life is critical. Although the individual experience shapes food preferences (e.g., taste), the collective modeling

of food choices in young childhood through direct observation of food intake by peers and adults also is paramount.⁴⁷

Recommendations for Advice to Caregivers

- Provide a variety of animal-source foods (meat, poultry, seafood, eggs, and dairy), fruits, and vegetables, nuts and seeds, and whole grain products, beginning at ages 6 to 12 months and continuing thereafter, to provide key nutrients, foster acceptance of a variety of nutritious foods, and build healthy dietary habits.
- For infants fed human milk at ages 6 to 12 months, consider providing iron-fortified infant cereals or similar products to ensure adequate iron intake.
- Provide good sources of omega-3 and omega-6 fatty acids, such as seafood, beginning at ages 6 to 12 months. To limit exposure to methylmercury for groups at risk, the U.S. Food and Drug Administration and the U.S. Environmental Protection Agency have issued joint guidance regarding the types of seafood to choose.⁴⁸
- Introduce peanut products and egg between ages 6 and 12 months. Be careful to choose forms of peanut that do not present a choking risk. Evidence regarding benefits of introducing other potentially allergenic foods (e.g., tree nuts, shellfish, fish) in the first year of life is limited, but there is no reason to avoid them (see ***Part D. Chapter 5: Foods and Beverages Consumed During Infancy and Toddlerhood***).
- For toddlers ages 12 to 24 months whose diets do not include meat, poultry, or seafood, provide eggs and dairy products on a regular basis, along with soy products and nuts or seeds, fruits, vegetables, grains, and oils.
- Avoid foods and beverages with added sugars during the first 2 years of life. The energy in such products is likely to displace energy from nutrient-dense foods, increasing the risk of nutrient inadequacies. Moreover, consumption of sugar-sweetened beverages is linked with increased risk of overweight or obesity. Because food preferences and patterns are beginning to form during this developmental stage, and taste and flavor preferences appear to be more malleable in this life stage than in older children,⁴⁹ it is important that caregivers limit consumption of foods that contain added sugars, while encouraging consumption of nutrient-dense foods.

Recommendations for Federal Agencies

- Develop communication and dissemination strategies that effectively address common misconceptions about diets for infants and children younger than age 24 months. The importance of carefully choosing CFB may not be fully appreciated by the public. For example, the rhyme that “food before one is just for fun” implies that the only goal during infancy is fostering pleasant eating experiences, and that the nutritional contribution of CFB is not critical. A more appropriate message is that “every bite counts,” emphasizing the nutrients of concern for potential inadequacy and excess, while also conveying the need to make eating enjoyable and the importance of responsive feeding practices.
- Consider strategies for assisting caregivers and program managers to use the information about the CFB combinations and patterns described in this chapter. In particular, guidance will be needed on how to operationalize providing the recommended amounts of food groups and subgroups shown in the Healthy U.S.-Style Pattern and Healthy Vegetarian Pattern for ages 12 to 24 months. This information is provided by energy level, but the energy intake of an infant or toddler is generally unknown by caregivers.

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PART D. CHAPTER 8: DIETARY PATTERNS

INTRODUCTION

Traditionally, associations of diet to health have focused primarily on a single nutrient or food and an identified health outcome. Since the early 2000s, the focus for quantifying dietary exposures has moved from single nutrients or foods to dietary patterns as a way to more comprehensively represent the totality of the diet and nutrient profiles. Research using the concept of dietary patterns presents certain advantages, including the reality that people do not eat nutrients in isolation, but rather a combination of foods that contain multiple nutrients. Foods and their associated nutrients are known to have synergistic effects,¹ complicating the detection of an effect of a single food or nutrient. Identification of a dietary pattern may reveal a stronger association with a particular indicator of health and may allow for a more comprehensive and inclusive understanding of how nutrients and other bioactive compounds in our food are consumed and how patterns of consumption influence health outcomes. Thus, an emphasis on foods and beverages rather than individual nutrients has improved translation to dietary recommendations for the broad public. Ultimately, dietary patterns can be applied to the general population, allowing researchers to demonstrate the effects of diet on health outcomes and surrogate endpoints.²⁻⁶

Since 2010, Dietary Guidelines Advisory Committees have placed increasing emphasis on examining dietary patterns and health outcomes. The 2010 Committee identified the importance of encompassing dietary patterns in addition to nutrient adequacy and recommended additional research to formally address this topic. The 2015 Committee conducted the first exploration of the influence of dietary patterns on health outcomes. The 2020 Committee built upon these previous reports and reviewed additional outcomes, including all-cause mortality and sarcopenia. The Committee also included an examination of diets based on macronutrient distributions in its review.

Definitions and Derivation

Dietary patterns are defined as the quantities, proportions, variety, or combination of different foods, drinks, and nutrients in diets, and the frequency with which they are habitually consumed.⁷ The approach of using dietary patterns as an assessment tool to determine diet quality provides a meaningful bridge toward disseminating messages intended to promote high-quality diets.^{1,6} Diet quality reflects dietary patterns comprised of foods and beverages that, in

total, are associated with better health and reduced risk for chronic disease. High-quality refers to the most nutrient-dense form of a food with the least amount of added sugars, sodium, and saturated fat.⁸ The nutritional quality of a dietary pattern can be determined by assessing the nutrient content of its constituent foods and beverages and comparing these characteristics to age- and sex-specific nutrient recommendations for inadequacy and quantitative limits, as shown in **Part D. Chapter 7: USDA Food Patterns for Children Younger than Age 24 Months** and **Part D. Chapter 14: USDA Food Patterns for Individuals Ages 2 Years and Older**.

Dietary patterns are derived using multiple methods. Among these methods the two commonly used for identifying dietary patterns include index-based patterns or exploratory patterns.⁹ An example of an index-based method is the Dietary Approaches to Stop Hypertension (DASH) score.¹⁰ The exploratory patterns methods include theoretical or data-driven methods using statistical techniques, such as principal component analysis (PCA) to determine dietary patterns based on shared variance across dietary variables within a population. Reduced rank regression (RRR), another example of an exploratory pattern, is an estimation procedure in which dietary patterns in a population are statistically derived relative to response variables that are often non-dietary outcomes. Various data reduction techniques have been used to identify dietary patterns based on both unsupervised and supervised statistical methods.²⁻⁶ More detail about these methods are outlined below.

Index-Based Patterns. A single numerical score to evaluate the diet, termed index-based or a dietary index, is an approach that relies upon pre-determined dietary standards against which each study observation is evaluated.¹¹⁻¹³ This method is based on a priori knowledge of dietary recommendations and scientific consensus using an evidence-based approach.²⁻⁶ Each of the components comprising the index are summed to determine a total score. The individual component scores also can be examined. Examples of diet quality scores include the Healthy Eating Index (HEI)-2010,¹⁴ the alternate Mediterranean Diet Score (aMED),¹⁰ the Alternate (HEI)-2010,¹⁵ and the DASH score.¹⁰ A distinct advantage of these structured patterns is the replication and comparability of study findings. On the other hand, these patterns may not represent all cultural or regional variations of dietary intakes. Some degree of subjective decision making may be used to develop the index or score. This may be a potential drawback. (The HEI-2015 is explained in greater detail in **Part D. Chapter 1: Current Intakes of Foods, Beverages and Nutrients**)

Exploratory Patterns. In addition to the PCA noted above, cluster and factor analysis also have been used to determine dietary patterns that arise from the data.¹⁶⁻²⁰ These methods are

considered data-driven or a posteriori approaches.²⁻⁶ The first step in most of these methods is to systematically reduce the number of foods or food groups reported by people to reach an optimal combination of food groups that best explains or predicts the outcomes of interest. Once food groups are formed, the inputs or predictors are aggregated into linear combinations that explain the maximum amount of the total variance across all input or predictor variables. These principal components or factors are referred to as dietary patterns.⁶ These dietary patterns are often labeled based on the foods that fall within each factor or principal component. Terms such as “sweets,” “healthy,” and “Western” are commonly used in published literature. For example, a sweets pattern can be composed of food such as cakes and other sweet desserts, while a healthy pattern can be composed of foods such as fish, whole grains, and vegetables.¹⁶⁻¹⁹

A combination of a priori and post priori methods known as reduced rank regression also has been used to derive dietary patterns.²¹⁻²⁴ A reduced rank regression analysis defines factors to be linear combinations of input variables that best explain the total variance in a set of response variables. For example, one may use the response variables of the nutrient density of total fat, carbohydrate, and dietary fiber to examine an outcome (e.g., cancer). The number of response variables determines the number of dietary patterns that will be generated. Factors are either positively or negatively correlated with the response variables. Replication of this method has been demonstrated.⁹ Based on the content of the correlated items, a name or label can be developed for each underlying factor. An example of one method of deciding a factor name is to base the name on the foods with greatest positive or negative correlations or loadings.^{6,22}

Pattern Direction. For all methods, dietary patterns can be developed with an emphasis on healthy food and beverage components comprising the dietary pattern (e.g., the DASH diet). In this case, the results (higher scores) will most likely reflect reductions in risk for the outcome of interest. In contrast, for dietary patterns emphasizing low nutrition quality (e.g., the NOVA²⁵ Food Classification System), the results (higher scores) will reflect higher risk for the outcome of interest. Both approaches can be used to confirm the effect of a healthier dietary pattern.

Strengths of the Approach

The dietary patterns approach has several major strengths. Because foods are consumed in combination and reflect dietary components acting in synergy, evidence suggests that a composite of foods and beverages, a dietary pattern, is more likely to influence health or chronic disease than will any single food. A dietary patterns strategy captures the relationship between the overall diet and the interactions between foods and nutrients as either health-promoting or

health-compromising. Patterns help to capture the complexity of the overall diet and its constituent parts so that researchers can relate the patterns to outcomes of interest. In doing so, we can essentially deal with the known collinearity among foods and nutrients. This information on a variety of food and beverage items has advanced research and offers evidence of new preventive approaches. As noted in previous Committee reports, individuals can achieve a healthy diet in multiple ways and preferably with a wide variety of foods and beverages. Results from the National Institutes of Health-National Cancer Institute (NIH-NCI) Dietary Patterns Methods Project¹ confirmed this recommendation, when higher scores on 4 independent high-quality dietary patterns were associated with marked reductions in mortality among 3 diverse cohorts, thus, reinforcing the concept that a diverse variety of healthy foods can achieve essential components of a healthy diet.

Expansion from Previous Reviews

The Dietary Patterns chapter reflects evidence the Committee considered on the relationship between dietary patterns and 8 broad health outcomes. Except for all-cause mortality and sarcopenia, these outcomes also were addressed by the 2015 Committee. Because dietary patterns encompass diverse foods and beverages, this chapter complements topics examined throughout this report, including dietary fats and seafood (see **Part D. Chapter 9: Dietary Fats and Seafood**), beverages (see **Part D. Chapter 10: Beverages**), alcoholic beverages (see **Part D. Chapter 11: Alcoholic Beverages**), and added sugars (see **Part D. Chapter 12: Added Sugars**). In most cases, the conclusions drawn from reviews of these food and beverage components align with the conclusions drawn for dietary patterns, though there are some differences in the conclusions drawn for alcoholic beverages. The Discussion section provides information on how these reviews can be considered together.

The 2020 Committee also examined studies adopting a new exposure, macronutrient distribution, defined as consuming at least 1 macronutrient outside of the Acceptable Macronutrient Distribution Ranges (AMDR), which provide ranges for percent of energy for fat, carbohydrate, and protein as established in the Dietary Reference Intakes.²⁶ Typical dietary patterns as reported do not include a macronutrient distribution, although increasing interest in this topic warranted inclusion in the Committee's review. In contrast to a dietary pattern's focus on foods, a diet's relative macronutrient distribution can be varied, with increased protein and reduced carbohydrates being the most common modifications.²⁷ Characteristics of popular diets of this type vary from 65 percent fat/25 percent protein/10 percent carbohydrate to 10 percent fat/20 percent protein/70 percent carbohydrate.²⁷ For this 2020 Committee review, most of the

evaluated articles examined distributions in which the proportion of energy from carbohydrate was below the AMDR, fat was above the AMDR, and protein was within the AMDR.

LIST OF QUESTIONS

1. What is the relationship between dietary patterns consumed and risk of cardiovascular disease?
2. What is the relationship between dietary patterns consumed and growth, size, body composition, and risk of overweight and obesity?
3. What is the relationship between dietary patterns consumed and risk of type 2 diabetes?
4. What is the relationship between dietary patterns consumed and bone health?
5. What is the relationship between dietary patterns consumed and risk of certain types of cancer?
6. What is the relationship between dietary patterns consumed and neurocognitive health?
7. What is the relationship between dietary patterns consumed and sarcopenia?
8. What is the relationship between dietary patterns consumed and all-cause mortality?

METHODOLOGY

All questions discussed in this chapter were answered using systematic reviews conducted with support from USDA's Nutrition Evidence Systematic Review (NESR) team. NESR's systematic review methodology provided a rigorous, consistent, and transparent process for the Committee to search for, evaluate, analyze, and synthesize evidence.

All questions examined the consumption of and/or adherence to a dietary pattern as the primary intervention or exposure of interest. The comparators of interest were consumption of and/or adherence to a different dietary pattern or different levels of consumption of and/or adherence to a dietary pattern. Dietary patterns were defined as "the quantities, proportions, variety, or combination of different foods, drinks, and nutrients in diets, and the frequency with which they are habitually consumed." To be included in the review on dietary patterns, studies needed to provide a description of the foods and beverages in the pattern. Dietary patterns considered in the review were measured or derived using a variety of approaches, such as adherence to a priori patterns (indices and scores), data-driven patterns (factor and cluster analysis), reduced rank regression, or other methods, including clinical trials. When reporting

results, we chose to respect the food/beverage names used by the authors and tried to refrain from inserting new descriptive language not a part of the original research efforts. Given the emphasis on foods and beverages, dietary patterns comprised of only nutrients and bioactive compounds were excluded.

Questions 1 through 3, 7, and 8, also examined diets based on macronutrient distribution outside of the AMDR, at any level above or below the AMDR, as an intervention or exposure of interest. The comparator of interest was consumption of and/or adherence to a diet with different macronutrient distributions of carbohydrate, fat, and protein. To be included in the systematic review, articles needed to describe the entire macronutrient distribution of the diet by reporting the proportion of energy from carbohydrate, fat, and protein, with at least 1 macronutrient proportion outside of the AMDR. The Committee established these criteria in order to take a holistic approach towards answering the scientific questions, and thus, requiring the entire distribution of macronutrients within the diet, rather than a select macronutrient in isolation. These criteria facilitated consideration of both the relationships with health outcomes associated with diets having 1 macronutrient outside of the AMDR, and also how consumption of that macronutrient displaces or replaces intake of the other macronutrients within the distribution. It was not required for a study to report the foods or food groups consumed to be included for consideration as a diet based on macronutrient distribution. Rather, criteria were designed to cast a wide, comprehensive net to capture any study that examined macronutrients outside the age-appropriate AMDR (e.g., in adults: carbohydrate levels less than 45 percent or greater than 65 percent of energy, fat levels less than 20 percent or greater than 35 percent of energy, and/or protein levels less than 10 percent or greater than 35 percent of energy). Furthermore, when describing and categorizing studies included in these reviews, the Committee did not label the diets examined as “low” or “high,” because no universally accepted, standard definition is currently available, for example, for “low-carbohydrate” or “high-fat” diets. Instead, the Committee focused on whether, and the extent to which, the proportions of the macronutrients were below or above the AMDR.

Details about the methods used to answer the questions discussed in this chapter are provided below. Due to the timeline relative to the workload volume, some questions required the Committee to consider additional inclusion and exclusion criteria prior to completion of literature screening to fine tune and strengthen the resulting body of evidence. The specific modifications from the initial protocol compared to the final protocol are specified below for each question. Three different approaches were used to answer all questions considered in this

chapter, including updating existing systematic reviews, using existing systematic reviews, and/or conducting new systematic reviews.

Questions 1 through 3 in this chapter were answered by updating existing systematic reviews (i.e., dietary patterns in children and adolescents), using existing systematic reviews (i.e., dietary patterns in adults), and conducting new systematic reviews (i.e., diets based on macronutrient distribution). The various processes used to accomplish this are described in **Part C. Methodology**. For all questions, the Committee developed a systematic review protocol, which described how they would apply NESR's methodology to answer the question. The protocol included an analytic framework and inclusion and exclusion criteria to guide identification of the most relevant and appropriate body of evidence to use in answering each systematic review question. Each analytic framework outlined core elements of the systematic review question (i.e., population; intervention and/or exposure and comparator [i.e., the alternative being compared to the intervention or exposure]; and outcomes), and included definitions for key terms, key confounders, and other factors to be considered when reviewing the evidence. The inclusion and exclusion criteria were selected, up front, to operationalize the elements of the analytic framework, and specify what made a study relevant for each systematic review question. Next, a literature search was conducted to identify all potentially relevant articles, and those articles were screened by 2 NESR analysts independently based on the criteria selected by the Committee. Then, for those reviews that were new or updates, for each included article, data were extracted and risk of bias assessed. The Committee qualitatively synthesized the body of evidence to inform development of a conclusion statement(s), and graded the strength of evidence using pre-established criteria for risk of bias, consistency, directness, precision, and generalizability. The existing systematic review conclusion statements that were updated and/or used for these questions were drawn by the 2015 Committee.²⁸ Detailed information about the 2015 Committee's review of the evidence can be found in their report, which is available at the following website: dietaryguidelines.gov/current-dietary-guidelines/process-develop-2015-2020-dg/advisory-committee. In addition, detailed information about methodology used to conduct the existing systematic reviews that were used or updated in these questions can be found at the following website: nesr.usda.gov/dietary-patterns-systematic-review-project-methodology.

To address dietary patterns consumed by children and adolescents, the 2020 Committee updated the existing systematic reviews used by the 2015 Committee.²⁸

To address dietary patterns consumed by adults, the 2020 Committee used the existing reviews previously conducted by the 2015 Committee.²⁸ The 2020 Committee conducted a

systematic evidence scan and determined that the existing systematic reviews still reflect the current state of science, and did not require a formal update. The systematic evidence scans involved a systematic literature search, with screening by two NESR analysts independently, to provide objective information to facilitate decisions about updating the existing systematic reviews. NESR analysts provided the Committee with all newly published articles that met inclusion criteria based on the results of the scan. Committee members considered the newly published articles to determine whether the new evidence was consistent with the body of evidence from the existing NESR systematic review and if newly published studies addressed key gaps or limitations identified in the existing review. The results of the scan, including a list of all new articles that met criteria for inclusion and the rationale for not updating the review, are documented and available online through the link that follows the summary of evidence for each question.

To address diets based on macronutrient distribution, the 2020 Committee conducted new systematic reviews with support from USDA's NESR team.

For Questions 1 through 3, the population of interest was children and adolescents (ages 2 to 18 years), adults (ages 19 to 64 years), and older adults (ages 65 years and older). Women who were pregnant or lactating were examined in a series of related questions that examined the relationship between dietary patterns and gestational weight gain, postpartum weight loss, hypertensive disorders during pregnancy, or gestational diabetes during pregnancy. These questions are detailed in ***Part D. Chapter 2: Food, Beverage, and Nutrient Consumption During Pregnancy*** and ***Chapter 3: Food, Beverage, and Nutrient Consumption During Lactation***.

Outcomes of interest are described below. Questions 1 and 3 included both intermediate and endpoint health outcomes, and their eligibility for inclusion varied by population (i.e., children or adults) and study design.

The outcomes of interest in each of these reviews are as follows:

- Risk of cardiovascular disease (CVD): Intermediate outcomes included total cholesterol, LDL cholesterol (LDL-C), HDL cholesterol (HDL-C) (including total cholesterol:HDL-C and LDL:HDL cholesterol ratios), triglycerides, and blood pressure (systolic and diastolic). Endpoint outcomes included myocardial infarction, coronary heart disease, coronary artery disease, congestive heart failure, peripheral artery disease, stroke, venous thrombosis, and CVD-related mortality. To focus on the strongest available evidence, criteria also were employed to specify which study designs were eligible for inclusion depending on the outcomes being examined. For adults (ages 18 years and

older), only evidence on intermediate outcomes from randomized controlled trials (RCTs) was included whereas evidence on endpoint outcomes was considered from all included study designs. For children (ages 2 to 18 years), evidence on intermediate and endpoint outcomes was considered from all included study designs (i.e., RCTs and certain types of observational studies).

- Growth, size, body composition, and risk of overweight and obesity, in ages 2 years and older: weight, weight-for-age, height, length/stature-for-age, body mass index (BMI), BMI z-score, weight-for-length, body circumferences (head, arm, waist, thigh, neck), body composition and distribution (e.g., percent fat mass, fat-free mass, lean mass), and incidence and prevalence of underweight, failure to thrive, stunting, wasting, healthy weight, overweight, or obesity.
- Risk of type 2 diabetes: Intermediate outcomes included hemoglobin A1C (HbA1c) and endpoint outcomes included type 2 diabetes. The original protocol also included glucose, insulin, and prediabetes as intermediate outcomes, but these were later removed to focus on HbA1C as a predictor of type 2 diabetes for which confirmation of fasting is not needed and day-to-day variability is minimized. To focus on the strongest available evidence, criteria also were employed to specify which study designs were eligible for inclusion depending on the outcomes being examined. For adults (ages 18 years and older), only evidence on intermediate outcomes from RCTs was included and evidence on endpoint outcomes was considered from all included study designs. For children (ages 2 to 18 years), evidence on intermediate and endpoint outcomes was considered from all included study designs.

To establish inclusion and exclusion criteria for Questions 1 through 3, the Committee used standard NESR criteria for publication status, language of publication, country, and study participants. Additional criteria for study duration, size of study groups, and energy-restriction were established in the final protocols to ensure that the most relevant and appropriate body of evidence was included to answer these questions. A key aspect of the definition of a dietary pattern is that it represents the habitual diet of an individual, over time. Thus, the Committee established study duration criteria to include studies on dietary patterns and diets based on macronutrient distribution that were longer in duration, and therefore, better represented the concept of a habitual diet. Studies with an intervention or exposure duration of 12 weeks or longer were included, and those shorter than 12 weeks were excluded. This duration of exposure also corresponded with a timeframe that would be expected to capture meaningful

changes in HbA1c values for diabetes-related outcomes²⁹ as well as changes in total cholesterol and LDL-C related to CVD risk. While a longer minimum duration may be advisable for select outcomes, such as CHD incidence,³⁰ imposing such a criteria could produce a body of evidence that is too narrow. The duration selected by the Committee was intended to obtain literature examining dietary patterns sustained for a sufficient period of time that would deliver valid results across the range in intermediate and endpoint outcomes of interest. Size of study groups criteria were applied to intervention and observational studies because effects or associations observed when power or sample size is inadequate could be due to random chance (i.e., low statistical power increases the likelihood that a statistically significant finding actually represents a false positive result). Therefore, intervention studies with fewer than 30 participants per-arm or no power calculation and observational studies with fewer than 1,000 participants were excluded. Standard health status criteria were applied, but expanded to ensure an evidence base that would allow for more direct comparisons between dietary patterns and outcomes that are independent of the effects that weight loss may have on cardiometabolic health factors. Studies that used hypocaloric or energy-restricted diets to induce weight loss in participants with overweight or obesity were excluded, as it is not possible to isolate whether outcomes were due to reduced energy intake, the proportion of macronutrients or dietary pattern consumed, and/or weight loss.

Two literature searches were conducted to identify all potentially relevant articles for Questions 1 through 3. The first search was designed to update the existing review by searching for articles that examined dietary patterns and all outcomes published from January 2014 to October 2019. This search also was designed to identify articles that examined diets based on macronutrient distribution and all outcomes. Because diets based on macronutrient distribution and these outcomes were not covered in an existing systematic review, the second search was designed to identify all potentially relevant articles published from January 2000 to December 2013. This date range was selected for consistency with the new dietary patterns reviews being conducted by the Committee. After the 2 searches were conducted, duplicates were moved, and the results were combined for screening.

Questions 4 through 6 in this chapter were answered by updating existing systematic reviews that were conducted by the 2015 Committee with support from USDA's NESR team. A description of the process the Committee used to update these existing systematic reviews is provided in **Part C. Methodology**. In addition, detailed information about the 2015 Committee's review of the evidence can be found in their report, which is available at the following website: nesr.usda.gov/dietary-patterns-foods-and-nutrients-and-health-outcomes-subcommittee and

dietaryguidelines.gov/current-dietary-guidelines/process-develop-2015-2020-dg/advisory-committee.

To address dietary patterns consumed, the 2020 Committee updated the existing systematic reviews used by the 2015 Committee. When prioritizing work within the timeline and considering lack of biological plausibility, diets based on macronutrient distribution were not examined for these outcomes.

For Question 4, the outcomes of interest included intermediate outcomes (i.e., bone mass, including bone mineral density, bone mineral content, and biomarkers of bone metabolism) and endpoint outcomes (i.e., osteoporosis, osteopenia, rickets, and fracture). The populations of interest were children and adolescents (ages 2 to 18 years), adults (ages 19 to 64 years), women who were pregnant or lactating, and older adults (ages 65 years and older). To focus on the strongest available evidence, criteria were added to specify which study designs were eligible for inclusion depending on the outcomes and age groups being examined. For adults (ages 18 years and older), only evidence on intermediate outcomes from RCTs was included, and for endpoint outcomes, evidence from RCTs and certain types of observational studies was included. In children (ages 2 to 18 years), evidence on intermediate and endpoint outcomes from both RCTs and certain types of observational studies were included. The Committee used standard NESR criteria for publication status, language of publication, country, study participants, and health status of study participants, and applied the same criteria for study duration and size of study groups as were established for Questions 1 through 3.

For Question 5, the outcomes of interest were initially incident cases of breast, colorectal, lung, prostate, liver, pancreatic, and endometrial cancer in adults and leukemia in children. The protocol was revised to focus on the 4 most common types of cancer in the United States—breast, colorectal, lung, and prostate cancer that were also considered by the 2015 Committee. The populations of interest for the intervention/exposure and outcome were children and adolescents (ages 2 to 18 years), adults (ages 19 to 64 years), and older adults (ages 65 years and older), and the Committee used standard NESR criteria for study design, publication status, language of publication, country, study participants, and health status of study participants.

For Question 6, the outcomes of interest initially included a comprehensive list of neurocognitive health outcomes across the lifespan (i.e., developmental domains [cognitive, language and communication, social-emotional, movement and physical]), attention deficit disorder or attention-deficit/hyperactivity disorder, autism spectrum disorder, academic performance, depression, anxiety, cognitive decline, mild cognitive impairment and dementia, Alzheimer's disease). However, due to timeline considerations, the final protocol was revised to

focus on only those outcomes that had also been considered by the 2015 Committee, which were incident cognitive decline, mild cognitive impairment, dementia, and Alzheimer's disease. The populations of interest for the intervention/exposure were children and adolescents (ages 2 to 18 years), adults (ages 19 to 64 years), women who were pregnant or lactating, and older adults (ages 65 years and older). The populations of interest for the outcome were adults (ages 19 to 64 years old) and older adults (ages 65 years and older). The Committee used standard NESR criteria for publication status, language of publication, country, study participants, and health status of study participants, and applied the same criteria for study duration and size of study group as were established for Questions 1 through 3.

A literature search was conducted for each question to identify all potentially relevant articles published since the existing review was conducted. For Question 4, studies were included if they were published between January 2014 and November 2019. For Question 5, studies were included if they were published between December 2013 and January 2020. For Question 6, studies were included if they were published between January 2014 to February 2020.

Questions 7 and 8 in this chapter were answered with new NESR systematic reviews. A detailed description of NESR's systematic review methodology is provided in **Part C. Methodology**, including standard inclusion and exclusion criteria applied in many of the Committee's systematic reviews. Complete documentation of each systematic review is available on the following website: nesr.usda.gov/2020-dietary-guidelines-advisory-committee-systematic-reviews. Below is a summary of the unique elements of the protocols developed to answer the questions on dietary patterns and sarcopenia, and dietary patterns and all-cause mortality.

For Question 7, the protocol initially included intermediate outcomes of skeletal muscle mass, muscle strength, muscle performance, and endpoint outcomes of severe sarcopenia and sarcopenia. To focus the review directly on sarcopenia, the protocol was revised to include only endpoint outcomes. The definition for sarcopenia was applied based on The Foundation for the National Institutes of Health (FNIH) Sarcopenia Project and consensus from multiple working groups (European Working Group on Sarcopenia in Older People, the European Society for Clinical Nutrition and Metabolism Special Interest Groups, and the International Working Group on Sarcopenia). The operational definition applied in this review for sarcopenia was a progressive and generalized loss of skeletal muscle mass, alone or in conjunction with either or both low muscle strength and low muscle performance. For Question 8, the outcome of interest

was all-cause mortality, or the total number of deaths from all causes during a specific time period. Cause-specific mortality was not included in Question 8.

For both Questions 7 and 8, the populations of interest for the intervention/exposure were children and adolescents (ages 2 to 18 years), adults (ages 19 to 64 years), and older adults (ages 65 years and older), and the populations of interest for the outcomes were adults (ages 19 to 64 years) and older adults (ages 65 years and older). Women who were pregnant or lactating were not considered in this review.

When establishing inclusion and exclusion criteria, the Committee used standard NESR criteria for study design, publication status, language of publication, country, study participants, and health status of study participants.

A literature search was conducted for each systematic review question. Both questions included studies published between January 2000 and October 2019. The Committee chose to search for and include studies published starting in 2000 because the field of dietary patterns research is relatively new. Several of the existing systematic reviews used or updated by this Committee searched for literature starting in 1980 but relevant studies published before the year 2000 were uncommon. Therefore, the Committee determined that the preponderance of evidence for these new reviews would be captured by searching literature starting in the year 2000. For consistency, a starting date of 2000 also was selected for studies examining diets based on macronutrient distribution. For the review on sarcopenia, a second search was conducted to ensure that all potentially relevant studies on this topic were identified. The full search strategy is documented in the final protocol within the full systematic reviews.

REVIEW OF THE SCIENCE

Question 1. What is the relationship between dietary patterns consumed and risk of cardiovascular disease?

Approach to Answering Question: NESR systematic review

Conclusion Statements and Grades

Dietary Patterns: Children

Limited evidence suggests that dietary patterns consumed by children and adolescents reflecting higher intakes of vegetables, fruits, whole grains, fish, low-fat dairy, legumes, and lower intake of sugar-sweetened beverages, other sweets, and processed meat, are associated

with lower blood pressure and blood lipid levels, including low-density lipoprotein cholesterol, high-density lipoprotein cholesterol, and triglycerides later in life. Grade: Limited

Dietary Patterns: Adults

The 2020 Dietary Guidelines Advisory Committee conducted a systematic evidence scan and confirmed that the conclusion drawn by the 2015 Dietary Guidelines Advisory Committee generally¹ reflects the current state of science: Strong and consistent evidence demonstrates that dietary patterns associated with decreased risk of cardiovascular disease are characterized by higher consumption of vegetables, fruits, whole grains, low-fat dairy, and seafood, and lower consumption of red and processed meat, and lower intakes of refined grains, and sugar-sweetened foods and beverages relative to less healthy patterns. Regular consumption of nuts and legumes and moderate consumption of alcohol also are shown to be components of a beneficial dietary pattern in most studies. Randomized dietary intervention studies have demonstrated that healthy dietary patterns exert clinically meaningful impact on cardiovascular risk factors, including blood lipids and blood pressure. Additionally, research that includes specific nutrients in their description of dietary patterns indicate that patterns that are lower in saturated fat, cholesterol, and sodium and richer in fiber, potassium, and unsaturated fats are beneficial for reducing cardiovascular disease risk. 2015 Dietary Guidelines Advisory Committee Grade: Strong

Diets Based on Macronutrient Distribution: Children

No evidence was available to determine the relationship between diets based on macronutrient distribution consumed by children or adolescents and concurrent or future development of cardiovascular disease. Grade: Grade Not Assignable

Diets Based on Macronutrient Distribution: Adults

Limited evidence suggests non-energy restricted diets based solely on macronutrient distribution with either carbohydrate, fat, and/or protein proportions outside of the Acceptable Macronutrient Distribution Range, are neither beneficial nor detrimental regarding risk of

¹ See the Discussion section of this chapter, and **Part D, Chapter 11: Alcoholic Beverages**, for additional information about alcohol consumption and health outcomes.

cardiovascular disease in adults, primarily among those at high-risk, such as those with overweight, obesity or features of metabolic syndrome. Grade: Limited

Summary of the Evidence

- One-hundred ninety articles were identified that met inclusion criteria and examined the relationship between dietary patterns and/or diets based on macronutrient proportion and risk of CVD.^{11-13,31-217} (See the Methodology section for more information about how dietary patterns and diets based on macronutrient distribution were operationalized for this review.)

Dietary Patterns: Children

- Four included articles, all from prospective cohort studies (PCSs) published between January 2014 and October 2019, examined the relationship between dietary patterns in children and CVD.^{55,60,66,166}
 - Two of the articles used index or score analyses to examine dietary patterns
 - Two of the articles examined dietary patterns identified with factor and cluster analyses.
 - Most of the studies examined intermediate CVD outcomes in childhood, although 1 study reported on incidence of CVD in adulthood.
 - This body of evidence updates an existing systematic review from the 2015 Dietary Guidelines Advisory Committee, which found insufficient evidence in pediatric populations published between 1980 and 2013 that met inclusion criteria on dietary patterns and CVD and therefore, was unable to form a conclusion statement at the time.

Dietary Patterns: Adults

- One-hundred forty-nine articles examined dietary patterns in adults and CVD.^{11-13,31-37,39-43,45-47,49-52,56-59,61-65,68-71,74,76-83,85,87,89,91-93,96,98,99,102-107,109-120,122-125,130-137,139-146,148-152,154-156,158-165,167,170-173,175,177-193,195-200,202,203,205-207,209-213,215-217}
 - These articles represent new evidence published since an existing systematic review that included articles published between January 1980 and 2013, which was reviewed by the 2015 Committee.²⁸
 - A systematic evidence scan was conducted to identify and examine newly published evidence, and determine whether a full systematic review update was warranted.
 - Based on results from the systematic evidence scan, the 2020 Committee determined that the newly published evidence was generally consistent with the body of evidence

from the existing review, and a full systematic review update was not needed at this time. Therefore, the conclusion statement and grade from the existing review were carried forward.

Diets Based on Macronutrient Distribution: Children

- No articles were identified that met inclusion criteria and examined diets based on macronutrient distribution consumed by children or adolescents and risk of CVD across the lifespan.

Diets Based on Macronutrient Distribution: Adults

- Forty-nine included articles examined diets based on macronutrient distribution in adults and CVD outcomes, met inclusion criteria, and were published between January 2000 and October 2019.^{38,44,48,53,54,61,67-69,72,73,75,77,84,86,88,90,94,95,97,100,101,108,111,121,126-129,134,138,147,148,153,157,168,169,171,174-176,180,185,194,201,204,205,208,214}
 - Nineteen articles came from RCTs and 30 articles came from PCSs.
 - Most studies enrolled participants who were overweight or obese, or exhibited features of metabolic syndrome.
 - The majority of RCTs (n=11) reported no significant effects of macronutrient distributions on intermediate CVD outcomes, such as LDL-C.
 - Although results from several RCTs (n=8) reported significantly improved intermediate CVD outcomes, diets compared between studies were heterogeneous with macronutrient proportions inconsistently above or below the AMDR and dependent upon the comparison of interest (e.g., fat within vs. above the AMDR).
 - Many PCSs reported no significant associations across specified macronutrient distributions and CVD mortality endpoint outcomes.
 - Among the PCSs (n=9 of 30) that also reported dietary patterns, the majority reported that diets with energy derived from total fat intakes above the AMDR were associated with increased CVD risk, and generally reflecting lower diet quality.
 - Numerous limitations were identified across the body of evidence:
 - Vastly different study designs and diet assessment approaches were used to examine macronutrient distributions.
 - Few studies evaluated macronutrient distribution in the context of dietary patterns in relation to CVD.

- Foods and food groups consumed as part of the diet pattern, were inconsistently assessed and reported, thereby limiting meaningful conclusions regarding nutrient density and overall nutritional quality.
- The gradient between proportions compared within and across studies varied widely.
- Although many studies compared proportions that were distinctly different, some compared only slight differences in macronutrient content (e.g., 42.0 fat vs 43.7 percent fat), thereby reducing the specificity of the impact.
- Due to the variability in methodology used to estimate macronutrient intake and/or adjust for total energy, confidence in the accuracy of reported proportions of energy falling outside the AMDR is low.
- Several studies focused on a particular macronutrient of interest, such as “high-protein” or “low-carbohydrate” intake, but the proportion for that macronutrient was within the AMDR.

For additional details on this body of evidence, visit: [nesr.usda.gov/2020-dietary-guidelines-advisory-committee-systematic-reviews/dietary-patterns-subcommittee/dietary-patterns-cardiovascular-disease](https://www.nesr.usda.gov/2020-dietary-guidelines-advisory-committee-systematic-reviews/dietary-patterns-subcommittee/dietary-patterns-cardiovascular-disease)

Question 2. What is the relationship between dietary patterns consumed and growth, size, body composition, and risk of overweight and obesity?

Approach to Answering Question: NESR systematic review

Conclusion Statements and Grades

Dietary Patterns: Children

Limited evidence suggests that dietary patterns consumed by children or adolescents that are lower in fruits, vegetables, whole grains, and low-fat dairy while being higher in added sugars, refined grains, fried potatoes, and processed meats are associated with higher fat-mass index and higher body mass index later in adolescence. Grade: Limited

Dietary Patterns: Adults

The 2020 Dietary Guidelines Advisory Committee conducted a systematic evidence scan and determined that the conclusion drawn by the 2015 Dietary Guidelines Advisory Committee

generally² reflects the current state of science: Moderate evidence indicates dietary patterns emphasizing vegetables, fruits, and whole grains; seafood and legumes; moderate in dairy products (particularly low and non-fat dairy) and alcohol; lower in meats (including red and processed meats), and low in sugar-sweetened foods and beverages, and refined grains are associated with favorable outcomes related to body weight (including lower BMI, waist circumference, or percent body fat) or risk of obesity. Components of the dietary patterns associated with these favorable outcomes include higher intakes of unsaturated fats and lower intakes of saturated fats, cholesterol, and sodium. 2015 Dietary Guidelines Advisory Committee
Grade: Moderate

Diets Based on Macronutrient Distribution: Children

No evidence is available to determine a relationship between diets based on macronutrient distribution consumed by children or adolescents and growth, size, body composition, and risk of overweight or obesity. Grade: Grade Not Assignable

Diets Based on Macronutrient Distribution: Adults

Insufficient evidence is available to determine the relationship between macronutrient distributions with proportions of energy falling outside of the Acceptable Macronutrient Distribution Range for at least 1 macronutrient and growth, size, body composition, and/or risk of overweight or obesity, due to methodological limitations and inconsistent results. Grade: Grade Not Assignable

Summary of the Evidence

- Eighty-eight articles were identified that met inclusion criteria and examined the relationship between dietary patterns and/or diets based on macronutrient proportion and growth, size, body composition, and/or risk of overweight or obesity.^{38,42,55,57,58,60,65,67-70,72,75-77,86,101,105,106,108,112,132,146,157,171,174,183,188,194,201,204,208,218-273} (See the Methodology section for more information about how dietary patterns and diets based on macronutrient distribution were operationalized for this review.)

² See the Discussion section of this chapter, and **Part D, Chapter 11: Alcoholic Beverages**, for additional information about alcohol consumption and health outcomes.

Dietary Patterns: Children

- Twelve articles examined dietary patterns consumed by children and growth, size, body composition, and/or risk of overweight or obesity, met inclusion criteria, and were published between January 2014 and October 2019.^{55,60,218-227}
 - All 12 articles were from PCSs.
 - Dietary patterns were assessed using a variety of methods, including factor or cluster analysis, indices or scores, latent class analysis, and reduced rank regression.
 - Outcome measures varied across studies and included incidence of overweight or obesity, fat mass, lean mass, BMI, central adiposity, and weight and height.
 - Despite variability in methods, dietary patterns in childhood or adolescence that tended to associate with higher fat-mass index and BMI later in adolescence reflect poorer diet quality (e.g., lower in vegetables and fruits, while higher in added sugars, refined grains, and fried potatoes). However, the findings should be interpreted with caution due to several limitations.
 - Across the body of evidence, the direction of significant findings was mixed, with relatively small and inconsistent magnitude.
 - Most of the studies assessed diet once at baseline with methods that were not necessarily validated, reliable, or applicable for children.

Dietary Patterns: Adults

- Fifty-four articles were identified by a systematic evidence scan examining dietary patterns consumed by adults and growth, size, body composition, and/or risk of overweight or obesity.^{42,57,58,65,68-70,76,77,86,105,106,108,112,132,146,171,183,188,228-262}
 - These articles represent new evidence published since a review done by the 2015 Committee.²⁸
 - A systematic evidence scan was conducted to identify and examine these articles, and determine whether a full systematic review update was warranted.
 - Based on results from the systematic evidence scan, the 2020 Committee determined that the newly published evidence was generally consistent with the body of evidence from the existing review, and a full systematic review update was not needed at this time. Therefore, the conclusion statement and grade from the existing review were carried forward.

Diets Based on Macronutrient Distribution: Children

- No studies identified met inclusion criteria that examined diets based on macronutrient distribution consumed during childhood and growth, size, body composition, and/or risk of overweight or obesity.

Diets Based on Macronutrient Distribution: Adults

- Thirty-one articles examined diets based on macronutrient distribution and growth, size, body composition, and/or risk of overweight or obesity, met inclusion criteria, and were published between January 2000 and October 2019.^{38,67-69,72,75,77,86,101,108,157,171,174,194,201,204,208,229,242,257,263-273}
- Twenty-two articles came from RCTs and 9 articles came from PCSs.
 - Most of the articles examined distributions in which the proportion of energy from carbohydrate was below the AMDR, fat was above the AMDR, and protein was within the AMDR in at least one of the exposure groups compared.
 - Foods or food groups consumed as part of the diet, were not consistently reported.
- Results across studies were inconclusive, with the majority of studies reporting no significant association between diets based on macronutrient distribution and growth, size, body composition, and/or risk of overweight or obesity.
- Numerous limitations that prevented adequate assessment were identified:
 - Several studies did not directly test the difference in macronutrient proportions in the context of various dietary patterns during energy balance.
 - Although statistically significant relationships were reported, the gradient between macronutrient distributions was relatively narrow within studies (e.g., 45.3 percent carbohydrate vs 43.8 percent carbohydrate) and between studies.
 - Due to the variety of methods used to estimate macronutrient intake and adjust intake for total energy, the confidence in the reported proportions of energy falling outside the AMDR is low.
 - Several studies reported to be examining 1 particular macronutrient of interest, such as “high-protein” or “low-carbohydrate” intake, but the proportion for that nutrient was within the AMDR.

For additional details on this body of evidence, visit: nesr.usda.gov/2020-dietary-guidelines-advisory-committee-systematic-reviews/dietary-patterns-subcommittee/dietary-patterns-growth-size-body-composition-obesity

Question 3. What is the relationship between dietary patterns consumed and risk of type 2 diabetes?

Approach to Answering Question: NESR systematic review

Conclusion Statements and Grades

Dietary Patterns: Children

Insufficient evidence is available to determine the relationship between dietary patterns consumed by children or adolescents and risk of type 2 diabetes. Grade: Grade Not Assignable

Dietary Patterns: Adults

The 2020 Dietary Guidelines Advisory Committee conducted a systematic evidence scan and determined that the conclusion drawn by the 2015 Dietary Guidelines Advisory Committee generally reflects the current state of science: Moderate evidence indicates that healthy dietary patterns higher in vegetables, fruits, and whole grains and lower in red and processed meats, high-fat dairy products, refined grains, and sweets/sugar-sweetened beverages reduce the risk of developing type 2 diabetes. 2015 Dietary Guidelines Advisory Committee Grade: Moderate

Diets Based on Macronutrient Distribution: Children

No evidence is available to determine a relationship between diets based on macronutrient distribution consumed by children or adolescents and risk of type 2 diabetes. Grade: Grade Not Assignable

Diets Based on Macronutrient Distribution: Adults

Insufficient evidence is available to determine the relationship between macronutrient distributions with proportions of energy falling outside of the Acceptable Macronutrient Distribution Range for at least 1 macronutrient and risk of type 2 diabetes, due to methodological limitations and inconsistent results. Grade: Grade Not Assignable

Summary of the Evidence

- Seventy-two articles were identified that met inclusion criteria and examined the relationship between dietary patterns and/or diets based on macronutrient distribution and risk of type 2 diabetes.^{32,42,53,57,58,65,66,77,81,85,106,108,112,167,178,188,206,274-328} (See the Methodology section for more information about how dietary patterns and diets based on macronutrient distribution were operationalized for this review.)

Dietary Patterns: Children

- One article from a PCS examined dietary patterns consumed during adolescence (retrospectively) and risk of type 2 diabetes.⁶⁶

Dietary Patterns: Adults

- Fifty-two articles examined dietary patterns consumed by adults and risk of type 2 diabetes.
 - These articles represent new evidence published since an existing systematic review that included articles published between January 1980 and 2013, which was reviewed by the 2015 Committee.²⁸
 - A systematic evidence scan was conducted to identify and examine newly published evidence, and determine whether a full systematic review update was warranted.
 - Based on results from the systematic evidence scan, the 2020 Committee determined that the newly published evidence was generally consistent with the body of evidence from the existing review, and a full systematic review update was not needed at this time. Therefore, the conclusion statement and grade from the existing review were carried forward.

Diets Based on Macronutrient Distribution: Children

- No articles were identified that met inclusion criteria and examined diets based on macronutrient distribution consumed during childhood and risk of type 2 diabetes across the lifespan.

Diets Based on Macronutrient Distribution: Adults

- Twenty-three articles examined diets based on macronutrient distribution consumed by adults and risk of type 2 diabetes, met inclusion criteria, and were published between January 2000 and October 2019.^{53,77,108,309-328}
 - Two studies were RCTs, and 21 articles were PCSs.
 - Most of the articles examined distributions in which the proportion of energy from carbohydrate was below the AMDR, fat was above the AMDR, and protein was within the AMDR in at least 1 of the exposure groups compared.
 - Foods or food groups consumed as part of the diet, were reported among most studies but with limited and inconsistent detail, such as “animal-based” macronutrient distributions.
 - Among studies that provided the context of foods or food groups, diets based on macronutrient distributions with proportions outside of the AMDR tended to have higher amounts of saturated fat, *trans* fat, and/or animal-based sources of protein and fat, such as processed meat, red meat, butter, and cheese as well as refined grains, sugar-sweetened beverages, and lower-fiber cereals and breads.
 - Numerous limitations that prevent adequate assessment across this body of evidence were identified:
 - Several studies did not directly test differences in macronutrient proportions in the context of a constant dietary pattern.
 - The gradient between macronutrient proportions compared within and across studies varied. Several studies compared distinct proportions between groups (e.g., 33.4 percent carbohydrate vs 47.5 percent carbohydrate), whereas others were much closer in proximity relative to one another (e.g., 41.0 percent carbohydrate vs 45.0 percent) or to the AMDR limit (e.g., 44.9 percent vs 45 percent).

For additional details on this body of evidence, visit: [nesr.usda.gov/2020-dietary-guidelines-advisory-committee-systematic-reviews/dietary-patterns-subcommittee/dietary-patterns-type-2-diabetes](https://www.nesr.usda.gov/2020-dietary-guidelines-advisory-committee-systematic-reviews/dietary-patterns-subcommittee/dietary-patterns-type-2-diabetes)

Question 4. What is the relationship between dietary patterns consumed and bone health?

Approach to Answering Question: NESR systematic review

Conclusion Statements and Grades

Dietary Patterns: Adults

Moderate evidence indicates that a dietary pattern higher in fruits, vegetables, legumes, nuts, low-fat dairy, whole grains, and fish, and lower in meats (particularly processed meats), sugar-sweetened beverages, and sweets is associated with favorable bone health outcomes in adults, primarily decreased risk of hip fracture. Grade: Moderate

Dietary Patterns: Children

Insufficient evidence is available to determine the relationship between dietary patterns consumed by children and adolescents and bone health. Grade: Grade Not Assignable

Summary of the Evidence

- This systematic review update includes 9 PCSs³²⁹⁻³³⁷ that examined the relationship between dietary patterns and bone health, met inclusion criteria, and were published between January 2014 and November 2019.
 - Seven studies examined dietary patterns in adults and bone health in older adults.³²⁹⁻³³⁵
 - Two articles from the same study were conducted that examined dietary patterns in children and adolescents and bone health outcomes after a 4-year follow-up (approximately age 17 years).^{336,337}
- The direction and magnitude of effect across the body of evidence was consistent, pointing to healthier dietary patterns leading to a reduced risk of hip fractures. The studies in adults had large analytic sample sizes with a sufficient number of hip fracture cases occurring over follow-up to examine associations. Although the search strategy included other bone health outcomes, the eligible studies looked only at fractures (mainly hip) and forearm bone mineral density (in adolescents).
- The body of evidence consistently had risks of bias, including lack of adjustment for all potential confounders and a lack of accounting for possible changes in dietary intake that may have occurred over follow-up.

- This systematic review updates and builds upon an existing systematic review from the 2015 Committee,²⁸ which previously determined that limited evidence suggests a relationship between dietary patterns and bone health in adults. In that previous review, a grade was not assignable in children and adolescents due to limited evidence from a small number of studies with wide variation in study design, dietary assessment methodology, and bone health outcomes.
 - Based on the 7 additional studies in this update to the existing review examining dietary patterns in adults, moderate evidence is now available to indicate a significant relationship between dietary patterns and risk of hip fracture in older adults.
 - Based on the 2 additional studies in this update to the existing review examining dietary patterns in children or adolescents, no change is warranted in the level of evidence to evaluate the relationship between dietary patterns and bone health in children.
 - Although the number of recent studies is modest, they are consistent in how dietary intake was evaluated, in magnitude of effect reported, and in evaluated outcomes.

For additional details on this body of evidence, visit: [nesr.usda.gov/2020-dietary-guidelines-advisory-committee-systematic-reviews/dietary-patterns-subcommittee/dietary-patterns-bone-health](https://www.nesr.usda.gov/2020-dietary-guidelines-advisory-committee-systematic-reviews/dietary-patterns-subcommittee/dietary-patterns-bone-health)

Question 5. What is the relationship between dietary patterns consumed and risk of certain types of cancer?

Approach to Answering Question: NESR systematic review

Conclusion Statements and Grades

Dietary Patterns: Breast Cancer

Moderate evidence indicates that dietary patterns rich in vegetables, fruits, and whole grains, and lower in animal-source foods and refined carbohydrates, are associated with reduced risk of postmenopausal breast cancer. The data regarding these dietary patterns and premenopausal breast cancer risk point in the same direction, but the evidence is limited as fewer studies include premenopausal breast cancer. Grade: Moderate - Postmenopausal breast cancer risk; Limited – Premenopausal breast cancer risk

Dietary Patterns: Colorectal Cancer

Moderate evidence indicates that dietary patterns higher in vegetables, fruits, legumes, whole grains, lean meats and seafood, and low-fat dairy and low in red and processed meats, saturated fat and sugar-sweetened beverages and sweets relative to other dietary patterns are associated with lower risk of colon and rectal cancer. Moderate evidence also indicates that dietary patterns that are higher in red and processed meats, French fries, potatoes, and sources of sugars (e.g., sugar-sweetened beverages, sweets and dessert foods) are associated with a greater colon and rectal cancer risk. Grade: Moderate

Dietary Patterns: Lung Cancer

Limited evidence suggests that dietary patterns containing more frequent servings of vegetables, fruits, seafood, grains and cereals, legumes and lean vs higher fat meats and lower fat or non-fat dairy products may be associated with lower risk of lung cancer, primarily among former smokers and current smokers. Grade: Limited

Dietary patterns: Prostate Cancer

Limited evidence suggests no relationship between dietary patterns and risk of prostate cancer. Grade: Limited

Summary of the Evidence***Dietary Patterns: Breast Cancer***

- This systematic review update includes 26 studies that examined the relationship between dietary patterns and risk of breast cancer, met inclusion criteria, and were published between January 2014 and January 2020:
 - Three studies were RCTs³³⁸⁻³⁴⁰
 - Twenty-one were PCSs^{206,341-360}
 - Two studies were nested case-control studies.^{361,362}
- The studies were heterogeneous, in terms of which methods were used to identify or assess dietary patterns, how dietary intake was assessed, and duration of follow-up. However, despite this heterogeneity, the body of evidence was consistent in the types of foods and beverages examined in a number of the patterns, particularly in those studies that reported statistically significant associations with lower risk of breast cancer.

- In a number of studies, dietary patterns that included vegetables, fruits, and whole grains, and that were lower in animal products and refined carbohydrates, were associated with reduced risk of postmenopausal breast cancer.
- Alcohol was not consistently included within the patterns found to be inversely associated with breast cancer risk.
- Few studies reported results for premenopausal breast cancer risk.
- The studies were direct and generalizable, in that the populations, interventions, comparators, and outcomes of interest in the included studies were directly related to the systematic review question, and were applicable to the U.S. population.
- The body of evidence had several risks of bias, particularly in the observational studies, including lack of adjustment for all key confounders, assessment of a dietary pattern only once at baseline or in the first few years of follow-up, and a lack of accounting for possible changes in dietary intake that may have occurred over follow-up.
- This systematic review updates and concurs with the conclusions drawn by the 2015 Committee.²⁸

Dietary Patterns: Colorectal Cancer

- This systematic review update includes 24 studies that examined the relationship between dietary patterns and risk of colorectal cancer, met inclusion criteria, and were published between January 2014 and January 2020:
 - Two studies were RCTs^{338,339}
 - Twenty-one studies were PCSs^{206,341,344,353,363-379}
 - One study was a nested case-control study³⁸⁰
- The studies were heterogeneous, in terms of which methods were used to identify or assess dietary patterns, how dietary intake was assessed, and duration of follow-up. However, despite this heterogeneity, the body of evidence was consistent in the types of foods and beverages examined in a number of the patterns, particularly in those studies that reported statistically significant associations with lower risk of colorectal cancer.
 - In a number of studies, dietary patterns that included vegetables, fruits, legumes, whole grains, lean meats and seafood, and low-fat dairy, and that were lower in red and processed meats, saturated fat, sodas, and sweets were associated with lower risk of colorectal cancer.

- Alcohol was not consistently included within the patterns found to be inversely associated with colorectal cancer risk.
- Results were more consistent in men, and for total colorectal cancer risk.
- The studies were direct and generalizable, in that the populations, intervention, comparators, and outcomes of interest in the included studies were directly related to the systematic review question and were applicable to the U.S. population.
- The body of evidence had several risks of bias, particularly in the observational studies, including lack of adjustment for all key confounders, assessment of a dietary pattern only once at baseline or in the first few years of follow-up, and a lack of accounting for possible changes in dietary intake that may have occurred over follow-up.
- This systematic review updates the conclusions drawn by the 2015 Committee.²⁸ The 2020 Committee determined that the body of evidence included in this update was consistent with that considered by the 2015 Committee, with the exception of alcohol. Because alcohol was not consistently part of the patterns found to be significantly associated with lower colorectal cancer risk, and in some cases, were part of cases associated with increased risk, “moderate alcohol” was removed from the conclusion statement.

Dietary Patterns: Lung Cancer

- This systematic review update includes 7 PCSs^{206,341,351,363,381-383} and one nested case-control study³⁸⁴ that examined the relationship between dietary patterns and risk of lung cancer, met inclusion criteria, and were published between January 2014 and January 2020
- Though the body of evidence had some inconsistencies in direction and magnitude of effect, most studies reported significant associations between adherence to a dietary pattern and lower risk of lung cancer.
 - In several studies, dietary patterns containing more frequent servings of vegetables, fruits, seafood, grains and cereals, legumes and lean vs higher fat meats and lower fat or non-fat dairy products were associated with lower risk of lung cancer.
 - The protective effects of the patterns were more consistent among participants who were former smokers and current smokers than among participants who were never smokers.
 - Alcohol was not consistently included within the patterns found to be inversely associated with lung cancer risk.

- Most studies had large analytic sample sizes with a sufficient number of lung cancer cases occurring over follow-up to examine associations. However, the width of confidence intervals indicates some degree of imprecision within the body of evidence.
- The studies were direct and generalizable, in that the populations, intervention, comparators, and outcomes of interest in the included studies were directly related to the systematic review question, and were applicable to the U.S. population.
- The body of evidence had several risks of bias, including lack of adjustment for all key confounders, assessment of dietary pattern only once at baseline or in the first few years of follow-up, and a lack of accounting for possible changes in dietary intake that may have occurred over follow-up.
- This systematic review updates and concurs with the conclusions drawn by the 2015 Committee.²⁸

Dietary Patterns: Prostate Cancer

- This systematic review update includes 7 PCSs^{341,343,344,351,353,385,386} and 1 nested case-control study³⁸⁷ that examined the relationship between dietary patterns and risk of prostate cancer, met inclusion criteria, and were published between January 2014 and January 2020.
- Though the direction and magnitude of effect across the body of evidence was inconsistent, most studies reported no significant associations between adherence to a dietary pattern and risk of prostate cancer. Most studies had large analytic sample sizes with a sufficient number of prostate cancer cases occurring over follow-up to examine associations. However, the width of confidence intervals indicates some degree of imprecision within the body of evidence.
- The studies were direct and generalizable, in that the populations, exposures, comparators, and outcomes of interest in the included studies were directly related to the systematic review question, and were applicable to the U.S. population.
- The body of evidence had several risks of bias, including lack of adjustment for all key confounders, assessment of a dietary pattern only once at baseline or in the first few years of follow-up, and a lack of accounting for possible changes in dietary intake that may have occurred over follow-up.
- This systematic review updates the review done by the 2015 Committee,²⁸ which did not draw a conclusion regarding the relationship between dietary patterns and the risk of prostate cancer due to limited evidence from a small number of studies with wide variation in

study design, dietary assessment methodology and prostate cancer outcome ascertainment. The 2020 Committee determined that, based on the 8 additional studies in their update, limited evidence is now available to suggest no relationship between dietary patterns and risk of prostate cancer.

For additional details on this body of evidence, visit: nesr.usda.gov/2020-dietary-guidelines-advisory-committee-systematic-reviews/dietary-patterns-subcommittee/dietary-patterns-cancer

Question 6. What is the relationship between dietary patterns consumed and neurocognitive health?

Approach to Answering Question: NESR systematic review

Conclusion Statement

Limited evidence suggests that dietary patterns containing vegetables, fruits, unsaturated vegetable oils and/or nuts, legumes, and fish or seafood consumed during adulthood are associated with lower risk of age-related cognitive impairment and/or dementia. Grade: Limited

Summary of the Evidence

- This systematic review update includes 26 articles that met inclusion criteria and were published between January 2014 and February 2020.^{206,388-412}
 - Four studies were RCTs.³⁸⁸⁻³⁹¹
 - Twenty-two articles were from observational studies, with 21 PCS designs and 1 nested-case control design.^{206,392-412}
 - This body of evidence updates and builds upon the existing systematic review from the 2015 Committee,²⁸ which consisted of 30 articles from a wide range of study designs that used different methods to measure neurocognitive outcomes but produced relatively consistent findings.
 - Studies in this update to the existing review produced similarly consistent results regarding the relationship between dietary patterns in adults and age-related cognitive decline, mild cognitive impairment, and/or dementia.
 - Dietary patterns were examined using various approaches, including 17 studies that examined adherence to a dietary pattern using indices or scores, 4 articles identified

dietary patterns using factor or cluster analysis, and 1 study using reduced rank regression.

- Outcomes were measured using various approaches and reported as global cognition, cognitive performance, mild cognitive impairment, and/or incident dementia.
 - The majority of significant findings reported dietary patterns consumed during adulthood were “protective” in either improving measures of cognitive impairment and/or reducing risk of cognitive impairment or dementia. These protective dietary patterns contained vegetables, fruits, unsaturated vegetable oils and/or nuts, legumes, and fish or seafood. Many of these dietary patterns also emphasized whole grains, non-refined grains, or (non-refined) breads/cereals.
 - Not all of these protective dietary patterns contained alcoholic beverages. The benefit of the overall dietary pattern with the outcome was still observed if alcoholic beverages, particularly red wine, were included.
 - The non-significant findings or those reporting mixed associations reported healthy dietary patterns consumed during adulthood did not worsen cognition.
- Numerous limitations were identified across the body of evidence, including the lack of RCTs, considerable variation in testing methods used, inconsistent validity and reliability of cognitive testing methods, and differences between dietary patterns and cognitive outcomes examined.
- The 2020 Committee updates, concurs, and builds upon the conclusion drawn by the 2015 Committee.²⁸

For additional details on this body of evidence, visit: nesr.usda.gov/2020-dietary-guidelines-advisory-committee-systematic-reviews/dietary-patterns-subcommittee/dietary-patterns-neurocognitive-health

Question 7. What is the relationship between dietary patterns consumed and sarcopenia?

Approach to Answering Question: NESR systematic review

Conclusion Statements and Grades

Dietary Patterns

Insufficient evidence is available to determine the relationship between dietary patterns and sarcopenia in older adults. Grade: Grade Not Assignable

Diets Based on Macronutrient Distribution

Insufficient evidence was available to determine the relationship between diets based on macronutrient distribution and sarcopenia. Grade: Grade Not Assignable

Summary of the Evidence

- This systematic review includes 4 PCSs that examined the relationship between dietary patterns and sarcopenia, 2 of which also examined diets based on macronutrient distribution that met inclusion criteria, and were published between January 2000 and June 2019. ⁴¹³⁻⁴¹⁶
 - Two of the studies reported macronutrient distributions in which the percent of energy from fat was higher than the AMDR.^{414,415}
- The studies were inconsistent, both in terms of which dietary patterns or macronutrient distribution was examined, how dietary intake was assessed, assessment of sarcopenia, and results reported regarding the association between dietary patterns and risk of sarcopenia. In addition, the studies had relatively small sample sizes with few cases of sarcopenia.
- The body of evidence had several risks of bias, including lack of adjustment for all potential confounders, assessment of diet only once at baseline, and a lack of accounting for possible changes in dietary intake that may have occurred over follow-up.
- The studies were direct and generalizable, in that the intervention, comparators, and outcomes of interest in the included studies were directly related to the systematic review question, and were applicable to the U.S. population. However, study participants may have been healthier than the average older adult.

For additional details on this body of evidence, visit: [nesr.usda.gov/2020-dietary-guidelines-advisory-committee-systematic-reviews/dietary-patterns-subcommittee/dietary-patterns-sarcopenia](https://www.nesr.usda.gov/2020-dietary-guidelines-advisory-committee-systematic-reviews/dietary-patterns-subcommittee/dietary-patterns-sarcopenia)

Question 8. What is the relationship between dietary patterns consumed and all-cause mortality?

Approach to Answering Question: NESR systematic review

Conclusion Statements and Grades

Dietary Patterns

Strong evidence demonstrates that dietary patterns in adults and older adults characterized by vegetables, fruits, legumes, nuts, whole grains, unsaturated vegetable oils, and fish, lean meat or poultry when meat was included, are associated with decreased risk of all-cause mortality. These patterns were also relatively low in red and processed meat, high-fat dairy, and refined carbohydrates or sweets. Some of these dietary patterns also included alcoholic beverages³ in moderation.

Diets Based on Macronutrient Distribution

Insufficient evidence is available to determine the relationship between diets based on macronutrient distributions and all-cause mortality. Grade: Grade Not Assignable

Summary of the Evidence

- This systematic review identified 153 articles, ^{11-13,18,24,40,41,43,49,50,52,53,59,61,64,73,78,84,97,98,102,103,109,111,114,116,124,126,128,136-138,141,147-149,154,156,161,163,164,172,179,181,182,185,186,189,197,202,206,207,210,211,213-215,217,417-511} including 1 RCT⁷⁸ and 152 PCS designs that met criteria for inclusion and were published between January 2000 and May 2019.

Dietary Patterns

- 141 studies examined the relationship between dietary patterns and all-cause mortality. The studies used multiple approaches to assess dietary patterns and all-cause mortality.
 - One RCT⁷⁸ assigned participants to consume a Mediterranean dietary pattern with extra virgin olive oil or mixed nuts compared to a control diet

³ See the Discussion section of this chapter, and **Part D, Chapter 11: Alcoholic Beverages**, for additional information about alcohol consumption and health outcomes.

- One hundred and ten articles^{11-13,40,43,49,50,52,59,61,64,98,102,103,109,111,116,124,136,156,161,163,164,172,179,181,182,186,189,197,202,206,207,210,211,213,215,217,417-488} examined dietary patterns using index or score analysis.
- Twenty-five articles^{18,41,53,59,114,137,141,149,154,424,440,469,476,489-500} examined dietary patterns identified with factor and cluster analysis
- Eleven articles^{24,185,494,501-508} used other methods, including only reduced rank regression, comparisons based on animal-based food consumption vs avoidance, or comparisons based on “ultra-processed” food consumption, to examine the relationship between dietary patterns and/or diets based on macronutrient distribution.
- Despite the variety of different methods applied to examine or derive dietary patterns, the majority of studies finding statistically significant relationships between dietary patterns consumed and all-cause mortality risk was remarkably consistent.
 - Although the dietary patterns examined were characterized by different combinations of foods and beverages due to the variety of methods used, protective dietary patterns emerged with the following themes:
 - Patterns emphasizing higher consumption of vegetables, legumes, fruits, nuts, whole grains, fish, lean meat or poultry, and unsaturated fats relative to saturated fats, either as a ratio of monounsaturated fatty acids to saturated fatty acids or monounsaturated fatty acids + polyunsaturated fatty acids to saturated fatty acids, or olive oil specifically were generally associated with decreased risk of all-cause mortality. Notably, the inclusion of fish and/or seafood showed particular consistency.
 - Some of these dietary patterns also included alcoholic beverages in moderation or within specific thresholds.
 - Reduced risk of all-cause mortality was observed in several studies that examined dietary patterns without animal-products, such as those described as vegetarian, vegan, or determined by “plant-based” diet indices.
 - Of the dietary patterns that included animal-based foods, protective associations were generally observed with relatively lower consumption of red and processed meat or meat and meat products. However, a limitation in the evidence is methodological heterogeneity in the food categories and terminology used to classify meat.
 - The inclusion of the ratio of white vs red meat, type and amount of dairy products, and refined carbohydrates and sweets as elements to these patterns was less

consistent across the evidence. The dietary patterns that included those elements and that tended to show reduced risk of all-cause mortality had:

- Higher consumption of white meat relative to red or processed meat,
 - Low-fat dairy relative to high-fat dairy, and/or
 - Lower relative to higher intake of refined carbohydrates and sweets.
- Despite the variability between approaches used to examine dietary patterns, higher adherence to dietary patterns with common labels, such as “Mediterranean,” dietary-guidelines-related (e.g., “Healthy Eating Index,” “DASH” scores), or “plant-based” were generally protective against all-cause mortality risk. This highlights that a high-quality dietary pattern comprised of nutrient-dense foods, regardless of the label, is associated with reduced all-cause mortality risk.
 - Results based on additional analyses according to a variety of key or potential confounders generally confirmed the robustness of results.
 - Although the majority of included studies were PCSs, most adjusted for key confounders, with the exception of race and ethnicity. The results are likely generalizable to adults of various races and ethnicities though it is difficult to determine the influence that race and ethnicity specifically may have on the relationship between dietary patterns and all-cause mortality due to a lack of reporting.

Diets Based on Macronutrient Distribution

- Twenty-eight articles^{53,61,73,84,97,111,126,128,136,138,147,148,156,185,214,430,435,438,442,467,480,489,494,497,498,509-511} examined the relationship between diets based on macronutrient distributions but results were inconsistent.
 - Diets with proportions of carbohydrate and fat within the AMDR compared to outside the AMDRs tended to associate with reduced all-cause mortality risk, particularly when the diets examined were of higher quality (i.e., emphasizing vegetables, fruits, nuts, whole grains, legumes, fish, and/or lean meat or poultry).
 - Comparison of macronutrient distributions with or without the context of the foods and food groups comprising the dietary pattern showed inconsistent findings, likely due to several limitations that prevent the adequate assessment of the body of evidence:
 - The gradient between the macronutrient proportions compared between distributions was often small, e.g., 41 percent vs 41.7 percent.
 - Methods used to estimate macronutrient intake differed between studies.

- Many of the proportions outside of the AMDR were only marginally outside and often estimated differently between studies.
- Most of these articles reported a proportion of energy from carbohydrate below and/or fat above the AMDR in at least one of the exposure groups compared.
- Some of these articles also described the dietary pattern (i.e., foods and beverages) consumed, in addition to having macronutrient proportions outside of the AMDR.
- Insufficient evidence was available to determine the relationship between dietary patterns and all-cause mortality in younger populations (approximately ages younger than 35 years).

For additional details on this body of evidence, visit: [nesr.usda.gov/2020-dietary-guidelines-advisory-committee-systematic-reviews/dietary-patterns-subcommittee/dietary-patterns-all-cause-mortality](https://www.nesr.usda.gov/2020-dietary-guidelines-advisory-committee-systematic-reviews/dietary-patterns-subcommittee/dietary-patterns-all-cause-mortality)

DISCUSSION

Overview

The dietary patterns approach captures the relationship between the overall diet and its constituent foods, beverages, and nutrients in relationship to health outcomes of interest. The evidence base for associations between eating patterns and specific health outcomes has grown since the previous review by the 2015 Committee.²⁸ Many dietary patterns were identified, with the most common ones defined using indices or scores, such as the HEI-2015, DASH, Mediterranean, or vegetarian patterns, and data-driven approaches.

The 2020 Committee assessed evidence in adults for the relationship of dietary patterns with 8 broad health outcomes: CVD and associated risk factors; overweight and obesity; type 2 diabetes; bone health; cancers of the colon, lung, breast, and prostate; neurocognitive health; sarcopenia; and all-cause mortality. For adults, evidence was considered Moderate or Strong for the association between dietary patterns and all health outcomes, except for neurocognitive health, and cancers of the prostate and lung, where the evidence was Limited. Insufficient evidence was available to evaluate dietary patterns and sarcopenia outcomes.

The Committee's examination of the association between dietary patterns and various health outcomes revealed remarkable consistency in the findings and implications that are noteworthy. When looking at the dietary pattern conclusion statements across the various health outcomes, certain characteristics of the diet were consistently identified (Table D8.1). Common characteristics of dietary patterns associated with positive health outcomes include higher intake

of vegetables, fruits, legumes, whole grains, low- or non-fat dairy, seafood, nuts, and unsaturated vegetable oils, and low consumption of red and processed meats, sugar-sweetened foods and drinks, and refined grains. Although vegetables and fruits were consistently identified in every conclusion statement across the health outcomes, whole grains were identified in all except 1 of the health outcomes examined. Low- or non-fat dairy, seafood, legumes and nuts were identified as beneficial components of the diet for many, but not all, outcomes. In addition, the Committee found that negative (detrimental) health outcomes were associated with dietary patterns characterized by higher intake of red and processed meats, sugar-sweetened foods and beverages, and refined grains. A noteworthy difference from the 2015 Committee report is that whole grains are now identified with almost the same consistency as vegetables and fruits as beneficial for the outcomes examined, suggesting that these 3 plant-based food groups are fundamental constituents of a healthy dietary pattern. Legumes and seafood also are consistently identified. In identifying the dietary components, the Committee used the terminology in the papers evaluated and a limitation is that terms such as lean meat, red meat, processed meat were not always defined clearly or differentiated from each other. This type of specification is important for future work on dietary patterns.

The Committee addressed the complexities of interpreting the role of alcoholic beverage consumption as a potential component of a healthy dietary pattern. Previous evidence from the 2015 Committee noted in some studies, moderate alcohol intake as a component of a dietary pattern with favorable outcomes for CVD and body weight. Similarly, the 2020 Committee found that alcohol was reported as a component in some studies as part of a dietary pattern that reduced the risk of all-cause mortality. However, this was widely inconsistent across studies, including some that found alcohol to be significantly associated with a lower risk of incident colorectal cancer and others reporting alcohol to be part of a dietary pattern associated with increased risk. Thus, “moderate alcohol” was not included in the 2020 Committee’s conclusion statement on dietary patterns associated with reduced risk for colorectal cancer.

Studies that examine overall dietary patterns in adults often vary in how alcoholic beverage intake is assessed, the thresholds applied for amounts of alcohol consumed, and scoring procedures of alcohol as a dietary component (e.g., a positive component, positive in moderation, or negative component). Studies of alcoholic beverage intake have many potential sources of bias that are unique to this exposure, some of which can be mitigated using a Mendelian randomization study design. Although alcohol is often consumed by those following a Mediterranean-style diet, newer evidence (including Mendelian randomization studies) suggests low-dose alcohol consumption may not have beneficial effects on CVD (see **Part D. Chapter**

11: Alcoholic Beverages for a discussion of recent Mendelian randomization studies). For these reasons, the Committee does not agree with including moderate alcohol intake for the specific purpose of CVD risk reduction within the context of otherwise healthy dietary patterns, particularly in the absence of RCTs of healthy dietary patterns (e.g., the Mediterranean diet) that have been randomized with respect to the alcohol component.

Rather, the Committee encourages adherence to the *2015-2020 Dietary Guidelines for Americans* recommendations to not begin drinking for the purpose of improved health. For those who choose to drink and those who consume alcohol in excess of *Dietary Guidelines* recommended limits, moderating consumption to lower levels is recommended to better protect health. Additional information and discussion of related topics is included in **Part D. Chapter 11: Alcoholic Beverages**.

The Committee also considered evidence for dietary patterns and 4 health outcomes in children: overweight and obesity, type 2 diabetes, CVD risk factors, and bone health. Overall, the evidence was graded as Limited for overweight and obesity and CVD risk factors. The characteristics of dietary patterns associated with overweight and obesity and CVD risk factors were similar to adults, including dietary patterns that are higher in fruits, vegetables, whole grains and low-fat dairy and lower in added sugars (for example, sugar-sweetened beverages) and processed meats. Type 2 diabetes and bone health were both classified as Grade Not Assignable, indicating that insufficient evidence was available.

Table D8.1. Dietary pattern components in the Committee's Conclusion Statements that are associated with the health outcomes of interest.**

<i>Health Outcome of Interest:</i>	<i>All-cause mortality</i>	<i>Cardiovascular disease^a</i>	<i>Growth, size, body composition and risk of overweight and obesity^a</i>	<i>Type 2 diabetes^a</i>	<i>Bone health^a</i>	<i>Colorectal Cancer^b</i>	<i>Breast Cancer (Post-menopausal)^b</i>	<i>Lung Cancer^b</i>	<i>Neurocognitive health</i>
Grade:	<i>Strong (adults)</i>	<i>Strong (adults); Limited (children)</i>	<i>Moderate (adults); Limited (children)</i>	<i>Moderate (adults)</i>	<i>Moderate (adults)</i>	<i>Moderate (adults)</i>	<i>Moderate (adults)</i>	<i>Limited (adults)</i>	<i>Limited (adults)</i>
Dietary patterns associated with lower risk of disease consistently included the following components.									
Components									
Fruits	X	X	X	X	X	X	X	X	X
Vegetables	X	X	X	X	X	X	X	X	X
Whole grains/cereal	X	X	X	X	X	X	X	X	
Legumes	X	X	X (adults)		X	X		X	X
Nuts	X	X (adults)			X				X
Low-fat dairy	X	X	X		X	X		X	
Fish and/or seafood	X	X	X (adults)		X	X		X	X
Unsaturated vegetable oils	X	X	X (adults)						X
Lean meat	X					X		X	
Poultry	X								
Dietary patterns associated with higher risk of disease consistently included the following components.									
Red meat	X	X (adults)	X (adults)	X		X			
Processed meat	X	X	X	X	X	X			
High-fat meat								X	
High-fat dairy	X			X					
Animal-source foods							X		
Saturated fats		X (adults)	X (adults)			X			

Sugar-sweetened beverages and/or foods	X	X	X	X	X	X			
Refined grains	X	X	X	X			X		
Fried potatoes/ French fries and potatoes			X (children)			X			
Added sugars			X (children)						
Sodium		X (adults)	X (adults)						

* Note: The reader is directed to the full conclusion statement above for more information on the relationship between dietary patterns and health outcomes.

+ An empty box indicates the research examined in the body of evidence on dietary patterns and the health outcome of interest in that column did not consistently include that component as part of the dietary patterns. Some research efforts may have included that individual component, but that component was not consistently mentioned in the aggregate body of evidence examined. It was beyond the scope of these systematic reviews examining dietary patterns and health outcomes of interest to reclassify or standardize the component categories as originally used in the evidence reviewed.

^a For both cardiovascular disease and growth, size, body composition and risk of overweight and obesity outcomes, the components listed are applicable to both adults and children. The components that are relevant only to adults or children are identified with parentheses. Evidence for the relationship between children's dietary patterns and type 2 diabetes and bone health also were examined but the evidence was insufficient to determine a relationship.

^b The relationship between dietary patterns and prostate cancer was reviewed. Limited evidence suggested no relationship between dietary patterns and risk of prostate cancer.

Dietary Patterns and Health Outcomes

Cardiovascular Disease

The current review confirmed a grade of Strong evidence for dietary patterns in reducing risk of CVD, and emerging evidence suggests the need to support healthy eating patterns in childhood to prevent CVD in adulthood. Intermediate risk factors including blood lipids, blood pressure, overweight, blood glucose, and inflammatory markers are favorably influenced by habitual adherence to dietary patterns that include fruits, vegetables, whole grains, legumes, nuts, unsaturated vegetable oils, fish, seafood, lower fat dairy products, and that reduce intake of sugar, sodium and saturated fats. Such an eating pattern initiated early and maintained over the life course offers long-term benefits, but adopting these eating behaviors at any age may improve endpoint outcomes, including cardiovascular and all-cause mortality. The research reviewed provided evidence that cross-cultural differences in dietary pattern preferences were common and that food choices within and across most of the dietary patterns studied vary. Specifying the macronutrient distribution and identifying sources of carbohydrates (refined vs complex), protein (animal vs vegetable), and fat (unsaturated vs saturated vs monounsaturated and/or specific fatty acids) within these dietary patterns is recommended in future studies, as these differences may be related to the cardiovascular intermediate and endpoint outcomes.

Growth, Size, Body Composition and Risk of Overweight and Obesity

The current review confirmed and expanded upon a central tenant of the 2015 Committee—excess weight gain is preventable by consuming a nutrient-dense, high-quality dietary pattern over time. Although treatment of obesity was beyond the scope of the reviewed questions, evidence regarding avoidance of excess weight gain is critical and essential to addressing dietary recommendations to reverse the epidemic of obesity appearing in the United States over the past 3 decades. Excess adiposity is driving an increase in other chronic diseases considered by the 2020 Committee. To address this public health epidemic, reducing the incidence and prevalence of overweight and obesity is critical at every stage of life to preserve ideal health. Dietary patterns that focus on nutrient-dense foods to prevent excessive weight gain starting in pregnancy, continuing through infancy and childhood, adolescence, and adulthood are of high public health relevance.

The dietary patterns considered in the Committee's review offer potential evidence of a key prevention strategy that could be combined with systems to support broader population adoption.

The Limited strength of evidence for the effect of dietary patterns on growth and body size in children in the current review was likewise reported in the 2015 Committee's review. This lack of scientific evidence represents a significant need and an opportunity to fill a major research gap needed to draw meaningful conclusions regarding the role of dietary patterns specifically tailored to this stage of life to prevent excess weight gain and preserve maintenance of a healthy weight over the life course.

Type 2 Diabetes

The role of weight and weight management in the prevention of type 2 diabetes is well established. Thus, the identification of evidence for consumption of a high-quality dietary pattern over time to reduce the risk of type 2 diabetes is expected. Indeed, the current literature review led to concurrence with the 2015 Committee in support of established healthy patterns in which the evidence extends beyond body weight benefits to reducing the risk of developing type 2 diabetes. The available evidence has 3 important limitations, however. First, while several PCSs demonstrated that improvement in weight status is a mediator of the association of high-quality dietary patterns with reduced risk of developing type 2 diabetes, the magnitude of effect both for weight-dependent and weight-independent effects of specific dietary patterns remains unclear. Second, the role of macronutrient distribution in the context of an overall healthy dietary pattern to reduce type 2 diabetes risk is unknown. The 2020 Committee recognizes the high level of interest in low-carbohydrate diets relative to a variety of health outcomes. However, studies that met the criteria for inclusion to address this question relative to type 2 diabetes risk reduction for either weight-dependent or weight-independent effects could not answer the question due to methodological limitations and inconsistent results. Third, the potential for benefit of a high-quality dietary pattern beginning early in life to reduce type 2 diabetes risk throughout adolescence into adulthood is unknown. This is a critical point because of the increasing incidence⁵¹² and prevalence⁵¹³ of type 2 diabetes in youth.

Bone Health

The 2020 Committee's update of the 2015 systematic review on dietary patterns and bone health outcomes resulted in a strengthening of the evidence grade from Limited to Moderate. The Committee upgraded the evidence because of the consistency across studies in the direction and magnitude of effect of dietary patterns on bone health outcomes, in the outcomes evaluated (i.e., hip fracture), and how dietary intake was assessed. Notable differences with the

2015 Committee's conclusion include the addition of key foods and beverages that should be limited as a part of a dietary pattern associated with a low risk of fracture. Whereas the previous evidence for added sugars was less consistent, the 2020 Committee noted a consistent pattern of greater risk associated with larger intakes of added sugars in foods and beverages. A similar association was noted for higher intakes of processed meats. As a result, limited intakes of processed meats, sweets and sugar-sweetened beverages are now specifically noted in the 2020 Committee conclusion given the consistent association with a greater risk of fracture when larger amounts of these foods and beverages are consumed.

Although the consistency in evaluated outcomes was a strength of the reviewed literature, these observations do not limit the Committee's ability to express views more broadly beyond the outcome of hip fracture. Hip fracture is a major bone health outcome that is estimated to affect approximately 18 percent of women and 6 percent of men globally and to have significant negative societal effects.⁵¹⁴ However, it remains important to understand the influence of dietary patterns on outcomes that are proximal to hip fracture, including bone mineral density and risk for osteopenia and osteoporosis. Future Dietary Guidelines Advisory Committee reviews may be able to expand their reviews to these outcomes. Another limitation of the conclusions related to bone health in the 2020 assessment of dietary patterns was a lack of data in children, an important age to begin assessing and recommending optimum dietary patterns. An important note is the lack of RCT data and that understanding how dietary patterns modulates formation of peak bone mass in children and teens relies on PCSs and it is very hard to study bone development without longitudinal data starting in childhood.⁵¹⁵ As bone mineralization in children is vital for promoting bone strength in adulthood, it is important to study bone quality in childhood and adolescence with a focus on dietary patterns that provide optimum levels of essential minerals combined with dietary components that maximize absorption of these minerals.

Cancer

For colon and rectal cancer, the 2020 systematic review changed one recommendation from the previous 2015 Committee report. Alcohol was not consistently a part of the patterns found to be significantly associated with a lower risk of incident colorectal cancer and in some cases was part of patterns associated with increased risk. Thus, "moderate alcohol" was removed from the 2020 Committee conclusion statement. Otherwise the conclusions and grade of Moderate strength of evidence for the 2020 Committee were consistent with the 2015 Committee's conclusion statement. The systematic review conclusions for breast cancer (Moderate –

postmenopausal breast cancer; Limited – premenopausal breast cancer) and lung cancer (Limited) both concur with the 2015 Committee. The 2015 Committee review for prostate cancer was unable to establish a firm conclusion whereas the 2020 review found the additional available studies provided Limited evidence suggesting no relationship between dietary patterns and the risk of developing prostate cancer.

The Committee did not have time to address dietary patterns and pancreatic cancer, and liver cancer was not identified as a priority. Future Committees may prioritize liver cancer because non-alcoholic fatty liver disease (NAFLD) and non-alcoholic steatohepatitis (NASH) are increasing in prevalence and linked to liver cancer risk. (Additional information about the prevalence of liver enzymes associated with underlying liver disease and inflammation can be found in **Part D. Chapter 1: Current Intakes of Foods, Beverages and Nutrients.**) NAFLD and NASH now represent the most common liver diseases in high-income countries and are recognized as associated with metabolic co-morbidities that include type 2 diabetes, metabolic syndrome, and liver cancer.⁵¹⁶⁻⁵¹⁸ NAFLD also is the most common liver disease in children worldwide.⁵¹⁸ Evidence also suggests racial and ethnic disparities regarding propensity to accumulate fat intra-abdominally and within the liver.⁵¹⁹ Three European professional associations addressing liver health, diabetes, and obesity, respectively, created joint clinical practice guidelines for the management of NAFLD that include diet and lifestyle changes. The European Joint Clinical Practice Guidelines⁵²⁰ established the Mediterranean diet as the lifestyle modification of choice in the management of NAFLD. The dietary patterns identified by the 2020 Committee that were associated with reductions in risk for some cancers, CVD, and obesity could likely affect NAFLD through effects on intra-abdominal adipose tissue, which has greater metabolic activity than does subcutaneous adipose tissue because of a close proximity to the portal vein⁵²¹⁻⁵²³ and is associated with an increased risk of cardiometabolic diseases and certain malignancies, including liver and pancreatic cancer. The emerging research mandates a broader examination of dietary patterns and their effect on NAFLD, NASH, and liver and pancreatic cancers.

Neurocognitive Health

Evidence for relating dietary patterns to age-related cognitive impairment, such as dementia and Alzheimer's disease, has expanded since release of the 2015 Committee's report, with high-quality published observational studies. Compared to the 2015 NESR systematic review on dietary patterns and cognitive impairment, dementia, and Alzheimer's disease, the current review included about the same number of articles (n=26) for a 6-year period (2014-2020) as Scientific Report of the 2020 Dietary Guidelines Advisory Committee

the previous review (n=30) included from 1980 to 2014. With the near doubling of the literature base related to neurocognitive health and dietary patterns, the Committee was able to evaluate whether different conclusions could be drawn compared to the previous review. Ultimately, the Committee reached a similar conclusion as the 2015 Committee, identifying all of the same elements in the dietary pattern as previously delineated in the 2015 report as being associated with a lower risk of age-related cognitive impairment, dementia, and Alzheimer's disease. The notable addition in this update to that review is the inclusion of unsaturated vegetable oils as a part of the dietary pattern of intake. The inclusion of unsaturated vegetable oils is a result of the high representation of Mediterranean-style patterns in the included reviews where unsaturated vegetable oils, such as olive oil, are the primary sources of fat intake, and by contrast, many of the dietary patterns associated with a greater risk of cognitive decline included greater amounts of saturated fats and/or lower levels of unsaturated fats.

The Limited strength of evidence points to some ongoing challenges with the body of literature that remain since the prior review, when the evidence grade also was Limited. A primary challenge for an outcome that is likely influenced by multiple exposures over a long time trajectory is the limited assessment of dietary exposures. In many instances, dietary intake was assessed only once, with a very distant follow up to assess the outcome. This may not be representative of the typical dietary intake for the individual and contributes to increased risk of bias. Additionally, as more objective measures of cognitive function are developed and ways to link functional brain imaging to cognitive outcomes emerge, these types of outcomes should be linked to dietary intakes to increase precision and directness of the findings. Although this type of outcome assessment may be ideal, routine measures of neurocognitive functioning as assessed by questionnaires and surveys are likely to continue as the mainstay. Given this likelihood, higher levels of validation are needed, along with corresponding medical diagnoses that are often missing in current studies. This is particularly true in children, where a parent may be identifying a neurocognitive problem based on a few questions from non-validated questionnaires without a pediatrician's medical diagnosis.

Sarcopenia

With the increasing life expectancy of Americans over the past several decades, the problem of age-related loss of skeletal muscle mass and functional capacity is of intense public interest. Sarcopenia is accompanied by an increased risk of adverse outcomes and premature mortality.⁵²⁴ Discussions regarding the role of diet continue in the scientific community, beginning with how to define and prevent sarcopenia and other closely related disorders

characterized by subnormal levels of skeletal muscle mass and function.⁵²⁵ The Committee considered a broad definition of sarcopenia as operationalized by the consensus statements of several working groups and included loss of skeletal muscle mass alone or in conjunction with either low muscle strength (e.g., handgrip strength) or low muscle performance (e.g., walking speed).

The Committee streamlined this question to focus only on the endpoint outcomes of sarcopenia and severe sarcopenia and not intermediate outcomes or on as-yet ill-defined conditions such as pediatric sarcopenia, pre-sarcopenia, or sarcopenic obesity. The review included outcomes in adults and older adults, but most evidence concentrated on older adults due to the prevalence of sarcopenia as an age-related disease. **Part D. Chapter 1: Current Intakes of Foods, Beverages and Nutrients** provides more detail on the incidence of reduced muscle strength and bone mass in the U.S. population. The literature on this topic is in a nascent stage with only 4 articles found for review, all prospective cohort designs. These investigations similarly involved diet that was assessed only once, at baseline in older participants, with no evidence of potential influence of dietary patterns earlier in life. This represents a major gap in our understanding regarding the role of diet over the life course as it may contribute risk for developing sarcopenia. This condition typically begins in mid-life and slowly progresses into the seventh and eighth decades. Accordingly, insufficient evidence was available to establish the relationship between dietary patterns and sarcopenia in older adults; thus, the strength of evidence was Grade Not Assignable. Future studies are encouraged that include multiple evaluation time points and study groups that are large and diverse with respect to sex and race and ethnicity, both of which are associated with variation in muscularity and the rate of skeletal muscle mass loss with age. RCTs that go beyond the few observational studies now available for review would help to strengthen future dietary recommendations for reducing the risk of developing sarcopenia.

All-Cause Mortality

This Committee is the first to examine the associations between self-reported dietary patterns and all-cause mortality. A vital question for Americans is whether there is an optimal pattern of food and beverage intakes over the lifespan that is associated with a long and healthy life. A review of more than 150 studies that met the criteria for review provided the Committee with compelling and consistent evidence linking consumption of specific dietary patterns with lower all-cause mortality in adults and older adults, resulting in a strength of evidence grade of Strong. These robust findings are supported by multiple analytic approaches, including index or

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score analysis, factor and cluster analysis, and multiple other methods. Studies were well-designed and conducted using rigorous methods, with most having low or moderate risk of bias across various domains despite being prospective cohort study designs.

The current efforts extend and strongly support the 2015 Committee's report, which noted that the 2014 NIH-AARP Diet and Health Study of 492,823 adults found high adherence scores on several indices (e.g., the HEI-2010, DASH)¹¹ were associated with a significantly lower risk of overall CVD and cancer mortality. These observations led the 2015 Committee to articulate the important concept that the dietary pattern approach as represented by multiple indices reflecting core tenets of a healthy diet may lower the risk of mortality outcomes. One year later, in 2015, the NIH-NCI Dietary Patterns Methods Project¹ reported that higher scores on independent high-quality diet patterns were associated with substantial reductions in mortality among adult cohorts.

The totality of the evidence reinforces recommendations supporting dietary patterns comprised of vegetables, fruits, legumes, nuts, whole grains, unsaturated vegetable oils, and fish, and lean meat or poultry (when meat is included). Such a dietary pattern is generally associated with a decreased risk of cardiovascular and all-cause mortality. When alcohol intake was considered in addition to the eating pattern, lower intake of alcohol was associated with a lower risk of cancer and all-cause mortality compared to higher intakes. These patterns associate with a variety of labels including, for example "Mediterranean" and "DASH," but generally have a common feature emphasizing plant-based foods as the core of the diet. This feature was typically present in studies that identified a beneficial dietary pattern for reducing the risk of all-cause mortality.

Another feature that was apparent across the range of studies and dietary patterns considered was the benefit of preferentially including nutrient-dense choices in the diet. The Committee viewed this feature as a marker of dietary quality, where higher quality choices within a food group or subgroup would tend to have lower amounts of added sugars, sodium, and solid fats while providing a major contribution toward meeting essential nutrients, including nutrients of concern. The effect of nutrient-dense choices was most apparent for meat, dairy, and sources of carbohydrates. When any of these foods were reported by study participants, nutrient density was enhanced and resulted in dietary patterns that were linked to a lower risk of all-cause mortality. Consistent with these findings, consumption of red and processed meats, high-fat dairy, and refined carbohydrates should be lower and fruits, vegetables, whole grains, legumes, nuts, lean meats, lower fat dairy foods, and fish and seafood are preferred choices.

Despite the high level of consistency regarding certain aspects of evaluated literature, several limitations of the Committee's review should be considered. Insufficient evidence was available to determine the relationship between dietary patterns and all-cause mortality in younger populations, particularly for those younger than around age 35 years. Evidence also was insufficient to determine the impact that race and ethnicity may have in the relationship between dietary patterns and all-cause mortality.

Diets Based on Macronutrient Distribution and Health Outcomes

The question of optimal macronutrient distribution in relation to health outcomes is of great public interest, as demonstrated by the plethora of books, print media, and Internet resources that address this topic, including diets that are low or very low in carbohydrate, high in fat, or promote higher intakes of protein. In an attempt to address this issue, the Committee reviewed studies where at least 1 macronutrient was outside the AMDR established by the National Academies of Sciences (e.g., the AMDR in adults is: protein, 10 to 35 percent; fat, 20 to 35 percent; carbohydrate, 45 to 65 percent of total energy intake). Articles needed to describe the entire macronutrient distribution of the diet by reporting the proportion of energy from carbohydrate, fat, and protein. The Committee established these criteria in order to examine the entire distribution of macronutrients in the diet, and not 1 macronutrient in isolation. These criteria allowed the Committee to both consider the relationships with health outcomes of consuming a diet with 1 macronutrient outside of the AMDR, and also how consumption of that macronutrient displaces or replaces intake of other macronutrients within the distribution. The Committee did not label the diets examined as "low" or "high," because no standard definition is currently available for "low-carbohydrate" or "high-fat" diets. Instead, the Committee focused on whether, and the extent to which, the proportions of the macronutrients were below or above the AMDR. Of note, the Committee was not charged with evaluating the evidence for dietary patterns to treat disease and the Committee excluded interventions designed to induce weight loss or treat overweight and obesity through energy-restriction/hypocaloric diets for the purposes of treating additional or other medical conditions. Its review was thus limited to consideration of macronutrient distribution in relation to reducing risk of overweight, obesity, and related health outcomes.

The resulting evaluation of the literature was ultimately unable to address the specific outcomes of type 2 diabetes; growth, size, body composition, and risk of overweight and obesity; sarcopenia; and all-cause mortality as framed by the Committee due to several issues with study designs. For CVD, the evidence was graded only as Limited. The available literature

lacked consistency in defining macronutrient distributions such as “low carbohydrate” or “high protein” and most did not examine distributions at extreme ends of the ranges for multiple macronutrients. In many instances, these qualifiers were labelling macronutrient distributions that were within the AMDR. Studies assessed macronutrient distribution using various statistical methods. In several instances, all of the macronutrients of interest were outside of the AMDR, providing an inadequate comparator. Often, the variability in macronutrient proportions within and between distributions was limited and included only small deviations from the AMDR, providing insufficient contrasts of diet comparisons. The major challenge for the Committee was that included studies generally did not maintain the overall dietary pattern as constant, and as a result, the effect of differences in macronutrient distribution on outcomes could not be discerned from effects of diet quality and composition. This made directness difficult to assess across the body of evidence. Ideally, to adequately address the question of how differences in macronutrient distribution affect key health outcomes, studies should be designed to isolate the effects of macronutrients within the context of a constant dietary pattern. For example, it would be possible to compare the effect of a low carbohydrate (e.g., less than 25 percent of energy) to a moderate carbohydrate (i.e., within the AMDR) Mediterranean dietary pattern with specified foods and amounts, in an isocaloric design. Overall, particularly given the level of public interest, future research is essential to further the understanding of the effect of altering macronutrient distribution outside of the current AMDR beyond diets currently used to treat CVD, obesity, or type 2 diabetes.

Limitations and Challenges with Examining Children’s Dietary Patterns

A limited number of manuscripts met the systematic review criteria regarding dietary patterns in children. Validated diet assessment methodology is scarce and remains dependent upon the age and literacy level of the child as well as the need for adaptation of adult assessment methods to children’s food preferences, serving sizes, and variability.⁵²⁶ Early feeding (birth to age 24 months) represents an important area of consideration.⁵²⁷⁻⁵³⁰ The effects of maternal diet on human milk composition is discussed in **Part D. Chapter 3: Food, Beverage, and Nutrient Consumption During Lactation**. As highlighted in **Part D. Chapter 5: Foods and Beverages Consumed During Infancy and Toddlerhood**, evidence indicates that introducing peanut and egg in the first year of life (after age 4 months) may reduce the risk of food allergy to peanuts and eggs.⁵³¹ For other types of food allergy (to fish, shellfish, cow milk products, tree nuts, seeds, wheat, and soy), the evidence for such protective effects is less clear, but the Committee found no evidence that avoiding such foods in the first year of life is beneficial with regard to

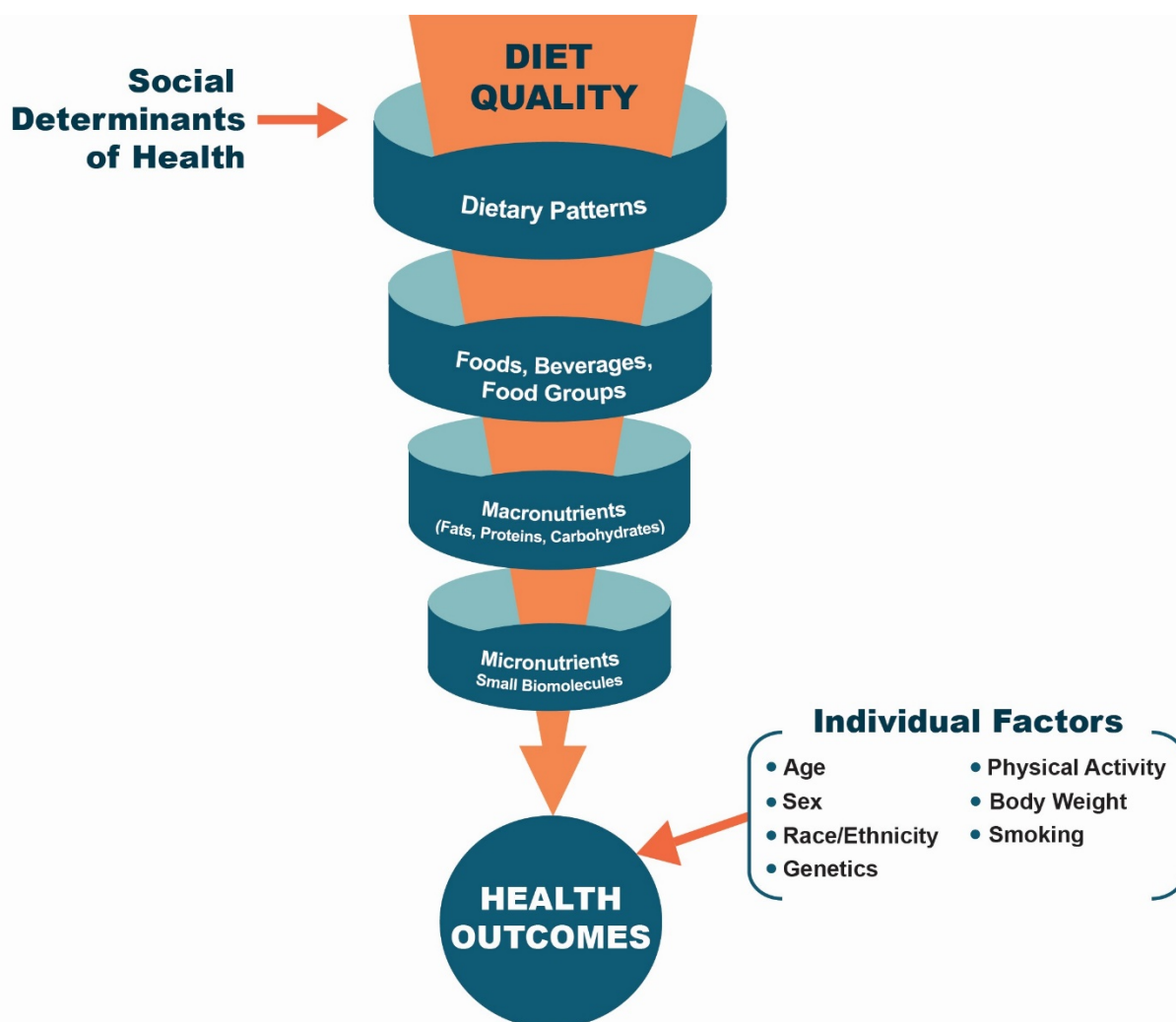
preventing food allergies or other atopic or allergic diseases. Recent guidelines from high-income countries are generally consistent in recommending that introduction of potentially allergenic foods should not be delayed beyond the first year of life.⁵³²⁻⁵³⁴ Exposure to different tastes and textures of foods appears to be crucial in early stages to better develop a child's interest and willingness to consume and enjoy a variety of foods.^{535,536} Moving forward, the influence of different dietary patterns on the health of the gut microbiome merits attention.⁵³⁷⁻⁵³⁹

Limitations and Challenges with Assessing Dietary Patterns

Regarding dietary assessment methods (e.g., food frequency questionnaires), concerns have been raised regarding measurement error interfering with fully enumerating the association of dietary patterns with risk of disease. Biomarkers can provide objective information. To address this concern, intake biomarkers based on measures in urine, blood, or other biospecimens, and use of metabolomics to identify dietary patterns have been recommended.^{540,541} Indeed, biomarkers of doubly-labeled water are useful for indirectly estimating energy intake.⁵⁴² Guillermo et al⁵⁴³ examined the association of 4 a priori diet quality indexes with blood levels of lipid-soluble micronutrients and biomarkers of inflammation, lipid, and glucose metabolism among 910 men and women representing 5 ethnic groups. Multiple significant relationships confirmed associations between diet quality and nutrition-related biomarkers, supporting the idea of high-quality diets positively influencing biological pathways. Broadly adopting these research ideas may reduce bias and strengthen the important role the high-quality dietary exposures can play to positively influence health and disease. However, cooking methods, the mixture of food eaten together, or the context in which food is consumed are not captured with biomarkers, metabolomics, or doubly-labeled water.⁵²⁶ Collection of dietary intakes along with biomarkers are needed to provide data on diet quality. For infants and children, age-appropriate and validated diet assessment methods (starting at birth and continuing forward as complementary foods and beverages are introduced) are lacking. Multiple caregivers who may or may not know what others have fed the child further confounds this problem. Potential use of mobile diet monitoring in children has yet to be fully explored. Promoting analytical progress, such as supporting efforts to automate collection of images either using active or passive methods should be encouraged. Using technology-based methods hold promise for more independent capture of foods and beverages among children ages 6 to 12 years⁵⁴⁴ and across the lifespan.⁵⁴⁵

SUMMARY

People eat foods and drink beverages for many reasons, including, but certainly not limited to, nourishment. The quantities, proportions, variety or combination of different foods, drinks, and nutrients in diets and the frequency with which they are habitually consumed, constitute dietary patterns. These patterns, which can be characterized by mathematical approaches for research purposes, may vary in their beneficial effects on growth, development, reproduction, and aging. Dietary patterns' nutritional effects exert *in vivo* actions through each food type's content of macronutrients (e.g., protein, fat, and carbohydrate), micronutrients (e.g., vitamins, minerals), essential trace elements, plant-based phytochemicals and phytonutrients, and bioactive compounds.⁸ Figure D8.1 depicts the connections between food patterns, individual food groups, nutrients at the molecular and elemental levels, and health outcomes.

Figure D8.1. Dietary patterns and health outcomes

This figure depicts the connection between dietary patterns and its component parts. It demonstrates how food, beverages, food groups, macronutrient and micronutrients are components of dietary patterns. Diet quality runs throughout each component of the pattern. As an individual adheres to a healthy dietary pattern, the pattern can play a protective role in health, and conversely, less healthy patterns can negatively influence health. The figure also recognizes that social determinants of health, such as food access, food security, settings and environments can play a role in influencing the diet quality of a dietary pattern. Additionally, individual factors also affect health outcomes.

The 2020 Committee examined these food patterns and macronutrient linkages as a means of answering 8 specific questions related to the broad areas of growth, development, and the risk of chronic metabolic, structural, neoplastic, and neurocognitive diseases. The Committee also examined, for the first time, the association between dietary patterns and all-cause mortality. The Committee's extensive review of published literature and the findings therefrom are summarized in Table D8.1 for 7 of the 8 questions; available data were inadequate for an analysis of dietary patterns and the risk of sarcopenia. The question of dietary patterns and the risk of developing cancer is summarized for 3 specific cancer types (breast, lung, and colorectal). A consistent dietary pattern associated with beneficial outcomes was present across

all 7 of the reviewed questions for which grades of variable strength were assignable: higher intake of vegetables, fruits, legumes, whole grains, low- or non-fat dairy, lean meat and poultry, seafood, nuts and unsaturated vegetable oils, and low consumption of red and processed meats, sugar-sweetened foods and drinks, and refined grains. Dietary patterns associated with adverse or detrimental outcomes included higher intake of red and processed meats, sugar-sweetened foods and beverages, and refined grains. A notable new observation was an association of the main components of the aforementioned dietary pattern with lower all-cause mortality, a finding the Committee graded as Strong.

Collectively, these observations have major implications for recommending dietary patterns to the U.S. population. Although the patterns identified in Table D8.1 represent different named “diets” (e.g., DASH, Mediterranean), the Committee’s review conveys a public health message reflecting key foods across studies that in common comprise a healthy diet that promotes optimum growth and development while minimizing risk factors underlying the onset of chronic diseases.

The Committee’s in-depth scientific review identified limitations of the dietary pattern approach to assess the effect of diet on health outcomes and several important gaps in the available published literature. These limitations are advanced by the Committee as recommendations for future research and as suggestions for future Advisory Committees.

Nevertheless, these public health messages are vital, especially in an era undergoing an epidemic of non-communicable diseases, including obesity, type 2 diabetes, CVD, cancer, sarcopenia, and dementias, and that pose potential further immunological risks associated with infectious diseases as well. These chronic diseases often have their origins early in life, highlighting the importance of initiating and maintaining a healthy diet across the life course.

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PART D. CHAPTER 9: DIETARY FATS AND SEAFOOD

INTRODUCTION

Since its inception in 1980, the *Dietary Guidelines for Americans* has offered evidence-based recommendations on dietary fats due to their well-documented influence on cardiometabolic disease risk, including weight regulation. This chapter updates and expands the review conducted by the 2015 Dietary Guidelines Advisory Committee, which focused on saturated fat and replacement with other fatty acids or carbohydrates.¹ Seafood is also a high priority dietary exposure of interest, due both to its unique nutrient contributions, particularly the omega-3 fatty acids, and its role as a food component within dietary patterns. The reviews undertaken by the Committee examined these topics with a life course approach, beginning with pregnancy, lactation, and early childhood and continuing throughout adulthood.

Past reviews of the scientific literature on the relationship between dietary fat intake and cardiovascular disease (CVD) risk have included research from Federally-funded, longitudinal, multi-site studies going back to the 1960s. These landmark studies, both clinical trials and prospective cohort studies (PCSs), continue to guide clinical practice for advancing cardiovascular health of Americans. For the current review on dietary fats, the 2020 Dietary Guidelines Advisory Committee examined evidence from studies conducted in adults published since the 2015 Committee's review of saturated fat and risk of CVD. This Committee's review considered fat types, amounts, proportions, and replacement. The types of fat considered in the systematic review included saturated fat, omega-3 and omega-6 polyunsaturated fats, monounsaturated fat, and dietary cholesterol. Additionally, the Committee examined evidence on dietary fat intake and risk of CVD in children from 1990 to present.

Although the Committee initially sought to conduct its dietary fats review on a range of health outcomes including CVD, all-cause mortality, certain types of cancer, and neurocognitive health, it ultimately chose to focus on CVD outcomes. However, two of these outcomes—all-cause mortality and cancer—were included in the Committee's reviews of dietary patterns, which took into account not only the dietary fat component of the diet but all other food components (see **Part D. Chapter 8: Dietary Patterns**).

Seafood intake also is of public health interest due to its association with reduced CVD risk² as well as with potentially beneficial neurocognitive outcomes. The Committee reviewed the current literature pertaining to seafood consumption during childhood and adolescence and risk of CVD and neurocognitive outcomes that present in both childhood and adulthood. The

childhood neurocognitive outcomes explored included the developmental domains, academic performance, attention deficit disorder (ADD) or attention-deficit/hyperactivity disorder (ADHD), autism spectrum disorder (ASD), anxiety, and depression. The adulthood outcomes included cognitive decline, mild cognitive impairment, dementia, anxiety, and depression. For purposes of these reviews, seafood was defined as marine animals that live in the sea and in freshwater lakes and rivers. Seafood includes fish (e.g., salmon, tuna, trout, tilapia) and shellfish (e.g., shrimp, crabs, oysters).³

The Committee also reviewed seafood intake during pregnancy and lactation and neurocognitive development of the infant. These topics are discussed in ***Part D. Chapter 2: Food, Beverage, and Nutrient Consumption During Pregnancy*** and in ***Part D. Chapter 3: Food, Beverage, and Nutrient Consumption During Lactation***.

Diet and neurocognitive health is an emerging and complex topic reviewed by this Committee, which sought to expand upon the reviews of the 2015 Committee examining dietary patterns and neurological and psychological illnesses. Although still a relatively under-researched area of scientific inquiry, the study of this relationship is expanding and could offer additional insight into how to promote optimal brain health and/or reduce the risk of neurocognitive diseases.

Current Intakes of Dietary Fat

The *2015-2020 Dietary Guidelines for Americans* encourage replacement of saturated fat with unsaturated fat while keeping saturated fat intake to less than 10 percent of calories per day,² however only 23 percent of the U.S. population report intakes aligned with this guidance (see ***Part D. Chapter 1: Current Intakes of Foods, Beverages, and Nutrients***). Saturated fats are found in the highest amounts in tropical oils (i.e., coconut, palm kernel and palm), butter, and animal (beef, pork, and chicken) fats. Common food sources of saturated fat are mixed dishes containing cheese and/or meat, pizza, full fat dairy products (cheese, cream and ice cream, and whole milk), and baked goods and sweets. Both the 2015 Committee and this 2020 Committee identified saturated fat as a nutrient of concern for overconsumption because saturated fat intakes exceed current recommendations (see ***Chapter 1*** and the 2015 Dietary Guidelines Advisory Committee report).³

Mean saturated fat intake in the U.S. population ages 2 years and older in 2015-2016 was approximately 12 percent of total daily calories (2 percentage points higher than guidance), regardless of sex and age, according to National Health and Nutrition Examination Survey.⁴ By race and ethnicity, non-Hispanic whites had the highest intake (12.2 percent daily calories) and

non-Hispanic Asians had the lowest intake (9.7 percent daily calories). Non-Hispanic whites had the highest prevalence (83 percent) of those exceeding the recommended limit of less than 10 percent energy contribution from saturated fat, followed by Hispanics (70 percent), non-Hispanic blacks (69 percent), and non-Hispanic Asians (43 percent) based on the NHANES 2013-2016 data analysis (Energy contribution from NHANES 2013-2016; see **Part D. Chapter 1**).⁵

In contrast, saturated fat intake and its energy contribution varied little by family income as a percentage of poverty level.⁴ No significant trends in saturated fat intake by meal patterns, snack occasions, or place of consumption were noted.⁴

The food category called “solid fat” includes a variety of fats, but predominantly saturated fat and to a small extent, *trans* fat. This category includes the saturated fats naturally found in animal products (e.g., meats, dairy) as well as vegetable sources with high saturated fat content, like tropical oils, e.g., coconut oil and hydrogenated vegetable shortenings. Although as a category, solid fat intake has decreased in recent years, as shown in NHANES data between 2003-2004 and 2015-2016, this appears to be largely attributable to the reduction of *trans* fat in the food supply. No significant change in the percentage of energy from saturated fat has occurred since the 1999-2000 NHANES.⁶

The top food subcategory sources of solid fats among American adults and children include burgers and sandwiches (12 to 22 percent) and desserts and sweet snacks (14 to 19 percent). Higher-fat milk/yogurt provide 19 percent of solid fats in the diets of children ages 2 to 5 years and 11 percent of solid fats among those ages 6 to 11 years. Similar to sources of solid fats, burgers and sandwiches are the top food subcategory source of oils across all age groups (15 to 20 percent). The next most common food subcategory source of oils is chips, crackers, and savory snacks for individuals ages 2 to 49 years, and vegetables for individuals ages 51 years and older (see **Part D. Chapter 1**).

Additionally, the *2015-2020 Dietary Guidelines for Americans* recommend keeping dietary cholesterol intake to a minimum while consuming a healthy eating pattern. In general, only animal foods contain dietary cholesterol and some, such as fatty meats and full-fat cheese, are also higher in saturated fats. The exceptions to this are eggs and shellfish (e.g., shrimp), which are high in dietary cholesterol, but are not high in saturated fat. Currently, the mean intake of dietary cholesterol is 282 mg per day for the general population ages 2 and older. Males have a higher mean dietary cholesterol intake of 321 mg per day compared to 245 mg per day for females.⁴ This represents an increase in mean dietary cholesterol consumption compared to 4 years prior when the mean population intake was 267 mg per day.⁷

Current Intakes of Seafood

Current guidance on seafood encourages consumption of 8 ounces or more per week of a variety of seafood for the general population,² with more specific guidance for women who are pregnant. However, recent intake data document that most people do not meet this recommendation, and, in fact, among both children and adults, seafood intake has decreased since 2005-2006 (see **Part D. Chapter 1**).

Data from two 24-hour dietary recalls conducted as part of the What We Eat in America component of NHANES 2013-2016 reported that among children (ages 1 to 18 years), usual seafood intake was less than 0.3 ounce-equivalents per day and among adults, intake was 0.5 to 0.7 ounce-equivalents per day.⁸ Given the episodic nature of seafood consumption in the United States, a non-quantitative food-frequency questionnaire (FFQ) focusing on fish and shellfish consumption during the previous 30 days was also administered as part of the same NHANES survey. Based on these supplemental data, approximately 20 percent of adults consumed seafood at least two times per week. Non-Hispanic Asian adults (41 percent) report a higher frequency of consuming seafood at least two times per week, when compared to non-Hispanic white (19 percent), non-Hispanic black (23 percent), and Hispanic (15 percent) adults. Among youths ages 2 to 19 years, about 5 percent report consuming seafood at least two times per week, with little variation by age group. Non-Hispanic Asian youth report a significantly higher frequency of consuming seafood at least two times per week (20 percent), compared to non-Hispanic white (4.1 percent), non-Hispanic black (7.5 percent), and Hispanic (4.8 percent) youth.

This chapter will discuss the findings, limitations, and recommendations from the Committee's review of these important topics.

LIST OF QUESTIONS

Dietary Fats

1. What is the relationship between types of dietary fat consumed and risk of cardiovascular disease?

Seafood

2. What is the relationship between seafood consumption during childhood and adolescence (up to 18 years of age) and risk of cardiovascular disease?
3. What is the relationship between seafood consumption during childhood and adolescence (up to 18 years of age) and neurocognitive development?

METHODOLOGY

All questions discussed in this chapter were answered using systematic reviews conducted with support from USDA's Nutrition Evidence Systematic Review (NESR) team. NESR's systematic review methodology provided a rigorous, consistent, and transparent process for the Committee to search for, evaluate, analyze, and synthesize evidence.

The Committee developed a systematic review protocol for each question, which described how the Committee would apply NESR's methodology to answer the question. The protocol included an analytic framework and inclusion and exclusion criteria to guide identification of the most relevant and appropriate body of evidence to use in answering each systematic review question. Each analytic framework outlined core elements of the systematic review question (i.e., population, intervention and/or exposure and comparator [i.e., the alternative being compared to the intervention or exposure], and outcomes), and included definitions for key terms, key confounders, and other factors to be considered when reviewing the evidence. The inclusion and exclusion criteria were selected, up front, to operationalize the elements of the analytic framework, and specify what made a study relevant for each systematic review question.

Next, a literature search was conducted to identify all potentially relevant articles, and those articles were screened by two NESR analysts independently, based on the criteria selected by the Committee. For each included article, data were extracted and risk of bias assessed. The Committee qualitatively synthesized the body of evidence to inform development of a conclusion statement(s), and graded the strength of evidence using pre-established criteria for risk of bias, consistency, directness, precision, and generalizability. Finally, recommendations for future research were identified. A detailed description of NESR's systematic review methodology is provided in **Part C. Methodology**, including standard inclusion and exclusion criteria applied in many of the Committee's systematic reviews. Complete documentation of each systematic review is available on the following website: nesr.usda.gov/2020-dietary-guidelines-advisory-

[committee-systematic-reviews](#). Below is a summary of the unique elements of the protocols developed to answer the dietary fats and seafood questions addressed in this Chapter and in **Part D. Chapter 2: Food, Beverage, and Nutrient Consumption During Pregnancy** and **Part D. Chapter 3: Food, Beverage, and Nutrient Consumption During Lactation**.

Dietary Fats

Question 1 was answered using a new systematic review conducted with support from USDA's NESR team to build on evidence reviewed by the 2015 Committee. A description of the process the 2020 Committee used when existing systematic reviews were available is provided in **Part C. Methodology**. In addition, detailed information about the 2015 Committee's review of the evidence can be found in their report, which is available at the following website:

dietaryguidelines.gov/current-dietary-guidelines/process-develop-2015-2020-dg/advisory-committee.

For the current review, the intervention or exposure of interest was types of dietary fat, including saturated fat, omega-3 and omega-6 polyunsaturated fats, monounsaturated fat, and dietary cholesterol. The comparators of interest were consumption of different types, sources, amounts, and/or proportions of dietary fats, or replacement with other dietary fats, carbohydrates, and/or protein. To maintain the focus of the review on types of dietary fat, the Committee established criteria for the intervention and exposure to exclude studies that:

- Did not assess consumption of type(s) of dietary fats (e.g., studies that examined only biomarkers for consumption),
- Assessed only total fat intake or overall macronutrient composition; *trans* fat; intake of fat from supplements or fish oils; or human milk and/or infant formula,
- Examined food products not widely available to U.S. consumers, or
- Examined multi-component interventions that do not isolate the impact of type of fat.

The population of interest for the intervention or exposure was infants and toddlers (birth to age 24 months, children and adolescents (age 2 to 18 years), adults (ages 19 to 64 years), and older adults (ages 65 years and older).

Outcomes of interest included both CVD intermediate and endpoint health outcomes, and the types of outcomes examined varied by population (i.e., children or adults) and study design. Intermediate outcomes included blood pressure (systolic and diastolic; in children only), and blood lipids (i.e., total cholesterol (TC), low-density lipoprotein cholesterol (LDL-C), high-density lipoprotein cholesterol (HDL-C), and triglycerides in children and adults). The original protocol

also included lipid ratios (e.g., LDL-C:HDL-C) and blood pressure in adults, but these were later removed to focus on the strongest predictors of CVD and due to the lack of evidence on the effect of types of dietary fat on blood pressure, respectively. Endpoint CVD health outcomes included CVD (i.e., myocardial infarction, coronary heart disease, coronary artery disease, congestive heart failure, and peripheral artery disease), stroke, venous thrombosis, and CVD-related mortality.

To focus on the strongest available evidence, additional criteria were employed to specify which study designs were eligible for inclusion depending on the outcomes being examined. For adults (ages 19 years and older), only evidence on intermediate outcomes from controlled trials, both randomized controlled trials (RCTs) and non-randomized controlled trials, was included, whereas evidence on endpoint outcomes was considered from all included study designs. For children (birth to age 18 years), evidence on intermediate and endpoint outcomes was considered from all included study designs (i.e., RCTs and certain types of observational studies). Furthermore, the Committee established inclusion and exclusion criteria for intervention duration. For all experimental studies (RCTs and non-RCTs), studies were included if the intervention duration was equal to or greater than 4 weeks; studies were excluded if the intervention duration was less than 4 weeks. Interventions shorter than 4 weeks were considered inadequate in length to assess change in blood lipids.

When establishing other inclusion and exclusion criteria, the Committee used standard NESR criteria for publication status, language of publication, country, study participants, and health status of study participants. The inclusion and exclusion criteria for date of publication was selected to build on the evidence previously reviewed by the 2015 Committee, which reviewed evidence only on adults, and therefore, the inclusion and exclusion criteria varied by the age of study participants. Specifically, the publication date range for studies in children was January 1990 to October 2019, and the date range for studies in adults was January 2010 to October 2019.

Two literature searches were conducted to identify all potentially relevant articles for this question on risk of CVD. The first search identified articles published between January 1990 and December 2009 on types of dietary fat consumed by children and adolescents. The second search identified articles published between January 2010 and October 2019 on types of dietary fat consumed by children, adolescents, and adults. After the two searches were conducted, duplicate articles were removed, and the total number of articles were combined for screening.

Seafood

Questions 2 and 3 in this chapter and questions on seafood consumption during pregnancy (see **Part D. Chapter 2: Food, Beverage, and Nutrient Consumption During Pregnancy**) and lactation (see **Part D. Chapter 3: Food, Beverage, and Nutrient Consumption During Lactation**) were answered by conducting new NESR systematic reviews. The intervention or exposure of interest was consumption of seafood. Studies that assessed only biomarkers of seafood consumption (e.g., blood levels of omega-3 polyunsaturated fatty acids and environmental pollutants) were excluded. The comparators of interest included different amounts, frequency, timing, types, or sources of seafood. When evaluating whether a study's results represented a true effect of seafood consumption, the Committee considered multiple factors such as 1) nutrients in seafood (e.g., omega-3 polyunsaturated fatty acids, iodine, selenium, iron, fish protein, vitamin D), 2) environmental chemicals within seafood (e.g., methylmercury, persistent organic pollutants, and polychlorinated biphenyls), 3) blood and human milk biomarkers of seafood intake (e.g., omega-3 polyunsaturated fatty acids, and environmental pollutants), and 4) infant feeding mode. These factors, along with key confounders, were considered while evaluating study findings and synthesizing evidence.

For Questions 2 and 3, the population of interest at intervention or exposure was children and adolescents from birth to age 18 years. Seafood consumption in women during pregnancy and lactation and neurocognitive development of the infant also was examined; results are reported in **Part D. Chapter 2** and **Part D. Chapter 3**.

For Question 2, the outcomes of interest included both CVD intermediate outcomes, including blood pressure (systolic and diastolic) and blood lipids (i.e., TC, LDL-C and HDL-C [including TC:HDL-C and LDL-C:HDL-C ratios], triglycerides), and CVD endpoint health outcomes, including CVD (i.e., myocardial infarction, coronary heart disease, coronary artery disease, congestive heart failure, peripheral artery disease), stroke, venous thrombosis, and CVD-related mortality. The population of interest for CVD intermediate outcomes included children and adolescents (ages 2 to 18 years), adults (ages 19 to 64 years) and older adults (ages 65 years and older). The populations of interest for CVD endpoint health outcomes were adults (ages 19 to 64 years) and older adults (ages 65 years and older).

For Question 3, and the questions regarding seafood consumption in women during pregnancy and lactation and neurocognitive development of the child reported in Chapters 2 and 3, the outcome of interest was neurocognitive development. Neurocognitive development included developmental domains, academic performance, ADD or ADHD, anxiety, depression, and ASD. Developmental domains (including developmental milestones) were examined

individually, as seafood intake may have different influences on different developmental domains, and included cognitive, language and communication, movement and physical, and social-emotional and behavioral development. In the questions regarding seafood consumption in women during pregnancy or lactation, these outcomes were assessed in infants and toddlers (birth to age 24 months), and in children and adolescents (ages 2 to 18 years). In Question 3 of this chapter, these outcomes were assessed in children and adolescents (ages 2 to 18 years). An existing systematic review previously conducted by USDA's Nutrition Evidence Systematic Review (NESR) team as part of the Pregnancy and Birth to 24 Months Project reviewed evidence on seafood intake as a component of complementary feeding and neurocognitive outcomes (developmental milestones). These findings are discussed in **Part D Chapter 5: Foods and Beverages Consumed During Infancy and Toddlerhood**.⁹ Question 3 also examined neurocognitive health outcomes, including cognitive decline, mild cognitive impairment, and dementia (including Alzheimer's disease), anxiety, and depression assessed in adults (ages 19 to 64 years) and older adults (age 65 years and older).

When establishing inclusion and exclusion criteria, the Committee used standard NESR criteria for study design, publication status, language of publication, country, study participants, and health status of study participants. One literature search from January 2000 to July 2019 was conducted to answer Question 2. Another literature search was conducted to identify studies published from January 2000 to October 2019 to answer questions on seafood consumption by children (Question 3) and women during pregnancy and lactation and neurocognitive outcomes.

REVIEW OF THE SCIENCE

Dietary Fats

Question 1. What is the relationship between types of dietary fat consumed and risk of cardiovascular disease?

Approach to Answering Question: NESR systematic review

Conclusion Statements and Grades

Cardiovascular Disease Intermediate Outcomes: Children

Strong evidence demonstrates that diets lower in saturated fatty acids and cholesterol during childhood result in lower levels of total blood and low-density lipoprotein cholesterol throughout childhood, particularly in boys. Grade: Strong

Moderate evidence indicates that diets higher in polyunsaturated fatty acids during childhood result in lower levels of total blood cholesterol throughout childhood, particularly in boys. Grade: Moderate

Insufficient evidence is available to determine the relationship between monounsaturated fatty acid intake during childhood and total blood and low-density lipoprotein cholesterol throughout childhood. Grade: Grade Not Assignable

Insufficient evidence is available to determine the relationship between intake of types of dietary fat during childhood and blood pressure throughout childhood. Grade: Grade Not Assignable

Cardiovascular Disease Endpoint Outcomes: Children

Insufficient evidence is available to determine the relationship between intake of types of dietary fat during childhood and cardiovascular disease health outcomes during adulthood. Grade: Grade Not Assignable

Cardiovascular Disease Intermediate Outcomes: Adults

Strong and consistent evidence from randomized controlled trials demonstrates that replacing saturated fatty acids with unsaturated fats, especially polyunsaturated fatty acids, in adults

significantly reduces total and low-density lipoprotein cholesterol. Replacing saturated fatty acids with carbohydrates (sources not defined) also reduces total and low-density lipoprotein cholesterol, but significantly increases triglycerides and reduces high-density lipoprotein cholesterol. Since the 2015 Dietary Guidelines Advisory Committee review, evidence remains inadequate to differentiate among sources of carbohydrate and their impact on blood lipids.

Grade: Strong

Insufficient evidence is available to determine an independent relationship between dietary cholesterol intake in adults and blood lipids, given the co-occurrence of cholesterol with saturated fats in foods. Grade: Grade Not Assignable

Cardiovascular Disease Endpoint Outcomes: Adults

Strong evidence demonstrates that replacing saturated fatty acids with polyunsaturated fatty acids in adults reduces the risk of coronary heart disease events and cardiovascular disease mortality. Grade: Strong

Insufficient evidence is available to determine whether replacing saturated fatty acids with polyunsaturated fatty acids in adults affects the risk of stroke or heart failure. Grade: Grade Not Assignable

Insufficient evidence is available to determine whether replacing saturated fatty acids with different types of carbohydrates (e.g., complex, simple) in adults affects the risk of cardiovascular disease. Grade: Grade Not Assignable

Limited evidence is available regarding whether replacing saturated fatty acids with monounsaturated fatty acids in adults confers overall cardiovascular disease endpoint health benefits. Main sources of monounsaturated fatty acids in a typical American diet are animal fats, with co-occurrence of saturated fatty acids and monounsaturated fatty acids in these foods thereby obscuring the independent association of monounsaturated fatty acids with cardiovascular disease. Evidence reviewed from randomized controlled trials and prospective studies demonstrated benefits of plant sources of monounsaturated fats, including olive oil and nuts on cardiovascular disease risk. Grade: Limited

Moderate evidence indicates that total intake of omega-3 polyunsaturated fatty acids, particularly eicosapentaenoic acid and docosahexaenoic acid from food sources, by adults is associated with lower risk of cardiovascular disease. Grade: Moderate

Limited evidence suggests that intake of linoleic acid, but not arachidonic acid, during adulthood may be associated with lower risk of cardiovascular disease, including cardiovascular disease mortality. Grade: Limited

Insufficient evidence is available from randomized controlled trials to quantify an independent relationship between dietary cholesterol intake in adults and overall risk of cardiovascular disease. Grade: Grade Not Assignable

Summary of the Evidence

Children

- This systematic review included 37 articles,¹⁰⁻⁴⁶ 22 articles from 7 RCTs and 16 articles from 14 prospective cohort studies (PCSs), published between January 1990 and October 2019 that examined the relationship between intake of types of dietary fat during childhood and CVD risk. (Note: One article from an RCT also was analyzed as a PCS.)
 - The RCTs modified child fat intake either through dietary counseling that focused primarily on reducing saturated fat and dietary cholesterol intake, with additional encouragement to increase polyunsaturated fat intake, or through provision of food products (i.e., eggs, extra virgin olive oil, or oily fish) that differed in types of fat including saturated fat, monounsaturated fat, polyunsaturated fat, and/or dietary cholesterol.
 - The PCSs primarily assessed saturated fat or polyunsaturated fat intake, with fewer studies on monounsaturated fat or dietary cholesterol intake; only two studies modeled replacement between different types of fat or macronutrients.
- Most included studies assessed the relationship between intake of types of dietary fat during childhood and blood lipids.
 - Evidence from RCTs predominantly indicated that consuming less saturated fat and dietary cholesterol resulted in lower blood total cholesterol and LDL-C throughout childhood, particularly in boys; evidence from PCSs was consistent with the RCTs.
 - Although reduction of saturated fat intake was the primary focus of most RCTs,

evidence from these RCTs also showed that higher polyunsaturated fat intake resulted in decreased total blood cholesterol, particularly in boys; evidence from PCSs was broadly consistent with the RCTs.

- Few studies, RCTs or PCSs, focused on the relationship between monounsaturated fat intake and blood lipids and the results were predominantly null.
- The majority of studies assessed blood lipids during childhood; few assessed intake of types of fat during childhood and blood lipids into early adulthood.
- Fewer studies assessed the relationship between intake of types of dietary fat during childhood and blood pressure.
 - It was difficult to discern the effect of consuming different types of fat in the RCT that contributed the most evidence due to additional advice to reduce sodium consumption.
 - Few PCSs were conducted on this topic and results were predominantly null.
- Only 1 study included in this review assessed the relationship between intake of types of dietary fat during childhood and CVD endpoint outcomes and methodological limitations related to the dietary assessment confounded interpretation of results. Therefore, no conclusion could be drawn.
- Limitations of this body of evidence:
 - Most articles did not report race and ethnicity, but those that did included predominantly White or Caucasian participants.
 - Some studies specifically recruited children with elevated or higher than average blood lipid levels, reducing generalizability.
 - RCTs had predominantly low risk of bias, but few pre-registered their analysis intentions and several RCTs did not provide information on allocation of randomization sequences.
 - Although many PCSs accounted for most or many key confounders, all PCSs did not account for at least one key confounder.
 - Approximately half of the diet assessment methods used in the PCSs were not validated; many PCSs had high attrition rates and did not provide information on those lost to follow-up.

Adults

Adults: CVD Intermediate Outcomes

- This systematic review included 97 articles⁴⁷⁻¹⁴³ that examined the relationship between intake of types of dietary fat during adulthood and CVD intermediate outcomes, published

between January 2010 and October 2019. Of these, 47 were from 47 parallel design RCTs, 46 were from 44 crossover design RCTs, and 5 were from non-RCT designs. (Note: One parallel design RCT was also analyzed as a crossover design RCT.)

- The articles examined intake of saturated fat, monounsaturated fat, polyunsaturated fat, and dietary cholesterol.
- The majority of articles specifically examined types of fat from different food sources, including food sources that were predominantly fat (e.g., butter and olive oil).
- The relationship between types of dietary fat and blood lipids varied by the type of fat examined and the comparator.
 - Saturated fat intake: Predominantly null effects were reported for saturated fat intake when replacement was not considered or when saturated fat was partially replaced by carbohydrates. However, among the studies that detected significant effects, all reported significantly higher total cholesterol, LDL-C, and HDL-C with higher intake of saturated fat, compared to either lower intake of saturated fat or substitution with carbohydrate.
 - Replacement of saturated fat with monounsaturated fat: More than half of articles reported a beneficial effect of replacing a portion of saturated fat intake with monounsaturated fat intake on total cholesterol and LDL-C. Predominantly null effects were reported for HDL-C and triglycerides.
 - Replacement of saturated fat with polyunsaturated fat: More than half of articles reported a beneficial effect of replacing a portion of saturated fat intake with polyunsaturated fat intake on total and LDL-C. Predominantly null effects were reported for HDL-C and triglycerides.
 - Monounsaturated fat intake: Predominantly null effects were reported for monounsaturated fat intake when replacement was not considered or when monounsaturated fat was partially replaced with carbohydrates.
 - Replacement of monounsaturated fat with polyunsaturated fat: Predominantly null effects were reported in articles that examined partial replacement of monounsaturated fat intake with polyunsaturated fat intake.
 - Among the studies that found significant effects, the majority detected significantly lower levels of or significant decreases in total cholesterol and LDL-C when polyunsaturated fat intake replaced a portion of monounsaturated fat intake.
 - Studies replacing a portion of monounsaturated fat intake with polyunsaturated fat intake predominantly detected significant decreases or greater decreases in HDL-

C and significantly higher levels of, smaller decreases in, or greater increases in triglycerides.

- Polyunsaturated fat intake: The vast majority of articles that assessed the effect of polyunsaturated fat intake (without considering replacement) on total cholesterol, LDL-C, or HDL-C and triglycerides were null. However, among the few articles that detected significant effects, total cholesterol and LDL-C were significantly lower with greater polyunsaturated fat intake, compared with lower polyunsaturated fat intake; HDL-C significantly increased or had smaller decreases with greater polyunsaturated fat intake; and triglycerides were significantly lower or had greater decreases with greater polyunsaturated fat intake.
- Few articles published during the search years of the present review assessed the relationship between dietary cholesterol intake and blood lipids
 - Predominantly null effects were reported for dietary cholesterol. However, among the few articles that found significant results, higher intake of dietary cholesterol, compared to lower intake, significantly increased or resulted in higher levels of total cholesterol, LDL-C, and HDL-C.
 - In several articles, it was not possible to isolate the independent effect of dietary cholesterol on blood lipids due to simultaneous changes in the total amount of fat or proportion of different types of fat in the study diet.
- Limitations of this body of evidence:
 - Several articles involved small sample sizes and lacked sufficient power.
 - Race or ethnicity was not consistently reported, but among those studies that provided this information, the majority included participants who were predominantly White or Caucasian.
 - It was not possible to isolate the independent effect of saturated fat, monounsaturated fat, polyunsaturated fat, or dietary cholesterol on blood lipids in several articles due to simultaneous changes of those three types of fat.
 - The majority of articles did not control for other dietary components beyond the intervention or test meal.
- This systematic review builds and expands on the work of the 2015 Committee, which answered the question “What is the relationship between intake of saturated fat and risk of cardiovascular disease?” and considered evidence from RCTs and PCSs from the 1960s to 2010. This systematic review concurs with and updates the conclusions drawn by the 2015 Committee.

Adults: CVD Endpoint Outcomes

- This systematic review included 94 articles¹⁴⁴⁻²³⁷ that examined the relationship between intake of types of dietary fat during adulthood and CVD endpoint outcomes, published between January 2010 and October 2019. Of these, 90 were from 47 PCSs and 4 were from 3 nested case-control studies.
 - The articles primarily examined saturated fat, total polyunsaturated fat, omega-3 polyunsaturated fat (including alpha-linolenic acid [ALA], eicosapentaenoic acid [EPA], docosahexaenoic acid [DHA], or docosapentaenoic acid [DPA]), or monounsaturated fat intake. Fewer articles examined omega-6 polyunsaturated fat (including linoleic acid [LA] or arachidonic acid [AA]) or dietary cholesterol intake.
 - Several articles modeled replacement between different types of fats or macronutrients or, in some cases, between different sources of the same type of fat. Few articles specifically assessed food sources that are predominantly fat (i.e., butter and olive oil) or types of fat from different food sources.
- The relationship between types of dietary fat and CVD endpoint outcomes varied by the type of fat examined and the specific outcome assessed, with the most consistent results observed when replacement was modeled.
 - Replacement of saturated fat with polyunsaturated fat: In this review, replacement of saturated fat with polyunsaturated fat (predominantly total polyunsaturated fat) in many studies was associated with significantly lower risk of CVD mortality and/or coronary heart disease (CHD) or associations were null. Fewer articles in this review reported data regarding the relationship between replacement of saturated fat with polyunsaturated fat and other specific types of CVD including heart failure or stroke, and results were predominantly null.
 - Replacement of saturated fat with carbohydrates: In this review, replacement of saturated fat with carbohydrates and CVD outcomes were predominantly null. Most articles did not specify or differentiate between the types of carbohydrate replacing saturated fat (e.g., complex or simple carbohydrates/sugar).
 - Replacement of saturated fat with monounsaturated fat: In this review, predominantly null associations were observed between replacement of saturated fat with monounsaturated fat and total CVD and CHD. However, among the few articles that differentiated plant and animal sources, monounsaturated fat from plants tended to be associated with lower risk.
- In addition to articles that reported on total polyunsaturated fat intake, many specifically

assessed omega-3 polyunsaturated fat and some assessed omega-6 polyunsaturated fat.

- Total omega-3 polyunsaturated fat: Predominantly null or beneficial associations were observed between total omega-3 polyunsaturated fat intake and CVD outcomes.
- Types of omega-3 polyunsaturated fat: When “long chain” omega-3 polyunsaturated fat (EPA, DHA, and sometimes DPA), primarily from marine sources, were assessed separately from ALA, more consistent associations with lower risk of CVD were observed.
- Total omega-6 polyunsaturated fat: Associations between total omega-6 polyunsaturated fat intake and CVD were predominantly null.
- Types of omega-6 polyunsaturated fat: In the few articles specifically assessing LA and AA separately, beneficial associations were more often observed for LA as compared to AA.
- Few articles, with inconsistent results, assessed the independent relationship between dietary cholesterol intake and CVD endpoint outcomes, thereby further confounding meaningful conclusions. Due to the co-occurrence of dietary cholesterol and saturated fat in animal source foods, disentangling independent associations between dietary cholesterol and CVD endpoint outcomes in these observational studies is challenging.
- Limitations of this body of evidence:
 - Many articles did not report race or ethnicity, but the majority of those that did involved participants who were predominantly White or Caucasian. Other important characteristics of participants in some included articles did not mirror those of the U.S. population, such as BMI and diet at baseline.
 - Although many articles accounted for the majority of key confounders, few accounted for all key confounders.
 - Some studies did not use validated dietary assessment methods or were limited by high attrition.
 - Although most studies included in this body of evidence were specifically designed to evaluate the relationship between diet and CVD, several articles were less direct as a result of being secondary analyses of RCTs or cohorts originally designed to assess outcomes other than CVD.
- This systematic review builds upon the work of the 2015 Committee, which answered the question “What is the relationship between intake of saturated fat and risk of cardiovascular disease?” and considered evidence from RCTs and PCSs from the 1960s to 2010.
 - Regarding the relationships between replacement of saturated fat with polyunsaturated

fat or carbohydrate, this systematic review concurs with and updates the conclusions drawn by the 2015 Committee, providing additional context regarding specific CVD endpoint outcomes and the type of carbohydrate replacing saturated fat.

- Regarding the relationship between replacement of saturated fat with monounsaturated fat, this systematic review concurs with and updates the conclusions drawn by the 2015 Committee.

For additional details on this body of evidence, visit: [nesr.usda.gov/2020-dietary-guidelines-advisory-committee-systematic-reviews/dietary-fats-and-seafood-subcommittee/dietary-fat-cardiovascular-disease](https://www.nesr.usda.gov/2020-dietary-guidelines-advisory-committee-systematic-reviews/dietary-fats-and-seafood-subcommittee/dietary-fat-cardiovascular-disease)

Discussion: Dietary Fats

Background

CVD remains the leading cause of death in the United States, currently totaling 647,000 deaths per year.^{238,239} This 2020 Committee updated and expanded the 2015 Committee's review of the evidence on dietary fats and CVD risk in children and adults. This Committee conducted a systematic review of more recent studies, including those examining the effects of dietary saturated fat intake and its replacement by other types of fats, specifically polyunsaturated fat, monounsaturated fat, and carbohydrates as they relate to intermediate (e.g., blood lipids, blood pressure) or endpoint CVD outcomes (e.g., incidence of, or mortality from, CVD). Previous research has found that RCTs that reduced dietary saturated fat or replaced saturated fat with polyunsaturated fat from vegetable oil reduced CVD by approximately 30 percent, similar to the reduction achieved by statin treatment.²⁴⁰ Likewise, cross-cultural PCSs report that reduced saturated fat intake, along with higher polyunsaturated fat or monounsaturated fat intake, are associated with reduced incidence of CVD and all-cause mortality.²⁴⁰ Conversely, replacement of saturated fat with refined carbohydrates and/or added sugars is not consistently associated with lower rates and may cause higher rates of CVD. Replacement of saturated fat with unsaturated fat lowers LDL cholesterol (LDL-C), a known cause of atherosclerosis, also called Atherosclerotic Cardiovascular Disease (ASCVD). ASCVD is distinct from stroke, heart failure or other components commonly included more broadly within CVD terminology.

The following sections will discuss the Committee's findings about the relationship of dietary fat with various outcomes in children and in adults and will highlight areas in which additional research is needed. These areas are described in greater detail in ***Part E. Future Directions***.

Studies in Children

Dietary fat contributes energy (calories) to the diet of growing children and is especially important in infants and young children because they are not able to consume very large quantities of food at one time. Therefore, the higher caloric density of fat (9 calories/gram, compared to protein and carbs, which have 4 calories/gram) is important because it helps to meet the energy demands of the rapid growth that occurs during this life stage. Fatty acids also play a major role in brain development and other important physiological functions. Before the age of 12 months, approximately 40 percent of energy intake comes from dietary fats, with a reduction to about 30 percent from age 24 months throughout preschool years (see **Part D. Chapter 1: Current Intakes of Foods, Beverages, and Nutrients**).

Studies examined in this review demonstrated strong evidence that diets lower in saturated fat and cholesterol during childhood, primarily after 24 months of age, result in lower levels of total blood and LDL cholesterol throughout childhood, particularly in boys. Additionally, the Committee found moderate evidence suggesting that diets higher in polyunsaturated fat during childhood result in lower levels of total blood cholesterol throughout childhood, particularly in boys. The dominant sources of evidence for these conclusions are the Special Turku Coronary Risk Factor Intervention Project (STRIP) and Dietary Intervention Study in Children (DISC) studies.

The STRIP study, a widely cited population-based RCT conducted in Finland, which had the highest CVD mortality rate worldwide at baseline, randomized more than 1,000 participants to reduce saturated fat and dietary cholesterol intake while increasing polyunsaturated fat intake beginning at age 7 months. For participating infants who were consuming human milk or formula, the saturated fat reduction applied only to complementary foods and beverages. Participants were followed over a period of 20 years.^{17,19,20,23,24,30-33,37-40} This dietary counseling-based intervention resulted in lower total cholesterol, LDL-C, and triglycerides in boys, providing longitudinal evidence of cardiovascular benefit. At different ages, favorable blood lipid responses appeared to occur in both males and females but at other times only boys appeared to have reduced LDL-C levels, thus demonstrating male-female differences in blood lipid response to dietary intervention, possibly attributed to changes in hormones during and throughout puberty.

The U.S.-based DISC study randomized more than 650 preadolescent children with elevated levels of LDL-C (80th to 90th percentile) to test the efficacy, safety and feasibility of reducing saturated fat within the context of a heart healthy diet in growing children, especially during puberty.^{15,22,34,41} The DISC counseling intervention, which continued for approximately 7

years, reduced total cholesterol and LDL-C at 1- and 3-year follow-up, with no adverse impact on growth and development, but these differences in blood lipids were not sustained at 5- and 7-year follow-up. The study ended prior to all children reaching age 18 years or Tanner Stage 5, thereby limiting the ability to determine post-pubertal impact of dietary intervention on CVD risk in adulthood. The study also did not find significant influences on blood pressure, but sodium intake was not addressed in this study.^{15,22,34,41} Both the STRIP and DISC studies provide important longitudinal evidence of the influences of dietary modification starting in childhood through adulthood.

Five RCTs conducted in children more recently provided food products to modulate dietary cholesterol, saturated fat, and monounsaturated fat and/or polyunsaturated fat intake. Consistent with the studies described above, LDL-C and total cholesterol were increased or were higher following consumption of food products higher in saturated fat and dietary cholesterol, compared to alternatives that replaced saturated fat with other types of fat or reduced dietary cholesterol.

Most of the 14 PCSs included in the Committee's review were conducted in the United States and primarily reported intermediate outcomes during childhood. The results were broadly consistent with those of the RCTs, either reporting predominantly null findings or reporting that higher intakes of saturated fat were associated with higher levels of total cholesterol or LDL-C.

This review found insufficient evidence to draw conclusions about the relationship between dietary fat during childhood and blood pressure throughout childhood. Studies varied considerably in their design and age-ranges and whether salt intake, a known mediator of blood pressure, was assessed. In addition, insufficient evidence was available to determine how monounsaturated fat intake during childhood affects total blood and LDL-C throughout childhood. All associations between monounsaturated fat intake, including those that modeled replacement, and blood lipids were non-significant. Lastly, only one article studying the association between saturated fat consumed during childhood and CHD mortality or stroke mortality in adulthood was included in this review.²⁸ Although the study reported results after approximately 60 years of follow-up, the Committee identified significant flaws with the dietary assessment method employed, and determined insufficient evidence was available to determine the relationship between dietary fat during childhood and CVD endpoint outcomes during adulthood.

Dietary studies in children are difficult to conduct not only due to ethical concerns, but also because of issues with compliance, follow-up, accuracy in assessing dietary adherence and confounders. Despite these challenges, dietary intervention studies in children are of critical

importance, particularly given the growing evidence that poor nutrition in childhood heavily contributes to poor health outcomes—both chronic and acute—and subsequently poorer quality of life in adulthood.²⁴¹⁻²⁴⁴ Inadequate research meeting systematic review criteria was available to draw meaningful conclusions regarding outcomes of interest within this review. Additional longitudinal RCTs involving dietary intervention among growing children with a focus on separating male and female data are needed to provide more definitive preventive recommendations, particularly regarding food sources of dietary fats and replacement with unsaturated fats and carbohydrates, with a focus on type of carbohydrate. See additional recommendations for future research in **Part E. Future Directions**.

Because there is no biological requirement for saturated fat or dietary cholesterol, diets lower in these components that also contain foods consistent with the recommended dietary patterns, can be applied to children age 2 years and older. This approach appears to be safe and promotes dietary adherence useful for establishing healthy lifelong eating behaviors and potential cardiovascular benefits across the life course.^{243,244}

Studies in Adults

Intermediate Outcomes

This Committee concurs with the conclusion from the 2015 Committee's review, which stated: Strong and consistent evidence from RCTs shows that replacing saturated fat with unsaturated fats, especially polyunsaturated fat, significantly reduces total and LDL-C.

The 2015 Committee reviewed evidence from existing systematic reviews and meta-analyses published between 2009 and 2014, including the American Heart Association/American College of Cardiology (AHA/ACC) Lifestyle Guidelines and associated National Heart, Lung, and Blood Institute (NHLBI) Lifestyle Report,²³⁸ which included primarily RCTs on intermediate risk factors. The evidence reviewed included the landmark studies and RCTs from the 1960s, which first identified the relationship between saturated fat and CVD risk. In their report, the 2015 Committee found a high consistency of the evidence from PCSs and RCTs in supporting the benefits of replacing saturated fat with unsaturated fats, especially polyunsaturated fat, in reducing CVD risk.

The 2020 Committee's systematic review added 97 articles—all from RCTs—to the evidence reviewed by the 2015 Committee and found this new evidence to be broadly consistent with the conclusions drawn by the 2015 Committee. In articles that examined replacement of saturated fat with monounsaturated fat or polyunsaturated fat, the intervention

predominantly resulted in lower levels of, or larger decreases in, LDL-C and total blood cholesterol or null effects. Within the group of articles assessing the effect of polyunsaturated fat intake replacing a portion of saturated fat, the majority reported a statistically significant, beneficial effect of polyunsaturated fat on LDL-C or total cholesterol. Likewise, of the studies that examined the effect of monounsaturated fat intake replacing a portion of saturated fat, approximately half reported a beneficial effect of monounsaturated fat on LDL-C or total cholesterol, with the remaining studies reporting null effects.

Consistent with this Committee's findings, a World Health Organization review found that replacing dietary saturated fat with unsaturated fats decreases LDL-C levels and replacement with omega-6 polyunsaturated fatty acids reduces LDL-C more than does replacement with monounsaturated fat.²⁴⁵ More specifically, based on regression analyses, it has been estimated that decreasing saturated fat intake by 1 percent of total daily calories with a corresponding 1 percent increase in polyunsaturated fat, monounsaturated fat, or carbohydrate results in reductions in LDL-C of 2.1 mg/dL, 1.6 mg/dL and, 1.3 mg/dL, respectively.²⁴⁵

When evaluating replacement of saturated fat with carbohydrates, the Committee concurs with the conclusion from the 2015 Committee: Replacing saturated fat with carbohydrates (sources not defined) also reduces LDL-C and total cholesterol, but significantly increases triglycerides and reduces HDL-C. Relative to studies reporting results on replacement of SFA with unsaturated fats, far fewer (only 2 articles) studies within the 2020 Committee's body of evidence examined the effect of replacing saturated fat with carbohydrates. Results from these articles were null or showed lower LDL-C, and HDL-C and total cholesterol when saturated fat was replaced with carbohydrates. The new evidence the Committee reviewed remains inadequate to differentiate among types and food sources of carbohydrates and their impact on blood lipids. However, in the context of dietary patterns, benefits in CVD risk factors were shown in dietary patterns that include whole grains and are lower in refined carbohydrates (See **Part D. Chapter 8: Dietary Patterns**).

The mechanism by which different types of carbohydrates influence blood lipids is not yet fully understood and evidence reviewed by the Committee did not provide insight into this relationship. Diets high in refined carbohydrates are often associated with elevated levels of triglycerides and very low-density lipoprotein (VLDL) cholesterol, especially among individuals with overweight and obesity.²⁴⁰ Some research suggests that this may shift the distribution of LDL-C particles to smaller, cholesterol-depleted LDL-C particles. Researchers are studying whether atherogenicity differs by LDL-C particle size. However, measures of overall LDL-C that do not differentiate between particle size are currently considered sufficient to monitor

atherogenic risk and response to therapeutic intervention.^{246,247} More research is needed on biomarkers with increased specificity compared to LDL-C regarding intermediate and endpoint cardiovascular risk.²⁴⁸

This review focused on types rather than sources of dietary fats. However, the Committee recognizes the importance of and growing body of research on the specific fatty acids, food matrix and sources of fats, explicitly saturated fat. Differences in the effects of specific saturated fatty acids on CVD are important to examine. Based on meta-regression analysis,²⁴⁵ replacement of carbohydrates with specific saturated fat sources including lauric, myristic, palmitic, and stearic acids increased LDL-C and HDL-C while decreasing triglycerides. Because pure stearic acid does not increase LDL-C, but represents approximately 20 percent of the fat in beef, 30 percent of the fat in pure cocoa (chocolate), and 10 to 15 percent of the fat in lard (pork fat) and lamb, it remains challenging to quantify the impact of saturated fat on LDL-C without dietary assessment data that distinguishes between specific fatty acids.²⁴⁰ Likewise, the health effects of the different fatty acids may vary also according to their proportion on specific foods and other components within the food matrix.

CVD Endpoint Outcomes

The Committee reviewed 94 articles from PCSs that provided assessment of dietary fat intake and endpoint cardiovascular outcomes. Compared with RCTs, PCSs typically include large populations that report self-selected dietary intake over longer duration and often, periodically during a follow-up period. Although observational studies, including PCSs, cannot demonstrate causality, they do identify associations between dietary intake and long-term health outcomes that would be difficult to assess through RCTs, and therefore, are critical to include in the evidence base for determining dietary recommendations for public health purposes (i.e., health promotion and chronic disease risk reduction).

This Committee's review found strong evidence demonstrating that replacing saturated fat with polyunsaturated fat in adults reduces the risk of CHD events and CVD mortality. (Note: This outcome is distinctly different from risk of stroke or heart failure, about which the Committee found insufficient evidence to draw a meaningful conclusion; see below.) The vast majority (71 of 94) of the articles included in this review of endpoint outcomes assessed the relationship between polyunsaturated fat intake—either total polyunsaturated fat intake, polyunsaturated fat as replacement for saturated fat, or specific polyunsaturated fatty acids (e.g., EPA, DHA, LA)—during adulthood and CVD outcomes. Studies that examined the relationship of total polyunsaturated fat intake and CVD without consideration of replacement, had null results or

showed associations with lower risk of CVD. When polyunsaturated fat was studied as a replacement for saturated fat, results were more consistent, predominantly reporting associations with lower risk of CVD.

One illustrative study is the National Institutes of Health (NIH)-AARP cohort, which included more than 500,000 men and women. At baseline, higher saturated fat intake at a mean age of 63 years was associated with higher risk of CVD mortality over 16 years of follow up and lower risk when saturated fat was replaced with total and omega-3 polyunsaturated fatty acids, as well as plant-sourced monounsaturated fat.²³⁵ Likewise, the National Health and Nutrition Examination Survey (NHANES) cohort similarly reported that substitution of saturated fat with polyunsaturated fat was associated with reduced CVD mortality.²¹⁰ Studies conducted outside the United States found similar results. A small study in Finland²²² with isocaloric substitution of saturated fat with polyunsaturated fat showed reduced fatal and nonfatal CHD. In the PREDIMED (Prevención con Dieta Mediterránea) cohort, substitution of saturated fat with polyunsaturated fat showed significantly reduced risk of CVD.^{172,173}

In addition to total polyunsaturated fat intake, studies further investigated intake of types of polyunsaturated fats: omega-3, omega-6, and specific fatty acids (i.e., EPA, DHA, DPA, LA, AA) on CVD outcomes.

The Committee found moderate evidence suggesting that total intake of omega-3 polyunsaturated fatty acids, particularly EPA and DHA from food sources, in adults is associated with lower risk of CVD. In articles studying the relationship between long chain omega-3 polyunsaturated fatty acids (EPA, DHA, with or without DPA) and CVD endpoint health outcomes, most focused on CHD, coronary artery disease, and myocardial infarction or CVD and showed predominantly beneficial associations.

Less evidence was available from this review to determine associations between intake of the omega-6 polyunsaturated fatty acids during adulthood and CVD, including CVD mortality. Omega-6 polyunsaturated fatty acids (e.g., LA, AA) are more prevalent than omega-3 polyunsaturated fatty acids in the diet as they are found widely in vegetable oils. Studies that evaluated the intake of LA, an essential omega-6 polyunsaturated fatty acid, reported predominantly beneficial or null associations. Relatively few studies assessed the relationship between AA and CVD endpoint outcomes. Results from these studies were inconsistent and resulted in inconclusive findings.

Similar to the 2015 Committee's review, this updated review did not provide clear evidence on whether replacing saturated fat with monounsaturated fat confers CVD benefits because of the co-occurrence of saturated fat and monounsaturated fat in animal fats, which are the main

sources of monounsaturated fat in the typical American diet. Within this review, many of the same cohorts reporting on substitution of saturated fat with polyunsaturated fat also reported substitution effects with monounsaturated fat. Compared to replacement of saturated fat with polyunsaturated fat, associations between risk of CVD and replacement of saturated fat with monounsaturated fat were predominantly null. However, differences between monounsaturated fat from plant-based (e.g., olive oil and nuts) vs animal sources were noted, suggesting benefits from plant sources of monounsaturated fat.

With growing research interest in the health effects of olive oil and specifically extra virgin olive oil and nuts as used in the PREDIMED trial, additional studies are needed to differentiate the effects of specific forms of monounsaturated fat from plant-source vs animal-source foods and to compare the effects of different forms of monounsaturated fat with polyunsaturated fat as part of well-characterized dietary patterns. Few studies to date include diet assessment methodology or nutrient biomarkers that permit such specificity and that could further allow evidence-based conclusions to be drawn.

As noted above, insufficient evidence was available from studies examining the replacement of saturated fat with polyunsaturated fat in adults and risk of stroke or heart failure. Among the few studies examining the relationship between saturated fat intake and stroke, most reported null associations between saturated fat intake and incident total stroke or subtypes of stroke such as ischemic stroke or hemorrhagic stroke. Only two articles assessed the relationship between saturated fat intake and heart failure and both reported null associations.

Lastly, in reviewing studies that examined replacing saturated fat with different types of carbohydrates (e.g., complex vs simple), insufficient evidence was available to determine how the exposures affected the risk of CVD. Associations between replacement of saturated fat with carbohydrate and risk of CVD, including total CVD and CHD, were predominantly null. Although 12 articles examined this relationship, only 6 articles reported results specifying different types of carbohydrates. Of these, the comparisons between types of carbohydrates in the interventions varied, making it difficult to arrive at a conclusive finding.

Recent analyses assessing replacement of saturated fat with carbohydrates have suggested beneficial effects when saturated fat is replaced with complex carbohydrates vs refined carbohydrates. As reported by Sacks et al.,²⁴⁰ and based on calculations developed by Willet et al.,²⁴⁹ replacing 5 percent of energy intake from saturated fat with equivalent energy intake from complex carbohydrates from whole grains was significantly associated with a 9 percent lower risk of CHD. However replacing saturated fat with refined carbohydrates (e.g., starches, added sugars) was associated with a slight increase in CHD risk.²⁴⁰

Not all recently published studies have arrived at conclusions consistent with this Committee's systematic review findings regarding the relationship between saturated fat intake and CVD risk. Some of the disparate findings relate to differences in methodology, including non-validated dietary assessment techniques; differences in study design; small sample sizes; distinctly different population characteristics, especially high body mass index; outcome measures; and cross-cultural differences in background dietary intake, such as in findings in those consuming diets vastly different from typical U.S.-style diets. One example of differences in methodology leading to findings inconsistent with the Committee's review is shown in meta-analyses that compare diets higher or lower in saturated fat, yet do not examine the replacement of saturated fat when it is reduced.^{250,251} As summarized by Sacks et al., comparing disease rates between people in a population who have low compared with high intake of saturated fat—without defining the usual dietary pattern, i.e. types of carbohydrates consumed—leads to the potential for misinterpretation of the role saturated fat plays in relation to risk of CVD.²⁴⁰

Dietary Cholesterol

The Committee found insufficient evidence published since 2010 to determine an independent relationship between dietary cholesterol and blood lipids given the co-occurrence of cholesterol and saturated fat in foods. Nine articles from 4 parallel design and 5 cross-over design RCTs assessed the relationship between dietary cholesterol intake and blood lipids. Eight of the 9 studies provided whole eggs as the source of dietary cholesterol and 1 study provided prawns. Comparators varied, including egg whites, egg substitutes, or carbohydrate foods. Across this small body of evidence, higher dietary cholesterol intake, compared to lower dietary cholesterol intake, had mainly null effects on blood lipids. Among the few studies that reported significant effects, higher dietary cholesterol intake resulted in higher levels of, or greater increases in, total blood cholesterol, LDL-C, and HDL-C. No studies found a significant effect on triglycerides. However, because several studies concurrently modulated intake of total fat or other types of fat through the dietary intervention, it was difficult to evaluate the independent effect of dietary cholesterol.

Likewise, insufficient evidence published since 2010 was available to determine an independent relationship between dietary cholesterol intake in adults and overall risk of CVD. Eleven articles met inclusion criteria and results were inconsistent, with most studies reporting null associations, some reporting detrimental associations with higher intake of dietary cholesterol, and fewer reporting beneficial associations with higher intake. One article, a pooled

analysis of 6 large PCSs from the United States, found that higher consumption of dietary cholesterol was significantly associated with higher risk of incident CVD mortality, incident CVD, and incident stroke in a dose-response manner; this article did not detect significant associations between dietary cholesterol intake and heart failure or CHD.²³³ Other articles that assessed CVD incidence or mortality reported null associations or significant associations between higher intake of dietary cholesterol and lower risk.^{149,177,193} Among other articles that examined stroke, some did not detect associations with dietary cholesterol intake, whereas 1 additional study detected significant associations between higher dietary cholesterol intake and higher risk of stroke.^{144,188,229,233} Results also were inconsistent for heart failure outcomes. All articles that assessed the relationship between dietary cholesterol intake and CHD or MI reported null associations.^{196,204,223,233} As mentioned above, the co-occurrence of dietary cholesterol and saturated fat in animal-source foods as well as relatively lower population-wide dietary cholesterol intake (compared to the mean intake of the U.S. population) reported in several studies, made it difficult to evaluate independent associations between dietary cholesterol and CVD endpoint outcomes in this body of evidence. Well-designed PCSs and RCTs with long-term follow-up are required to better quantify the impact of dietary cholesterol on overall CVD and CHD incidence and mortality.

The lack of studies evaluating a number of outcomes in this review highlights the need for additional research, which is further discussed in **Part E. Future Directions**.

Conclusions

Based on the totality of the scientific evidence, including the rigorous systematic reviews considered by the 2015 Committee and further examined by the 2020 Committee, it remains evident that reducing saturated fat intake and replacing it with unsaturated fats, specifically polyunsaturated fat, reduces the incidence of CVD.

Conversely, evidence to differentiate among sources of carbohydrate (e.g., sugars, refined vs complex) and their impact on blood lipids and CVD outcomes remains inadequate to draw clear conclusions. Although some evidence indicates that replacing saturated fat with complex carbohydrates may reduce CVD risk, replacing saturated fat with mostly refined carbohydrates and sugars shows no change or slightly increased risk of CVD.

Because dietary cholesterol is found only in animal-source foods that are typically also sources of saturated fat, the independent effects on blood lipids and CVD are difficult to assess. Nevertheless, because dietary patterns associated with reduced risk of CVD are characterized

by lower levels of both saturated fat and dietary cholesterol, it seems prudent to recommend lower intake of foods high in dietary cholesterol as well.²⁴⁰

Seafood

Question 2. What is the relationship between seafood consumption during childhood and adolescence (up to 18 years of age) and risk of cardiovascular disease?

Approach to Answering Question: NESR systematic review

Conclusion Statement and Grade

Insufficient evidence is currently available to accurately determine the relationship between seafood consumption during childhood and adolescence and risk of developing cardiovascular disease. Grade: Grade Not Assignable

Summary of the Evidence

- Four articles,^{28,252-254} 2 RCTs and 2 PCSs, met inclusion criteria for this systematic review.
- Few articles were identified that examined the relationship between seafood intake during childhood and adolescence and blood pressure, lipid levels, and cardiovascular-related mortality, and no articles examined the relationship with incidence of CVD.
- Studies had serious methodological limitations that made interpretation of the results difficult.
- Evidence was insufficient, and no conclusion could be drawn.

For additional details on this body of evidence, visit: nesr.usda.gov/2020-dietary-guidelines-advisory-committee-systematic-reviews/dietary-fats-and-seafood-subcommittee/seafood-childhood-adolescence-cardiovascular-disease

Question 3. What is the relationship between seafood consumption during childhood and adolescence (up to 18 years of age) and neurocognitive development?

Approach to Answering Question: NESR systematic review

Conclusion Statements and Grades

Developmental Domains

Cognitive development: Insufficient evidence is available to determine whether there is a favorable relationship between seafood intake during childhood and adolescence and measures of cognitive development in children and adolescents. However, no unfavorable relationships were found between seafood consumption during childhood and adolescence and measures of cognitive development. Grade: Grade Not Assignable

Language and communication development: Insufficient evidence is available to determine whether there is a favorable relationship between seafood intake during childhood and adolescence and measures of language and communication development in children and adolescents. However, no unfavorable relationships were found between seafood consumption during childhood and adolescence and measures of language and communication development. Grade: Grade Not Assignable

Movement and physical development: Insufficient evidence is available to determine the relationship between seafood intake during childhood and movement and physical development in children. Grade: Grade Not Assignable

Social-emotional and behavioral development: Insufficient evidence is available to determine the relationship between seafood intake during childhood and adolescence and social-emotional and behavioral development in children and adolescents. Grade: Grade Not Assignable

Attention Deficit Disorder or Attention Deficit/Hyperactivity Disorder

Insufficient evidence is available to determine the relationship between seafood consumption during childhood and adolescence and attention deficit disorder or attention-deficit/hyperactivity disorder-like traits or behaviors. Grade: Grade Not Assignable

Autism Spectrum Disorder

No evidence is available to determine the relationship between seafood intake during childhood and adolescence and autism spectrum disorder-like traits or behaviors or autism spectrum disorder diagnosis. Grade: Grade Not Assignable

Academic Performance

Insufficient evidence is available to determine the relationship between seafood intake during adolescence and academic performance in adolescents. Grade: Grade Not Assignable

Anxiety and Depression

Insufficient evidence is available to determine the relationship between seafood consumption during childhood and adolescence and anxiety and depression. Grade: Grade Not Assignable

Summary of the Evidence

- This review included 13 articles,²⁵⁵⁻²⁶⁷ 6 articles from 3 RCTs and 7 articles from 6 PCSs, published between January 2000 and October 2019.
- The majority of studies addressed developmental domain outcomes - cognitive development (7 articles), language and communication development (5 articles), movement and physical development (2 articles), and social-emotional and behavioral development (3 articles).
- No conclusion regarding the relationship between seafood intake during childhood and adolescence and developmental domains could be drawn due to an inadequate number of studies, inconsistency in results, risk of bias in classification of exposures, and heterogeneity of outcome assessments.
 - Seafood intake during childhood and adolescence was predominantly beneficial or null across all domains, and had a few detrimental relationships, primarily in social-emotional and behavioral development.
 - Results from 3 RCTs found that 3 fatty fish meals per week (about 50 to 80 grams per meal) compared to meat meals for 12 weeks in adolescents or 16 weeks in children had a predominantly null effect on developmental domain outcomes.
 - Results from 3 PCSs generally found a beneficial association between fish intake in children and adolescents and development outcomes.

- The vast majority of analyses showed no detrimental relationship between seafood intake during childhood and adolescence and cognitive, language and communication, and movement and physical development.
- No conclusion regarding the relationship between seafood consumption during childhood and adolescence and academic performance, ADD or ADHD, anxiety and depression, and ASD could be drawn due to an inadequate number of studies and variation in outcome assessment and child age.

For additional details on this body of evidence, visit: [nesr.usda.gov/2020-dietary-guidelines-advisory-committee-systematic-reviews/dietary-fats-and-seafood-subcommittee/seafood-childhood-adolescence-neurocognitive-development](https://www.nesr.usda.gov/2020-dietary-guidelines-advisory-committee-systematic-reviews/dietary-fats-and-seafood-subcommittee/seafood-childhood-adolescence-neurocognitive-development)

Discussion: Seafood

The scientific literature supports the health benefits of seafood consumption alone or as part of an overall dietary pattern across life stages. However, for young children, the potential for negative health consequences raises concerns due to possible contamination with heavy metals, mainly methylmercury. Seafood is the primary sources of methylmercury exposure for humans. Methylmercury is not naturally found within seafood, but rather it results from a complex interplay of environmental factors that culminate in its accumulation in the water column resulting in methylmercury accumulation in the flesh of fish. Although all seafood contains some level of methylmercury, the amount varies by species, as described by the Environmental Protection Agency.²⁶⁸ Exposure to methylmercury is considered detrimental to the cognitive development and performance of infants and children, especially during critical windows of neurocognitive development in the first 1,000 days of life, though the risks have not been entirely characterized.²⁶⁹

Two previous Dietary Guidelines Advisory Committees (2010 and 2015) examined the topic of seafood. The 2010 Committee conducted an extensive safety analysis of seafood consumption and the 2015 Committee reviewed seafood in the context of an overall dietary pattern. The 2010 Committee concluded that the health benefits from consuming seafood outweigh the risks associated with potential toxins, including exposure to methylmercury and persistent organic pollutants. Because seafood is an important source of many nutrients and food components that are of public health relevance, the 2015 Committee found the role of seafood in dietary patterns was associated with lower risk of CVD (Grade: Strong), lower risk of overweight and obesity (Grade: Moderate), lower risk of colorectal cancer (Grade: Moderate).

However, the 2015 Committee found no clear associations with other cancer types or neurocognitive factors in adulthood (Grade: Limited). The 2020 Committee reviewed seafood by focusing on specific populations and health outcomes.

The Committee's review of seafood consumption during childhood and risk of CVD found insufficient evidence to make a conclusion about the relationship. Four articles, which reported on 2 RCTs and 2 PCSs, met inclusion criteria for this systematic review. Three studies evaluated intermediate markers of CVD risk, including blood pressure, total cholesterol, HDL-C, LDL-C, and triglycerides. Findings were predominantly insignificant with a few favorable associations. Only 1 study reported an association between fish consumption during childhood and CVD health outcomes in adulthood. However, this study's design had multiple flaws, including a lack of rigorous diet assessment methodology, serious risk of bias, and a failure to account for key confounders. All of these limitations likely affected the outcome. For the reasons outlined above, the Committee found insufficient evidence to make a conclusion about the relationship between seafood consumption during childhood and risk of CVD.

The systematic review of seafood consumption during childhood and neurocognitive development and neurocognitive health yielded 13 studies, including 6 articles from 3 RCTs. Due to inconsistency in the results and a variety of limitations among the studies, the Committee determined that insufficient evidence was available to draw a meaningful conclusion about this relationship. A few studies reported results suggesting favorable associations in measures of cognitive development and language and communication development. However, studies that focused on other domains, including movement and physical development and social and behavioral development, resulted in inconclusive findings.

Although the Committee's questions did not specifically focus on safety, a few studies reported an unfavorable association between seafood intake and measures of social-emotional and behavioral development, while none found a detrimental impact on cognitive, language and communication, and movement and physical development. The overwhelming majority of studies showed a null or favorable association between seafood intake during childhood and measures of neurocognitive development.

Additionally, insufficient data were available to grade evidence for the outcomes of academic performance, anxiety, and depression as well as ADD/ADHD. No studies reported on the relationship between seafood consumption during childhood and ASD or between seafood consumption during childhood and neurocognitive health outcomes in adulthood.

Although the scientific literature on the topic of seafood consumption during childhood and health outcomes has recently expanded, our synthesis of the literature was limited due to the

number of challenges with the body of evidence. The following discussion highlights a number of areas in which the current literature base is lacking and where additional research is needed. These are described further in **Part E. Future Directions**.

First, while all seafood contains some level of methylmercury, substantial heterogeneity in the methylmercury content of seafood exists by the type, age, geographic location, and source (i.e., farm raised vs wild caught) of the fish. Local departments of natural resources or fish and game boards are sources of information specific to the mercury content in the fish from local communities and municipalities.

Second, few studies with high-quality data exist to inform decisions about seafood intake during childhood and neurocognitive development. RCTs with appropriate sample size and robust assessment of exposures and outcomes are used to infer causality, but are limited in part by ethical issues. In the absence of RCTs, the scientific and policy communities rely on well-designed observational studies, which are weaker in quality due to confounding and selection-bias but are often large, diverse in relevant characteristics (e.g., exposure of interest, ages), and typically have longer duration for follow-up than feeding trials. Rigorous studies on the relationship between seafood consumption and health outcomes in children—including the birth to age 24 months population—and that account for key cofounders that are generalizable to the United States need to be conducted to address the gaps and limitations in the existing body of evidence.

Third, assessment of exposure to seafood intake was not uniform across studies. The observational studies reviewed used FFQs, a diet diary, or single questions in a questionnaire to assess intake, with different definitions of what “seafood” entailed and often with multiple types of seafood with varying mercury content aggregated into one question. FFQs and questionnaires also varied in their response options for types of seafood (e.g., fatty or oily fish vs shellfish) sources (i.e., farmed or wild caught) or processing method (e.g., canned), or preparation method. The metric used to quantify fish intake also varied (e.g., servings per week, grams, high consumer vs low consumer). Measurement reference periods often differed as well, and most studies assessed the diet only at one time point. Likewise, it was unclear how database values were applied for the presumably beneficial effects of seafood, including omega-3 fatty acids, iron, iodine, vitamin D, and protein. Variability also surrounded whether the FFQs were validated; some studies used a “semi validated” tool and other studies did not indicate. Few studies reported biomarker data to compare omega-3 fatty acid levels with self-reported intake.

Fourth, the measurement error inherent in all self-reported dietary data was an unavoidable limitation of the existing data used to address this topic. FFQs have considerable systematic measurement error that is known to attenuate relationships with health outcomes in general. More specifically, little is known regarding measurement error in reporting of fish and seafood.

Fifth, measuring neurocognitive development is very challenging. Various assessment methods were used. Some were general cognitive development tests and some were specific to certain conditions, such as ADD or ADHD. A variety of tests were used for screening and assessment, and many were specific to particular age groups. Among the studies the Committee examined, few included a clinical or comprehensive psychological evaluation. Most often social-emotional and behavioral assessments were based on parental or self-report, which may have introduced bias. The tests varied in their level of evaluation of psychometric properties, like reliability and validity, and some tests were commonly used while others were not. Some tests measured specific cognitive domains directly, while others measured secondary characteristics, like emotion and sociability, intelligence/IQ, or adaptive functioning skills. Statistical analysis and modeling of data also varied across the body of literature, with some studies controlling for methylmercury in the models while other studies did not measure methylmercury or did not adjust for its potential confounding role.

Additional research is needed to address these limitations and further contribute standardized data regarding specific intermediate and long-term outcomes resulting from seafood consumption during childhood.

SUMMARY

Fats are an important component of the American diet, contributing about one-third of the total calories consumed after infancy. The types and food sources of fats consumed have distinct metabolic and health effects. This chapter reviewed and summarized the current scientific evidence on the types of dietary fat consumed over the life course and risk of CVD. Most Americans consume more than 10 percent of their total calories as saturated fat, exceeding the recommendations of current dietary guidelines.² Because of the high incidence of CVD in the United States, the health effects of reducing saturated fat in the diet is of particular public health importance.

The Committee concluded that reducing saturated fat intake and replacing it with unsaturated fats, particularly polyunsaturated fat, lowers the incidence of CVD in adults. Also,

the replacement of saturated with unsaturated fats in the diet reduces serum total and LDL-C in adults and children, particularly boys. However, the benefits of replacing saturated fat with carbohydrates are less clear. This replacement reduces total and LDL-C, less so than with polyunsaturated fat but also lowers HDL-C, and it raises triglycerides. Evidence to differentiate among sources of carbohydrate (e.g., sugars, refined vs complex) and their impact on blood lipids remains inadequate to draw clear conclusions.

In agreement with the 2015 Committee, the differing effects of the type and food source of macronutrient substitution for saturated fat in the diet may be a reason for the limited evidence regarding whether replacing saturated fat with carbohydrates or with monounsaturated fat confers CVD benefits. Most studies did not report, or analyses did not distinguish between substitutions of saturated fat by different types of carbohydrates (e.g., refined grains vs whole grains). Similarly, it is challenging to identify an independent association of replacing saturated fat with monounsaturated fat and CVD because the main sources of monounsaturated fat in a typical American diet are animal fats, which contain both saturated fat and monounsaturated fat. Evidence reviewed from RCTs and PCSs showed benefits of plant sources of monounsaturated fats, such as olive oil and nuts, on CVD risk. Thus, it is pertinent that future studies assess, quantify and distinguish the type and food sources of the macronutrients compared.

Different types of fatty acids also may elicit distinct cardiometabolic effects. This is especially relevant among polyunsaturated fats. Intake of omega-3 polyunsaturated fatty acids, particularly EPA and DHA from food sources such as seafood and algae, lowers blood triglycerides, and in adults, is associated with lower risk of CVD. Intake of food sources of omega-6 polyunsaturated fatty acids such as some vegetable oils, lowers blood total and LDL-C, and LA but not AA, intake may be associated with lower risk of CVD in adults.

Because dietary cholesterol is found only in animal-source foods that are typically also sources of saturated fat, the independent effects on CVD are difficult to assess. Nevertheless, dietary patterns that include lower intake of dietary cholesterol are associated with reduced risk of CVD.²⁷⁰ This further illustrates the importance of considering the effect of any nutrient or food component on CVD within the context of the overall dietary pattern, rather than a reductionist approach of one food component in isolation.

Considering the totality of the scientific evidence, including the present systematic review, the Committee concluded that lowering intake of saturated fat and replacing it with primarily plant-sourced unsaturated fats, lowers serum total and LDL-C and the incidence of CVD. This recommended shift from saturated to unsaturated fats most naturally occurs in the context of healthy dietary patterns such as those with high Healthy Eating Index (HEI) scores, including

the Healthy Mediterranean-Style or Healthy Vegetarian Eating Patterns diets (see **Part D. Chapter 14: USDA Food Patterns for Individuals Ages Two and Older**). These healthy dietary patterns are characterized by higher consumption of vegetables, fruits, whole grains, low-fat dairy, and seafood, and lower consumption of red and processed meat, and lower intakes of refined grains, and sugar-sweetened foods and beverages (See **Part D. Chapter 8: Dietary Patterns**).

Humans have no dietary requirements for saturated fat or cholesterol because they synthesize them from other dietary substrates. Additionally, the intake of both nutrients are associated with the risk of CVD. Thus, the Committee recommends that dietary cholesterol and saturated fat intake be as low as possible within a healthy dietary pattern, and that saturated fat intake be limited to less than of 10 percent of total energy intake, as recommended by the *2015-2020 Dietary Guidelines for Americans*. This recommendation applies to adults and children ages 2 years and older. It is important to recognize that the health effects of dietary saturated fat—or any other nutrient—depend not only on the total amount consumed, but also the specific type of saturated fatty acids inherent within the food matrix, sources and degree of processing, and the overall dietary pattern. The recommended dietary pattern should replace food sources of saturated fat with food sources of polyunsaturated fats by substituting some animal-source foods, especially processed meats and certain dairy products, with sources of polyunsaturated fats, such as seafood, seeds, nuts, legumes, and appropriate vegetable oils. In addition, if meat and dairy foods are included in the dietary pattern, choosing lean cuts and lower fat dairy options is preferred.

This chapter also reviewed and discussed the scientific evidence on the consumption of seafood during childhood and adolescence and two outcomes: 1) risk of CVD, and 2) neurocognitive development and health. The Committee found insufficient evidence to draw a conclusion about the relationship of seafood intake during childhood and these outcomes. However, no adverse associations were reported.

For each of the neurocognitive outcomes examined, the Committee concluded that the evidence available was insufficient to determine an association with seafood intake. This was mostly due to the relatively small number of studies, the methodological heterogeneity among them and the mainly null or mild positive associations. Although the present review did not specifically focus on the safety of seafood intake, the Committee relied on safety evaluations conducted by the U.S. Food and Drug Administration and the Environmental Protection Agency, and noted that among the studies reviewed, all but one did not find negative associations of seafood intake and cognitive outcomes. Thus, within the parameters of the studies reviewed,

intake of seafood during childhood is not related to unfavorable neurocognitive development. The Committee also reviewed the evidence of seafood intake during pregnancy and cognitive development in the infant (see **Part D. Chapter 2: Food, Beverage, and Nutrient Consumption during Pregnancy**) and found favorable associations with some but not all neurocognitive development domains.

The Committee recommends that the seafood-related guidance of the 2010 and 2015 Committees remain in place, with slight modifications: Two or more servings of cooked seafood per week are recommended for ages 2 years and older to ensure intake of key nutrients and as part of an overall healthy dietary pattern; serving sizes vary based on age (see FDA guidance).²⁷¹ Choices of fish and seafood with emphasis on species higher in omega-3 polyunsaturated fatty acids and with low methylmercury and are advised, following Federal and local fish and seafood advisories. For those following dietary patterns that do not include seafood, regular intake of other foods high in omega-3 fatty acids, such as flaxseeds, walnuts, soy oil, algae and eggs that contain omega-3 fatty acids, is appropriate. The *2020-2025 Dietary Guidelines for Americans* should contain information on amounts and types of seafood to consume as well as those to avoid based on the methylmercury content. Special emphasis should be made with regard to the birth to age 24 months age group and women who are pregnant or lactating. The Committee recognizes that recommendations to increase seafood consumption by the American public can have environmental consequences and such impacts should be evaluated in the development of the *Dietary Guidelines for Americans*.

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PART D. CHAPTER 10: BEVERAGES

INTRODUCTION

Beverages, broadly defined as any type of energy or non-energy-yielding drink, substantially contribute to the dietary patterns of Americans in both favorable and adverse ways. Beverages can provide energy and key nutrients to improve health and prevent chronic diseases. From a physiological perspective, beverages fulfill unique roles in the diet by fulfilling hydration needs, quenching thirst, and assisting with food mastication and digestion. In addition, culturally, beverages serve a unique role in enhancing social interactions, sensory properties of foods, and quality of life.

Despite these benefits, beverages can contribute to excess energy, primarily in the form of added sugars, which promotes positive energy balance and weight gain. The *2015-2020 Dietary Guidelines for Americans* included recommendations to limit the amount of added sugars consumption, especially in the form of sugar-sweetened beverages (SSB), as a result of the moderate to strong evidence that higher added sugars consumption is associated with overweight and obesity, type 2 diabetes, and cardiovascular disease (CVD).¹ Given the diverse nutritional, sensory, and physical characteristics of beverages consumed in America, a critical examination of all beverage categories is needed to gain a better understanding of the role of beverages in a healthy dietary pattern.

This chapter examines the available data concerning the relationships between beverage consumption and achieving nutrient and food group recommendations; growth, size and body composition; and risk of overweight and obesity in children and adults. The 2020 Dietary Guidelines Advisory Committee also reviewed the relationship between beverages and gestational weight gain; this topic is discussed in ***Part D. Chapter 2: Food, Beverage, and Nutrient Consumption During Pregnancy***.

Importance and Relevance of this Topic

Beverages are consumed at most ingestive events. They can be part of a meal or snack, consumed as “the” meal or snack, or “sipped” throughout the day with no discrete ingestive event. Although beverage consumption as a whole has declined over the past decade in children and adults,² beverages continue to be a significant source of energy and nutrients in the diet. Specifically, beverages contribute 18 percent of daily energy for adults ages 20 to 64

years and 13 to 16 percent of daily energy in children ages 19 years and younger (Bev_DS¹). Further, although some beverages, like milk and 100% fruit juice, provide at least one-third of the daily intake of shortfall nutrients (e.g., vitamin C, vitamin D, calcium), others, including SSB, provide at least one-third to one-half of the added sugars within the diet in children and adults.^{3,4} Thus, beverages contribute positive health benefits, but they also may lower diet quality and increase risk of developing chronic diseases including obesity, type 2 diabetes, and CVD.

A number of published systematic reviews and meta-analyses have examined the specific relationship between SSB and chronic diseases. Consistent evidence in prospective cohort studies (PCSs) and randomized controlled trials (RCTs) within these articles report associations between SSB consumption and adiposity markers in children and/or adults.⁵⁻⁷ Similar associations also have been observed with respect to type 2 diabetes and CVD. However, given the discrepancy of findings and methodological limitations with some of the studies included in recent reviews, a few recent reviews have questioned the link between SSB and chronic disease.^{8,9} Understanding is limited with respect to whether selected beverages, such as milk, juice, or low- or no-calorie sweetened beverages (LNCSB) are associated with markers of adiposity in children and adults. Thus, this chapter takes a broad look at the effects of beverage consumption on multiple diet quality and health outcomes in children and adults.

Setting the Review Criteria

A critical first step in examining the scientific literature on beverage consumption and growth, size, body composition, and risk of overweight and obesity was to establish a definition for beverages and identify the specific beverage categories of interest. The Committee broadly defined beverages as any type of energy or non-energy-yielding drink consumed from a cup, glass, or bottle. Given this definition, soups and any other liquids or semi-solids that were not considered “drinks” were excluded. This definition does not include human milk, infant formula, or beverages consumed during complementary feeding, which are addressed in **Part D.**

Chapter 4: Duration, Frequency, and Volume of Exclusive Human Milk and/or Infant Formula Feeding and **Part D. Chapter 5: Foods and Beverages Consumed During Infancy and Toddlerhood**. The Committee classified beverages into the following categories: milk,

¹ For details, see data supplements that provide results of analyses conducted for the Committee, referenced as Beverages (Bev_DS) and Food Categories Sources (Cat_DS). These supplements can be found at <https://www.dietaryguidelines.gov/2020-advisory-committee-report/data-analysis>.

flavored milk, dairy drinks and substitutes, 100% juice, SSB, LNCSB, nutritional beverages, coffee and tea, plain water (tap or bottled), and flavored or enhanced water. Given that the focus of this chapter is on beverages as a “food category,” the Committee generally did not examine specific nutrients, compounds, and sensory and physical characteristics. One exception is the examination of the fat content of milk. Alcohol also was considered a beverage category, and this topic is discussed in **Part D. Chapter 11: Alcoholic Beverages**.

When assessing outcomes, the Committee distinguished “healthy growth” from “excessive growth” in children. Thus, weight status (prevalence or incidence of overweight or obesity), body mass index (BMI) and BMI z-scores, and body composition measures, such as waist circumference, body fat, and abdominal obesity, were considered to reflect “adiposity,” whereas height and lean mass were considered to reflect “healthy growth.” In adults, weight status (prevalence or incidence of overweight or obesity), BMI, and body composition measures, such as waist circumference, body fat, and abdominal obesity, were considered to be “markers of adiposity.” Sarcopenia was not included in this review.

The Committee also considered a number of factors that act as covariates or confounders when interpreting studies of beverage consumption. Of particular concern was adjustment for total energy intake. This is crucial, given that beverages might displace nutrient-dense foods or add excess energy to the diet. Further, although the Committee was unable to explore potential mechanisms linking beverage consumption and adiposity, considering adjustment for total energy intake allowed the Committee to determine whether beverages contribute to adiposity irrespective of the additional energy from the beverage. Alternately, when not controlling for total energy intake, effects could be attributed to the additional energy that the beverage provides to the total diet. Therefore, findings from analyses that did and did not control for energy intake were reviewed.

LIST OF QUESTIONS

1. What is the relationship between beverage consumption and achieving nutrient and food group recommendations?
2. What is the relationship between beverage consumption and growth, size, body composition, and risk of overweight and obesity?

METHODOLOGY

The Committee developed a data analysis protocol for Question 1 that described how the Committee would use data analyses to answer the question. The protocol included an analytic framework that described the overall scope of the analyses, including the population and type of analyses and data sources identified to answer the question. It also included the definitions of key terms.

This question relied on analysis of data from What We Eat in America (WWEIA), the dietary component of the National Health and Nutrition Examination Survey (NHANES). Existing data tables were used when available. In some cases, new analyses were conducted by the Data Analysis Team (DAT) to provide additional information, at the Committee's request. For example, the DAT conducted analyses by specific population groups such as infants and toddlers and women who are pregnant or lactating.

A description of the data analysis methodology is provided in **Part C. Methodology**, including more information on the data sources. Complete documentation of the data analysis protocol and the referenced results is available on the following website: [placeholder for site]. Below is a summary of the unique elements of the protocol developed to answer the question addressed in this chapter.

Data analyses outlined in the analytic plan focused on beverage contributions to food group intakes, as well as intakes of nutrients and other food components. Life stages from infancy through older adults and including women who are pregnant or lactating were considered. Dietary intake data were collected using 24-hour dietary recalls as part of WWEIA, NHANES. For the general population ages 2 years and older, the 2015-2016 cycle of data were examined. For infants and toddlers ages 6 to less than 24 months, WWEIA, NHANES 2007-2016 were combined. For women who are pregnant or lactating, as well as analyses describing current intakes, WWEIA, NHANES 2013-2016 were used.

Beverage categories specific to the data analyses are used to describe results in the summary of evidence. Discrete beverage categories are described as follows:

- **Milk:** Plain and flavored milk, other dairy drinks and milk substitutes (excludes milk or milk substitutes added to alcoholic beverages, coffee, tea, and/or foods such as cereal)
- **100% Juice:** 100% fruit and/or vegetable juice
- **Coffee and tea:** Regular and decaffeinated coffee or tea with additions such as milk, cream and/or sweeteners, and coffee and tea drinks, including ready-to-drink products that may contain added sugars.

- **Diet beverages:** Diet soft drinks, diet sports and energy drinks and other diet drinks that are low- and no-calorie-sweetened with 40 kcal or less per reference amount customarily consumed.
- **Sweetened beverages:** Energy-containing soft drinks, fruit drinks, and sports and energy drinks with added sugars that contain more than 40 kcal per reference amount customarily consumed. This category does not include flavored milks or coffees and teas with added sugars.
 - Soft drinks: Energy-containing drinks made with carbonated water.
 - Fruit drinks: Energy-containing fruit and/or vegetable drinks that are not 100% juice.
 - Sports and energy drinks: Energy-containing sports and energy drinks; nutritional beverages and protein and nutritional powders consumed with a beverage; smoothies and grain drinks.
- **Water:** Tap, bottled, flavored, carbonated, and enhanced/fortified water containing less than 5 kcal per reference amount customarily consumed.

Because data analysis and systematic review are different approaches to review the evidence, the presentation of the summary of evidence is organized differently below. In each case, however, the conclusion statements are informed by the evidence reviewed, as outlined in the protocol. The Committee took the strengths and limitations of the data quality and analyses into account in formulating conclusion statements. The grading process used for questions answered by the NESR systematic review methodology does not apply to questions using data analysis; therefore, data analysis conclusions were not graded.

Question 2 in this chapter was answered using a systematic review conducted with support from USDA's Nutrition Evidence Systematic Review (NESR) team.

NESR's systematic review methodology provided a rigorous, consistent, and transparent process for the Committee to search for, evaluate, analyze, and synthesize evidence. The Committee developed a systematic review protocol, which described how the Committee would apply NESR's methodology to answer the question. The protocol included an analytic framework and inclusion and exclusion criteria to guide identification of the most relevant and appropriate body of evidence to use in answering the question. The analytic framework outlined core elements of the systematic review (i.e., population; intervention and/or exposure and comparator (i.e., the alternative being compared to the intervention or exposure); and outcomes), and included definitions for key terms, key confounders, and other factors to be considered when reviewing the evidence. The inclusion and exclusion criteria were selected

before the literature review to operationalize the elements of the analytic framework, and specify what made a study relevant for the systematic review question.

Next, a literature search was conducted to identify all potentially relevant articles, and those articles were screened by two NESR analysts, independently, based on the criteria selected by the Committee. For each included article, data were extracted and risk of bias assessed. The Committee qualitatively synthesized the body of evidence to inform development of conclusion statements, and graded the strength of evidence using pre-established criteria for risk of bias, consistency, directness, precision, and generalizability. Finally, recommendations for future research were identified. A detailed description of NESR's systematic review methodology is provided in **Part C. Methodology**, including standard inclusion and exclusion criteria applied in many of the Committee's systematic reviews. Complete documentation of each systematic review is available on the following website: nesr.usda.gov/2020-dietary-guidelines-advisory-committee-systematic-reviews. Below is a summary of the unique elements of the protocol developed to answer the question addressed in this chapter.

For the systematic review on beverages and growth, size, body composition, and risk of overweight and obesity, the population of interest was children and adolescents (ages 2 to 18 years), adults (ages 19 to 64 years), and older adults (ages 65 years and older).

The intervention or exposure of interest was the type and amount of specific beverage consumption, including the following beverage types: milk (i.e., dairy milk and milk substitutes including flavored milk), 100% juice, LNCSB (e.g., diet soft drinks or diet sports and energy drinks), and SSB (i.e., beverages sweetened with various forms of added sugars). Studies were excluded if the intervention or exposure of interest was a nutrient added to a beverage (i.e., the beverage was the delivery mechanism for the exposure nutrient). Further, studies were excluded if the beverage of interest was not commercially available (e.g., experimentally manipulated beverages). Liquid supplements, alcoholic beverages, and soups also were excluded. Initially, the Committee planned to examine *all* types of beverages and beverage patterns. The Committee later revised the protocol to focus the review of evidence on beverages considered to be of greatest public health concern: milk, 100% juice, SSB, and LNCSB. Beverage categories that were not examined include: water, nutritional beverages, coffee and tea, plain water (tap or bottled), and flavored or enhanced water.

The comparator of interest was consumption of a different amount of the same beverage, including no consumption or versions of the beverage diluted with water. The comparison also could be water or the solid version of the beverage (relevant for juice, e.g., oranges vs orange juice). Two additional beverage-specific comparisons were assessed. For sweetened

beverages, a comparison of SSB and LNCSB was included. For milk, comparisons of dairy milk with different amounts of fat were included. Different types of beverages within a category were not compared (e.g., different types of 100% juice or different types of sweetener for LNCSBs). Initially, the comparator was described as different type or amount of beverage consumed (including no consumption or plain water as a control when appropriate) and different volume, nutrient content, sensory property, or physical form. However, to improve clarity, more directly answer the systematic review question, and focus on comparisons of greatest public health importance, the description of the comparator was updated to include different amount of the same beverage (including no consumption and versions diluted with water), beverage vs solid, beverage vs water, SSB vs LNCSB, and dairy milk with different amounts of fat. The description of the comparator also was updated to exclude studies comparing different beverage types.

Outcomes included measures of: body weight; weight-for-age; height; length/stature-for-age; BMI; BMI z-score; weight-for-length; body circumferences: head, arm, waist, thigh, neck; body composition and distribution (e.g., percent fat mass, percent fat-free mass). Outcomes also included incidence and prevalence of: underweight, failure to thrive, stunting, wasting, healthy weight, overweight, obesity.

When establishing inclusion and exclusion criteria, the Committee used standard NESR criteria for study design, publication status, language of publication, country, study participants, and health status of study participants. In addition, the Committee clarified that Mendelian randomization studies are eligible for inclusion by noting this study design specifically in the inclusion criteria. Studies were included if they were published from January 2000 to June 2019, with the exception of studies where the intervention or exposure was SSB and the comparator was different level of SSB or water, which were included if they were published from January 2012 to June 2019. This different publication date range criteria was applied to the review of SSB evidence because the 2015 Dietary Guidelines Advisory Committee reviewed evidence on the relationship between added sugars, including SSB, and body weight/obesity, published up to January 2012.¹ This Committee initially established an inclusion criterion that experimental studies must have a minimum duration of 8 weeks. However, this criterion was removed for consistency with other reviews addressing the same outcome.

REVIEW OF THE SCIENCE

Question 1. What is the relationship between beverage consumption and achieving nutrient and food group recommendations?

Approach to Answering Question: Data analysis

Conclusion Statements

Beverages are diverse in their contribution to food groups and dietary components. Selection of beverage choice can contribute positively to food groups currently consumed in amounts below recommendations (i.e., dairy, fruit) and nutrients that are under consumed (e.g., potassium, calcium, vitamin D). Beverages can also increase dietary components that exceed recommended limits (i.e., added sugars).

Plain fluid milk, plain calcium fortified soy beverage, and 100% juice contribute to meeting food group and nutrient needs without contributing energy from added sugars. Coffee, without additions of added sugars is a notable source of potassium for adults.

Beverages account for 13 to 16 percent of total daily energy intake in children and adolescents, 18 percent of total daily energy intake for adults ages 20 to 64 years, and 13 percent of total daily energy intake for adults ages 65 years and older. Beverages' contribution to added sugars intake is 32 percent for young children and 49 percent for adolescents. Among adults, beverages contribute 58 percent of added sugars intakes for adults ages 20 to 64 years and 35 percent of added sugars intakes for adults ages 65 years and older.

The top beverage sources of added sugars are regular soft drinks, fruit drinks, sports and energy drinks, smoothies, and coffee and tea inclusive of added sugars.

Summary of the Evidence

The following sections describe the results of data analyses conducted to answer Question 1. Additional details can be found in data supplements, referenced below as Beverages (Bev_DS).

The food group and food component contribution of beverages is diverse. Generally, beverages contribute to 2 food groups, dairy foods and fruit. Fluid cow milk and calcium-fortified soy beverages contribute to the dairy foods group. For each, an 8 oz portion of the beverage

contributes 1 cup equivalent (cup eq) to the dairy foods group. One cup of 100% fruit juice contributes one cup eq of fruit. Cow milk, calcium-fortified soy beverages, and 100% juice also may be added to, or be an ingredient in, beverages. Thus, other beverages may contribute to these food groups (e.g., coffee with cow milk added).

Beverage intakes, including the proportions of population groups consuming beverage types, are described in ***Part D. Chapter 1: Current Intakes of Foods, Beverages, and Nutrients***. For this question, the focus is on the contribution of beverages to intakes of energy, food groups, nutrients, and other food components, such as added sugars.

Infants and Toddlers Ages 6 to 24 Months

Older infants, ages 6 to 12 months, consume fluids predominantly through human milk and/or infant formula (Bev_DS). Approximately one-third of these infants consume some 100% fruit juice and nearly 60 percent drink plain water on a given day. Cow milk and sweetened beverages are reported for about 5 percent of infants. Other beverages are rarely consumed in this population. Excluding human milk and infant formula, whole milk accounts for 36 percent of energy consumed through beverages, 100% juice contributes 32 percent, and reduced-fat, low-fat, and fat-free milk accounts for 14 percent.

Toddlers, ages 12 to 24 months, consume a wider variety of beverage types. Together, all beverages account for 32 percent of total energy (371 kcal) intake among toddlers. More than half consume some 100% juice, which contributes 5 percent of total energy intake, 10 percent of carbohydrates, and 8 percent of potassium in their diets. A large proportion of toddlers have reported consumption of cow milk; 64 percent report whole milk and 23 percent report reduced-fat, low-fat, or fat-free milk on a given day. A very small proportion of toddlers have flavored milk or milk substitutes of any kind (6 percent and 5 percent, respectively). Cow milk is a source of energy and several nutrients that have been identified as underconsumed in this population, with whole milk providing 18 percent of total energy, 57 percent of vitamin D, 39 percent of calcium, and 25 percent of potassium in the diets of toddlers. Whole cow milk also contributes 36 percent of saturated fat in the diets of toddlers. Plain cow milk that is reduced-fat, low-fat, or fat-free is consumed by a smaller proportion of toddlers and contributes to similar food components as whole milk (e.g., vitamin D, calcium, potassium). Sweetened beverages (i.e., soft drinks, fruit drinks, and sports and energy drinks with added sugars) are consumed by 29 percent of toddlers and account for 3 percent of total energy intake and 27 percent of added sugars intake. They make very little contribution to other nutrient intakes.

Children

The volume of total reported daily beverage intakes is 31 fluid ounces (fl oz) for children ages 2 to 5 years, 38 fl oz for children ages 6 to 11 years, and 52 fl oz for children ages 12 to 19 years.³ The proportion of children with reported intakes of beverage categories other than water vary by age. More than half of children ages 2 to 5 years report consuming milk as a beverage (65 percent) on a given day. A significantly smaller proportion of children ages 6 to 11 years (53 percent) and 12 to 19 years (34 percent) consume milk as a beverage.³ The mean volume of milk reported is similar across age groups (12 to 13 fl oz). The reported intakes of sweetened beverages are significantly more common after age 5 years, while intake of 100% juice is significantly less common. Mean volume of 100% juice is significantly lower for children ages 6 to 11 years (7 fl oz) when compared to other age groups (10 fl oz). Mean volume of sweetened beverages is significantly and incrementally higher by age group; 9 fl oz for ages 2 to 5 years, 13 fl oz for ages 6 to 11 ages, and 18 fl oz for ages 12 to 19 years. A similar trend is seen with sweetened beverages' percent contribution to total beverage energy. Among children ages 2 to 5 years, sweetened beverages comprise 19 percent of total energy from beverages, compared to 37 percent and 44 percent of total beverage energy for children ages 6 to 11 years and ages 12 to 19 years, respectively.

Differences by race and ethnicity are apparent, especially for intakes of sweetened beverages.⁴ Non-Hispanic Black children have the highest intakes of sweetened beverages and Asian children have the lowest intakes. Within the category of sweetened beverages, fruit drinks in particular are reported by non-Hispanic Black children more frequently than by any other race or ethnic group. In addition, 100% juice is reported by significantly more Hispanic (34 percent) and non-Hispanic Black (33 percent) than non-Hispanic White (25 percent) or Asian (23 percent) children. Fewer Hispanic (78 percent) and non-Hispanic Black (76 percent) children report water than did non-Hispanic White (86 percent) or Asian children (93 percent). Milk is consumed by a smaller proportion of non-Hispanic Black (34 percent) children than children of other race/ethnic groups (45-56 percent).

Beverages account for 13 to 16 percent of mean energy intake.⁴ Beverages, namely milk and 100% juice, account for nearly 50 percent of vitamins C and D for children ages 2 to 5 years and about 40 percent of these vitamins for older children. Approximately 20 percent to 30 percent of calcium, potassium, and magnesium come from beverages as well. Beverages, mainly sweetened beverages, account for 32 percent of added sugars for ages 2 to 5 years, 39 percent for ages 6 to 11 years, and 49 percent for ages 12 to 19 years. For younger children, nearly half of energy from beverages comes from milk, whereas 44 percent of energy from

beverages comes from sweetened beverages and 13 percent comes from coffee and tea, inclusive of additions.

Adults

The volume of total reported daily beverage intake is 88 fl oz for adults ages 20 to 64 years, and males have a significantly higher intake compared to females (about 17 fl oz/day difference) (Bev_DS). For both males and females, the mean daily intake of water (53 fl oz/d) is greater than the consumption of any other beverage type. About 50 percent of adults ages 20 to 64 years report consuming sweetened beverages on a given day, while 15 percent report consuming diet beverages. Sixty-four percent of adults report consuming coffee or tea. Consumption of these beverage types ranges from 22 to 27 fl oz/d. Males consume significantly higher daily volumes of coffee or tea (5 fl oz difference) and sweetened beverages (7 fl oz difference) compared to females; a significant difference in the consumption of diet beverage consumption is not seen between sexes (Bev_DS). In this age category, only 17 percent report consuming milk, milk drinks, and milk substitutes with mean daily intakes of 16 fl oz for males compared to 12 fl oz for females.

The volume of total reported daily beverage intake is 66 fl oz for adults ages 65 years and older, which is 22 fl oz lower than the daily consumption among younger adults (Bev_DS). Similar to younger adults ages 20 to 64 years, the mean daily intake of water in older adults (39 fl oz) is greater than the consumption of any other beverage type. Coffee or tea, sweetened beverages, and diet beverages also are consumed in volumes of 14 fl oz/d or greater. Eighty-one percent of adults ages 65 years and older report consuming coffee or tea, whereas approximately 30 percent or less report consuming sweetened beverages and diet beverages (29 percent and 18 percent, respectively). In this older age category, a slightly higher percentage report consuming milk, milk drinks, and milk substitutes compared to younger adults (21 percent vs 17 percent). Likewise, a higher percentage of older adults report consuming 100% juice, compared to younger adults (24 vs 15 percent) though mean intake in fluid ounces is similar for older and younger adults, at 12 and 9 fl oz on a given day, respectively (Bev_DS).

In adults ages 20 to 64 years, beverages contribute 18 percent of the total daily intake of energy (Bev_DS). The contribution of beverages is significantly less in females at 17 percent compared to 20 percent in males. Beverage's contribution to intake of added sugars is 54 percent for females and 61 percent for males (Bev_DS). In adults ages 20 to 64 years, beverages also contribute about 30 percent to the daily intake of calcium and vitamin D and about 20 percent to the daily intake of potassium (Bev_DS). For both males and females,

beverage consumption in adults ages 20 to 64 years contributes 32 percent and 26 percent to the total daily intake of fruit and dairy equivalents, respectively. The contribution of beverages to the total daily intake of grain, oil, vegetables, and protein equivalents is 1 percent or less (Bev_DS).

In adults ages 65 years and older, beverages contribute 13 percent to the total daily intake of energy, 27 percent less than the contribution for adults ages 20 to 64 years (Bev_DS). The percent of added sugars coming from beverages is also lower among older adults when compared to younger adults. Older adult males consume 37 percent and females consume 33 percent of total added sugars from beverages (Bev_DS). Older adults had no significant sex differences in these contributions. Similar to younger adults, the consumption of beverages contributes approximately 30 percent or more to the daily intake of riboflavin, vitamin C, vitamin D, calcium, and caffeine (Bev_DS). For both males and females, beverage consumption in adults ages 65 years and older contributes 25 percent and 30 percent to the total daily intake of fruit and dairy equivalents, respectively. This contribution is slightly lower for fruit equivalents and slightly higher for dairy equivalents as compared to younger adults. The contribution of beverages to the total daily intake of grain, oil, vegetables, and protein equivalents is 3 percent or less (Bev_DS).

Women Who Are Pregnant or Lactating

The volume of total reported daily beverage intake for women ages 20 to 44 years who are not pregnant or lactating and those who are pregnant and those who are lactating is 78 fl oz, 79 fl oz and 88 fl oz, respectively (Bev_DS). Regardless of pregnancy or lactation status, the mean daily intake of water (53 to 65 fl oz/d) is greater than the consumption of any other beverage type. Eighty-five percent of women ages 20 to 44 years who are pregnant, and 94 percent of those who are lactating consume water on a given day. Forty-three percent of women who are pregnant consume coffee or tea, with mean reported intake of 18 fl oz on a given day. A higher percentage of women who are lactating (60 percent) report coffee or tea consumption, with mean reported intake of 23 fl oz. Diet beverages are the least frequently consumed non-alcoholic beverage among women ages 20 to 44 years who are pregnant or lactating (7 and 9 percent report consumption, respectively). The percentage of women who are pregnant or lactating who consume milk, milk drinks, and milk substitutes (33 percent and 26 percent, respectively), is greater than the percentage of women who are not pregnant or lactating who consume these beverages (14 percent), though the volumes consumed are similar (Bev_DS).

In women who are neither pregnant nor lactating, beverages contribute nearly 20 percent to total energy intake (Bev_DS). Beverages contribute slightly less to total energy intake for women who are pregnant or lactating (15 percent and 9 percent). For women who are pregnant and those who are lactating, beverages contribute 31 and 29 percent to daily intakes of calcium; 19 and 17 percent to intakes of potassium; 23 and 19 percent to intakes of magnesium; and 36 and 26 percent to intakes of vitamin D, respectively (Bev_DS).

For women who are pregnant, beverage consumption contributes 21 percent and 35 percent to the total daily intake of fruit and dairy equivalents, respectively (Bev_DS). Among women who are lactating, the contribution of beverages is slightly higher for the fruit equivalent (28 percent), and slightly lower for the dairy equivalent (28 percent). Beverages contribute slightly more to total intake of fruit equivalents (32 percent), and slightly less to dairy equivalents (24 percent) for women who are neither pregnant nor lactating as compared to women of the same age who are pregnant or lactating. Beverages contribute 48 percent to total added sugars intake among women who are pregnant and 31 percent among women who are lactating. Irrespective of pregnancy or lactation status, the contribution of beverages to the total daily intake of grain, oil, vegetables, and protein equivalents is 2 percent or less.

To access the data analyses referenced above, visit:

<https://www.dietaryguidelines.gov/2020-advisory-committee-report/data-analysis>

Question 2. What is the relationship between beverage consumption and growth, size, body composition, and risk of overweight and obesity?

Approach to Answering Question: NESR systematic review

Conclusion Statements and Grades

Sugar-Sweetened Beverages

Moderate evidence indicates that higher sugar-sweetened beverage intake is associated with greater adiposity in children. Grade: Moderate

Limited evidence suggests that higher sugar-sweetened beverage intake is associated with greater adiposity in adults. Grade: Limited

Insufficient evidence is available to determine the relationship between sugar-sweetened beverages compared with low- and no- calorie sweetened beverages on adiposity in children. Grade: Grade Not Assignable

Limited evidence suggests no association between sugar-sweetened beverages compared with low- and no- calorie sweetened beverages on adiposity in adults. Grade: Limited

Low and No-Calorie Sweetened Beverages

Limited evidence suggests no association between low- and no-calorie sweetened beverage consumption and adiposity in children. Grade: Limited

Limited evidence suggests that low- and no- calorie sweetened beverage consumption is associated with reduced adiposity in adults. Grade: Limited

Milk

Limited evidence suggests that milk intake is not associated with adiposity in children. Grade: Limited

Insufficient evidence is available to draw a conclusion about the relationship between the type of milk (i.e., milk fat content, flavor) and adiposity in children. Grade: Grade Not Assignable

Limited evidence suggests that higher milk intake is associated with a greater increase in height compared to lower intake in children. Grade: Limited

Limited evidence suggests that milk intake is not associated with adiposity in adults. Grade: Limited

100% Juice

Limited evidence suggests 100% juice intake in children is not associated with adiposity or height in children. Grade: Limited

Limited evidence suggests 100% juice consumption is not associated with measures of adiposity in adults. Grade: Limited

Summary of the Evidence

Sugar-Sweetened Beverages

- Seventy-six studies were identified through a literature search from June 2012 to June 2019 were included in this systematic review.¹⁰⁻⁸⁵ Studies were synthesized based on comparator (no/different amount of SSB or LNCSB) and age of participants (children or adults).
 - SSB consumption compared to different amounts or water
 - Children: 46 articles
 - RCTs: 2 articles
 - Non-randomized controlled trials (non-RCTs): 1 article
 - PCSs: 43 articles
 - Adults: 27 articles
 - RCTs: 3 articles
 - Non-RCTs: 1 article
 - PCSs: 23 articles
 - SSB consumption compared to LNCSB
 - Children: 2 articles
 - RCTs: 2 articles
 - Adults: 6 articles
 - RCTs: 5 articles
 - PCSs: 1 article
- In studies examining SSB intake in children, the majority of studies (about 80 percent) reported a significant effect or association between SSB intake and adiposity. However, this was not always consistent within studies that reported multiple outcome measures. Risk of bias and generalizability also were of concern.
- In studies examining SSB intake in adults, the majority of studies (about 70 percent) reported a significant effect or association between SSB intake and adiposity. However, this was not always consistent within studies that reported multiple outcome measures. The 3 included RCTs raised significant risk of bias concerns related to the methodology, particularly around the comparator, and concerns with generalizability.
- Two articles from 1 RCT addressed the relationship between SSB compared to LNCSB intake in children and the evidence was insufficient to draw a conclusion.
- The studies comparing intake of SSB and LNCSB in adults were inconsistent in findings and in methodology. Of the 5 RCTs, 3 did not find a significant difference between groups.

However, 2 of these studies had small sample sizes and may have been underpowered. The 2 studies that did report a significant effect did not show a significant effect across all reported outcomes. For example, 1 study reported differences based on the type of sweetener within LNCSB and the other did not find a difference in weight or BMI between groups, but did report that those who consumed LNCSB were more likely to achieve 5 percent weight loss.

Low- and No-Calorie Sweetened Beverages

- Thirty-seven studies identified through literature search from January 2000 to June 2019 were included in this systematic review, which examined the relationship between LNCSB and outcomes related to growth, size, body composition, and risk of overweight and obesity.^{29,34-36,38,40,43,53,55,56,58,59,65,67,71,77,81,82,86-104}
 - Of the 17 articles in children, all were PCSs.
 - Of the 20 articles in adults, 6 were from RCTs and 14 were from PCSs.
- In studies examining LNCSB intake in children, the majority of studies (about 75 percent) reported no association for the main outcome measure(s) of adiposity among the study populations. The remaining studies had mixed associations and raised methodologic concerns.
 - 3 articles had findings of increased adiposity measures.
 - 1 article had findings of decreased adiposity measures.
 - 1 article reported only height-related outcomes.
- The body of evidence from children had several limitations:
 - Inadequate adjustment for confounders
 - Inconsistency in methods for assessing beverage intake
 - Short study duration
 - High attrition
- In studies examining LNCSB intake in adults, the majority of studies (72 percent) reported a significant effect or association between LNCSB intake and adiposity. However, this was not always consistent within studies that reported multiple outcome measures.
 - One well-designed RCT and 2 large PCSs reported an association between LNCSB and reduced adiposity.
- The body of evidence from adults had several limitations:
 - Experimental studies had short study duration, no assessment of compliance, and

difference in comparators.

- Cohort studies had confounding, difference in assessment methods, poor generalizability, and high attrition.

Milk

- The body of evidence includes 62 articles: 30 articles on children and 32 articles on adults.^{29,30,38,39,43,49,58,59,65,79,81-83,86-88,92,94,98,100,104-145} Of the evidence on children, 4 articles were from RCTs and 26 articles were from PCSs. Of the evidence on adults, 7 articles were from RCTs; 24 articles were from PCSs; and 1 article used a Mendelian randomization design.
- The majority of the findings for measures of adiposity in children were not significant. The few findings that were significant were not consistent in direction.
- Four studies reported on height, a measure of healthy growth in children, as an outcome: 3 cohort studies reported a significant positive association between milk intake and height in children, and 1 RCT found no effect of milk intake on height compared to drinking water though this study's duration was only 12 weeks.
- Seven cohort studies specifically examined types of milk (i.e., milk fat levels, flavored milk) and adiposity outcomes in children. However, the results were not consistent.
- The majority of the studies in adults found no significant association between milk intake and adiposity. The studies had some significant associations but these were inconsistent in direction.
- The body of evidence from children and adults had several significant limitations, including lack of specificity and consistency in definition of the exposure, the use of non-validated methods for assessing beverage intake, uncontrolled confounding, and inconsistencies in findings.

100% Juice

- 42 articles examined the relationship between 100% juice intake and outcomes related to growth, size, body composition, and risk of overweight or obesity: 23 articles on children and 19 articles on adults.^{14,22,29,30,34,38,39,42,43,58,59,65,81,83,86-88,94,98,100,104,114,115,118,125,136,146-161} Of the evidence in children, 1 article was from an RCT and 22 articles were from PCSs. Of the evidence on adults, 4 articles were from RCTs; 1 article from a non-RCT; and 14 articles were from PCSs.

- Evidence in children:
 - The 1 RCT and the majority of the higher quality PCSs found no statistically significant relationship between 100% juice intake and adiposity.
 - The few studies that were significant were not consistent in direction.
 - The evidence in children was limited by lack of clarity in defining the juice exposure, inconsistent quantification of juice consumption, inconsistent measures of adiposity, lack of evidence from stronger study designs, and inadequate adjustment for confounders.
- Evidence in adults:
 - The 4 RCTs and 1 non-RCT found no statistically significant relationship between 100% juice intake and adiposity.
 - The PSCs found inconsistent evidence depending on the specific measure of adiposity. For example, roughly half of the studies (n=4) found that greater consumption of 100% juice intake was related to a greater increase in weight, while the others (n=3) found no significant relationship. Studies examining waist circumference were more consistent, with 5 of the 6 studies finding no significant association with 100% juice intake. Further, all studies (n=3) examining body fat or prevalence of (abdominal) obesity found no significant associations with 100% juice intake.
 - The evidence from the RCTs and non-RCT were limited by the short durations and small sample sizes.
 - The evidence from the PCSs were limited by the single measurement of the exposure, reliance on self-reported outcome data, inadequate adjustment for confounders, and limited generalizability of the experimental data.

For additional details on this body of evidence, visit: [nesr.usda.gov/2020-dietary-guidelines-advisory-committee-systematic-reviews/beverages-and-added-sugars-subcommittee/beverages-growth-size-body-composition-obesity](https://www.nesr.usda.gov/2020-dietary-guidelines-advisory-committee-systematic-reviews/beverages-and-added-sugars-subcommittee/beverages-growth-size-body-composition-obesity)

DISCUSSION

Beverages serve multiple important roles in the diet. Foremost, they help to meet hydration needs. Declines of only 2 percent of body water result in compromised cognitive and physical performance and this may occur rapidly, necessitating regular fluid intake.¹⁶²⁻¹⁶⁵ Approximately 70 percent of drinking is peri-prandial, stemming largely from the ability of beverages to facilitate swallowing. The Committee examined data on the role of beverage consumption in achieving

nutrient and food group recommendations. Selected beverages contribute important nutrients (e.g., protein, minerals, vitamins) and thereby enhance diet quality. Some beverages inherently contain energy or may have energy-yielding substances added to them (e.g., addition of milk or sugar to coffee) and thereby serve as a source of energy. Moreover, water and components in beverages may influence digestive, absorptive, and metabolic processes. Drinking beverages is also a widely-practiced social behavior that reflects and reinforces cultural norms and contributes to quality of life. Although these potentially beneficial roles are commonly accepted, questions also have arisen about whether the types, amounts, and frequency of beverage consumption may contribute to health complications, most notably, overweight and obesity. Hence, the Committee was asked to review the evidence pertaining to the relationship between beverage consumption and growth, size, body composition, and risk of overweight and obesity for children as well as adults.

For this analysis, outcome variables for children included body weight (prevalence or incidence of overweight or obesity), BMI and BMI z-scores, and body composition measures, such as waist circumference and body fat. Height also was considered for children. These indices permitted differentiation between normal and excess weight gain. For adults, the outcome measures included weight status (prevalence or incidence of overweight or obesity), BMI, and body composition measures, such as waist circumference, body fat, and abdominal adiposity. Very limited data were available on each particular outcome. Consequently, reports containing data on any of these outcomes were included and the outcome was collectively termed “adiposity.”

The motivation to evaluate the contribution of beverages to unhealthy weight gain stems largely from recognition that despite being energy dilute (i.e., low energy:weight ratio), beverages contribute a considerable amount of energy to the diet due to their high level of intake. At the time the *2015-2020 Dietary Guidelines for Americans* were developed, beverages accounted for 19 percent of total energy intake in the U.S. population of which SSB contributed 35 percent.¹ Since that time, the energy derived from beverages has declined, but remains high. Currently, beverages account for 13 to 16 percent of total daily energy intake in children and 18 percent of total daily energy intake in adults ages 20 to 64 years, of which SSB contribute about 32 percent. This has led to an observation that SSB, in particular, are important contributors to the positive energy balance driving weight gain and overweight and obesity. However, this observation is confounded by sugar as an energy source as well as a metabolic and behavioral stimulus. Body weight change is driven primarily by total energy balance and, at the metabolic level, the source of the energy may hold limited importance. Comparisons between diets varying

in energy source reveal more similarity than differences in effect.¹⁶⁶ SSB are targeted for moderation because they provide little nutrient value besides energy and simple carbohydrate. SSB may evoke a weaker energy compensation response compared to solid foods, so are more apt to add to, rather than displace, other energy sources.¹⁶⁷ Other beverages, such as milk and 100% juices, are more nutrient-dense and thus play an added role in health promotion and disease prevention.

The Dietary Reference Intake (DRI) for water is set as an Adequate Intake (AI) level to “...prevent deleterious, primarily acute, effects of dehydration, which include metabolic and functional abnormalities”.¹⁶⁸ Estimates of water consumption by children (ages 4 to 13 years)¹⁶⁹ and adults (ages 20 years and older)¹⁷⁰ have been published using NHANES 2005-2010 data. Considering all sources water from beverages and foods, tap and bottled contributed 25 percent to 30 percent of dietary water intake among children and 30 percent to 37 percent of dietary water intake among adults. At least 75 percent of children, 83 percent of women and 95 percent of men ages 71 years and older have intakes below the AI values that were established by the Institute of Medicine, Food and Nutrition Board based on median total water intakes in the United States for each age group. More recent NHANES 2013-2016 data show on a given day, adults consume an average of 53 fl oz of water (1.6 liters) with average intake much lower among older adults (39 fl oz or 1.1 liters). The AI for these groups is 3.7 liters per day for men and 2.7 liters per day for women, which may be obtained from multiple sources (including foods and many types of beverages). Thus, water itself as a beverage currently represents between 30 percent and 59 percent of the AI in these groups.

Although these data question the adequacy of hydration status in segments of the population, they cannot be viewed as a basis for assigning risk for health complications because adequate hydration can be achieved over a wide range of intake levels in the setting of normal renal function.¹⁶⁸ Additionally, water needs may be met by intake of many sources (i.e., other beverages and foods). Plain water has been recommended to displace other energy-yielding beverages in the diet to dilute the energy density of the diet, reduce total energy intake, and aid weight management.¹⁷¹ The success of this strategy has not been established and warrants further study, as described in **Part E. Future Directions**. The Committee did not review evidence on water intake and adiposity because of concerns about the adequacy of estimates of water ingestion. Methods to accurately quantify water intake are needed.

Different beverages contribute varying levels of energy and nutrients that affect diet quality. However, diet composition may not just reflect the nutrient profile of ingested beverages themselves. Beverages also may modify food choices with variable impact on diet quality. An

improved understanding of such a secondary effect will be important for assessing the role of beverages in a healthy diet (see **Part E. Future Directions**).

The Committee assessed the strength of evidence based on methodologic quality and the uniformity of the evidence as determined by consensus of findings across studies. Where methodologic quality was strong, greater weight was assigned to RCTs compared to PCSs. Agreement between the 2 study designs permitted stronger conclusions. PCSs were especially limited when the estimate of intake was obtained only at baseline and used to characterize usual intake over the duration of the, often multiple year, follow-up period. Such an approach fails to account for individual and population-level changes in ingestive behaviors over time.

Sugar-sweetened Beverages

Sweetened beverages, not including coffee and tea with their additions, account for approximately one-third of total beverage consumption and contribute approximately 30 percent, 50 percent, and 60 percent of added sugars to the diet of young children, adolescents, and adults, respectively. Because of this large contribution, they may be a marker of added sugars intake. The 2015 Committee reviewed the evidence on added sugars and health outcomes up to 2012 and found that intake of added sugars from food and/or SSB was associated with excess body weight in children and adults.¹ However, the vehicle by which added sugars are ingested may have a substantive impact on various outcomes. For this reason, the 2020 Committee decided to focus on the unique question regarding the effects of SSB on health outcomes rather than analyzing the data as an extension of the findings from the 2015 analysis of added sugars, including foods and SSB. For analysis, the evidence was partitioned into studies examining the effects of ingestion of SSB with the comparator of water or a different amount of SSB as well as studies of SSB vs LNCSB. Effects in children and adults were assessed separately. Where the comparator was water or different level of SSB consumption in children (46 studies), the evidence included only 2 RCTs and 2 non-RCTs. For adults, only 3 of the 27 studies reviewed were RCTs and 1 was a non-RCT.

Findings on SSB intake in children showed marked uniformity, with about 80 percent indicating a positive association between intake and at least 1 marker of adiposity. However, the evidence varied across the component indices of adiposity within and across studies and the risk of bias and generalizability of findings were of concern. Thus, the conclusion was: Moderate evidence indicates that higher sugar-sweetened beverage intake is associated with greater adiposity in children. Findings for adults were similar, but weaker, with about 70 percent of studies noting a positive association between SSB intake and at least 1 marker of adiposity.

This was tempered by concerns about the risk of bias and generalizability. Hence the conclusion was: Limited evidence suggests that higher sugar-sweetened beverage intake is associated with greater adiposity in adults.

Low- and No-calorie Sweetened Beverages

The 2015 Committee indicated that evidence was insufficient (due to a paucity of data) to recommend the use of low- or no-calorie sweeteners (LNCS) as a strategy for long-term weight loss and weight maintenance. Because the long-term effects of LNCS were considered uncertain, the 2015 Committee concluded that those sweeteners should not be recommended for use as a primary replacement or substitute for added sugars in foods and beverages. Additional evidence has become available since that report and was reviewed by the 2020 Committee to examine the role of LNCSB on growth, size body composition, and risk of overweight and obesity. The concern about the use of LNCSB for weight management has multiple dimensions. One relates to the safety of these compounds. This was not an issue considered by this Committee. However, the World Health Organization, U.S. Food and Drug Administration, European Food Safety Authority, and other regulatory bodies have issued guidance that the commercially available LNCS are safe when consumed in moderation.¹⁷² The question of whether and in what direction and magnitude LNCSB may alter food choice and, as a consequence, diet quality, was also outside the scope of the present analysis. This is an issue of considerable importance that warrants future attention. This review focused on the role of LNCSB on adiposity.

Thirty-seven articles published between January 2000 and June 2019 were included in the systematic review. All 17 articles pertaining to children were PCSs and many had methodologic limitations (e.g., imprecise measurement of beverage intake, short study duration, high attrition, inadequate adjustment of confounding variables). Seventy-five percent (12 studies) reported no association between LNCSB consumption and the main study outcome among the entire study population, and the remaining 5 studies included mixed findings. In the absence of RCTs and with a predominance of null findings, the conclusion reached was that: Limited evidence suggests no association between LNCSB consumption and adiposity in *children*. The paucity of a strong evidence base is problematic for setting policy on use of these compounds to manage body weight in children because of the high prevalence of overweight and obesity in this age group¹⁷³ and the increasing presence of these beverages in the food supply.¹⁷⁴

The literature search meeting the eligibility criteria for adults yielded 6 RCTs and 14 PCSs. Seventy-five percent (16 articles) indicated a significant association between LNCSB intake and

adiposity. However, effects were not consistent across the component adiposity indices, the studies had substantive methodological limitations, and the 1 RCT and 2 PCSs viewed as methodologically strong found no association between LNCSB intake and adiposity.

Nevertheless, the conclusion reached was: Limited evidence suggests that LNCSB consumption is associated with reduced adiposity in *adults*. The studies reviewed in adults and children did not provide evidence that LNCSB promote weight gain or adiposity.

Taken together the current review is broadly consistent with findings from the 2015 Committee. However, recognizing that: a) mean responses may not reflect individual responses, b) robust, effective tools to manage body weight are lacking, c) individuals with overweight or obesity are at elevated risk of multiple health complications, and d) multiple national regulatory bodies agree that LNCS can be used safely, the Committee recommends these food ingredients be considered as an option for managing body weight.

Low- and No-calorie Sweetened Beverages vs Sugar-Sweetened Beverages

The role of LNCSB vs SSB on indices of body weight has been the topic of multiple meta-analyses in recent years. The 2 largest data sets differed (by age of participants in one and outcome measure in the other) and had only partial overlap in included studies.^{175,176} Nevertheless, they yielded similar findings. PCSs revealed no association or a slight positive association between LNCSB vs SSB and BMI, but not waist circumference, while the RCTs consistently indicated LNCSB vs SSB consumption was associated with lower adiposity. However, many of the studies included in these meta-analyses did not meet the eligibility criteria established in the Committee's systematic review. In the Committee's review, the evidence was derived primarily from RCTs (2/2 for children; 5/6 for adults). The 2 reports in children were based on a single study. Hence, the Committee determined that the evidence was insufficient to evaluate the effects of SSB vs LNCSB in children.

For adults, 3 RCTs reported no significant differences in adiposity outcomes in comparisons between SSB and LNCSB consumption. However, limited sample sizes in 2 of these studies left open questions about the adequacy of statistical power. The remaining 2 RCTs yielded mixed findings. One study revealed differences based on type of LNCS, a contrast not examined by any other study. Consequently, the conclusion was: Limited evidence suggests no association between sugar-sweetened beverages compared with low- and no- calorie sweetened beverages on adiposity in adults.

Given the high level of consumption of SSB and concern about their contribution to positive energy balance, and the widespread use of LNCSB as a potential approach to mitigate this

outcome, resolution of this question about substituting LNCSB for SSB to manage body adiposity remains a high priority.

Milk

Views on the role of milk in a healthful diet are strongly-held. They range from strongly critical to strongly supportive and are based on diverse criteria, including environmental sustainability, animal welfare, allergenicity, prevalence of lactose intolerance, nutrient density, disease risk, and weight management. In adults, the role of milk in adiposity was the sole focus of this review. For this beverage category, indices of growth (height and lean body mass) also were considered for children. Additionally, potential differential effects of milk varying in flavor and fat content were explored only in children.

Based on the analytical model, the systematic literature review yielded 62 articles; 30 pertaining to children and 32 on adults with a predominance of PCSs. Studies in children included 4 RCTs and 25 PCSs, while those in adults included 7 RCTs, one based on a Mendelian randomization design, and 24 PCSs. For children, studies examining healthy growth were synthesized separately from studies examining adiposity.

One RCT assessed milk intake and height in children and reported no association, but it was only of 12 weeks duration, limiting its power to detect such changes. The 3 available PCSs indicated a positive association between milk intake and height. As a result, the conclusion was: Limited evidence suggests that higher milk intake is associated with a greater increase in height compared to lower intake in children.

With respect to adiposity outcomes in children, findings from 1 RCT indicated a positive association. However, the result appeared to reflect a reduction in energy intake by the water intake comparator group, and the single additional RCT reported no association. The 4 PCSs reported largely null findings on overweight and obesity. Fifteen of 16 reports indicated a non-significant association between milk intake and BMI-Z score or BMI and 4 PCSs yielded weak and largely non-significant (3 of 4 studies) associations with body fat or waist circumference. The uniformity of these observations led to the conclusion: Limited evidence suggests that milk intake is not associated with adiposity in children.

Seven PCSs provided evidence on variations in milk composition and adiposity in children, with 6 contrasting graded concentrations of fat and one manipulating flavor. With only a single study addressing the relationship between flavored milk intake and adiposity, no conclusions could be reached. Studies comparing responses to ingestion of milk varying in fat content

yielded mixed findings across component adiposity outcomes and inconsistent findings across studies. Hence, the conclusion was: Insufficient evidence is available to draw a conclusion about the relationship between the type of milk (i.e., milk fat content, flavor) and adiposity in children.

In adults, the RCTs and PCSs yielded mixed findings across component adiposity outcomes and inconsistent findings across studies. This body of evidence included studies of substantive sample size and study duration, strengthening the confidence placed in their findings. The uniformity of findings led to the conclusion: Limited evidence suggests that milk intake is not associated with adiposity in adults.

100% Juice

Analysis of juice consumption and adiposity was limited to studies of 100% juice and did not differentiate between types of fruit or vegetable juice. Forty-two studies (23 in children and 19 in adults) meeting inclusion criteria were evaluated. Only 1 RCT was included for the analysis in children and only 4 RCTs and 1 non-RCT were included for the analysis in adults. Generally, the literature evaluated was of limited quality due to lack of consistency in describing the juices under study, how intake was quantified, and measures of adiposity. In addition, many studies inadequately adjusted for possible confounders.

The RCT and the majority of PCSs related to children reported no significant associations between 100% juice intake and component indices of adiposity. Those that did indicate significant findings were inconsistent across the adiposity indices and studies. This led to the conclusion: Limited evidence suggests 100% juice intake in children is not associated with growth, size, body composition, or risk of overweight or obesity in children.

The RCTs and non-RCT examining the relationship between 100% juice intake and adiposity in adults reported non-significant associations. The PCS evidence yielded inconsistent results, though the studies showed greater consistency for waist circumference (5 out of 6 studies) and measures of body fatness (3 out of 3 studies) finding no significant association. The RCTs had limited sample sizes and the PCSs typically included only a single measure of intake at baseline, had limited generalizability, and inadequately adjusted for possible confounders. Thus, the conclusion was: Limited evidence suggests 100% juice consumption is not associated with measures of adiposity in adults.

SUMMARY

The relationship between beverage consumption and diet quality has been explored previously, but this is the first time that a Dietary Guidelines Advisory Committee has directly examined the relationship between beverage consumption and health outcomes related to growth, size, body composition, and risk of overweight and obesity. Given that beverages vary in energy content, energy sources and nutrient composition, separate analyses were conducted on different categories of beverages (i.e., SSB, LNCSB, milk, 100% juice).

All beverages contribute to hydration needs. The degree to which hydration is a problem in segments of the population is an open question. Many beverages (e.g., milk and 100% juice) are nutrient-rich and contribute substantively to attainment of recommended intake goals. Beverages in the milk and 100% juice categories were not associated with indices of adiposity, but the strength of the evidence to evaluate this outcome was limited. Thus, when nutrient-rich beverages are incorporated into the diet, it will be important to be mindful of their contribution to total energy intake. On the other hand, SSB contribute the highest percent of energy from beverages to the diet but typically contribute very little toward meeting nutrient and food group recommendations. Among the beverages examined in the NESR systematic review, only SSB intake was associated with adiposity and this held in both children and adults. The evidence was viewed as moderate for children and limited for adults. Because of their low nutrient/energy content ratio and the high prevalence of overweight and obesity in the population, it is important to continue encouraging only limited intake of this class of beverages. Importantly, the influence of intake of these beverages on food intake was not evaluated so understanding of their impact on total diet quality remains incomplete.

The effects of LNCSB on adiposity outcomes was also assessed. No significant association was observed between consumption of beverages containing these sweeteners and adiposity outcomes in children, but their intake was associated with reduced adiposity in adults. Again, the evidence base used to draw these conclusions was limited, but viewed as sufficient to acknowledge such beverages may be a useful aid in weight management in adults. The role beverages play in diet quality and energy balance varies across the life span so recommendations should be tailored appropriately.

Lastly, beverage patterns, defined as the quantities, proportions, variety or combinations of different beverages in the diet, were not examined by the 2020 Dietary Guidelines Advisory Committee due to a lack of available literature. This Committee's examination of individual beverages of public health importance lays the foundation for the future examination of overall beverage patterns and highlights the need for additional research in this area. Furthermore, due

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to time constraints, not all beverage types were evaluated. Each type contains different components (e.g., energy, nutrients, carbonation, flavors, phytochemicals) and is consumed under different conditions. Thus, the implications of each for growth, size, body composition, and risk of overweight and obesity has not been fully explored by this Committee. Beverage intake behaviors, such as the predominant time of day of use, frequency of ingestion, typical and range of portion sizes, and whether they are consumed alone or in association with foods, are also important factors to consider when developing use guidelines. Finally, critical to a full understanding of the role of beverages in health will be determination of the relative importance of their physical form vs nature of the energy and components they contain. That is, do the form of food (solid, liquid) and mode of ingestion (e.g., drunk, spoon delivery) hold unique implications for health? This leaves several areas for additional research and consideration by future Dietary Guidelines Advisory Committees, which are further discussed in **Part E. Future Directions**.

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PART D. CHAPTER 11: ALCOHOLIC BEVERAGES

INTRODUCTION

Alcohol consumption in the United States has increased during the past 20 years, and 41 states exceed Healthy People 2020 limits for per capita alcohol consumption.^{1,2} Fifty-six percent of adults ages 21 years and older report past-month alcohol consumption, and nearly half of current drinkers across most age categories report past-month binge drinking.³ Binge drinking itself has increased, including among middle- and older-aged adults,^{4,5} as has mortality from fully alcohol-attributable causes of death, including alcoholic liver disease.⁶ Other than energy (i.e., calorie) intake, alcohol provides little nutritional value. Among U.S. adults, alcohol accounts for approximately 5 percent of energy intake, or approximately 9 percent of energy intake among those who drink (Cat_DS¹). Among those who consume excessive amounts of alcohol, the percent of energy intake may be considerably higher, and binge drinking is associated with obesity.⁷

Because alcohol is not a component of USDA food pattern guidance, its added energy is discretionary and should be considered in the present context of high and increasing obesity prevalence. In the United States, a standard alcoholic drink is 14 grams of ethanol (0.6 fluid ounces [fl oz]), which is equivalent to 12 fl oz of 5% alcohol by volume (ABV) beer, 5 fl oz of 12% ABV wine, or 1.5 fl oz (a typical shot) of 40% ABV (80 proof) distilled spirits.⁸ Because ethanol has 7 calories per gram, the ethanol content of 1 standard drink is approximately 100 calories, and the non-alcoholic components add further calories. In addition, alcohol serving sizes may often exceed the size of a standard drink, which also increases calorie content.⁹

Alcohol consumption accounts for approximately 100,000 deaths annually in the United States.¹⁰ Excessive drinking is defined on the basis of high average amounts consumed, or per-occasion consumption that results in acute impairment (i.e., binge drinking). Although terminology and definitions in this field of study are inconsistent, excessive drinking is typically defined as consuming 5 or more drinks per occasion or 15 or more drinks per week for men, and 4 or more drinks per occasion or 8 or more drinks per week for women.^{11,12} Of all alcohol-

¹ For details, see data supplements that provide results of analyses conducted for the Committee, referenced as Food Categories Sources (Cat_DS) and Beverages (Bev_DS). These supplements can be found at <https://www.dietaryguidelines.gov/2020-advisory-committee-report/data-analysis>.

attributable deaths, approximately 88,000 are accounted for by excessive drinking; more than twice the number of deaths from excessive drinking occur among men compared to women.¹⁰ Excessive drinking is responsible for approximately 10 percent of deaths among working age adults.¹³ Because a sizable fraction of mortality from excessive drinking occurs among young and middle-aged adults, each alcohol-attributable death from excessive drinking accounts for an average of 30 years of potential life lost.¹⁰ Overall, approximately 20 percent of people who begin drinking will develop an alcohol use disorder (formerly referred to as alcohol use or dependence¹⁴) at some point in their lives.^{15,16} However, only a minority of people who drink excessively or who binge drink have an alcohol use disorder.¹⁷ As such, excessive drinking and alcohol-related problems are prevalent, and are not restricted to those with an alcohol use disorder.

Although the 2020 Dietary Guideline Advisory Committee's systematic review focused on relationships between alcohol and all-cause mortality, other alcohol-related mortality, morbidity, social aspects and economic costs also are important to review,¹⁸ particularly as a high proportion of those who drink in the United States consume alcohol excessively.¹⁹⁻²³ At all levels, and particularly for high per occasion alcohol consumption and resulting blood alcohol concentrations, alcohol is positively associated with intentional injuries (e.g., suicide, homicide) and unintentional injuries (e.g., motor vehicle crash fatalities, drownings).^{22,24} Although observational studies find protective effects of low average levels of consumption for some cardiovascular outcomes (e.g., coronary heart disease and ischemic stroke), high average levels of consumption and binge drinking are associated with increased risk of coronary heart disease, stroke, congestive heart failure, atrial fibrillation, and hypertension.²⁵ Alcohol is recognized as a human carcinogen by the World Health Organization (WHO) and the U.S. government, and is likely causally associated with at least 7 types of cancer.²⁶⁻²⁹ For some common cancers (e.g., breast cancer, colorectal cancer), an increased risk is observed starting with any consumption above zero and continues to increase with higher consumption amounts. Overall, alcohol consumption is responsible for approximately 3.5 to 5.5 percent of all cancer deaths in the United States.^{30,31} Alcohol also is a risk factor for a range of gastrointestinal health outcomes, including chronic liver disease, pancreatitis, gastritis, gastro-esophageal reflux disease, and peptic ulcer disease.³²

Alcohol also is an important risk factor for, or contributor to, a variety of social and mental health problems, including depression, child abuse and neglect, fetal alcohol spectrum disorder, motor vehicle crashes, domestic violence, sexual assault, vandalism and other property crimes, and nuisance violations.³³⁻³⁷ Although the legal drinking age is 21 years in all 50 states and

Washington, DC, alcohol is the most commonly consumed psychoactive substance by underage individuals and contributes to a variety of health, social, and academic problems.³⁸ Approximately 4,300 alcohol-attributable deaths occur annually among those younger than the legal drinking age, either due to underage drinking or to secondhand effects from another person's drinking.¹⁰

Excessive alcohol consumption costs \$224 billion annually in the United States, or approximately \$750 per adult annually, or \$2 per drink sold.³⁹ These costs are based on lost productivity, medically-related costs, and costs to the legal and criminal justice systems, and do not include less quantifiable costs, such as suffering.

The majority of U.S. adults consume alcohol, and alcohol can be a source of enjoyment for many. However, not consuming alcohol also is a preference for many Americans, and not drinking can also be a source of enjoyment and improved quality of life. In the absence of binge drinking, low volume alcohol consumption (sometimes referred to as “moderate” alcohol consumption, and defined variably) has low risk for most adults. Individuals have many personal, cultural, social, and religious reasons for choosing to drink alcohol or to not drink alcohol, apart from health considerations. Evaluating the predisposing factors for drinking is beyond the scope of this chapter. Ultimately, the *Dietary Guidelines for Americans* are oriented to health and well-being.

The *Dietary Guidelines for Americans* recommendations on alcohol pertain to those who currently drink. The 2015-2020 and 2010-2015 editions of the *Dietary Guidelines for Americans* explicitly discouraged anyone from beginning to drink alcohol for “any reason” (2015-2020) or “to begin drinking or drink more frequently on the basis of potential health benefits” (2010-2015).^{40,41} Previous editions defined “drinking in moderation” as consuming “up to 1 drink per day for women and up to 2 drinks per day for men” for adults of legal drinking age. This applies to the number of drinks consumed during days when alcohol is consumed rather than average consumption amounts. No consumption is recommended for a number of individuals, including those younger than age 21 years, women who are or may be pregnant, those with health conditions that can be caused or exacerbated by alcohol consumption, those who take medications or other drugs that can interact negatively with alcohol,¹¹ and those who are performing complex or dangerous tasks.

In addition to describing alcohol's health, social, and economic effects, this chapter summarizes the Committee's review of evidence on the relationship between alcohol consumption and achieving nutrient and food group recommendations and the relationship between alcohol consumption and all-cause mortality. The Committee prioritized the review of Scientific Report of the 2020 Dietary Guidelines Advisory Committee

alcohol and all-cause mortality because it is arguably the most important mortality outcome related to alcohol, and because Dietary Guidelines Advisory Committees had not previously reviewed this topic. However, a scientific challenge is that no randomized controlled trials (RCTs) of alcohol and all-cause mortality (nor any cause-specific mortality or morbidity outcome) have been conducted, so the Committee contextualized its findings in considerable detail. This chapter also discusses findings from Mendelian randomization (MR) studies of how genetic factors related to alcohol consumption are related to cardiovascular disease (CVD) and cancer, both of which are leading causes of death in the United States. MR studies are a relatively new type of study and offer some advantages and insights in comparison to studies of these topics using observational study designs. MR studies assess variants of genes that correlate with an exposure of interest (in this case, alcohol consumption).^{42,43} These genetic variants are then related to the alcohol-related outcomes of interest in comparison to the other variant of the gene as an instrumental variable in order to circumvent unmeasured confounding, which is a common limitation of epidemiologic alcohol studies.

Because the Committee's purpose was to provide evidence to support advice about alcohol consumption for those who drink, the primary focus of its review on alcohol and all-cause mortality was to assess the relationship between average consumption and patterns of consumption among those who drink. However, the Committee also assessed the relationship between various levels of alcohol consumption and the risk of mortality compared with never drinking alcohol. This evidence base also consisted of observational studies of established drinkers in comparison to those who report never consuming alcohol, and does not directly address popular questions about whether one should purposefully begin drinking, continue drinking, or stop drinking for health reasons.

LIST OF QUESTIONS

1. What is the relationship between alcohol consumption and achieving nutrient and food group recommendations?
2. What is the relationship between alcohol consumption and all-cause mortality?

METHODOLOGY

The Committee developed a data analysis protocol for Question 1 that described how data analyses would be used to answer the question. The protocol included an analytic framework that described the overall scope of the analyses, including the population, types of analyses, and data sources identified to answer each question, and definitions of key terms.

Consideration of this question drew from analyses of data from What We Eat in America (WWEIA), the dietary component of the National Health and Nutrition Examination Survey (NHANES); the Behavioral Risk Factor Surveillance System (BRFSS); the National Survey on Drug Use and Health (NSDUH); Healthy People 2020; and the Alcohol Epidemiologic Data System (AEDS).¹ Existing data tables were used when available. In some cases, upon the Committee's request, the Data Analysis Team (DAT) conducted new analyses to provide additional information. These requests included, for example, analyses by specific population groups, such as adults younger and older than age 65 years, and women who are pregnant or lactating.

A description of the data analysis methodology is provided in **Part C. Methodology**. Complete documentation of the data analysis protocol and the referenced results are available on the following website: <https://www.dietaryguidelines.gov/2020-advisory-committee-report/data-analysis>. Below is a summary of the key elements of the protocol developed to answer Question 1.

Data analyses outlined in the analytic plan focused on alcohol use and alcoholic beverage contributions to food group intakes and intakes of nutrients and other food components. The primary life stages considered were adults of legal drinking age (21 years and older), including women who are pregnant or lactating, although some analyses were of adults ages 20 years and older. In the WWEIA, alcohol intake data were collected using 24-hour dietary recalls. In the NSDUH, these data were collected using interviews. For the general population ages 20 years or older, the DAT examined the WWEIA NHANES 2015-2016 cycle of data. For analyses by age group and for women who are pregnant or lactating, WWEIA 2013-2016 data cycles were combined. Analyses of the NSDUH examined data from 2015 and 2016. The following definitions were used:

- **Standard drink in the United States:** 14 grams (0.6 fl oz) of pure alcohol (ethanol), which is equivalent to 12 fl oz of 5% ABV beer, 5 fl oz of 12% ABV wine, or 1.5 fl oz of 40% ABV (i.e., 80 proof) distilled spirits.

- **Binge drinking:** Consuming 5 or more drinks on the same occasion for men, or 4 or more drinks on the same occasion for women.
- **Frequent binge drinking:** Binge drinking on 5 or more days during the past month.

The Committee took into account the strengths and limitations of data quality and analyses when formulating conclusion statements. The grading process used for questions answered by the USDA's Nutrition Evidence Systematic Review (NESR) systematic review methodology does not apply to questions using data analyses and therefore data analyses conclusions were not graded. Because data analysis and systematic review are different approaches to reviewing the evidence, the presentation of the summary of evidence is organized differently, although in each case, the conclusion statements are informed by the evidence reviewed, as outlined in the protocol.

Question 2 in this chapter was answered using a new systematic review conducted with support from USDA's Nutrition Evidence Systematic Review (NESR) team. NESR's systematic review methodology provided a rigorous, consistent, and transparent process for the Committee to search for, evaluate, analyze, and synthesize evidence.

The Committee developed a systematic review protocol, which described how the Committee would apply NESR's methodology to answer the question. The protocol included an analytic framework and inclusion and exclusion criteria to guide identification of the most relevant and appropriate body of evidence to use in answering the systematic review question. The analytic framework outlined core elements of the systematic review question (i.e., population; intervention and/or exposure and comparator (i.e., the alternative being compared to the intervention or exposure; and outcomes), and included definitions for key terms, key confounders, and other factors to be considered when reviewing the evidence. The inclusion and exclusion criteria were selected, a priori, to operationalize the elements of the analytic framework, and specify what makes a study relevant for the systematic review question.

Next, a literature search was conducted to identify all potentially relevant articles, and those articles were screened by 2 NESR analysts independently based on the criteria selected by the Committee. For each included article, data were extracted and risk of bias assessed. The Committee qualitatively synthesized the body of evidence to inform development of conclusion statements, and graded the strength of evidence using pre-established criteria for risk of bias, consistency, directness, precision, and generalizability. Finally, recommendations for future research were identified. A detailed description of NESR's systematic review methodology is provided in **Part C. Methodology**, including standard inclusion and exclusion criteria applied in

many of the Committee's systematic reviews. Complete documentation of each systematic review is available on the following website: [nesr.usda.gov/2020-dietary-guidelines-advisory-committee-systematic-reviews](https://www.nesr.usda.gov/2020-dietary-guidelines-advisory-committee-systematic-reviews). Following is a summary of the unique elements of the protocol developed to answer the questions addressed in this chapter.

The population of interest for the question on alcohol consumption and all-cause mortality, was adults ages 21 years and older. The interventions or exposures of interest were average consumption of alcoholic beverages and the pattern of consumption of alcoholic beverages (i.e., the number of drinks per drinking day or drinks per drinking occasion). Information on the type of beverage (e.g., beer, wine, distilled spirits) was collected, if available.

The primary comparator of interest was differing average alcohol consumption or patterns among those who currently drink alcohol. The secondary comparison was between those who currently drink alcohol and those who have never consumed alcohol (i.e., lifetime abstainers). Studies for the secondary comparison were excluded if the non-drinking reference group included a mix of lifetime abstainers and former drinkers.

The outcome of interest in this review was all-cause mortality (i.e., total mortality), which was defined as the total number of deaths from all causes during a specific time period. Although some studies disaggregated causes of death, the outcome for this review did not include cause-specific mortality (i.e., total number of deaths from a specific disease, such as CVD or cancer).

When establishing inclusion and exclusion criteria, the Committee used standard NESR criteria for study design, publication status, language of publication, country, and health status of study participants. Initially, studies were included in the review if they were published from January 2000 to March 2020. However, due to time constraints, the Committee revised their protocol to focus the review on studies published from January 2010 to March 2020. Studies that *exclusively* enrolled participants younger than age 21 years also were excluded to focus on adults of legal drinking age, to whom *Dietary Guidelines for Americans* recommendations apply. In addition, the Committee clarified that MR studies were eligible for inclusion by noting this study design specifically in the inclusion criteria. In addition, observational studies enrolling fewer than 1,000 participants were excluded.

REVIEW OF THE SCIENCE

Question 1. What is the relationship between alcohol consumption and achieving nutrient and food group recommendations?

Approach to Answering Question: Data analysis

Conclusion Statement

Beyond contributing to energy intakes, ethanol has no nutritional value and alcoholic beverages (including their non-ethanol components) contribute little toward average intakes of food groups or nutrients. Alcohol consumption has increased in the United States since 2000, and most states exceed Healthy People 2020 objectives for per capita alcohol consumption.

Approximately 60 percent of individuals report alcoholic beverage consumption in the past month, and of those, approximately 40 percent binge drink, often multiple times per month. During days when men or women consume alcohol, their consumption also typically exceeds current *Dietary Guidelines for Americans* recommended daily limits of less than or equal to 1 drink per day for women and 2 for men. Alcohol consumption during pregnancy remains a persistent public health problem.

Summary of the Evidence

The following sections describe the results of data analyses conducted to answer Question 1. Additional details can be found in data supplements, referenced below as Beverages (Bev_DS) and Food Categories Sources (Cat_DS).

Adults

Per capita alcohol consumption has increased in the United States since 2000, and 41 states currently exceed Healthy People 2020 objectives for per capita alcohol consumption.¹ The majority of adults, ages 21 years and older, consume alcoholic beverages. Among those ages 21 years and older, 55.8 percent report alcohol consumption in the past month. Alcohol use is most prevalent (67.6 percent) among adults ages 21 to 26 years, and tends to decrease slightly with increasing age, although use remains prevalent across most age groups. Of adults ages 26 to 44 years, 61.5 percent consume some alcohol, and 55.2 percent of adults ages 45 to 64 years of age consume some alcohol.³

Binge drinking is common. Approximately one-quarter of all adults ages 21 years and older report past-month binge drinking, including 47.0 percent of those who drink alcohol. Among those who binge drink, 25.0 percent report frequent binge-drinking. By age, approximately 70 percent of drinkers ages 21 to 26 years report past-month binge drinking. Among age groups 26 and older, 44.3 percent of those who drink report binge drinking, although this proportion is somewhat lower among those ages 65 years and older (22.9 percent). Men are more likely to report binge drinking than women. Thirty-two percent of men ages 21 years and older report past-month binge-drinking compared to 20.9 percent of women; among those who binge-drink, 29.1 percent of men and 19.6 percent of women frequently binge-drink.

Among those who consume alcohol, on any given day men are more likely to drink than are women across all age groups (32 percent and 25 percent for men ages 20 to 64 years and ages 65 and older vs 21 percent and 15 percent for women in these age categories) (Bev_DS). For adults, ages 20 to 64 years, on any given day when alcohol is consumed, the type of alcohol differs by sex. Men more commonly report consuming beer (23 percent beer vs 5 percent for wine), while women are slightly more likely to consume wine (9 percent vs 8 percent for beer). Among those ages 65 years and older, wine is the most commonly reported alcoholic beverage consumed by both men and women. Data on distilled spirits consumption were not available for this analysis.

Among all those ages 20 to 64 years, alcohol contributes more than 20 percent of the total daily energy from beverages (Bev_DS). A greater proportion of total daily beverage energy comes from alcohol for men (31 percent) vs women (21 percent). Based on U.S. standard drink sizes, during days when beer or wine is consumed, men drink an average of 3.5 servings of beer (43 fl oz) or 1.8 servings of wine (9 fl oz). During days when beer or wine is consumed, women drink an average of 2.2 servings of beer (26 fl oz) or 2.0 servings of wine (10 fl oz) (Bev_DS). Data on distilled spirits consumption were again not available for this analysis. Therefore, usual consumption amounts for men and women drinking beer and women drinking wine exceed “drinking in moderation” based on recommended limits in the *2015-2020 Dietary Guidelines for Americans*.

Among the entire adult population (including those who do not drink), alcoholic beverages contribute approximately 5 percent of daily energy intake (3 to 4 percent of total daily energy for women and 5 to 7 percent for men); based on the percentage of those who consume alcohol this translates into approximately 9 percent of energy intake among drinkers (Bev_DS). However, alcoholic beverages contribute relatively little to other food group and nutrient intakes

for all age groups; specifically, they contribute less than 3 percent to added sugars, potassium, calcium, and fruit intakes (Cat_DS).

Women who are Pregnant or Lactating

Overall, 59.0 percent of women ages 18 to 44 years report alcohol consumption in the past month and, of those who drink, 59.0 percent report past-month binge drinking.⁴⁴ Because many pregnancies are unintended (either mistimed or unwanted) and because the mean gestational age of pregnancy awareness is 5.5 weeks, this creates potential harm to the unborn fetus, if a woman consumes alcohol before pregnancy is recognized. Binge drinking before pregnancy also is a risk factor for drinking and for binge drinking once pregnancy is recognized. Among women who are pregnant, 11.5 percent and 3.9 percent report current drinking and binge drinking in the past 30 days, respectively. Although alcohol consumption may be underreported generally, it may be more underreported among women who are pregnant because of associated stigma. In women who are pregnant, the reported prevalence of past-month alcohol consumption is 8.9 percent for Hispanics, 10.7 percent for White non-Hispanic women, 14.0 percent for Black non-Hispanic women, and 19 percent for other non-Hispanic women. Differences by marital status also exist, with 8.6 percent of married women who are pregnant reporting past-month alcohol consumption compared to 15.2 percent of women who are pregnant and not married. On a given day when beer or wine consumption is reported, women ages 20 to 44 years and who are pregnant consume an average of 2 drink equivalents (24 fl oz) of beer or 2.2 drink equivalents (13 fl oz) of wine. Data on distilled spirits consumption were not available.

Eight percent of women who are lactating report beer or wine consumption on a given day, consuming approximately 1 standard drink of beer (15 fl oz) or wine (4 fl oz) (Bev_DS). Data on distilled spirits consumption were not available.

To access the data analyses referenced above, visit:

<https://www.dietaryguidelines.gov/2020-advisory-committee-report/data-analysis>

Question 2. What is the relationship between alcohol consumption and all-cause mortality?

Primary Comparisons (Among Those Who Currently Drink Alcohol)

Approach to Answering Question: NESR systematic review

Conclusion Statements and Grades

Moderate evidence indicates that higher average alcohol consumption is associated with an increased risk of all-cause mortality compared with lower average alcohol consumption among those who drink. Grade: Moderate

Moderate evidence indicates that binge drinking (consuming 5 or more drinks for men or 4 or more drinks for women during a drinking occasion) is associated with increased risk of all-cause mortality, and that more frequent binge drinking is associated with increased risk of all-cause mortality compared with less frequent or no binge drinking among those who drink. Grade: Moderate

Summary of the Evidence

- Sixty studies that met the inclusion criteria for this systematic review addressing alcohol consumption and all-cause mortality were identified through the literature search from January 2010 to March 2020.^{25,45-103}
 - The body of evidence included 1 MR study, 1 retrospective cohort study, and 58 prospective cohort studies. The evidence included no RCTs.
- Consistent evidence reported increased all-cause mortality among those with higher average volume of alcohol consumption compared to lower average alcohol consumption. Although consumption categories varied, among those who drank alcohol, most studies found lower risk among men consuming within ranges up to 2 drinks per day and women consuming within ranges up to 1 drink per day compared to those consuming higher average amounts. Among studies assessing continuous distributions or based on dose-response relationships among narrower consumption ranges, among men who drink, the lowest levels of risk were generally up to 1 or 1.5 drinks on average (depending on how consumption was categorized). Relatively few studies among women examined risk based on categories within the range of up to 1 drink per day on average.

- Consistent evidence among those who drink alcohol reported higher all-cause mortality with more frequent binge drinking (consuming 5 or more drinks for men or 4 or more drinks for women during a drinking occasion) compared with less frequent or no binge drinking.
- Generally, the evidence was limited by inadequate adjustment for confounders, selection bias, and generalizability (studies often included middle- and older-aged adults), and potential misclassification or bias from an exposure assessment based on one-time measurements of alcohol consumption.
- Because the studies provided no consistent definition or categorization of higher average or lower average consumption, these terms are used in a descriptive sense in the conclusion statement. However, across most studies definitions of binge drinking or levels that corresponded to binge drinking were generally consistent; thus binge drinking is defined based on a set number of drinks in the conclusion statement.

Discussion about Relationships between Alcohol Consumption and All-Cause Mortality among Drinkers

The primary comparisons addressed were relationships between alcohol consumption and all-cause mortality among those who currently drink. These comparisons are relevant to those who already consume alcohol, to whom *Dietary Guidelines for Americans* recommendations on alcohol are meant to apply. For these primary comparisons, the Committee assessed relationships between different levels of average consumption, and different levels consumed per drinking occasion or per drinking day.

The body of evidence was comprised of observational studies, with no randomized trials. A relatively large number of studies informed the primary comparisons, with generally consistent findings for both the United States and other high-income nations. Most studies had large sample sizes (greater than 10,000). In terms of alcohol exposure, most studies were of average consumption, with fewer studies examining binge drinking, and even fewer assessing the number of drinks consumed per drinking day. Most studies examined adults of middle age and older, but some population-based studies of adults (e.g., ages 18 years and older) or more representative age groups (e.g., ages 35 to 75 years) were included. Most studies assessed consumption at one point in time. The MR study did not provide drinking levels.

The risk of confounding bias was high overall, both because of known issues with confounding in observational alcohol studies generally and because of specific weaknesses in the reviewed studies. Specifically, studies typically lacked consideration of multiple key

confounders (e.g., adequate adjustment for socioeconomic factors, diet quality or pattern), and did not typically account for patterns of alcohol consumption (i.e., the number of drinks per drinking day or frequency of consumption) for studies of average consumption, nor average consumption in studies assessing patterns of consumption. The lack of adjustment for patterning is important because cohort or survey participants may be less likely to binge drink or have alcohol-related problems compared to people in the general population, even among those with similar consumption levels.^{104,105} This could lead to underestimates of alcohol-related risk in cohort or survey participants compared to the general population, and adversely affect the generalizability of findings. Selection bias, based on the age of the study cohorts, also is a consideration, as approximately 40 percent of alcohol-attributable deaths occur before age 50 years,¹⁰⁶ and those who have been established moderate drinkers for longer periods or until later in life may be advantaged, socially, or in terms of health. In general, therefore, studies of older cohorts could lead to underestimation of alcohol-mortality associations compared with studies that are population-based.

The effects of measuring alcohol at one point in time are unclear. Alcohol consumption typically changes throughout the life course, but may have independent associations with outcomes based on the time at which consumption changes, or among those with relatively stable vs shifting consumption over the life course. At a minimum, changes in consumption over time suggest that measuring consumption at only 1 point in time may result in misclassification of either average consumption or patterns of consumption compared to what was usually consumed, and when, over the life course.

In terms of average consumption, these observational studies found increased mortality among those with higher average volume of consumption compared to lower average volume consumption, with generally consistent dose-response relationships, at least with respect to point estimates. Although the most common ranges defining lower consumption levels were up to an average of 2 drinks per day for men and up to 1 drink per day for women, studies often used different levels of comparison (and terminology) to classify relatively lower vs higher average consumption. Among studies that examined finer gradations of consumption, the lowest levels of risk for men were generally up to 1 or 1.5 drinks per day on average. For women, relatively few studies examined average consumption among gradations within the range of up to 1 drink per day on average.

Summarizing these data presents other challenges. Few studies reported consumption in grams of ethanol, but rather in drinks per day or per week. In many cases, it was not clear how carefully respondents had standard drink sizes defined for them, or how carefully their drink

estimates were translated into grams of ethanol by researchers. Furthermore, while in the United States a standard drink consists of 14 grams (or 0.6 fl oz) of pure ethanol, other countries have different standard drink sizes (typically in the range of 10 to 12 grams per drink). For international studies in which consumption was reported in drinks or units rather than grams of ethanol, the Committee assumed that a drink corresponded to the number of grams of ethanol for that particular country, and translated that into U.S. standard drinks.

Among those with lower average volume consumption, some studies assessed a subgroup of “infrequent,” “occasional,” or “light” drinkers. When assessed, this group was defined variably (sometimes based only on drinking frequency, and/or on the basis of miniscule amounts of alcohol), and had variable risk estimates for all-cause mortality compared to other lower average volume drinkers. Studies using “occasional/light” drinkers as the reference group had less precision because occasional drinkers are not a large proportion of most study populations.

Although they were not included in the Committee’s systematic review, precise estimates of effect sizes at finer gradations in consumption are best addressed by meta-analyses and modeling studies. Meta-analyses of average alcohol consumption and all-cause mortality find that, based on continuous risk curves, risk starts to increase above the equivalent of one-half U.S. standard drink per day on average for women, above one-half to 1 drink per day on average for men, and above 1 drink per day on average for both women and men,¹⁰⁷⁻¹¹¹ including among those with CVD.¹¹² Rather than using meta analyses, others have advocated an approach combining multiple, weighted cause-specific mortality risk curves to estimate relationships between consumption and mortality.¹¹³ Based on data from high-income countries, studies using this approach have similarly found that among drinkers all-cause mortality risk curves generally increase above 10 grams of ethanol per day (i.e., at or below approximately two-thirds of a U.S. standard drink per day) for both men and women.^{24,107,114-117}

Studies consistently found that among those who drink, binge drinking was associated with increased mortality risk compared to not binge drinking, and that more frequent binge drinking was associated with increased risk compared with less frequent binge drinking. Although not all studies defined binge drinking by the 5 drinks for men and 4 drinks for women per occasion used in the NSDUH (e.g., some used 6 drinks, some used 5 drinks for both sexes, some constrained the time period for the drinking occasion), findings were generally consistent in terms of the direction of association, magnitude of effect, and significance. To date, no randomized studies of binge drinking have been conducted, and performing such studies would likely be deemed unethical and are unlikely to be conducted.

Other than at thresholds defining binge drinking, relatively few studies considered the relationship between the number of drinks consumed per drinking day or per drinking occasion and all-cause mortality. Among men, all 3 studies found that consuming more than 2 drinks per drinking day (i.e., at levels above the *2015-2020 Dietary Guidelines for Americans* recommended limits for men) was associated with higher mortality risk compared with consuming less; only 1 study examined differences among men comparing 1 vs 2 drinks. For women, 2 studies found increased risk for all-cause mortality with consumption greater than 1 drink (i.e., at levels above the *2015-2020 Dietary Guidelines for Americans* recommended limits for women). These findings are generally consistent with studies of other morbidity and mortality outcomes that find increased risk with increased consumption per drinking day or per drinking occasion (and related blood alcohol concentrations), including at levels exceeding *2015-2020 Dietary Guidelines for Americans* recommended daily recommended limits for men and women, respectively.¹¹⁸⁻¹²⁴ In addition, recent modeling studies of alcohol and all-cause mortality found that at all levels of total weekly consumption, risk is typically lowest for both men and women when fewer drinks are consumed per drinking day given a fixed amount of total consumption.^{107,125}

Secondary Comparison (Between Those Who Currently Drink Alcohol and Those Who Have Never Consumed Alcohol)

Approach to Answering Question: NESR systematic review

Conclusion Statement and Grade

Limited evidence suggests that low average alcohol consumption, particularly without binge drinking, is associated with a lower risk of all-cause mortality compared with never drinking alcohol. However, in light of the many scientific and public health issues associated with alcoholic beverages, any conclusions about low average consumption compared to never drinking alcohol require careful consideration. Grade: Limited

Summary of the Evidence

- For the secondary comparison between current drinkers and never drinkers, the limited available evidence suggested that low average consumption was associated with lower risk of mortality compared with never drinking status. Included studies were a subset of the 60 studies above that were used to assess the primary comparisons of interest.

- Twenty-five studies compared those who consumed alcohol with never drinkers. Approximately half of the studies reported significant findings that low average alcohol consumption (particularly without binge drinking) was associated with reduced risk of all-cause mortality compared with never drinking alcohol, approximately half of the studies indicated no significant relationship, and 2 studies reported that low alcohol consumption was significantly associated with greater all-cause mortality compared to never drinking alcohol.
- Generally, the evidence was limited by inadequate adjustment for confounders, selection bias, and limited generalizability (studies often included only middle- and older-aged adults), and potential misclassification or bias from an exposure assessment based on single-time measurements of alcohol consumption. As with the primary comparison, low average volume was classified variably.

Discussion about Comparisons between Drinking Alcohol and Never Drinking Alcohol for All-Cause Mortality

A pre-designated secondary comparison was developed to assess relationships with all-cause mortality for self-reported consumers of alcohol compared with those who self-reported never consuming alcohol. Although not drinking is a level of alcohol consumption (i.e., zero consumption), this was designated as a secondary comparison because the *2015-2020 Dietary Guidelines for Americans* recommendations on alcohol provided advice for those who currently drink and, for a variety of health-related reasons, recommend against beginning to drink.^{40,41} This body of research is based exclusively on non-randomized studies of established alcohol drinkers and lifelong never drinkers of alcohol. Because established drinkers are different from those who might initiate alcohol consumption, this comparison does not address the question of whether non-drinkers or lifelong never drinkers might initiate alcohol consumption to improve health.

The evidence grade of “Limited” was weaker than for the within-drinker comparisons for several reasons. First, those who have never consumed alcohol have more adverse confounding factors,¹²⁶⁻¹²⁹ and all studies lacked inclusion of key pre-specified confounders. Second, approximately half of self-described never drinkers may actually have previously consumed alcohol, and are therefore misclassified.¹³⁰ Third, fewer studies of never drinkers were reviewed than those of within-drinker comparisons because some studies were restricted to drinkers, while others assessed non-drinkers as a group and could not or did not

disaggregate former drinkers (arguably a type of drinker) from those who had never drunk alcohol. Fourth, the definition of never drinkers varied among studies, and sometimes included those who had consumed at least some alcohol at some point in time. Fifth, a smaller proportion of studies using never drinker comparisons with low average drinkers had significant findings compared with those comparing lower and higher average consumption of alcohol. And last, generalizability was limited because many study populations were not representative of the age distribution of all adults who typically begin to consume alcohol.

For studies comparing never drinking and non-drinking to the consumption of low average amounts of alcohol, confounding is more than a theoretical risk, as moderate drinking is strongly associated with many favorable health, social and economic factors¹³¹ that are independently associated with longevity.¹³² Conversely, non-drinking and never drinking tend to be associated with adverse confounding factors (e.g., poorer baseline health status, lower incomes).^{126-129,131} Therefore, unmeasured or residual confounding tends to bias studies in favor of low average alcohol consumption relative to non-drinking and never drinking. Selection bias favoring low average consumption of alcohol also is a concern, as established moderate drinkers are a select group who are not representative of all those who might start drinking (including those who become heavy drinkers or who quit drinking).¹³³ Furthermore, older study populations cannot include persons who have died prematurely from alcohol-related causes, some of which affect younger adults disproportionately (e.g., deaths from unintentional injury or violence).

Although it is possible that alcohol consumption at low levels may have some benefits, the likely direction of confounding and selection bias in observational studies means that associations with better health among low average drinkers compared with never drinkers may be a statistical artifact. A recent meta-analysis that weighted studies on quality measures to address sources of bias found no significant protection for low average drinkers compared with never drinkers of alcohol.¹¹⁰

Associations of reduced mortality for those who consume low amounts of alcohol in comparison to non-drinkers, including never drinkers, are driven by reduced associations with CVD mortality. The 2010 Dietary Guidelines Advisory Committee conducted a review on the topic of alcohol intake and coronary heart disease, and concluded that “strong evidence consistently demonstrates that compared to non-drinkers, individuals who drink moderately have lower risk of coronary heart disease.”¹³⁴ Since that time, observational studies and meta-analyses of observational studies have affirmed that the “J-shaped curve” for coronary heart disease and ischemic stroke demonstrates higher risk among those who do not consume alcohol compared with those who consume low volumes of alcohol, followed by higher risk

among those consuming progressively higher amounts of alcohol.^{135,136} However, a relatively new type of study design, referred to as MR or genetic randomization studies, has resulted in evidence that challenges previous conclusions about the protective association between low average consumption and CVD.¹³⁷⁻¹⁴⁰

For additional details on this body of evidence, visit: [nesr.usda.gov/2020-dietary-guidelines-advisory-committee-systematic-reviews/beverages-and-added-sugars-subcommittee/alcohol-all-cause-mortality](https://www.nesr.usda.gov/2020-dietary-guidelines-advisory-committee-systematic-reviews/beverages-and-added-sugars-subcommittee/alcohol-all-cause-mortality)

Additional Topics Considered: Mendelian Randomization Studies on Alcohol and Cardiovascular Disease and Cancer

Due to time constraints and the desire to prioritize the review of alcohol and all-cause mortality, the Committee did not conduct systematic reviews with the support of NESR to examine the relationship between alcohol consumption and risk of CVD or cancers. However, the Committee wanted to address MR studies on these topics because CVD and cancer are leading contributors to all-cause mortality, and because MR studies are relatively new. Furthermore, large bodies of observational evidence already exist about these topics, which are also discussed and referenced in this chapter. The Committee searched the literature to identify any MR study published on these topics from January 2000 through March 2020. This resulted in consideration of MR studies from China when data were collected while China's Human Development Index categorization was medium. The MR studies identified are described and discussed below.

MR studies assess variants of genes that correlate with an exposure of interest (e.g., alcohol consumption). Genetic variants are then related to the outcomes of interest. Overall, genetic variants are analogous to instrumental variables used in epidemiological studies (the idea being that genes assort randomly and thus reduce confounding). To do this type of study, it is necessary to have available genetic variants that are reliably related to the exposure of interest. For alcohol, some variants of the alcohol dehydrogenase gene and the aldehyde dehydrogenase gene associate with reduced consumption among drinkers of alcohol, and higher rates of non-drinking, among those with the variant genotype.

Strengths of these studies, compared to observational studies, are that they reduce confounding and selection bias⁴²; these studies are sometimes referred to as nature's RCTs. No possibility of reverse causation (i.e., poor health causing non-drinking status) exists because genotypes are present from birth and therefore precede outcomes, nor does exposure

misclassification occur because genotypes are time-invariant. Genotypes are a better proxy of lifetime alcohol consumption, as opposed to measuring alcohol consumption at one or even several points in time as is done in traditional epidemiological studies. Despite their advantages, MR studies have limitations. Genetic instruments may lack robust associations between the genotype and the exposure of interest. Genotypes may have “pleiotropy,” meaning that the genotype could affect other physiological pathways that are independent of the exposure variable (alcohol) and that affect the outcome of interest. They also may have “linkage disequilibrium,” meaning that the genotype might be independently associated with other genes that may affect the outcome of interest (i.e., genes do not always assort randomly relative to one another).

Five articles were identified that examined the relationship between alcohol consumption and CVD; 4 could be related to actual or modelled levels of consumption or compared epidemiological approaches to MR approaches. The overview of the findings is that MR studies do not find reduced associations for coronary heart disease and ischemic stroke among low average consumers compared with non-drinkers of alcohol, which is inconsistent with findings from observational studies. In terms of coronary heart disease, a large study of individuals of European descent found that a genetic variant that is associated with less alcohol consumption was associated with reduced risk of coronary heart disease overall. Although this relationship held among those within low, medium, and high categories of self-reported alcohol consumption, importantly, among non-drinkers of alcohol, the genetic variant had no association with coronary heart disease. Thus, the genetic variant was conditional on exposure to alcohol, rather than having an independent effect on coronary heart disease mortality, in the absence of alcohol. A small study from China compared a MR vs a conventional epidemiological approach; neither approach found a protective association for low average consumption compared with nondrinking status. In terms of stroke, a medium-sized study from Denmark reported reduced risk among those consuming 1 to 20 alcoholic drinks per week compared to those consuming fewer than 1 drink per week using a conventional epidemiological approach. However, the MR approach found only non-significant, but positive, associations with increasing genotype-predicted alcohol consumption.¹³⁸ Finally, a large study of Chinese men assessed both stroke and coronary heart disease. For stroke, U-shaped associations were observed for alcohol and stroke risk using a conventional epidemiological approach (i.e., increased risk at no consumption, reduced associations at low volumes, followed by increasing risk thereafter), but only a positive association with increasing genotype-predicted consumption using the MR approach. The MR analysis also revealed no evidence of reduced associations for myocardial

infarction or total coronary heart disease at low levels of alcohol consumption, with little overall effect of alcohol consumption on those outcomes.

Findings about MR studies and CVD mortality in this report are supported by MR studies and RCTs about CVD risk factors. These studies find positive associations between alcohol consumption and blood pressure without protective associations among low volume consumers, no protective associations for blood glucose, diabetes or body mass, and no associations with low-density lipoprotein cholesterol.¹⁴¹⁻¹⁴⁶ Although experimental studies and most MR studies find alcohol consumption is positively associated with high-density lipoprotein cholesterol (HDL-C),¹⁴⁷ MR studies do not suggest a causal relationship between HDL-C and coronary heart disease.¹⁴⁸ Furthermore, a causal role for the association between HDL-C and coronary heart disease has been challenged because medications that raise HDL-C have not shown benefit in clinical trials,¹⁴⁹ and because trials of statin medications (which lower LDL-C, but also raise HDL-C to a lesser extent) find no independent effect of raising HDL-C, after controlling for statin's effects on LDL-C.¹⁵⁰

The Committee identified and reviewed 3 articles on 3 cancer types, and found positive associations between alcohol consumption and head and neck,¹⁵¹ esophageal,¹⁵² and colorectal cancers.¹⁵³ Although the direction of these findings is consistent with existing observational studies and meta-analyses, the MR results were based on genetic variants associated with more or less consumption, but amounts of consumption by genotype were not available except in a subset of participants in the study of colorectal cancer. Overall, the few MR studies about alcohol consumption and cancer indicate that alcohol consumption is positively associated with certain types of cancer, and are consistent with evidence from prospective cohort studies.²⁶⁻²⁹

Research Needs Related to Alcohol and Mortality

More studies are needed with stronger research designs, including RCTs, MR studies, and non-randomized intervention studies with mortality outcomes. Because RCTs of alcohol and all-cause mortality would require large sample sizes for adequate power and/or long follow-up periods, evidence of this type is unlikely to be available any time soon. However, MR studies of alcohol are an emerging area of the literature that will likely expand during the next 5 to 10 years. In addition, more research is needed to disentangle effects of average (i.e., total) consumption vs daily consumption (e.g., usual number of drinks consumed on days or occasions when alcohol is consumed, including the maximum number of drinks consumed during a particular recall period). These studies also need to evaluate effects of drinking

frequency, as higher per occasion consumption is inversely related to drinking frequency among participants bounded by specific levels of total or average consumption of alcohol. Although increasing attention is being paid in the research literature to the effects of alcohol consumption patterns (i.e., how much is consumed, and how often), more evidence is needed on this topic with respect to mortality outcomes, and all-cause mortality in particular. Finally, more research is needed on the relationship between alcohol consumption and alcohol consumption patterns and broader dietary and beverage consumption patterns.

SUMMARY

In this chapter the Committee considered a wide array of evidence about alcohol consumption, which in turn is related to a variety of diseases and social issues.²³ Although the Committee evaluated the relationship between alcohol consumption and all-cause mortality in a new systematic review, these findings also are discussed in context with existing evidence about alcohol's relationship with other diseases and health outcomes,²³ and in context with other types of evidence about alcohol and all-cause mortality and leading alcohol-related diseases. This additional evidence is drawn from traditional meta-analyses, studies of mortality based on composite condition-specific risk curves for alcohol-associated outcomes, MR studies about leading causes of mortality, and relevant literature published before 2010. The Committee's review also considers alcohol-related social and economic costs, harms to others than those who consume alcohol, and alcohol's contribution to meeting nutrient and hydration requirements.

Many U.S. adults consume alcohol excessively, and an even higher proportion consume alcohol at a level exceeding *2015-2020 Dietary Guidelines for Americans* recommended limits for "drinking in moderation" during days when alcohol is consumed. Aside from energy, ethanol has no nutritional value and can also impair the absorption of other nutrients. Alcohol consumption and binge drinking are increasing in the United States, and excessive alcohol consumption is a leading behavioral risk factor for a variety of morbidity and mortality outcomes, social harms, and economic costs. Binge drinking is consistently associated with increased risk of all-cause mortality and other diseases (e.g., injury, CVD) compared to not binge drinking, and more frequent binge drinking is associated with increased risk compared to less binge drinking. Similarly, based on the Committee's review of alcohol and all-cause mortality, higher average consumption is consistently associated with increased mortality risk compared to lower

consumption. Based on meta-analyses and studies with continuous risk curves, the preponderance of evidence indicates that risks are increased at levels above 1 drink per day on average for both men and women.^{107-110,116}

Despite limitations of the observational evidence base, the conclusion that higher consumption is associated with increased risk compared to lower consumption is affirmed by outcomes that are fully alcohol-attributable (alcoholic cirrhosis), or outcomes for which alcohol is a predominant risk factor with short and relatively easily studied exposure-outcome relationships (e.g., motor vehicle crashes, falls, drownings). The findings from the Committee's review of current intakes of alcoholic beverages, and their relationships with all-cause mortality and other outcomes raise important questions that have implications for future guidance for Americans.

Should the Dietary Guidelines for Americans continue to recommend against initiating alcohol consumption for health reasons? People drink alcohol for many reasons, and for those who already do so at low levels, risks appear to be low. However, there are several compelling reasons to continue the advice that non-drinkers or never drinkers should not begin to drink on the basis of the notion that alcohol would improve their health. The observational evidence base with respect to alcohol consumption is insufficient to recommend drinking at any level, particularly for a substance that is intoxicating, potentially addictive, and a leading preventable cause of death and other harms. Established low volume drinkers in observational studies are a select group who did not become heavy drinkers or die prematurely from an alcohol-related condition, and differ from non-drinkers who might purposefully begin to drink in middle or older age, some of whom might have adverse effects even at relatively low levels of consumption. As stated by the WHO, “there is no merit in promoting alcohol consumption as a preventive strategy.”¹⁵⁴

Are current recommended limits of no more than 2 drinks per day for men and no more than 1 drink per day for women (i.e., 2/1 consumption limits) reasonable? Although the 2/1 levels (that have been in previous *Dietary Guidelines for Americans* since 1990) constitute reasonably low risk, evidence justifies tightening guidelines for men (discussed below). These 2/1 limits were initially based on theoretical considerations including relative differences in body mass between men and women,¹⁵⁵ but also aligned with increased mortality for men and women above those consumption levels based on an early and influential meta-analysis of alcohol and all-cause mortality.¹⁵⁶

Continuing to base *Dietary Guidelines for Americans* recommendations on consumption during drinking days (i.e., daily consumption limits) rather than average amounts is justified on

scientific and public health grounds. First, although less scientific literature has been published on daily consumption limits, mortality risk is typically lowest among those who drink less on days when alcohol is consumed, and increasing consumption per drinking day or occasion, and associated blood alcohol concentrations, is typically positively associated with risk for injuries, violence, and a number of other outcomes.¹⁵⁷ Furthermore, the risks of several outcomes were higher modeling 2/1 *average* limits compared with the current 2/1 daily limits¹⁵⁸ because even in the absence of binge drinking, basing guidelines on 2/1 average limits allows for drinking up to 4 drinks per drinking day for men and up to 3 drinks per drinking day for women, so long as implied weekly limits are not exceeded. Consumption at these levels typically leads to some degree of alcohol impairment, including legal intoxication for some people. Drinking levels based solely on the amount consumed in any drinking day has the added advantage of being easier to communicate and interpret compared to having recommendations based on average consumption or some combination of daily and average consumption limits. The guidance should be more explicit that recommended limits are based on consumption per drinking day.

For women, evidence exists that consumption of more than 1 drink per drinking day or of more than 1 drink per day on average (i.e., assuming that a woman drinks 1 drink every day) is associated with increased all-cause mortality risk, with meta-analyses and modeling studies finding that the risk of mortality among women is lowest at approximately one-half drink per day on average. However, it does not seem practical to base recommendations on fractions of a drink, and risk differences for women within ranges of up to 1 drink per day are modest. Therefore, maintaining the current recommendation for women is reasonable.

Why is tightening recommendations for men justified? The rationale to tighten current recommendations for men is based on 2 principal considerations. The first is that based on existing observational data (i.e., in the absence of RCTs, and ignoring MR studies), the preponderance of evidence indicates that consuming 2 drinks per day among men is associated with a modest but meaningful increase in risk compared to consumption of lower amounts, including 1 drink per day. For those who consume alcohol on most or all days of the week, current United States guidelines sanction consumption of up to an average of 2 drinks per day in men, which is associated with higher mortality risk than drinking up to an average of 1 drink per day. This is consistent with findings of the Committee's review in which studies examining smaller consumption strata generally find that the lowest risk of all-cause mortality among men is consumption of up to 1 or 1.5 drinks per day (depending on how consumption was categorized) compared to higher amounts. Evidence that drinking 2 drinks per day has

increased all-cause mortality risk compared to 1 drink per day among men is more specifically supported by studies with designs that better identify narrower consumption strata or continuous risk functions including traditional meta-analyses,¹⁰⁷⁻¹¹¹ survival analyses,²⁵ and modeling studies using weighted composite risk curves based on multiple alcohol-related causes of death.^{24,107,115,116,125} For example, a recent Australian modeling study that incorporated protective effects for CVD found that men drinking approximately 2 drinks per day on average had an approximately 2.5 to 5 percent increase in alcohol-related mortality compared with drinking 1 drink per day (depending on the pattern of consumption); this absolute risk difference was similar in a sensitivity analysis in which no cardio-protective effects were modeled. A 2.5 percent increase in absolute risk translates into 1 additional death for every 40 men drinking 2 instead of 1 alcoholic drinks. In studies examining relative risk (rather than absolute risk), drinking 2 drinks compared to 1 alcoholic drink corresponds to similar or larger increases in mortality risk.¹⁰⁷

In addition, among those who do not necessarily consume alcohol on most days, available evidence indicates that for any given amount of total consumption, consuming fewer alcoholic drinks per drinking day is generally associated with lower mortality risk than consuming more drinks per drinking day.^{107,125} Conversely, the Committee is not aware of studies demonstrating that drinking 2 drinks per drinking day is as safe or safer than drinking 1 drink per drinking day for men. Furthermore, for a variety of “acute” conditions (e.g., injuries from motor vehicle crashes, falls drownings, violence), the number of drinks consumed per drinking day or per drinking occasion is the primary determinant of risk as mediated through blood alcohol concentration; although these risks increase exponentially at higher levels of consumption, risk increases above zero drinks.^{124,157,159,160} These acute outcomes, which are more common among men than women, comprise a substantial proportion of all alcohol-attributable deaths,¹⁰ and are of particular concern because they disproportionately affect younger and middle aged adults, result in disproportionate harms to vulnerable populations, and may involve harms to persons other than the drinker him or herself.¹⁶¹

The second consideration is that emerging evidence suggests the magnitude of risk associated with low volume alcohol consumption may have been underestimated. This warrants consideration of a more conservative approach to recommendations, particularly because alcohol is a potentially harmful substance with minimal nutritional value. As discussed previously, more recent observational studies and meta-analyses that focus on mitigating confounding and selection bias find reduced protection or no risk reduction for all-cause mortality compared with previous studies. Importantly, MR studies suggest no cardio-protective

effects from low volume consumption for CVD (coronary heart disease and ischemic stroke drive the J-shaped curve for all-cause mortality at low levels of consumption), suggesting that increased all-cause mortality risk (albeit limited) may begin even at very low levels of consumption. Were this the case, the lowest level of risk would be no consumption.

Finally, recognition is growing that alcohol is a causal factor for at least 7 types of cancers, many of them common, with increased risk beginning at levels of consumption starting above zero. For example, in the United States the consumption of less than 1.5 drinks (20 gms) per day on average accounts for approximately 30 percent of all alcohol-attributable cancer deaths.³¹ Although effects on alcohol and cancer are reflected in findings in studies of alcohol and all-cause mortality in earlier studies, the possibility of increased risk of certain cancers (e.g., colorectal cancers) needs to be carefully considered when endorsing the consumption of even low amounts of alcohol, particularly because cancer now accounts for a similar number of deaths as heart disease in the United States.¹⁶² The *2020 American Cancer Society Guideline on Diet and Physical Activity for Cancer Prevention* concludes that “it is best not to drink alcohol.”¹⁶³ Although this precautionary approach regarding cancer applies to both men and women, current guidelines for women are already at 1 drink per day and are written such that consumption of less than 1 drink per day, or 1 drink but not every day, is by no means discouraged and may be associated with better health outcomes for women.

Why should the limit for men be the same as that for women? Although a woman has a higher risk than a man of most harms (including all-cause mortality) at all levels of alcohol consumption, at lower levels of consumption the risk differences between men and women are considerably less than those observed at higher levels of consumption such that different sex-based recommendations are not supported. Furthermore, because men are more likely to drink and accrue alcohol-related outcomes compared to women, reducing consumption in men would have a relatively large health impact at the population level. Over the past decade, other high-income countries (Australia, the Netherlands, the United Kingdom, and France) have tightened alcohol drinking guidelines for men, and harmonized them with women.¹⁶⁴⁻¹⁶⁷

Final Thoughts

Orienting guidelines around increasing levels of risk is the general approach used to develop recommendations for other risk factors such as blood pressure, cholesterol, blood glucose, and body mass. That alcohol is a popular product should not change this approach, at least in the context of guidance to promote health. Given a public health orientation and

limitations of current evidence, the fact that most existing evidence indicates increased risk of all-cause mortality among men drinking 2 drinks per day compared to 1 drink per day, and the possibility that no protection exists for low volume drinking on CVD, changing recommended limits to 1 drink daily for men is justified and should be strongly considered. It is important to acknowledge that many men consume alcohol in excess of this recommendation (and the current recommendation, for that matter), and may not find revised recommendations achievable or desirable, at least on a consistent basis. Nonetheless, although guidelines may be aspirational they are important for communicating evidence around health, stimulating thought around behavior change, and prioritizing policies that may lead to changes in consumption.¹⁶⁸

Finally, these guidelines are intended to improve public health, and should not be interpreted to mean that consumption above these amounts is necessarily indicative of Federal definitions of excessive drinking,^{10-12,18} which are based on higher consumption amounts with higher levels of risk that have been identified as targets for further screening, counseling, and possibly treatment in a clinical context.

Overall, alcohol is an unhealthy substance, and the United States population is far from achieving alcohol consumption levels that would meaningfully reduce alcohol-related harms. Alcohol can be consumed at low levels with relatively low risk, and is consumed by U.S. adults for a variety of reasons. However in terms of health, among those who consume alcohol, drinking less is better for health than drinking more. Currently, no evidence exists to relax current *Dietary Guideline for Americans* recommendations, and there is evidence to tighten them, for men in particular, such that recommended limits for both men and women should be 1 drink per day on days when alcohol is consumed. The Committee's suggestions regarding advice to the general public about drinking in moderation for the next *Dietary Guidelines for Americans* can be summarized as follows:

- Do not begin to drink alcohol or purposefully continue to drink because you think it will make you healthier.
- If you drink alcohol, at all levels of consumption, drinking less is generally better for health than drinking more.
- For those who drink alcohol, recommended limits are up to 1 drink per day for both women and men.

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PART D. CHAPTER 12: ADDED SUGARS

INTRODUCTION

The *2015-2020 Dietary Guidelines for Americans* emphasized healthy dietary patterns across the lifespan that include nutrient-dense foods consumed at an appropriate energy level to help achieve and maintain healthy body weight as well as to support nutrient adequacy and reduce the risk of chronic disease. As such, a major recommendation was to limit energy from added sugars; specifically, to consume less than 10 percent of energy from added sugars.¹ This value (less than 10 percent of energy) was based on food pattern modeling and national data that informed an estimate of energy intake from added sugars that would be possible while meeting food group and nutrient needs within energy limits appropriate for healthy weight. Because added sugars and saturated fats were considered together, the *2015-2020 Dietary Guidelines for Americans* included a cautionary note that for most energy levels, not enough energy would be available, after meeting food group needs, to consume 10 percent of energy from added sugars and from saturated fats. Similar to the previous approach, the 2020 Dietary Guidelines Advisory Committee focused on analyses of the amount of added sugars that can be accommodated in healthy dietary patterns without exceeding energy needs.

Guidance on added sugars is of great relevance because of the high prevalence in the United States of overweight and obesity, type 2 diabetes, cardiovascular disease (CVD), and adiposity-related cancers (see **Part D. Chapter 1: Current Intakes of Foods, Beverages, and Nutrients**). The prevalence of obesity among adults in the U.S. population was 38.9 percent (95% CI: 37.0%, 40.7%) in 2013-2016, with the prevalence of severe obesity at 7.6 percent (95% CI: 6.8%, 8.6%).² Among U.S. youth ages 2 to 19 years, the prevalence of obesity and severe obesity during the same time period was 17.8 percent (95% CI: 16.1%, 19.6%), and 5.8 percent (95% CI: 4.8%, 6.9%), respectively.³ For adults, between 2007-2008 and 2015-2016, the prevalence of obesity and severe obesity increased. However, for youth, no significant trends were observed.⁴ Because obesity is a risk factor for numerous health outcomes, the Committee was asked to address a series of questions on diet and health outcomes assessing the relationship between consumption of added sugars and: 1) growth, size, body composition and risk of overweight and obesity, including gestational weight gain during pregnancy and postpartum weight loss during lactation, 2) risk of CVD, and 3) risk of type 2 diabetes. These questions were addressed as follows:

- **Added sugars in relation to growth, size, body composition and risk of overweight and obesity.** *Part D. Chapter 10: Beverages* presents evidence for the effects of sugar-sweetened beverages (SSB) on these outcomes for children and adults. Given time constraints and because SSB account for a substantial proportion of total energy from added sugars in the U.S. population ages 2 years and older (24 percent for sweetened beverages, not including coffees and teas with added sugar), the Committee relied on evidence from the SSB component of the beverage review for this question. Pregnant and lactating populations were not addressed in this review.
- **Added sugars in relation to risk of CVD.** The review of evidence and conclusions is presented in this Chapter, below, and includes evidence for outcomes including CVD risk profile, CVD clinical endpoints, and CVD mortality. This outcome was prioritized due to the “moderate” grade it received from the 2015 Committee compared to a grade of “strong” for growth, size, body composition, and risk of overweight and obesity and for type 2 diabetes.
- **Added sugars in relation to risk of type 2 diabetes.** Due to time constraints, this evidence was not reviewed, and the 2020 Committee refers to the 2015 Dietary Guidelines Advisory Committee report, in which a review of 5 systematic reviews and a meta-analysis yielded a conclusion of strong evidence that higher consumption of added sugars, especially SSB, increases risk of type 2 diabetes in adults,¹ and that this association was explained, in part, by body mass index.

In addition to these questions on diet and health outcomes, the Committee was asked to consider the relationship between added sugars consumption and achieving nutrient and food group recommendations using data analyses, and the amount of added sugars that can be accommodated in a healthy diet using food pattern modeling.

The Committee defined the term “added sugars” according to the 2016 U.S. Food and Drug Administration (FDA) guidance, which is sugars that are either added during the processing of foods, or are packaged as such (e.g., a bag of sugar). Added sugars include sugars (free, mono-, and disaccharides), sugars from syrups and honey, and sugars from concentrated fruit or vegetable juices that are in excess of what would be expected from the same volume of 100% fruit or vegetable juices of the same type.⁵ In its review, the Committee included studies on consumption of total added sugars from foods and beverages, as well as studies that focused on added sugars from a single substantial source (e.g., sucrose, SSB). List of Questions

1. What is the relationship between added sugars consumption and achieving nutrient and food group recommendations?
2. What is the relationship between added sugars consumption and risk of cardiovascular disease?
3. How much added sugars can be accommodated in a healthy diet while still meeting food group and nutrient needs?

METHODOLOGY

Question 1 was answered using data analysis. Before examining any evidence, the Committee developed a protocol that described how data analyses would be used to answer the question. The protocol included an analytic framework and analytic plan. The analytic framework described the overall scope of the analyses, including the population, types of analyses, and data sources. It also included definitions of key terms.

This question relied on analyses of data from What We Eat in America (WWEIA), the dietary component of the National Health and Nutrition Examination Survey (NHANES). The WWEIA, NHANES collects dietary intake data using 24-hour dietary recalls. Data analyses outlined in the analytic plan focused on the contribution of added sugars to food group intakes as well as intakes of nutrients and other food components. Existing data tables were used when available with new analyses conducted by the Data Analysis Team (DAT) at the Committee's request to provide additional information for specific population groups, such as infants and toddlers and women who are pregnant or lactating. Life stages from children ages 2 years through older adults and including women who are pregnant or lactating were considered. For the general population ages 2 years and older, the 2015-2016 cycle of data were examined. For women who are pregnant or lactating, and analyses of estimated mean added sugars as a percent of total energy, the 2013-2016 data cycles were combined and used. Analyses examining change in dietary intake over time also relied on the 2007-2010 data cycles.

A description of the data analysis methodology is provided in **Part C. Methodology**, including information about the data sources. Complete documentation of the data analysis protocol and the referenced results are available on the following website: <https://www.dietaryguidelines.gov/2020-advisory-committee-report/data-analysis>. Below is a summary of the key elements of the protocol developed to answer Question 1.

The Question describes usual intake distribution in the U.S. population of added sugars from all sources, defined according to FDA guidance. The percent of the U.S. population with added sugars intake less than or equal to and greater than 10 percent of total energy intake based on usual intake distributions also was determined. The Committee also assessed food category contributions to total added sugars intake and determined what, if any, contribution these food categories have on intake of food groups and nutrients as a percent of energy and other dietary components (e.g., intake of whole grains). Demographic subgroup analyses were conducted to look at differences by sex and by race and ethnicity.

The Committee took into account the strengths and limitations of data quality and analyses when formulating conclusion statements, but conclusion statements based on data analyses were not graded. Because data analysis and systematic review are different approaches to reviewing the evidence, the presentation of the summary of evidence is organized differently, but in each case, the conclusion statements are informed by the evidence reviewed, as outlined in the protocol.

Question 2 in this chapter was answered using a systematic review conducted with support from USDA's Nutrition Evidence Systematic Review (NESR) team. This review covered evidence published since the existing systematic review conducted by the 2015 Committee. NESR's systematic review methodology provided a rigorous, consistent, and transparent process for the Committee to search for, evaluate, analyze, and synthesize evidence. The new evidence was synthesized separately from the existing review, and used to draw and grade conclusion statements based solely on the new evidence. **Part C. Methodology** provides a description of the process the Committee used when existing systematic reviews were available. In addition, detailed information about the 2015 Committee's review of the evidence can be found in their report, which is available at the following website: nesr.usda.gov/2015-dietary-guidelines-advisory-committee-systematic-reviews / dietaryguidelines.gov/current-dietary-guidelines/process-develop-2015-2020-dg/advisory-committee.

The Committee developed a systematic review protocol for this question that described how the Committee would apply NESR's methodology to answer the question. The protocol included an analytic framework and inclusion and exclusion criteria to guide identification of the most relevant and appropriate body of evidence to use in answering each systematic review question. Each analytic framework outlined core elements of the systematic review question (i.e., population; intervention and/or exposure and comparator [i.e., the alternative being compared to the intervention or exposure]; and outcomes), and included definitions for key terms, key

confounders, and other factors to be considered when reviewing the evidence. The inclusion and exclusion criteria were selected, up front, to operationalize the elements of the analytic framework, and specify what made a study relevant for each systematic review question.

Next, a literature search was conducted to identify all potentially relevant articles, and those articles were screened by two NESR analysts independently based on the criteria selected by the Committee. For each included article, data were extracted and risk of bias assessed. The Committee qualitatively synthesized the body of evidence to inform development of a conclusion statement(s), and graded the strength of evidence using pre-established criteria for risk of bias, consistency, directness, precision, and generalizability. Finally, recommendations for future research were identified. Below is a summary of the unique elements of the protocol developed to answer the question addressed in this chapter. A detailed description of NESR's systematic review methodology is provided in **Part C. Methodology**, including standard inclusion and exclusion criteria applied in many of the Committee's systematic reviews. Complete documentation of each systematic review is available on the following website:

nesr.usda.gov/2020-dietary-guidelines-advisory-committee-systematic-reviews.

For the systematic review on added sugars and risk of CVD, the populations of interest were children and adolescents (ages 2 to 18 years) and adults (ages 19 years and older).¹

The intervention or exposure of interest was the consumption of added sugars, particularly added sugars from the overall diet or from a food or beverage group that represent a large portion of overall added sugars intake, such as SSB. Studies were excluded if the intervention or exposure examined was consumption of individual types of added sugars that do not represent a large proportion of overall added sugars intake, experimentally-manipulated foods or beverages, low- or no-calorie sweeteners, or sugar alcohols.

The comparator of interest was different levels of consumption of added sugars, including no consumption, or consumption of low- or no-calorie sweeteners. Studies were excluded if they did not examine a comparator.

Outcomes of interest included both intermediate and endpoint health outcomes, and their eligibility for inclusion ultimately varied based on participant age and study design. Intermediate outcomes included total cholesterol, low-density lipoprotein cholesterol (LDL-C), high-density

¹ Infants and toddlers (birth to age 2 years) were later added as a key population of interest for the intervention or exposure only, with corresponding health status criteria and confounders. Only 1 eligible study was found; therefore, all evidence for birth through age 18 years was summarized in this chapter rather than reporting findings separately for birth to age 24 months in the chapter specific to that population (**Part D. Chapter 5: Foods and Beverages Consumed During Infancy and Toddlerhood**).

lipoprotein cholesterol (HDL-C), triglycerides, and blood pressure (systolic and diastolic). The original protocol included cholesterol ratios (total cholesterol:HDL-C and LDL:HDL cholesterol), but they were later removed to enable a focus on a smaller number of intermediate outcomes. The endpoint health outcomes included CVD, myocardial infarction, coronary heart disease, coronary artery disease, congestive heart failure, peripheral artery disease, stroke (ischemic and hemorrhagic), venous thrombosis, and CVD-related mortality. To focus on the strongest available evidence, the Committee established criteria to specify which study designs were eligible for inclusion depending on the outcomes being examined. For adults (ages 18 years and older), only evidence on intermediate outcomes from controlled trials was included; for endpoint outcomes, evidence from controlled trials and certain types of observational studies was included. In children (ages 2 to 18 years), evidence on intermediate and endpoint outcomes from both controlled trials and certain types of observational studies was included.

When establishing inclusion and exclusion criteria, the Committee used standard NESR criteria for publication status, language of publication, country, study participants, and health status of study participants. Additional criteria were added for study duration and sample size, each of which varied by study design. Experimental studies fewer than 4 weeks in duration and observational studies enrolling fewer than 1,000 participants were excluded to focus on the most physiologically plausible and strongest evidence, respectively. Studies were included if they were published from September 2014 to September 2019. This publication date range was applied to this review because the 2015 Committee reviewed evidence on the relationship between added sugars and risk of CVD, which included evidence on this relationship published up to September 2014.

To answer Question 3, the Committee developed a food pattern modeling protocol. The protocol included an analytic framework that described the scope of the food pattern modeling exercises as follows: 1) estimating the energy in the USDA Food Patterns that can be used for added sugars, 2) redistributing energy from top reported sources of added sugars to foods and beverages that achieve food group and nutrient goals, and 3) estimating excess energy from added sugars when USDA Food Patterns are met with typical vs nutrient-dense choices. The analytic framework also described the population, data sources, and key terms used to answer this question.

The exercises relied on data from the U.S. Department of Agriculture Food and Nutrient Database for Dietary Studies (FNDDS) 2015-2016. The Food Patterns Equivalents Database (FPED) 2015-2016 and the National Nutrient Database for Standard Reference, Release 28

(2016 version) provided supporting data. The U.S. population ages 2 years and older, including women who are pregnant or lactating, was considered. The following are key definitions for the food pattern modeling Exercises 1-3:

- **USDA Food Pattern:** A pattern of consumption designed to articulate the evidence on the relationship between diet and health and meet the known nutrient needs of targeted age-sex groups within energy constraints. The patterns include recommended amounts to eat from 5 major food groups—Fruits, Vegetables, Grains, Protein Foods, and Dairy—with recommendations further defined for subgroups of Vegetables and Grains. The USDA Food Patterns do not account for beverages that are not constituents of food groups or subgroups such as soft drinks and coffee or tea.
- **Item Cluster:** Identified groupings of the same or similar foods within each food group and subgroup. Item clusters are used to calculate the composite nutrient profile for each food group and subgroup used to define the USDA Food Pattern.
- **Nutrient Profiles:** The anticipated nutrient content for each food group and subgroup that could be obtained by eating a variety of foods from that group/subgroup in nutrient-dense forms. The nutrient profiles are based on a weighted average of nutrient-dense forms of foods. The weighted average calculation considers a range of American food choices, but in nutrient-dense forms and results in a food pattern that can be adapted to fit an individual's preferences.
- **Nutrient-Dense Representative Food:** The food within an item cluster with the least amount of added sugars, sodium, and solid fats. For some item clusters, the nutrient-dense representative food contains some added sugars, solid fats, and/or sodium.
- **Typical Choice Representative Food:** The most frequently consumed food within an item cluster of foods, including any added sugars, solid fats, and/or sodium.

The analytic plan described the methods the Committee used to address the 3 food pattern modeling exercises. Exercise 1 used the base USDA Food Patterns (i.e., the Healthy U.S.-Style Pattern; see **Part D. Chapter 14: USDA Food Patterns for Individuals Ages 2 Years and Older**) to estimate the energy that could come from added sugars for individuals ages 2 years and older. This involved first identifying the amount of essential calories in the base USDA Food Patterns calculated using nutrient-dense representative foods, some of which contain small amounts of added sugars for palatability or as function of the available food supply. The essential calories from all food groups and oils in the base USDA Food Pattern were summed, with the remaining energy considered as the amount available for other uses. This remaining

energy was assigned exclusively to solid fats and added sugars based on the proportional, population-level intake of these nutrients (55 percent solid fats; 45 percent added sugars). The percent of energy available for added sugars consumption beyond the small amounts inherent to some nutrient-dense foods that comprise the USDA Food Patterns, also were calculated for each of the 12 energy levels.

For Exercise 2, the Committee sought to demonstrate how reducing added sugars intake from current levels of consumption could provide an opportunity to increase intake of more nutrient-dense foods that help meet components of the USDA Food Patterns and specific nutrient goals for age-sex groups. First, the energy from added sugars from the 5 top contributing sources was calculated for age-sex groups. Using current mean intakes for each of the 5 USDA Food Pattern food groups, the amount of additional Fruit, Vegetables, Grains, Protein Foods and Dairy needed to achieve current recommendations was quantified. The nutrient profiles for each food group were then used to estimate the energy needed to achieve these recommendations. Energy needed to meet food group goals were then compared to energy from the top 5 food sources of added sugars. As the final step, the Committee identified gaps in food groups and nutrient intakes that could be addressed by redistributing energy from the top 5 food category sources of added sugars for age-sex groups.

Exercise 3 estimated excess energy from added sugars and solid fats if the USDA Food Patterns were developed with typical choices rather than nutrient-dense representative foods. Typical choices were represented by the nutrient profile of the most frequently consumed food within each item cluster comprising the USDA Food Pattern. Energy and nutrient excesses and deficiencies that exist when typical vs nutrient-dense representative foods comprise the pattern were evaluated.

More information about the food pattern modeling methodology is provided in **Part C. Methodology**. Complete documentation of the food pattern modeling analyses and results is available on the following website: <https://www.dietaryguidelines.gov/2020-advisory-committee-report/food-pattern-modeling/FPM-added-sugars>.

REVIEW OF THE SCIENCE

Question 1. What is the relationship between added sugars consumption and achieving nutrient and food group recommendations?

Approach to Answering Question: Data analysis

Conclusion Statement

In the U.S. population ages 1 year and older, mean usual consumption of added sugars was 13 percent of daily energy intake in 2013-2016. Presently, mean intakes as a percent of total energy range from 10 to 15 percent across age-sex groups. The estimated proportion of the population that consumed greater than 10 percent of energy from added sugars has decreased from 70 percent in 2007-2010, to 63 percent in 2013-2016.

Intake of added sugars averaged 16.2 teaspoon equivalents on a given day for ages 2 and older in 2015-2016. Mean teaspoon equivalent intakes were similar across income and race-ethnicity groups, except that non-Hispanic Asians had lower mean teaspoon equivalent intakes of added sugars compared to other race-ethnic groups.

Nearly 70 percent of added sugars intake comes from 5 WWEIA, NHANES food categories: sweetened beverages, desserts and sweet snacks, coffee and tea (with their additions), candy and sugars, and breakfast cereals and bars. Added sugars intakes could be greatly reduced by decreasing intakes of foods and beverages in these categories and by consuming low- or no-sugar-added versions of foods and beverages that can make positive contributions to diet.

Summary of the Evidence

The following sections describe the results of data analyses conducted to answer Question 1. Additional details can be found in the added sugars data supplements, referenced below as the Food Group Intake Distribution (DIST_DS) and Food Categories Sources (Cat_DS).

Usual Intake Distribution of Added Sugars

Data from 2013 to 2016 show 37 percent of individuals ages 1 year and older consume less than or equal to 10 percent of daily energy from added sugars compared to 30 percent in 2007 to 2010 (Dist_DS). Among adults ages 19 years and older, men are more likely to consume less

than or equal to 10 percent of daily energy from added sugars than women (41 vs 38 percent for men and women, respectively). Among children, a higher percentage of older compared to younger children have mean intakes of added sugars greater than 10 percent: 48 to 50 percent of children ages 1 to 3 years consume more than 10 percent of energy from added sugars compared to 72 to 79 percent of children ages 4 to 18 years. During this time period, total energy consumption remained largely the same (2,065 kcal 2007-2010 vs 2,058 kcal 2013-2016) as the small reduction in consumption of added sugars, was largely offset by a small increase (11.1 to 11.4 percent of total energy) in saturated fat intake.^{6,7}

Mean intakes of added sugars in teaspoon equivalents (tsp eq) remain high across age, sex, race-ethnicity, and income groups. Reported intake of added sugars is 16.20 tsp eq for individuals ages 2 years and older.⁸ Mean intakes are lowest among non-Hispanic Asians (9.58 tsp eq), and similar across other race-ethnic groups, ranging from 15.61 to 17.68 tsp eq on a given day. Average consumption across income groups is 16.19 tsp eq, with less than a 2 tsp eq difference across the income groups.

The range of added sugars intake is wide. Ten percent of the population consumes approximately 100 kcal (approximately 6 tsp eq; 5 percent of a 2,000 kcal diet) or less from added sugars on a given day (Dist_DS). The remaining 90 percent consume in excess of this amount. At the 75th percentile of intake, men and women ages 19 to 70 years consume approximately 400 kcal (25 tsp eq; 20 percent of a 2,000 kcal diet) and 300 kcal (19 tsp eq; 15 percent of a 2,000 kcal diet) of added sugars, respectively. This pattern of consumption at the 75th percentile of intakes is similar among older adults (ages 71 years and older, as defined by these analyses): men consume an average of 350 kcals (22 tsp eq) or 15.7 percent of mean total energy from added sugars and women consume 275 kcal (17 tsp eq) or 15.5 percent of mean total energy.

Women who are pregnant or lactating consume slightly more added sugars, with intakes at the 75th percentile of 372 kcal (23 tsp eq) and 320 kcal (20 tsp eq), respectively, compared to females ages 19 years and older who are not pregnant or lactating who consume 306 kcal (19 tsp eq) from added sugars per day (Dist_DS).

Food Category Sources Contribution to Total Added Sugars Intake

Nearly 70 percent or more of added sugars intake across all age-sex groups comes from 5 food categories: sweetened beverages (i.e., soft drinks, fruit drinks, sports and energy drinks, including smoothies and grain drinks), desserts and sweet snacks, coffee and tea (with their

additions), candy and sugars (e.g., jams, syrups, toppings), and breakfast cereals and bars (Cat_DS). On average, these food categories are the top 5 contributors to added sugars intake for all individuals ages 2 years and older. Some differences exist within age groups. Among younger children ages 2 to 5 years and 6 to 11 years, higher fat milk and yogurt products and burgers and sandwiches, respectively, replace coffee and tea with their additions as a top 5 contributor to added sugars intake. Among adults ages 41 years and older, burgers and sandwiches contribute slightly more to added sugars intake than do breakfast cereals and bars.

Individuals who exceed recommendations for added sugars intake consume more added sugars across many food and beverage sources compared to individuals who meet recommendations.^{9,10} Based on 1 day of dietary recall data, adults who report greater than 10 percent of total energy from added sugars consume significantly more sweetened beverages, coffee, tea, sweet bakery products, candy, ready-to-eat cereals, other desserts, and flavored milks compared to adults who report less than 10 percent of total energy from added sugars. Similar trends are seen among children. This suggests the additional intake of added sugars among those who exceed recommendations does not come from 1 food category.

Across all age categories, beverages (not including milk and 100% juice) contribute 37.1 percent to total added sugars intake (Cat_DS). Among children ages 2 to 19 years, sweetened beverages alone contribute 16.4 to 32.1 percent of added sugars intake. Within this category, fruit drinks are a key contributor to added sugars intake for children ages 2 to 5 years, whereas in older children ages 6 to 19 years, soft drinks are greater contributors.

Table D12.1. Percent of energy from added sugars from the top 5 food category sources across individuals ages 2 years and older¹

	Age Group (Years) ²							
	2+	2-5	6-11	12-19	20-40	41-50	51-70	71+
Sweetened beverages	24.1	16.4	25.2	32.1	32.1	25.3	16.5	12.8
Desserts and sweet snacks	18.8	23.3	22.2	16.1	14.3	17.4	20.5	27.7
Coffee and tea (with their additions)	11.1	2.0	3.0	7.3	12.0	14.9	14.3	11.1
Candy and sugars	9.0	12.6	12.1	8.9	7.3	7.3	9.9	9.0
Breakfast cereals and bars	7.4	11.7	9.6	10.1	6.4	6.2	6.5	7.0
Total	70.4	66.0	72.1	74.5	72.1	71.1	67.7	67.6

¹Source: National Cancer Institute, Top Sources of Food Group Intakes, NHANES 2013-2016 (Cat_DS)

²On average, these 5 food categories are the top contributors to added sugars intake, although there are variations within certain age groups.

Nutrient and Food Group Contributions from Food Category Sources of Added Sugars

In addition to comprising the majority of added sugars intake, some of the top food category sources of added sugars also contribute to food group intakes (Cat_DS). The 5 food category sources that, on average, contribute the most to added sugars for individuals ages 2 years and older (Table D12.1) contribute 11.1 percent and 19.3 percent of total fruit intake in younger (ages 2 to 5 years) and older (ages 6 to 19 years) children, respectively. Although the majority (approximately 60 percent) of total fruit intake for these age groups comes from whole fruit and 100% fruit juice, consumption of sweetened beverages that contain fruit as a component contribute 7.1 to 12.9 percent. For adults ages 20 to 50 years, these 5 food categories contribute 21.7 to 24.2 percent of total daily fruit intake on a given day and slightly less (17.8 to 18.5 percent) for adults ages 51 years and older.

The 5 top food category sources of added sugars, primarily desserts and sweet snacks, and breakfast cereals and bars, account for 17.3 percent of total grain intake for individuals ages 2 years and older, with these foods making up a higher proportion of total grains intake for children ages 2 to 5 years (21.8 percent) and adults ages 71 years and older (24.8 percent) compared to other age groups (Cat_DS). Desserts and sweet snacks are typically made with refined grains, while breakfast cereals and bars often contain whole grains, which are underconsumed. Breakfast cereals and bars account for 40.3 percent of whole grains intake across the population ages 2 years and older and slightly more for children ages 2 to 5 (49.5 percent).

The 5 top food category sources of added sugars contribute to dairy intake across all age groups, but most prominently in adults ages 20 years and older, where one-fifth or more of dairy intake on a given day comes from these food sources (Cat_DS). Desserts and sweet snacks and coffee and tea with their additions contribute more to dairy intake than do the other food category sources of added sugars (3.9 to 11.4 percent from desserts and sweet snacks for ages 2 years and older, and 2.6 to 8.0 percent from coffee and tea with additions for ages 12 years and older).

With regard to nutrient contributions, the 5 top food category sources of added sugars contribute approximately 15 to 18 percent to total intakes of calcium, potassium, dietary fiber, and vitamin D in both children and adults (Cat_DS). The contribution of the 5 top food category sources of added sugars to these nutrients is slightly higher for the older adult population (ages 71 years and older). Of these 5 categories, coffee and tea contribute the most to intake of any single nutrient, as plain coffee, before additions, contributes 118 mg potassium per 8 oz and

plain black tea contributes 89 mg potassium per 8 oz. Otherwise, coffee and tea in their plain form contribute only small amounts of other dietary components.

To access the data analyses referenced above, visit:

<https://www.dietaryguidelines.gov/2020-advisory-committee-report/data-analysis>

Question 2. What is the relationship between added sugars consumption and risk of cardiovascular disease?

Approach to Answering Questions: NESR systematic review

Conclusion Statements and Grades

Limited evidence from prospective cohort studies that were based primarily on sugar-sweetened beverages suggests that higher consumption of added sugars in adulthood is associated with increased risk of cardiovascular disease mortality. Grade: Limited

Insufficient evidence is available to determine the relationship between added sugars consumption and risk of cardiovascular disease in children. Grade: Grade Not Assignable

Insufficient evidence is available to determine the relationship between added sugars intake in adulthood and cardiovascular disease risk profile. Grade: Grade Not Assignable

Insufficient evidence is available to determine the relationship between added sugars intake in adulthood and risk of stroke. Grade: Grade Not Assignable

Insufficient evidence is available to determine the relationship between added sugars intake in adulthood and incident ischemic cardiovascular disease events. Grade: Grade Not Assignable

Insufficient evidence is available to determine the relationship between added sugars intake in adulthood and risk of peripheral artery disease. Grade: Grade Not Assignable

Insufficient evidence is available to determine the relationship between added sugars intake in adulthood and risk of heart failure. Grade: Grade Not Assignable

Summary of the Evidence

- 23 studies examined the relationship between added sugars consumption and the risk of CVD¹¹⁻³³:
 - Children: 3 studies, including 1 randomized controlled trial (RCT) and 2 prospective cohort studies (PCSs).
 - Adults: 20 studies, including 4 RCTs, 2 cross-over studies, and 14 PCSs.
- The added sugars intervention/exposure included:
 - Total added sugars intake from foods and beverages.
 - Added sugars from a single substantial source of overall added sugars intake (e.g., SSB, total sucrose intake).
- CVD outcomes considered:
 - Intermediate outcomes: Total cholesterol, LDL-C, HDL-C, triglycerides, and blood pressure (systolic and diastolic).
 - Children: included intermediate outcome data from RCTs and observational studies.
 - Adults: included intermediate outcome data from RCTs and cross-over studies only.
 - Endpoint outcomes: CVD (including myocardial infarction, coronary heart disease, and coronary artery disease; congestive heart failure; and peripheral artery disease), stroke (separating ischemic and hemorrhagic when possible), venous thrombosis, and CVD-related mortality.
 - Children and adults: included endpoint outcome data from RCTs, cross-over, and observational studies.
- Evidence in children:
 - Three studies reported on intermediate CVD outcomes in children; no studies looking at endpoint outcomes in children met the inclusion criteria.
 - Findings from the 1 RCT and 1 cohort study found greater added sugars intake related to worse lipid profiles in children, namely detrimental change in total cholesterol and HDL-C over time.
 - The third study did not find a significant relationship between added sugars consumption

and CVD outcomes.

- The body of evidence was limited substantially by the small number of studies, the variability in age of the participants, and inconsistency in outcomes measured.
- Evidence in adults:
 - Intermediate outcomes:
 - Three RCTs reported in 4 articles and 2 cross-over studies examined intermediate CVD outcomes; 4 of these studies found no significant effect of added sugars consumption.
 - One RCT found that reducing added sugars consumption led to improved triglyceride levels, and the second paper from a larger sample of participants from the same RCT found that continued high levels of SSB consumption led to detrimental changes in total cholesterol and triglyceride levels.
 - RCT evidence was limited by small sample sizes and inconsistency in exposures and outcomes measured.
 - Endpoint outcomes:
 - CVD-related mortality was assessed by 8 PCSs; 6 of the 8 found no significant effect; 1 found an effect before adjustment for adiposity, and the other reported repeat exposure assessment in 2 independent cohorts and found a significant, positive association
 - A small number of studies examined ischemic CVD events, peripheral artery disease, stroke, and heart failure, which limited the ability to draw conclusions.
 - Most studies adjusted for adiposity, though four studies presented data both with and without adjustment, and all but one found the relationship did not change
 - Observational evidence was limited by inadequate adjustment for confounders, inconsistency in exposures and outcomes measured, and measures of exposure taken at baseline only.

For additional details on this body of evidence, visit: [nesr.usda.gov/2020-dietary-guidelines-advisory-committee-systematic-reviews/beverages-and-added-sugars-subcommittee/added-sugars-cardiovascular-disease](https://www.nesr.usda.gov/2020-dietary-guidelines-advisory-committee-systematic-reviews/beverages-and-added-sugars-subcommittee/added-sugars-cardiovascular-disease)

Question 3. How much added sugars can be accommodated in a healthy diet while still meeting food group and nutrient needs?

Approach to Answering Questions: Food Pattern Modeling

Conclusion Statement

Estimating Remaining Energy for Added Sugars in the USDA Food Patterns

The amount of energy required to meet food group and nutrient needs using nutrient-dense representative foods comprises 85 percent or more of total energy available across most energy levels. Assuming the remaining energy is distributed exclusively to solid fats and added sugars according to population-level proportional intakes, this leaves 6 percent or less of additional energy available for the consumption of added sugars for most energy levels. In the highest energy levels analyzed of 3,000 kcal/day and 3,200 kcal/day, 7 and 8 percent or fewer additional energy would be available, respectively. Even these modest percentages of energy available for added sugars represent relatively rare scenarios where individuals consume only recommended amounts of nutrient-dense foods and beverages and no energy from alcohol. These scenarios assume a constant amount of energy consumed with no change in body weight.

Redistributing Energy from Top Reported Sources of Added Sugars

Five food categories contribute the majority of added sugars intake in the U.S. population and these foods are often energy-dense with low amounts of key dietary nutrients. The redistribution of energy from food categories with added sugars to underconsumed food groups and nutrients could have a significant positive impact on overall diet quality and nutrient status (for example, by allowing age-sex groups to better meet food group recommendations for Fruits, Vegetables, and Dairy) and also could increase consumption of key nutrients contained in these food groups.

Estimating Excess Energy from Added Sugars with Typical vs Nutrient-Dense Choices

When the USDA Food Patterns are constructed with the most frequently consumed typical food choices rather than nutrient-dense representative foods, the contribution of added sugars to total energy increases. If consumers choose to eat the recommended quantities from each food group or subgroup, but do not choose nutrient-dense foods lower in added sugars, total energy will exceed daily needs due to a relatively higher contribution of added sugars as well as solid fats.

Summary of the Evidence

Estimating Remaining Energy for Added Sugars in the USDA Food Patterns

In Exercise 1, the Committee estimated the energy available for added sugars in the base USDA Food Pattern under the assumption that individuals consume nutrient-dense representative foods that are lean or no-fat with low or no added sugars and generally without added salt (i.e., the base pattern, the Healthy U.S.-Style Pattern [see **Part D. Chapter 14: USDA Food Patterns for Individuals Ages 2 Years and Older**]). The results demonstrate that across most energy levels, assuming population-level proportional intakes of solid fats and added sugars, no consumption of alcoholic beverages, and that nutrient-dense foods and beverages are not consumed in excess of recommended amounts, 6 percent or fewer calories are available for the consumption of added sugars across all but the 2 highest energy levels analyzed.

The number of essential calories (i.e., the energy associated with the foods and beverages ingested to meet nutritional goals through choices that align with the USDA Food Patterns in forms with the least amounts of saturated fat, added sugars and sodium) was less than the amount of total energy for all energy levels. Essential calories comprise greater than 85 percent of total energy across most levels of the base USDA Food Pattern, the Healthy U.S.-Style Pattern (see **Part D. Chapter 14**). The remaining energy is available for consumption of solid fats or added sugars, alcohol, or additional consumption of nutrient-dense foods beyond food group needs. Table D12.2 assigns the remaining energy exclusively to solids fats and added sugars, with 55 percent of energy from solid fats and 45 percent from added sugars, according to population-level proportional intakes.

The energy remaining and assigned to solid fats and added sugars are low across calorie levels below 2,000, and lowest in patterns between 1,200 to 1,600 kcal/day. The higher energy

limit for solid fats and added sugars at the 1,000 kcal/day pattern is attributed to a lower amount of dairy compared to the 1,200, 1,400 and 1,600 kcal/day patterns that are designed for older children and adult women with a higher Recommended Dietary Allowance (RDA) for calcium. Assuming population-level proportional intakes of solid fats and added sugars, no alcohol consumption, and no consumption of nutrient-dense foods beyond recommended amounts, the percent of energy available for added sugars is 6 percent or less at nearly all energy levels analyzed, with 3 to 5 percent of energy available for added sugars among the majority of the population, with the exception of the 3000 kcal/day and 3,200 kcal/day levels of intake (7 and 8 percent, respectively). The added sugars inherent to the nutrient-dense foods in the Healthy U.S.-Style Pattern is small, ranging from 17 to 50 total kcal from added sugars across energy levels, or 1.5 to 1.9 percent of total energy.

Table D12.2. Essential calories and limit on solid fats and added sugars across energy levels in the Healthy U.S.-Style Food Patterns for ages 2 years and older

	Essential Calories ¹	Percent Essential Calories ¹	Energy Limit for Solid Fats and Added Sugars ²	Energy Assigned to Solid Fats ³	Energy Assigned to Added Sugars ³	Grams of Solid Fats ⁴	Grams of Added Sugars ⁴	Percent Energy Added Sugars
Level	kcal	% kcal	kcal	kcal	kcal	g	g	%
1,000	868	87	132	72	59	9	15	6
1,200	1120	93	80	44	36	5	9	3
1,400	1310	94	90	49	40	6	10	3
1,600	1496	94	104	57	47	7	12	3
1,800	1657	92	143	79	65	9	16	4
2,000	1759	88	241	133	109	16	27	5
2,200	1947	88	253	139	114	17	29	5
2,400	2079	87	321	176	144	21	36	6
2,600	2251	87	349	192	157	23	39	6
2,800	2431	87	369	203	166	24	41	6
3,000	2559	85	441	243	199	29	50	7
3,200	2620	82	580	319	261	38	65	8

¹ The energy associated with the foods and beverages ingested to meet nutritional goals through choices that align with the USDA Food Patterns in forms with the least amounts of saturated fat, added sugars and sodium.

² Calculated from pattern calorie level minus essential calories.

³ Calculated as 55 percent of energy from solid fats and 45 percent from added sugars, based on mean population intakes (NCI Usual Intakes data for NHANES 2013-2016).

⁴ Calculated using caloric values of 8.4 kcal per 1 gram of solid fats and 4 kcal per 1 gram of added sugars.

Importantly, the added sugars focus of this analysis assumes a specified solid fat intake and no alcohol consumption. If intake of solid fat is increased or alcohol is consumed, the energy from added sugars would have to be decreased markedly to meet energy goals. For example,

at the 2,000 kcal/day level, if an individual consumes 2.4 tablespoons of butter (241 kcal) in addition to the nutrient-dense foods that comprise the Healthy U.S.-Style Pattern, no energy remains for the consumption of foods and beverages with added sugars. Conversely, lower intake of fat would permit a more liberal inclusion of added sugars in a diet otherwise comprised of nutrient-dense foods. For instance, if saturated fat intake is reduced by 5 grams (about 45 kcal) then added sugars intake could be increased by about 11g (about 44 kcal) while remaining within energy balance. Table D12.3 provides hypothetical ratios of added sugars:solid fat intake at the 2,000 calorie per day level and sample foods to represent each amount of intake. Note the first row of this table is taken from Table 12.2 in which the proportion of added sugars:solid fat ratio is that of the population age 2 years and older.

Table D12.3. Example distributions of solid fats and added sugars with sample food amounts in the 2,000 kcal level in the Healthy U.S.-Style Food Pattern

	Energy Limit for Solid Fats and Added Sugars ^{1,2}	Energy Assigned to Solid Fats ³	Energy Assigned to Added Sugars ³	Grams of Solid Fats ⁴	Sample food equivalent ⁵ (Butter)	Grams of Added Sugars ⁴	Sample food equivalent (Regular soda)	Percent Energy Added Sugars
Level	kcal	kcal (%)	kcal (%)	g	Tbsp	g	~Oz.	%
2,000	241	0 (0)	241 (100)	0	N/A	60	Soda: 20	12
2,000	241	60 (25)	181 (75)	7	Butter: 0.5	45	Soda: 16	9
2,000	241	109 (45)	133 (55)	12	Butter: 1.1	33	Soda: 12	6
2,000⁵	241	133 (55)	109 (45)	16	Butter: 1.2	27	Soda: 9	5
2,000	241	181 (75)	60 (25)	20	Butter: 1.7	15	Soda: 5	3
2,000	241	241 (100)	0 (0)	27	Butter: 2.4	0	N/A	0

¹ Calculated from pattern energy level minus essential calories

² The energy limit for solid fats and added sugars assumes consumption of nutrient-dense foods that meet nutritional goals through choices that align with the USDA Food Patterns in forms with the least amounts of saturated fat, added sugars and sodium.

³ Based on mean population intakes (NCI Usual Intakes data for NHANES 2013-2016)

⁴ Calculated using caloric values of 8.4 kcal per 1 gram of solid fats and 4 kcal per 1 gram of added sugars

⁵ As shown in table D 12.2, the remaining energy for added sugars and solid fats is assigned in a 55:45 ratio based on mean population-level intakes

Redistributing Energy from Top Reported Sources of Added Sugars

In Exercise 2, the Committee demonstrated how reducing added sugars intake from the top contributing sources and reassigning energy to underconsumed food groups can help better achieve food group and nutrient goals across age-sex groups.

As described earlier in this chapter for Question 1, 5 food categories (sweetened beverages, desserts and sweet snacks, coffee and tea (with their additions), candy and sugars, and

breakfast cereals and bars) make up approximately 70 percent of total added sugars intake. For many age-sex groups, these 5 food categories contribute 200 or more kcal daily to total energy intake.

The analysis of current mean intakes shows that most age-sex groups fall short of meeting food group and nutrient recommendations (<https://www.dietaryguidelines.gov/2020-advisory-committee-report/data-analysis>). More specifically, with the exception of males and females ages 2 to 3 years, age-sex groups underconsume fruits, vegetables, and dairy. Although grains are generally not underconsumed, all age-sex groups meet this food group recommendation through the consumption of refined grains rather than nutrient-dense whole grains. Protein is underconsumed by certain age-sex groups, specifically males ages 4 to 8 years, and females ages 9 to 13 years and 14 to 18 years.

Considering nutrient shortfalls across age-sex groups, as described in **Chapter 1: Current Intakes of Foods, Beverages, and Nutrients**, reassigning the energy available from the top contributors of added sugars intake (e.g., desserts and sweet snacks) to underconsumed food groups across age-sex groups could be beneficial. For example, for males ages 4 to 8 years, the redistribution of energy from the top food sources of added sugars to the Vegetables food group; particularly Dark Green, Red and Orange, and Starchy subgroups; as well as the Protein Foods group, particularly seafood and eggs, would contribute substantially to food group and nutrient goals for this age-sex group. For women of childbearing age, redistributing the energy from added sugars to the Dairy and Vegetables food groups and consuming foods rich in calcium (e.g., milk, cheese, yogurt) and folate (e.g., dark green vegetables and legumes) could help reduce these nutrient shortfalls across this population.

The redistribution of energy from refined to whole grains sources to better meet nutrient recommendations must be considered with caution, however. Specifically, certain food categories, such as breakfast cereals and bars, are both a source of whole grains and a top contributor to added sugars intakes. In these instances, shifting to a lower sugar or no-sugar added version of the breakfast cereal or bar would be preferable rather than shifting energy to other food sources.

Estimating Excess Energy from Added Sugars with Typical vs Nutrient-Dense Choices

Exercise 3 on typical choices demonstrates that although the USDA Food Patterns allow for some additional energy for added sugars when nutrient-dense representative foods are used

(Exercise 1), when typical choices are assumed, excess energy is consumed, added sugars consumption is increased, and no dietary energy remains for other uses.

The USDA Food Patterns are constructed to provide adequate levels of nutrients within calorie limits. The base USDA Food Pattern, the Healthy U.S.-Style Pattern, achieves this by including representative foods in their most nutrient-dense forms (rather than the most commonly consumed representative foods) in which solid fats and added sugars are generally limited to very small amounts. When typical rather than nutrient-dense representative food choices are included, total energy exceeds that specified in most USDA Food Patterns. For example, when typical foods are used to meet nutrient goals at the 1,600-calorie level, the food pattern includes an additional 355 kcal above the total energy target; the 2,000 kcal pattern has 264 excess energy within the foods pattern.

When typical vs nutrient-dense foods are consumed, the contribution of added sugars to total energy intake also increases. Based on a 2,000-calorie pattern, added sugars contribute more energy to the Dairy, Grains, and Fruit food groups in the USDA Food Pattern when typical rather than nutrient-dense representative foods are assumed. Within the Dairy group, the typical choices of milk shakes, flavored milks, and regular ice cream are the primary contributors to this increase. For Grains, the inclusion of desserts and sweetened cereals contribute to an increase in added sugars in this analysis. With Fruit, the typical choices analysis includes fruits packed in syrup and cooked fruit with sugar rather than fruit in its whole form, leading to higher consumption of added sugars.

It is important to note that the analysis of typical choices does not account for beverages, including alcohol, soft drinks, or coffee and tea, which are not constituents of food groups or subgroups. Therefore, the contribution of these beverages to energy intake and added sugars is not addressed or captured in the Exercise 3. Given that many beverages contribute to energy intake, but do not contribute to food group intakes and therefore are not included in these analyses, the estimate of excess energy from added sugars with typical vs nutrient-dense choices is conservative.

For additional details on the Food Pattern Modeling described above, visit:
<https://www.dietaryguidelines.gov/2020-advisory-committee-report/food-pattern-modeling>

DISCUSSION

The totality of evidence across systematic reviews conducted either as part of the Committee's report or as part of the *2015-2020 Dietary Guidelines for Americans* effort generally support conclusions that favor limiting the consumption of added sugars to, at most, very low amounts. This evidence is particularly important in light of the high proportion of total energy accounted for by added sugars among children and adults in the United States. In addition to the various specific concerns described above, the available evidence related to health effects of added sugars has a number of limitations that are important to highlight here:

- Challenges in Exposure Assessment:** In addition to the usual limitations of dietary assessment in free-living children and adults, a question exists as to the extent to which SSB (the source of much of the research about added sugars) can inform the question of exposure to added sugars. On the one hand, these products contribute a substantial proportion of total intake of added sugars and, thus, can be used as a marker of exposure. However, on the other hand, it is possible that the health impacts of SSB may differ from those of sugars added to solid food. In either case, SSB themselves represent a specific exposure to a source of added sugars that is relevant to the U.S. population due to how commonly these beverages are consumed. An additional limitation in the available literature is that exposures were quantified in different ways across studies, with no standard approach to create categories of intake and, for continuous variable approaches, infrequent consideration of a potential non-linear dose response curve.
- Challenges in PCSs:** Regardless of the specific approach to exposure assessment at any one time, with rare exception, PCSs considered intake of added sugars at baseline only and did not incorporate change in intake over time into the statistical analysis. This is a major limitation because changes in intake over time that are not accounted for would impose potential for serious misclassification bias.
- Challenges in RCTs:** Very few recent RCTs were available for review. Limitations included interventions that were not effective in substantially reducing intake over time, or in which the impact of change in consumption of added sugars could not be separated from other behaviors that could affect health outcomes.

Recently published systematic reviews and meta-analyses provide additional perspective. In one such article, a systematic review and dose-response meta-analysis of PCSs addressed

added sugars in relation to CVD.³⁴ Although evidence supported a threshold for harm from intake of added sugars for CVD mortality, many methodological issues were noted and the authors considered certainty in their estimates as “weak,” and called for more research on dose responsiveness, particularly with regard to potential differences in effect for SSB compared to sugar added to solid food. From a systematic review of the impact of SSB on blood pressure, another article reported evidence for an association of higher intake of SSB with higher blood pressure. Meta-analyses conducted separately for studies of children and adults, including both PCSs and RCTs, yielded evidence that higher intake of SSB was associated with excess body weight gain. Across these systematic reviews and meta-analyses, the limitations detailed in this report were apparent; nonetheless, the totality of evidence pointed to adverse effects of added sugars, including and particularly SSB, that is associated with unhealthy weight gain and obesity-related health outcomes.

Finally, in total, remarkably few studies addressed specific CVD risk factors (other than excess body weight) in either youth or adults. Only 1 of 2 studies in adults met inclusion criteria for each of several important outcomes, including ischemic CVD events, stroke, peripheral arterial disease, and heart failure.

SUMMARY

The addition of sugars to foods or beverages provides energy, generally without contributing additional nutrient content. Taking into account both the 2015 and 2020 Committee evidence reviews, relative to the goal of improving the health of a population in which the prevalence of overweight and obesity is high, the addition of sugar to the diet raises concerns about the potential risk of increasing unhealthy weight gain and, in turn, increasing risk of obesity-related health outcomes. Foods and beverages with added sugars comprise a part of the culture and traditions of many families and communities in the United States. Therefore, it would not be reasonable, or even desirable, to recommend no consumption of added sugars. However, reducing the amount of added sugars in the diet, through either changes in consumer behavior or in how food is produced and sold, or through food policy, is an achievable objective that could improve population health. Although intake of added sugars remains high, data reviewed by the 2020 Committee suggest the consumption of added sugars decreased slightly over the last decade suggesting a reduction is feasible. With the aim of providing a balanced perspective that retains the pleasure of eating while reducing risk of adverse health outcomes, Table D12.4

provides an update to the information provided in the 2015 Committee report on the relevant recommendations from various high profile national and international organizations on this topic.

Table D12.4. Recommendations or statements related to added sugars or SSB from international and national organizations

Organization	Recommendation
World Health Organization (WHO) ³⁷	Reduced intake of free sugars throughout the life course (strong) Reduced intake of free sugars to <10% of total energy (strong) Reduced intake of free sugars to <5% of total energy (conditional)
American Heart Association (AHA) ^{38,39}	Adults: Reduce to an upper limit of half of discretionary calorie allowance for a person to achieve or maintain healthy weight: For most American women, eat or drink no more than 100 kcal per day (about 6 teaspoons); for most American men, no more than 150 kcal per day (about 9 teaspoons) Children: Limit intake of SSB to ≤1 8-oz serving per week (Evidence Level A); <100 kcal/day (~ 6 tsp) (Evidence Level C); avoid added sugars in the diet of children <2 years old (Evidence Level C)
HealthyPeople 2020 ⁴⁰	Objective NWS-17.2: Reduce consumption of energy from added sugars (Target: 9.7 percent)
American Diabetes Association (ADA) ⁴¹	Replace SSB with water as often as possible and minimize added sugars
NHLBI Expert Panel Guidelines for Cardiovascular Health and Risk Reduction in Childhood ⁴²	Reduced intake of SSB is associated with decreased obesity measures (Grade B)

Updated analyses of dietary intake in America allow for model-based estimation of discretionary calories available after accounting for foods consumed to meet nutritional requirements, as summarized in Table D12.2. Based on those analyses, along with the scientific evidence for the potential health impacts of added sugars intake, the Committee suggests that for adults and children ages 2 years and older, a recommendation of less than 6 percent of energy from added sugars is more consistent with a dietary pattern that is nutritionally adequate while avoiding excess energy intake than is a pattern with less than 10 percent energy from added sugars. The reader is referred to **Part D. Chapter 7: USDA Food Patterns for Children Younger than Age 24 Months** in which the recommendation and rationale is provided for added sugars to be avoided during the first 2 years of life. In addition to recommendations for individuals to limit intake of added sugars, in 2019, the American Heart Association and the American Academy of Pediatrics published a joint policy statement to reduce intake of sugary drinks by children and adolescents. Although the Committee did not review these policies, they

contribute support for dietary recommendations for reduction of added sugars in the American diet, thereby enabling progress toward improved weight and health status for the United States.

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PART D. CHAPTER 13: FREQUENCY OF EATING

INTRODUCTION

Eating is a behavior that provides humans with nutrients for growth, function, and body maintenance. Eating behaviors can support or weaken health and strongly influence the quality and length of life. Although eating behavior is usually thought of in terms of the types and amounts of foods ingested, the frequency of eating is an equally important factor. A person's daily nutrient intake and overall nutritional status are determined by a complex interplay of these three factors. Eating more or less frequently might influence the types or amounts of foods eaten or alter digestive and metabolic processes. Thus, changes in frequency of eating could lead to changes in a person's nutritional and health status.

This chapter examines the available data concerning the relationships between frequency of eating and: achieving nutrient and food group recommendations; growth, body size and composition, overweight and obesity, cardiovascular disease, type 2 diabetes, and all-cause mortality. The available data on frequency of eating during pregnancy and gestational weight gain is addressed in ***Part D. Chapter 2: Food, Beverage, and Nutrient Consumption During Pregnancy*** and data on frequency of eating during lactation and post-partum weight loss are addressed in ***Part D. Chapter 3: Food, Beverage, and Nutrient Consumption During Lactation***.

Importance and Relevance of this Topic

The traditional American diet is organized around 3 meals/day (i.e., breakfast, lunch, and dinner). This 3-meal frequency of eating pattern is deeply embedded in popular culture, although Americans now report a mean of more than 5 meals or snacks per day.¹ This greater eating frequency is largely due to an increase in snacking, though consensus on clear definitions or distinctions between a meal versus a snack remains elusive. Forty-year trends in eating behaviors from the What We Eat In America (WWEIA), National Health and Nutrition Examination Surveys (NHANES) conducted from 1971 to 2010 found that American adults report an average of 2.8 meals and 2.3 snacks per day.¹ Similar patterns are also observed in children.² Of interest, some evidence suggests that eating frequency varies by time of day and days of the week.^{3,4}

Although no previous editions of the *Dietary Guidelines for Americans* have made specific eating frequency recommendations, they have promoted the consumption of nutrient-dense

breakfasts and snacks for improved health outcomes.^{5,6} Increasing public awareness and research activity related to selected aspects of eating frequency, such as “grazing,” intermittent fasting, meal skipping, and late-night eating reflects a high level of interest in the evolving science of eating frequency. An emerging scientific evidence base is now beginning to allow examination of eating frequency and health over varied populations, conditions, and health indices. Thus, an examination of whether eating frequency directly affects diet quality and health outcomes is warranted and is the focus of this chapter.

Setting the Scope of the Review

As alluded to above, studies vary widely in defining and measuring the eating occasions that are the unit of measure for frequency of eating. A critical first step before examining the scientific literature for the 2020 Dietary Guidelines Advisory Committee, therefore, was to establish a definition for eating occasions. When considering how to appropriately define eating occasions, the Committee considered the following kinds of issues:

- Should snacking be considered an eating occasion?
- Should meals and snacks be examined separately?
- Should an eating occasion include instances where no energy is consumed (e.g., water intake or low or no energy beverage intake alone)?
- Should energy, nutrients, or type of food be considered?
- Should beverage intake be considered an eating occasion when occurring alone?
- When does one eating occasion stop and another start?
- What time duration or interval is needed to accurately assess eating frequency?
- Should the time of the eating occasion (e.g., morning or first eating occasion, late night) and/or the time interval between eating occasions (e.g., time-restricted eating, intermittent fasting) be considered?

After careful deliberation, the Committee concurred that an eating occasion be defined as “any ingestive event (solid food or beverage, including water) that is either energy yielding or non-energy yielding.” Accordingly, frequency of eating was defined by the Committee as “the number of daily eating occasions.” No minimal or maximal time criteria between eating occasions was imposed, as no standard intervals have been used in the literature.

The following types of instruments are used in scientific studies to quantify the number of daily ingestive events: 24-hour dietary recall, 24-hour dietary record, and eating frequency

questionnaires. Food frequency questionnaires, in general, assess the frequency of specific foods and/or beverages consumed and not the number of ingestive events over a given amount of time. However, a study was included if specific questions related to ingestive events were coupled with the food frequency questionnaire.

As previously mentioned, this is the first Committee to directly evaluate the effect of frequency of eating on health outcomes and the Committee wanted to ensure the studies included in the systematic review collected enough data from which to ascertain that it was the frequency of eating, and not other dietary aspects, that were related to any health outcome. The literature on frequency of eating generally examines two experimental designs, those based on observational studies and those based on intervention studies. Therefore, the Committee set unique minimum criteria for studies to be included in the systematic review that answered Questions 2 through 5 in this Chapter (see Methodology section).

LIST OF QUESTIONS

1. What is the relationship between the frequency of eating and achieving nutrient and food group recommendations?
2. What is the relationship between the frequency of eating and growth, size, body composition, and risk of overweight and obesity?
3. What is the relationship between the frequency of eating and all-cause mortality?
4. What is the relationship between the frequency of eating and risk of cardiovascular disease?
5. What is the relationship between the frequency of eating and risk of type 2 diabetes?

METHODOLOGY

Data Analysis Methodology

Question 1 in this chapter was answered using data analysis. The Committee developed a protocol for the question, which described how the Committee would use data analyses to answer the question. The protocol included an analytic framework that describes the overall scope of the analyses, including the population and type of analyses and data sources identified to answer the question. It also includes the definitions of key terms.

Data from nationally representative federal datasets were analyzed by the Data Analysis Team (DAT). More information about the data analysis methodology is provided in **Part C**.

Methodology, including more detail on the data sources. Complete documentation of the data analysis protocol and the referenced results is available on the following website: [place holder for site]. Below is a summary of the unique elements of the protocols developed to answer the questions addressed in this chapter.

The data analyses considered for this question include the average number of ingestive events. Other analyses include data from the WWEIA, NHANES on named eating events as identified by the participant during a 24-hour dietary recall (e.g., breakfast, lunch, snack).⁷ The definition of each ingestive event label in both English and Spanish are defined in the key terms of the protocol. Data on the proportion of nutrients and other food components from each ingestive event was estimated by discrete meal categories (i.e., breakfast, lunch, dinner, and Spanish-language equivalents) and snacks (i.e., snacks, beverage only, and extended consumption events (events where foods or beverages were consumed over a long period of time). Also of interest was the proportion of food components consumed between 8 p.m. and midnight among adolescents and adults.

Because data analysis and systematic review are different approaches to review the evidence, the presentation of the summary of evidence is organized differently below. In each case, however, the conclusion statements are informed by the evidence reviewed, as outlined in the protocol. The Committee took the strengths and limitations of data analyses into account in formulating conclusion statements. The grading process used for questions answered by the NESR systematic review methodology does not apply to questions using data analysis; therefore, data analysis conclusions were not graded.

Systematic Review Methodology

Questions 2 through 5 in this Chapter were answered by conducting systematic reviews with support from USDA's Nutrition Evidence Systematic Review (NESR) team.

NESR's systematic review methodology provided a rigorous, consistent, and transparent process for the Committee to search for, evaluate, analyze, and synthesize evidence. The Committee developed a systematic review protocol for each question, which described how the Committee would apply NESR's methodology to answer the question. Each protocol included an analytic framework and inclusion and exclusion criteria that were used to guide identification of the most relevant body of evidence to use in answering each systematic review question.

Next, a literature search was conducted to identify all potentially relevant articles, and those articles were screened by 2 NESR analysts independently based on the criteria selected by the Committee. For each included article, data were extracted and risk of bias assessed. The

Committee qualitatively synthesized the body of evidence to inform development of a conclusion statement(s), and graded the strength of evidence using pre-established criteria for risk of bias, consistency, directness, precision, and generalizability. Finally, recommendations for future research were identified.

A detailed description of NESR’s systematic review methodology is provided in **Part C. Methodology**, including standard inclusion and exclusion criteria applied in many of the Committee’s systematic reviews. Complete documentation of each systematic review, including the protocol, is available on the following website: nesr.usda.gov/2020-dietary-guidelines-advisory-committee-systematic-reviews. Below is a summary of the unique elements of the protocols developed to answer the questions on frequency of eating.

For the questions on frequency of eating and all-cause mortality, cardiovascular disease, and type 2 diabetes, the population of interest was children and adolescents (ages 2 to 18 years); adults (ages 19 to 64 years); women during pregnancy or lactation; older adults (ages 65 years and older). For the question on frequency of eating and growth, size, body composition, and risk of overweight and obesity, “women during pregnancy or lactation” were removed from the population of interest. Women during pregnancy and women during lactation were the populations of interest in 2 additional questions examining the relationship between frequency of eating and gestational weight gain (see **Part D. Chapter 2: Food, Beverage, and Nutrient Consumption During Pregnancy** for these results) or post-partum weight loss (See **Part D. Chapter 3: Food, Beverages, and Nutrient Consumption During Lactation** for these results), respectively.

In all reviews, the intervention or exposure of interest was frequency of eating, with the comparator of interest being a different number of daily eating occasions. Frequency of eating was defined as “the number of daily eating occasions,” and daily eating occasions were defined as “any ingestive event (solid food or beverage, including water) that is either energy yielding or non-energy yielding.”

The outcomes of interest in each review are as follows:

- All-cause mortality: the total number of deaths from all causes during a specific time period
- Cardiovascular disease: total cholesterol (TC), low-density lipoprotein cholesterol (LDL-C), high-density lipoprotein cholesterol (HDL-C) (including TC:HDL cholesterol and LDL:HDL cholesterol ratios), triglycerides, blood pressure (systolic and diastolic), cardiovascular disease (myocardial infarction, coronary heart disease (CHD), coronary

artery disease, congestive heart failure, peripheral artery disease), stroke, venous thrombosis, and cardiovascular disease-related mortality

- Type 2 diabetes: glucose, insulin, hemoglobin A1c, prediabetes, and type 2 diabetes
- Growth, size, body composition, and risk of overweight and obesity: weight, weight-for-age, height, length/stature-for-age, body mass index (BMI), BMI z-score, weight-for-length, body circumferences (head, arm, waist, thigh, neck), body composition and distribution (e.g., percent fat mass, fat-free mass, lean mass), and incidence and prevalence of underweight, failure to thrive, stunting, wasting, healthy weight, overweight, or obesity

When establishing inclusion and exclusion criteria, the Committee used standard NESR criteria for study design, publication status, language of publication, country, study participants, and health status of study participants. Studies were included if they were published from January 2000 to June 2019. In addition, the Committee applied unique inclusion and exclusion criteria for eating frequency data collection and size of study groups, as follows:

- Data collection for eating frequency, in both intervention and observational studies, had to encompass a minimum of 3, 24-hour periods or a questionnaire that covered at least 3 days. In addition, for intervention studies, data collection had to occur on at least 2 occasions, including baseline and during or after the intervention. These criteria were selected to ensure a reasonable measure of customary eating frequency was used in both observational and intervention studies. Eating frequency varies across days and throughout the lifespan. To capture customary or habitual eating frequency, the Committee determined it necessary to have multiple days of data collection. With respect to intervention studies, the Committee required measurement of eating frequency on 2 occasions, at baseline, and then again during or after the intervention. This requirement allowed for the measurement of baseline (usual) eating frequency pattern before the intervention, whereas the second occasion measured eating frequency as a result of the intervention. The second occasion could also be a measure of compliance or adherence to the intervention.
- For intervention studies, at least 15 participants for studies using within-subject analyses, or 30 participants for studies using between-subject analysis, or a power calculation included was required. It is important to ensure that a study is adequately powered to find an effect. Including 30 participants in studies using between-subject

analysis, or 15 participants using within-subject analysis, resulted in being able to detect a less than 1 standard deviation of the mean.

REVIEW OF THE SCIENCE

Question 1. What is the relationship between the frequency of eating and achieving nutrient and food group recommendations?

Approach to Answering Question: Data analysis

Conclusion Statements

Eating patterns vary by frequency and timing in the United States, and are shaped by age, race/ethnicity, and income. On average, the U.S. population reports 5.7 eating occasions per day, occurring most often at noon or “evening.”

Most of the U.S. population report consuming 3 meals (64 percent of the population) or 2 meals (28 percent of the population) per day.

Snacking is ubiquitous, occurring in 93 percent of the U.S. population. Snacks provide 22 percent to 23 percent of total energy consumed and 2 to 3 snacking events are reported on average per day.

Late-night eating events often include alcohol intake (in adults), and intakes of added sugars, sodium, and saturated fats in adolescents and adults.

When compared with 2 meals, Americans who consume 3 meals per day tend to have approximately 5-point higher Healthy Eating Index scores.

Summary of the Evidence

Various eating patterns exist in America, especially with regard to the frequency and timing of eating, which are largely shaped by a number of demographic characteristics such as age, race/ethnicity, and income. A recent analysis examining the frequency of eating, timing of events, and labels applied to those eating events by Americans such as breakfast, lunch, or dinner and their Spanish equivalents indicated that on average, Americans report about 5.7

eating events a day, inclusive of meals, snacks, beverages, and extended consumption. The majority of these eating events cluster around certain times of the day that align with conventional naming of meals such as lunch and dinner. However, conventional naming of meals is limited given the extensive variability in eating behaviors among American demographic subpopulations. Nevertheless, conventional naming of meals helps shape context for providing and tailoring recommendations. The times associated with conventional meals were 7 to 9 a.m. for breakfast, 12 to 1 p.m. for lunch, and 6 to 8 p.m. for dinner. Most Americans report 2 or 3 snacks per day, most often in the afternoon time between lunch and dinner. Later temporal eating events were more likely to be reported by adolescents and young adults. Eating events after 8 p.m. represented one-quarter to one-third of food components recommended to be consumed in moderation: added sugars, sodium, and saturated fats. Additionally, among adults, most alcoholic beverages are consumed within this time range.

The majority of Americans report consuming 2 (28 percent) or 3 (64 percent) meals per day, and the likelihood of reporting 3 meals per day varied in magnitude by age group among Americans. Although U.S. adults (ages 20 years and older) were the least likely to report 3 meals per day and the largest proportion of their daily energy intake was reported at dinner time, adolescents (ages 14 to 18 years) and young adults (ages 20 to 39 years) were the least likely to consume breakfast, and tended to shift eating occasions to later in the day (i.e., after 8 p.m.). Alternatively, among children (ages 2 to 19 years), total daily energy was generally distributed between breakfast (18 percent), lunch (27 percent), dinner (32 percent), as well as snacks (23 percent). Although snacking is ubiquitous in the U.S. population (93 percent) and provides nearly 23 percent of total daily energy for most Americans, snacks alone provide as much as 35 percent of total added sugars among children. Similar patterns were also observed when evaluating differences in eating behaviors by race/ethnicity. The frequency and timing of eating varied by race/ethnicity, with Hispanic and non-Hispanic Black Americans as the least likely to report 3 meals per day. Hispanic children and adults report a higher percent of their daily energy and nutrients at breakfast than other meals. This subgroup then also was less likely to consume lunch or dinner than other race/ethnic groups.

Notable differences also were observed when assessing the frequency and timing of eating by family income. Those whose family income was less than 131 percent of the Federal poverty level had the lowest percent reporting eating occasions (i.e., meals and snacks) and lower frequency of eating when compared with those who had a family income greater than 131 percent of the poverty level. As a result, individuals residing in the lowest poverty-to-income-

ratio families had a lower proportion of nutrients consumed at lunch relative to other income groups, which was especially notable among children 2 to 11 years

When evaluating the relationship between the frequency of eating and dietary quality using the Healthy Eating Index (HEI),⁸ Americans who consumed 3 meals per day (HEI score = 61) consistently reported a diet higher in dietary quality than Americans who consumed 2 meals per day (HEI score = 55), regardless of population subgroup (see **Part D. Chapter 1: Current Intakes of Foods, Beverages, and Nutrients**, Question 3, for additional information about the HEI). These findings also were consistent with individual HEI dietary quality components. Americans reporting 3 meals per day were more likely to have higher intake of several adequacy components, including total vegetables, greens and beans, total fruit, whole fruit, whole grains, and dairy and lower intake of some moderation components, such as added sugar and sodium, than those who reported only 2 meals per day. Every eating occasion is a chance to make nutrient-dense food choices. Shifts in childhood and adulthood snacks, and adolescence eating frequency and timing could help align patterns with recommendations.

For additional details on this body of evidence, visit: <https://www.dietaryguidelines.gov/2020-advisory-committee-report/data-analysis>.

Question 2. What is the relationship between the frequency of eating and growth, size, body composition, and risk of overweight and obesity?

Approach to Answering Question: NESR systematic review

Conclusion Statement and Grade

Insufficient evidence is available to determine the relationship between the frequency of eating and growth, size, body composition, and risk of overweight and obesity. Grade: Grade Not Assignable

Summary of the Evidence

- This systematic review was undertaken to examine the relationship between the frequency of eating and growth, size, body composition, and risk of overweight and obesity.
- This review included 6 studies⁹⁻¹⁴ published between January 2000 and September 2019 that met the inclusion criteria for this systematic review: 1 randomized controlled trial (RCT) and 5 prospective cohort studies (PCSs).
- Four out of 6 included studies reported an association between frequency of eating and at least one growth, size, body composition, or overweight and obesity outcome. However, the studies were inconsistent in terms of how they defined and examined frequency of eating, the outcomes they examined, and their reported results.
- Several critical limitations were identified within the body of evidence:
 - Studies varied in intervention or exposure assessment methods.
 - Definitions of eating occasions and number of eating occasions in the comparison groups varied in every included study.
 - Outcomes varied across studies: BMI, change in BMI, body fat, fat-free mass, waist circumference, change in waist circumference, 5 kg weight gain, weight change, subcutaneous fat, preperitoneal fat, abdominal fat index.
 - Eating frequency assessment was conducted only at baseline, leading to concerns of possible changes over time.
 - Both energy yielding and non-energy yielding beverages were inconsistently accounted for within eating occasion definitions across studies.

- Water consumption was not explicitly mentioned in any included studies.
- The studies had high or unknown attrition rates.
- Study populations did not fully represent the race/ethnic or socioeconomic diversity of the American population.
- Due to the inconsistency and limitations in the body of evidence included in this systematic review, the Committee determined that the evidence was insufficient to draw conclusions about the relationships between frequency of eating and growth, size, body composition, and risk of overweight and obesity.

For additional details on this body of evidence, visit: [nesr.usda.gov/2020-dietary-guidelines-advisory-committee-systematic-reviews/frequency-eating-subcommittee/frequency-eating-growth-size-body-composition-obesity](https://www.nesr.usda.gov/2020-dietary-guidelines-advisory-committee-systematic-reviews/frequency-eating-subcommittee/frequency-eating-growth-size-body-composition-obesity)

Question 3. What is the relationship between the frequency of eating and all-cause mortality?

Approach to Answering Question: NESR systematic review

Conclusion Statement and Grade

No evidence is available to determine the relationship between the frequency of eating and all-cause mortality. Grade: Grade Not Assignable

Summary of the Evidence

- This systematic review was undertaken to examine the relationship between the frequency of eating and all-cause mortality.
- All-cause mortality was defined as the total number of deaths from all causes during a specific time-period.
- This review identified 0 studies published between January 2000 and June 2019 that met the inclusion criteria for this systematic review.

For additional details on this body of evidence, visit: [nesr.usda.gov/2020-dietary-guidelines-advisory-committee-systematic-reviews/frequency-eating-subcommittee/frequency-eating-all-cause-mortality](https://www.nesr.usda.gov/2020-dietary-guidelines-advisory-committee-systematic-reviews/frequency-eating-subcommittee/frequency-eating-all-cause-mortality)

Question 4. What is the relationship between the frequency of eating and risk of cardiovascular disease?

Approach to Answering Question: NESR systematic review

Conclusion Statement and Grade

Insufficient evidence is available to determine the relationship between the frequency of eating and cardiovascular disease. Grade: Grade Not Assignable

Summary of the Evidence

- This systematic review was undertaken to examine the relationship between the frequency of eating and cardiovascular disease.
- This review identified 2 PCSs^{15,16} published between January 2000 and September 2019 that met the inclusion criteria for this systematic review.
- The studies were inconsistent in terms of how they defined and examined frequency of eating, the outcomes they examined, and in their reported results:
 - One included study reported that a higher eating frequency at baseline was associated with lower blood pressure after a 5-year follow-up.
 - One included study reported no association between eating frequency at baseline and risk of coronary heart disease after a 16-year follow-up.
- Critical limitations were identified within the body of evidence:
 - Weak study designs were used to explore this question.
 - Eating frequency was measured only at baseline, leading to concern that changes in exposure status may have occurred over the follow-up time periods.
 - The amount of attrition was unknown.
 - The study showed several risks of bias.
 - Inconsistent outcomes were included across studies with respect to relative risks and 95% confidence intervals for CHD, systolic blood pressure, diastolic blood pressure, and hypertension.
 - Water consumption was not explicitly mentioned in either included study.
 - Due to the small body of evidence with inconsistency in design and reported results and several limitations, the Committee determined that the evidence was insufficient to draw

conclusions about the relationship between frequency of eating and cardiovascular disease.

For additional details on this body of evidence, visit: [nesr.usda.gov/2020-dietary-guidelines-advisory-committee-systematic-reviews/frequency-eating-subcommittee/frequency-eating-cardiovascular-disease](https://www.nesr.usda.gov/2020-dietary-guidelines-advisory-committee-systematic-reviews/frequency-eating-subcommittee/frequency-eating-cardiovascular-disease)

Question 5. What is the relationship between the frequency of eating and risk of type 2 diabetes?

Approach to Answering Question: NESR systematic review

Conclusion Statement and Grade

Insufficient evidence is available to determine the relationship between the frequency of eating and type 2 diabetes. Grade: Grade Not Assignable

Summary of the Evidence

- This systematic review was undertaken to examine the relationship between the frequency of eating and type 2 diabetes.
- This review included 2 PCSs^{12,17} published between January 2000 and September 2019 that met inclusion criteria.
 - One included study reported that adult men who reported 1 to 2 eating occasions per day had a higher risk of type 2 diabetes compared to men who reported 3 eating occasions after 16 years of follow-up.
 - One included study did not report an association between frequency of eating in adult women and risk of type 2 diabetes after a 6-year follow-up.
- Critical limitations were identified within the body of evidence:
 - Habitual eating frequency was measured only at baseline, leading to concern that changes in exposure status may have occurred over the follow-up time periods.
 - Weak study designs were used to explore this question.
 - Beverages and water were not included in assessments of eating occasions.
 - The amount of attrition was unknown.

- Due to a small, inconsistent body of evidence with critical limitations, the Committee determined that the evidence was insufficient to draw conclusions about the relationship between frequency of eating and type 2 diabetes.

For additional details on this body of evidence, visit: [nesr.usda.gov/2020-dietary-guidelines-advisory-committee-systematic-reviews/frequency-eating-subcommittee/frequency-eating-type-2-diabetes](https://www.nesr.usda.gov/2020-dietary-guidelines-advisory-committee-systematic-reviews/frequency-eating-subcommittee/frequency-eating-type-2-diabetes)

DISCUSSION

Eating frequency is associated with a wide range of appetitive, digestive, and metabolic processes that are relevant to the health and well-being of Americans.¹⁸⁻²⁴ Using rigorous criteria developed by this Committee for examining 5 questions on frequency of eating (see Methods section), the NESR staff identified 9 scientific publications to include in this review. Following analysis of these scientific publications, this Committee concluded that insufficient evidence was available at present to determine the relationship between frequency of eating and growth, body size and composition, overweight and obesity, cardiovascular disease, type 2 diabetes, and all-cause mortality. Further, due to insufficient evidence, grades for the strength of the evidence reviewed were not assignable.

Based on this review, the Committee identified a need to standardize the definition of ingestive events within the scientific community; to improve the methodology for measuring frequency of eating; to include the collection and analysis of eating frequency data within all study designs; and to complete more well-designed, RCTs that directly examine whether a causal role exists between frequency of eating and health.

Although the Committee was unable to find adequate evidence to address the questions on eating frequency and health, it was able to conduct a cross-sectional analysis from the only available sources of nationally representative data to describe the state of eating frequency in the U.S. diet. This analysis revealed a wide variety of eating frequency patterns that varied by socioeconomic and demographic factors. Diet quality was higher when self-reported meal intake increased from 2 meals per day to 3, whereas late-night eating often contained food components recommended to be consumed only in moderation.

As questions specific to frequency of eating and health were a new addition for the Committee, it was charged with the task of defining an eating occasion out of necessity. Eating occasions are the unit that, when summed over a given period of time, leads to a quantitative

measure of the frequency of eating. The scientific literature is inconsistent in defining an eating occasion or ingestive event. So the Committee decided for the purposes of informing Federal dietary guidelines that an eating occasion should be considered as “any ingestive event including preload (for intervention trials), meals, or snacks comprised of foods or beverages that are energy yielding or non-energy yielding”. The Committee recommends the scientific community raise the standardization of frequency of eating terms to a high priority (see Research Recommendations in **Part E. Future Directions**).

It was important to ensure that the studies testing frequency of eating and health hypotheses were capturing habitual or usual eating frequency. Thus, the Committee decided to add inclusion criteria for the systematic review question that would require studies collect a minimum of 3 days of dietary data. In addition to this criterion, intervention studies also were required to collect these data on at least 2 occasions, including baseline and during or after the intervention. This approach allowed for the measurement of: 1) usual eating frequency to determine whether a change occurred as a result of the intervention, and 2) compliance and/or adherence to the respective eating frequency intervention. These requirements did result in the exclusion of a small number of studies from the literature review. It should be noted that 3 days of eating frequency data collection were unavailable in the nationally representative data sources.^{7,25} Because no health hypothesis was tested in these data sources, the Committee was willing to accept a slightly lower data collection requirement to obtain an estimate of eating frequency in the current U.S. population.

Overall, the review of the literature on frequency of eating and health that did meet the Committee’s inclusion and exclusion criteria uncovered multiple concerns with PCSs, including: weak study designs, variations in intervention or exposure assessment methods, inconsistent definitions of eating occasions, diverse reported outcomes, dissimilar measures of eating frequency, missing data for comparisons across studies, different criteria for inclusion of energy-yielding and non-energy-yielding beverages, failure to explicitly report water consumption, high or unknown attrition rates, inclusion of populations that were not fully representative of the race-ethnic or socioeconomic diversity of the U.S. population, and high risk of bias.

Only 1 RCT met the inclusion and exclusion criteria for the systematic review. Overall, the RCTs pertinent to frequency of eating were observed to have major limitations, including: failure to report all eating occasions over a 24-hour period, weak study designs (e.g., low power, short duration, missing key control groups/conditions, absence of baseline characterization of study group ingestive behavior), variations in intervention or exposure assessment methods, inconsistent definitions of eating occasions, diverse reported outcomes, dissimilar measures of

eating frequency, missing data for comparisons across studies, different criteria for inclusion of energy-yielding and non-energy-yielding beverages, failure to explicitly report water consumption, high or unknown attrition rates; inclusion of populations that are not fully representative of the race-ethnic or socioeconomic diversity of the U.S. population, and high risk of bias.

The Committee recommends future studies on frequency of eating include all of the necessary data in a study to assess frequency of eating and outcomes, including key confounders and adequate dietary data collection. Quantifying and including water intake as an eating occasion is also a high priority.

Additionally, intermittent fasting, time-restricted eating, breakfast skipping, and late-night eating are all topics of current public interest. The manipulation of eating frequency and timing of ingestion is at the core of each of these eating behaviors. Although timing of eating occasions is also an important consideration in the relationship between frequency of eating and health, the Committee determined that the root of the questions posed required that the number of daily eating occasions be evaluated as the primary intervention or exposure of interest. Studies that adequately addressed the number of eating occasions and also tested the timing of the eating occasions would have been included in the body of evidence. Unfortunately, the current literature on timing of eating occasions typically did not adequately report the total number of ingestive events over a 24-hour period, which would have allowed for the disentanglement of the effects of the number of eating occasions vs the timing on health. Such data must be included in future research on timing of eating to determine the degree to which compensatory behaviors (e.g., increased energy-dense eating occasions following breakfast skipping) occur and affect the health outcomes. The Committee also recommends the 2025 Dietary Guidelines Advisory Committee consider separate questions examining how the timing of ingestive events influences health, and how food insecurity and other constraints on food choice and access fit into hypotheses around frequency of eating and health. All of these issues are addressed in Research Recommendations in **Part E. Future Directions**.

SUMMARY

The 3 main components that characterize a person's eating behavior are the frequency, types, and amounts of foods ingested. Although the types and amounts of foods consumed are traditionally a focus of the *Dietary Guidelines for Americans* and the Dietary Guidelines Advisory Committees, the 2020 Committee is the first to directly address the question of frequency of

eating. The frequency of eating is an increasingly relevant topic that contributes to a wide range of appetitive, digestive, and metabolic processes that are relevant to the health and well-being of Americans.

The NESR review did not yield specific answers to the questions concerning the relationship between frequency of eating and health outcomes of obesity, all-cause mortality, risk of cardiovascular disease, or risk of type 2 diabetes. This was primarily due to the limited availability of high-quality data. The Committee cannot therefore make recommendations to the Departments on frequency of eating and health.

The Committee was able to address the relationship between the frequency of eating and achieving nutrient and food group recommendations. The Committee determined that, on average, Americans self-report 5.7 eating occasions throughout the day with the majority (64 percent) consuming 3 meals per day and 28 percent consuming 2 meals per day. More than 90 percent of Americans also report 2 to 3 snacking occasions per day. Reported frequency of eating and types of ingested foods varied widely across age, race-ethnicity, and income groups.

Americans who reported consuming an average of 3 meals per day had a higher diet quality compared to those consuming 2 meals per day. This was attributable to relatively larger intakes of vegetables, greens and beans, fruit, whole grains, and dairy and smaller intakes of foods with added sugars and sodium in the 3 meal per day pattern.

Nearly one-fourth (22 percent to 23 percent) of energy consumed by Americans is provided by snacks. Although these eating occasions can contribute to meeting nutrient and food group recommendations (e.g., fruits, dairy), they also can include disproportionately large amounts of high-energy, low-nutrient foods and/or beverages that do not contribute substantively to meeting dietary recommendations. For example, snacks alone provide as much as 35 percent of total added sugars among children.

The Committee affirms that healthy dietary patterns and eating frequencies can be constructed in a variety of ways to suit differing life stages and cultural practices (see **Part D. Chapter 8: Dietary Patterns**). The Committee's findings also suggest that following a dietary pattern that reduces snacking and emphasizes meals, both primarily comprised of foods and beverages that contribute to nutrient and food group recommendations, can help align eating patterns with dietary guideline recommendations.

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PART D. CHAPTER 14: USDA FOOD PATTERNS FOR INDIVIDUALS AGES 2 YEARS AND OLDER

INTRODUCTION

Understanding the benefits of a healthy dietary intake and translating this into recommendations for dietary intake includes several different steps. The 2020 Dietary Guidelines Advisory Committee pursued systematic reviews to identify combinations of foods that have been associated with lower risk of all-cause mortality and a number of important health outcomes across the lifespan (see **Part D. Chapter 8: Dietary Patterns**). Translating this evidence into actionable guidance for the public at large means that the Committee also must determine whether combinations of foods within a pattern meet goals for nutrient adequacy.

The USDA Food Patterns represent the types and amounts of food groups that aim to provide sufficient nutrients or food components (e.g., fiber) to meet Dietary Reference Intakes (DRIs) and *Dietary Guidelines for Americans* recommendations, at various energy levels, by age-sex groups ages 2 years and older. The Food Patterns are updated every 5 years during the deliberations of the Committee and are presented to the Committee for its assessment of how well the Patterns align with the most current evidence on diet, health, and nutrient adequacy. During the Committee's deliberations, amounts recommended from each food group may be modified based on the Committee's review and/or to support nutrient adequacy to reach all or most of the specified goals.

The **Healthy U.S.-Style Pattern** is one of the 3 current USDA Food Patterns and is the base pattern for food pattern modeling analyses. This Pattern serves as the foundation for the Healthy Eating Index-2015 (HEI-2015) (see **Part D. Chapter 1: Current Intakes of Foods, Beverages, and Nutrients**) and is aligned with findings from the 2015 Committee's review of the evidence on dietary patterns and health outcomes.¹

Additionally, USDA's food pattern modeling was used in 2015 to assess whether the Healthy U.S.-Style Pattern could be adapted to a vegetarian style while maintaining nutritional adequacy. The resulting pattern was the **Healthy Vegetarian Pattern**. Compared with the Healthy U.S.-Style Pattern, the Healthy Vegetarian Pattern is higher in soy products (particularly tofu and other processed soy products), legumes, nuts and seeds, and whole grains. Meat, poultry and seafood were eliminated, however, dairy and eggs were included in this lacto-ovo vegetarian pattern. The 2015 Committee also recommended a **Healthy Mediterranean-Style Pattern**, which was based on evidence from a range of dietary intake patterns described as

“Mediterranean.” Common key components of these patterns include higher intakes of plant-based foods (e.g., fruit, vegetables, legumes, and whole grains), olive and other non-tropical vegetable oils, and nuts and seeds, with low to moderate intakes of eggs, meat, and seafood.¹ The Healthy Mediterranean-Style Pattern includes higher amounts of fruit and seafood and less dairy compared to the Healthy U.S.-Style Pattern. Ultimately, all 3 Patterns represent healthy approaches to eating that simultaneously address nutrient needs while promoting health and reducing risk of chronic disease.

The 2020 Committee used recommendations provided by the 2017 National Academies of Science, Engineering, and Medicine (NASEM) study on redesigning the process for establishing the *Dietary Guidelines for Americans* to guide its approach to using USDA’s food pattern modeling.² The NASEM study recommended that food pattern modeling could be used to better account for differences in the nutritional needs of the population, going beyond the generic characterization of the “average” American. This recommendation aligned well with a broader focus of the 2020 Committee on optimizing nutrition for each discrete life stage across the lifespan. Because this Committee’s report would consider birth to age 24 months as well as pregnancy and lactation, the need to apply food pattern modeling in a way that considered the needs of these unique phases of life was even more apparent. To accommodate this life-stage approach, the Committee used a new method in which the anticipated nutrient profiles were based on the proportions of foods consumed specific to each life stage, including children, adolescents, and younger, middle-aged and older adults. This chapter presents food patterns that apply to the U.S. population ages 2 years and older and **Part D. Chapter 7: USDA Food Patterns for Children Younger than Age 24 Months** presents, for the first time, food patterns that apply to the U.S. population from birth to age 24 months.

The results of this work should be informative at several levels. By taking a life-stage approach, the results of the USDA’s food pattern modeling exercises will be specific to a given stage of life when risk of inadequacy or nutrition-related disease may vary based on age. In addition to differing risks of disease by age, nutritional needs to ensure adequacy differ, particularly during pregnancy and lactation. Women in these life stages have different estimated energy requirements as well as unique nutritional needs that affect the woman’s health as well as the development and health of the infant. A specific evaluation of the USDA Food Patterns relative to these unique nutritional needs will be described. Lastly, the Committee was able to use food pattern modeling by life stage to examine opportunities to provide specific advice on improving nutritional intakes within given age-sex subgroups by examining ways to “repurpose calories” from foods with low nutrient density to foods that meet specific nutrient and food group

shortfalls specific to that age-sex group (see **Part D. Chapter 12: Added Sugars**). Again, this approach attempts to use food pattern modeling to go beyond universal advice for adopting a healthy eating pattern to specific, tailored, and actionable advice on small but meaningful cumulative changes to typical food intake patterns common for a given life stage.

The results of the data presented from the USDA's food pattern modeling exercises have some methodologic issues that are worth considering when they are put in the context of their potential applications. Notably, the USDA Food Patterns do not account for beverages that are not constituents of food groups or subgroups. In data reviewed by the Committee, a substantial percentage of energy intake for Americans ages 2 years and older comes from sweetened beverages (including soda, fruitades, sports drinks, energy drinks, sweetened water, and sweetened coffee and tea) and alcoholic beverages. The specific beverages omitted from the Patterns generally do not contribute to intakes of food groups or nutrients in the Patterns except for any portions that are a recognized food constituent in the beverage (e.g., dairy added to coffee, or 100% juice added to a sugar-sweetened beverage or alcoholic beverage). Therefore, in spite of the contribution of beverages to energy intake and added sugars (see **Part D. Chapter 10: Beverages**, **Part D. Chapter 11: Alcoholic Beverages**, and **Part D. Chapter 12: Added Sugars** for additional information), USDA food pattern modeling does not include beverages that do not contribute to food groups in the USDA Food Patterns.

Another limitation of the food pattern modeling approach is that it does not qualitatively address cultural variations in intake patterns; this type of issue may be more appropriately addressed as a menu planning activity. Nevertheless, a strength of the Food Patterns is that it has a tremendous amount of flexibility that allows it to be tailored to an individual's cultural and taste preferences. This flexibility occurs because the resulting Patterns are only prescriptive for the larger food groups and subgroups *amounts* but not the specific *types* of foods to be consumed, permitting choices and options for the consumer. Although a representative food is used for purposes of modeling, that food is not the only available choice within a food cluster. Many food items can be used that approximate the most nutrient-dense choices for given food group and subgroups. These items also can be combined in unique ways that meet an individual's dietary preferences.

Finally, in testing the patterns for pregnancy, the Committee presumed increased energy needs throughout pregnancy based on the NASEM's report on recommended weight gain during pregnancy.³ Excess weight gain during pregnancy has been associated with increased risk of adverse outcomes for the mother and infant.⁴ However, recent analyses also suggest that pre-pregnancy body mass index (BMI) may be more important than excess gestational weight

gain in predicting adverse events during pregnancy and may be associated with higher postpartum weight retention.⁵ Taken together, these data highlight the interconnected nature of the relationships between health and nutrition across life stages. USDA's food pattern modeling does not specify energy needs based on pre-pregnancy weight status and target weight gain during pregnancy. However, Patterns do support nutrient adequacy at any chosen energy level. Specific guidance on estimated energy requirements during pregnancy and lactation may require discussions with a qualified healthcare provider.

LIST OF QUESTIONS

1. Are changes to the USDA Food Patterns needed based on the relationships identified in the systematic reviews? If so, how well do USDA Food Pattern variations meet nutrient recommendations for each stage of life? If nutrient needs are not met, is there evidence to support supplementation and/or consumption of fortified foods to meet nutrient adequacy?

METHODOLOGY

The food pattern modeling methodology used to answer these questions involved aiming to establish food patterns that incorporate goals for nutrient adequacy for energy, nutrients, and other dietary components compared to the DRIs and potential Committee recommendations (see **Part C. Methodology** for more information on food pattern modeling). Nutrient profiles were developed from food groups and subgroups using 2015-2016 data on foods consumed by individuals ages 2 years and older, as collected by What We Eat in America (WWEIA), the dietary intake portion of the National Health and Nutrition Examination Survey (NHANES).⁶ The nutrient adequacy of variations of the USDA Food Pattern were then tested by comparing their nutrient content to the DRIs and potential Committee recommendations. The Committee then developed conclusion statements to summarize the answer to each food pattern modeling question and made research recommendations to inform future work on this topic.

Analytic Framework

The Committee developed a food pattern modeling protocol. The protocol included an analytic framework that described the scope of the food pattern modeling exercises. The

analytic framework also described the population, data sources, and key terms used to answer this question. The exercises relied on data from the U.S. Department of Agriculture Food and Nutrient Database for Dietary Studies (FNDDS) 2015-2016.⁷ The Food Patterns Equivalents Database (FPED) 2015-2016 and the National Nutrient Database for Standard Reference (SR), Release 28 (2016 version) provided supporting data.^{7,8} The U.S. population ages 2 years and older, including women who are pregnant or lactating, was considered. The following are key definitions for the food pattern modeling exercises:

- **Food Groups and Subgroups:** USDA Food Patterns provide amounts from the 5 major food groups and subgroups, including:
 - Fruits
 - Vegetables: Dark green, red and orange, beans and peas, starchy, and other
 - Dairy, including calcium-fortified soy beverages
 - Grains: Whole grains and refined grains
 - Protein Foods: Meats, poultry, and eggs; seafood; nuts, seeds, and soy products
- **Food Pattern Components:** Oils, solid fats, added sugars
- **Nutrient Profiles:** The anticipated nutrient content for each food group and subgroup that could be obtained by eating a variety of foods in each food group in nutrient-dense forms. The nutrient profiles are based on a weighted average of nutrient-dense forms of foods. The weighted average calculation considers a range of American food choices, but in nutrient-dense forms and results in a food pattern that can be tailored to fit an individual's preferences.
- **Item Cluster:** Identified groupings of the same or similar foods within each food group and subgroup. Item clusters are used to calculate the composite nutrient profile for each food group and subgroup used to define the USDA Food Pattern.
- **Nutrient-Dense Representative Food:** The food within an item cluster with the least amount of added sugars, sodium, and solid fats. For some item clusters, the nutrient dense representative food contains some added sugars, solid fats, and/or sodium.
- **Typical Choice Representative Food:** The most frequently consumed food within an item cluster of foods and inclusive of any added sugars, solid fats, and/or sodium
- **Essential Calories:** The energy associated with the foods and beverages ingested to meet nutritional goals through choices that align with the USDA Food Patterns in forms with the least amounts of saturated fat, added sugars and sodium.
- **Solid fats:** The food category called “solid fat” includes a variety of fats, but predominantly saturated fat and to a small extent, *trans* fat. This category includes the

saturated fats naturally found in animal products (e.g., meats, dairy) as well as vegetable sources with high saturated fat content, like tropical oils, e.g., coconut oil and hydrogenated vegetable shortenings

- **Added Sugars:** Sugars that are added during the processing of foods (such as sucrose or dextrose), foods packaged as sweeteners (such as table sugar), sugars from syrups and honey, and sugars from concentrated fruit or vegetable juices. They do not include naturally occurring sugars that are found in milk, fruits, and vegetables (see **Part F. Appendix F-1: Glossary**).

General Process for Developing and Updating the USDA Food Patterns

The overall food pattern modeling methodology used to develop and update the USDA Food Patterns includes: (1) identifying appropriate energy levels for the Patterns, (2) identifying nutritional goals for the Patterns based on sex and life stage, (3) establishing food groups and food group amounts, (4) determining the amounts of nutrients that would be obtained by consuming various foods within each group, (5) evaluating nutrient levels in each Pattern against nutritional goals, and (6) adjusting and re-evaluating the Patterns to align with current or potential recommendations.

1. Establish Energy Levels

The DRIs use formulas to calculate Estimated Energy Requirements (EER) for each age-sex group, with 3 age groups specific to pregnancy and lactation: women ages 14 to 18 years, 19 to 30 years, and 31 to 50 years.⁹ EER is based on sex, age, height, weight, and physical activity level. Median body height and weight for normal BMI are used to calculate appropriate energy levels for each age-sex group to be represented in the Patterns. The EERs for pregnancy account for additional energy expenditure and deposition that includes the products of conception and accretion of maternal tissues.⁹ The EERs specific to lactation were used to estimate appropriate energy levels for women in this life stage.⁹

The USDA Food Patterns include 12 energy levels from 1,000 to 3,200 kilocalories (kcal) at 200 kcal “step” intervals intended to cover energy needs for the majority of the population ages 2 years and older.

2. Establish Nutritional Goals

Specific nutritional goals for each food intake pattern (i.e., energy level) were selected based on the age-sex group(s) for which the pattern is appropriate. If a food intake pattern at a energy level aims to meet the nutritional needs of more than 1 age-sex group, the pattern is evaluated against the nutrient goals for all those groups. Goals for energy, 3 macronutrients, 3 fatty acids, dietary cholesterol, 12 vitamins, 9 minerals, and fiber are based on DRI reports released between 1997 and 2019 and on quantitative recommendations in the current *2015-2020 Dietary Guidelines for Americans*. When evaluating the dietary intakes of a group, the Estimated Average Requirement (EAR) is used as a benchmark for meeting the needs of at least 50 percent of the population. Because the USDA Food Patterns are designed as plans for individuals to follow, the goals were the Recommended Dietary Allowance (RDA) amounts for nutrients having an RDA, which are notably higher than the EAR (i.e., 2 standard deviations above the EAR, meeting the needs of 98% of a population). The Adequate Intake (AI) was used when an RDA is not published.

The lowest energy level (for sedentary individuals, determined in Step 1), rounded to the nearest energy level is determined for each age-sex group and used in evaluating the patterns against nutritional goals.

3. Establish Food Groupings and Food Group Amounts

Existing food groups and subgroups in the USDA Food Patterns published in the *2015-2020 Dietary Guidelines for Americans* were used in this exercise. The food groups and subgroups included in the Healthy U.S.-Style Eating Pattern, the Healthy Mediterranean-Style Eating Pattern, and the Healthy Vegetarian Eating Pattern were applied.¹⁰

4. Determine the Amounts of Nutrients That Would be Obtained by Consuming Various Foods Within Each Group

A “composite” system was used to determine the anticipated energy and nutrient content, or nutrient profile, of each food group, as described below. To create nutrient profiles, all foods reported by individuals ages 2 years and older as part of WWEIA, NHANES 2015-2016 were disaggregated into their ingredients. Similar ingredients were aggregated into food item clusters (see online Food Pattern Modeling report: <https://www.dietaryguidelines.gov/2020-advisory-committee-report/food-pattern-modeling/FPM-2-and-older>). A nutrient-dense form of the food was selected as the representative food for each cluster. The proportional intake of each item

cluster within each food group or subgroup was calculated and used to compute a weighted average of nutrient-dense forms of foods representing each food item cluster. The proportional intake was calculated based on intakes for ages 2 years and older, as had been done in previous updates.

To account for variation in eating patterns across different age groups, the Committee employed a new approach. Proportions by life stage were calculated for ages 2 to 3 years, 4 to 18 years, 19 to 70 years, and 71 years and older. Using the nutrients in each representative food and the item cluster's proportional intake using the life-stage approach, a nutrient profile was calculated for each food group or subgroup. Thus, a nutrient profile specific to each life stage was developed and then used to estimate the anticipated nutrients and other food components in the patterns. Nutrient profiles also were calculated for oils and solid fats using food supply data to determine proportional intakes because NHANES does not specify the type of oil or solid fat for most foods, and therefore those data cannot be used to determine proportional consumption.

5. Evaluate Nutrient Level in Each Pattern Against Nutritional Goals

The estimated nutrient composition of the Healthy U.S.-Style Pattern was calculated using the nutrient profiles for ages 2 years and older as well the nutrient profiles for specific life stages (2 to 3 years, 4 to 18 years, 19 to 30 years, 31 to 70 years, pregnant or lactating women, 71 years and older). For the Healthy Vegetarian and Healthy Mediterranean-Style Patterns, only the nutrient profiles for ages 2 years and older were used to calculate estimated nutrient composition.

Using the updated nutrient profiles that apply to ages 2 years and older and for each life stage, the nutrients provided in the Patterns were compared to the Pattern's goals, which in most cases aimed to meet at least 90 percent of the RDA or AI.

6. Adjust and Re-evaluate the Patterns to Align with Current or Potential Recommendations

After identifying any nutrient goals that were not met in the resulting Food Patterns, the Committee considered if additional adjustments in the Patterns were needed based on its systematic reviews. Four modifiable elements were available to further refine the Patterns: (1) food group amounts could be increased or decreased, (2) goals and constraints could be adjusted, (3) food group nutrient profiles could be adjusted through selection of different

representative foods or categorization of item clusters, and (4) certain foods could be included or excluded. If changes were needed, an iterative series of adjustments and evaluations to achieve patterns that aligned with recommendations could be applied. The Committee determined no modifications in the Patterns were needed based on its systematic reviews.

All necessary increases to a food group or subgroup were balanced with energy compensating decreases in other food groups. To maintain feasible dietary patterns for the population, the Patterns were compared with current usual intake distributions from NHANES data and limited to amounts between median and 95th percentiles of usual intakes, or in the case of overconsumed components, between the median and the 5th percentiles of usual intake.

After all adjustments were complete, energy from all food groups and oils, termed “essential calories,” were summed and the remaining energy (kcal) up to the energy limit for the pattern were calculated. The uses for any remaining energy were discussed, particularly in relation to limits on added sugars (see **Part D. Chapter 12: Added Sugars**).

REVIEW OF THE SCIENCE

1. Are changes to the USDA Food Patterns needed based on the relationships identified in the systematic reviews? If so, how well do USDA Food Pattern variations meet nutrient recommendations for each stage of life? If nutrient needs are not met, is there evidence to support supplementation and/or consumption of fortified foods to meet nutrient adequacy?

Approach to Answering Question: Food Pattern Modeling

Conclusion Statements

Are Changes to the USDA Food Patterns Needed Based on the Relationships Identified in the Systematic Reviews?

No major changes to the 3 USDA Food Patterns were needed based on the relationships identified in the systematic reviews conducted by the Committee. The 3 patterns published as part of the *2015-2020 Dietary Guidelines for Americans* include the Healthy U.S.-Style Eating Pattern, Healthy Vegetarian Eating Pattern, and Healthy Mediterranean-Style Eating Pattern. The Healthy U.S.-Style serves as a basis of the Healthy Eating Index (HEI). No additional patterns were identified in systematic reviews that provided both a clearly defined food pattern and were consistently associated with the health outcomes across life stages.

The Committee adapted the nutrient profiles of the 2015 USDA Food Patterns to facilitate the life-stage approach review of the evidence. Nutrient profiles for food groups and subgroups within the Patterns were developed for specific age groups (ages 2 to 3 years, 4 to 18 years, ages 19 to 30 years, ages 31 to 70 years, and ages 71 years and older) and life stages (i.e., women who are pregnant or lactating) to capture variation in the population by age. Life-stage dietary preferences inform the nutrient profiles, and provide a better estimate how patterns fulfill nutritional goals.

If So, How Well Do USDA Food Pattern Variations Meet Nutrient Recommendations for Each Stage of Life?

The 3 USDA Food Patterns meet the Recommended Dietary Allowance or Adequate Intake goals and stay within limits for the Tolerable Upper Intake Level or the Chronic Disease Risk Reduction target for the majority of nutritional goals for ages 2 years and older, including women who are pregnant or lactating. This applies both when using a general nutrient profile for the total population or a nutrient profile specific to an age group.

Nutrients that do not meet Recommended Dietary Allowance or Adequate Intake goals include the following. Iron: The patterns provide less than 90 percent of the Recommended Dietary Allowance for females ages 4 to 8 years, 19 to 30 years, 31 to 50 years, and less than 75 percent for women who are pregnant. Vitamin D: The patterns achieve 30 to 45 percent of the Recommended Dietary Allowance for children younger than age 8 years and approximately 55 to 70 percent the Recommended Dietary Allowance for the rest of the population. Vitamin E: The patterns generally provide less than 80 percent of the Recommended Dietary Allowance for Vitamin E, except for children younger than age 8 years, where 82 to 94 percent of the Recommended Dietary Allowance is achieved. Choline: The patterns generally provide less than 85 percent of the Adequate Intake for choline. Folate: The patterns provide approximately 85 percent of Recommended Dietary Allowance for folate at the 1,800 and 2,000 energy-levels during the first trimester for women who are pregnant.

If Nutrient Needs Are Not Met, Is There Evidence to Support Supplementation and/or Consumption of Fortified Foods to Meet Nutrient Adequacy?

Current evidence supports supplementation or targeted efforts to increase iron intakes through dietary choices and fortification for women who are pregnant or who are planning to become pregnant. Careful choices of foods high in iron, including fortified foods, should be considered by females, especially during adolescence and pregnancy, to meet the increased iron

requirements. Some women may need an iron supplement and should consult with a health care provider.

Vitamin D, an identified nutrient of public health concern for all age-sex groups, requires that individuals pay careful attention to dietary sources (both natural sources and fortified foods) even when taking into account an average level of UV exposure. Supplementation may be advised by a health care provider. (See 2015 Dietary Guidelines Advisory Committee Report,¹ Appendix E-3.3 Meeting Vitamin D Recommended Intakes in USDA Food Patterns.)

Folic acid intakes are critical in the first trimester of pregnancy to reduce the risk of neural tube defects therefore the Committee supports folic acid supplementation as the standard of care before and during pregnancy. Dietary intakes of folate are generally low and folate status may be compromised in some groups of women. Efforts to encourage inclusion of fortified foods or dietary supplements among women with low intakes are warranted.

Summary of the Evidence

Are Changes to the USDA Food Patterns Needed Based on the Relationships Identified in the Systematic Reviews?

No major changes to the 3 USDA Food Patterns were needed based on the relationships identified in the systematic reviews by the Committee. The Committee adapted the nutrient profiles of the 2015 USDA Food Patterns to facilitate the life-stage approach review of the evidence. The Patterns were developed for specific age groups (ages 2 to 3 years, ages 4 to 18 years, ages 19 to 30 years, ages 31 to 70 years, and ages 71 years and older) and life stages (i.e., women who are pregnant or lactating). The nutrient profiles for food groups and subgroups that were developed for specific age groups reflect variation in dietary intake within the population. The Committee reviewed the similarities and differences between nutrient profiles of specific age groups to consider how best to fulfill nutrient needs across all the life stages. Food Patterns for infants and young children (or toddlers) are addressed in **Chapter 7: USDA Food Patterns for Children Younger than Age 24 Months**.

The nutrient profiles specific to each age group were calculated as described above in Methodology. Notably, the nutrient-dense representative foods remained the same for each age group. A description of these nutrient profiles is available in the online Food Pattern Modeling Report (<https://www.dietaryguidelines.gov/2020-advisory-committee-report/food-pattern-modeling/FPM-2-and-older>). The online report provides the proportions of consumption for each item cluster within each food group or subgroup, the representative foods for each item cluster

for the population ages 2 years and older, and the proportions of consumption for each item cluster within each food group and subgroup by life stage

(<https://www.dietaryguidelines.gov/2020-advisory-committee-report/food-pattern-modeling/FPM-2-and-older>).

The proportions of consumption of the item clusters were similar across age groups for many food groups and subgroups with variations of only a few percentages. However, there were some notable exceptions. For example, apples contributed 36.5 percent to whole fruit consumption for those ages 4 to 18 years, but decreased to 17.6 percent for those ages 71 years and older. Apple juice was reported as almost 42 percent of fruit juice consumption among those ages 4 to 18 years, while only 17 percent among those ages 19 to 70 years and 14 percent for those ages 71 years and older. Conversely, orange juice contributed 62 percent to fruit juice consumption for those ages 71 years and older, 53 percent for ages 19 to 70 years, and 36 percent for ages 4 to 18 years. The proportion of broccoli in the dark green vegetable subgroup was highest among ages 4 to 18 years at nearly 48 percent of the subgroup, and lowest among those ages 71 years and older at 25 percent of the dark green vegetable subgroup. For those ages 71 years and older, only about 5 percent of the proportion of all starchy vegetable consumption were french fries, compared to 19 percent of starchy vegetables for ages 4 to 18 years. Whole grain bread accounted for 25 percent of whole grains among ages 4 to 18 years and 41 percent for those ages 71 years and older. More than 54 percent of the proportion of nuts and seeds profile among ages 4 to 18 years was from peanut butter and decreased to 23 percent of nuts and seeds for those ages 71 and older. Thus, modifications were made in the nutrient profiles to accommodate these observed changes in food choice based on life stage.

Food group and subgroup amounts modeled as part of the 2015 Committee's work and the 2020 Committee's work were the same.

If So, How Well Do USDA Food Pattern Variations Meet Nutrient Recommendations for Each Stage of Life?

The USDA Food Patterns at energy levels appropriate to life stages meet the RDA or AI and stay within limits for the Tolerable Upper Intake Level (UL) and Chronic Disease Risk Reduction (CDRR) for the majority of nutritional goals for ages 2 years and older, including women who are pregnant or lactating. For detailed results, including a summary of the nutrients provided by the patterns in comparison to nutrient goals, levels of all nutrients provided by each pattern, and a comparison of the nutrients in all patterns to all nutrient goals, see the online Food Pattern

Modeling Report (<https://www.dietaryguidelines.gov/2020-advisory-committee-report/food-pattern-modeling/FPM-2-and-older>).

Each age-sex group was assigned an intake pattern at a specific energy level that should meet their energy needs to maintain current body weight, assuming an average height and weight and physical activity within the healthy weight range. Each pattern was compared to the nutrient goals for that age-sex group, from the most recent DRIs or in some cases the *2015-2020 Dietary Guidelines for Americans*. Within the online Food Pattern Modeling report, the specific nutrient goals for each pattern and the age-sex group(s) for which the pattern was assigned is listed. For this evaluation, the pattern selected was at an energy level appropriate for sedentary (less active) individuals within the age-sex group. If this pattern met nutrient goals for adequacy, patterns at higher energy levels (for more physically active individuals) also would meet those goals. The DRI values are assigned to life-stage groups that correspond to various periods of the human lifespan. Therefore, when comparing the Patterns at the same energy levels for different age-sex groups, it is important to note that the RDA for a nutrient may be different between the age-sex groups. For example, Table D14.1 shows the Healthy U.S.-Style Pattern at 2,000 kcal for both women ages 19 to 30 years and men ages 51 and older. The 2,000-kcal Pattern meets 78 percent of the iron RDA for females ages 19 to 30 years, but 175 percent of the iron RDA for males ages 51 years and older. Other differences within the table are due to different DRI values for specific age-sex groups.

All foods are assumed to be in nutrient-dense forms, lean or lower-fat, and prepared with minimal added fats, sugars, refined starches, or sodium. The sum of energy from the food groups in nutrient-dense form and oils was considered “essential calories,” and any remaining energy calculated by subtracting essential energy from the energy goal for the pattern were considered remaining energy for other uses. Compared with the 2015 food pattern modeling exercise, the available remaining energy for other uses for the 2020 Patterns is slightly less because of updates to the nutrient profiles identified above. Further details on how the remaining energy for other uses were applied and analyzed is discussed in Chapter 12 (see **Part D. Chapter 12: Added Sugars**).

Healthy U.S.-Style Pattern

The Healthy U.S.-Style Food Pattern provides macronutrients within the Acceptable Macronutrient Distribution Range (AMDRs) as recommended by the National Academies of Science, Engineering, and Medicine.⁹ For all age groups, the percentage of energy from macronutrients varies slightly depending upon the energy level, but even at the lowest level, the

macronutrients are well within the AMDR. The 1 exception is at the 3,200 kcal level where 36 percent of energy come from fat, which is 1 percent above the AMDR (i.e., 25 to 35 percent of energy from fat). As mentioned above, it is important to note that the USDA Food Patterns do not account for energy, nutrients, or food components from beverages including sweetened or alcoholic beverages.

As shown in Table D14.1, for many nutrients, the amount provided by the Patterns is well above the RDA or AI but within limits for the UL and CDRR. Nutrients provided in amounts higher than 100 percent of RDA or AI for all age-sex groups include: protein, phosphorus, zinc, copper, selenium, manganese, vitamin C, thiamin, riboflavin, niacin, vitamin K, folate, vitamin B₆, and vitamin B₁₂. Even though provided in high amounts (e.g., 200 to 300 percent of RDA), these amounts are less than the UL, and thus likely to pose no risk of adverse health effects. These nutrients are found in many foods, and therefore, it is relatively easy to meet or exceed the RDA or AI when trying to meet goals for other nutrients that are not as plentiful. If amounts of some of the more common nutrients were to be reduced, it would result in not meeting recommendations for several key nutrients.

Some nutrients are slightly above the RDA or AI, or marginally below (i.e., 90 to 100 percent) the goal amounts for several age-sex groups. For example, amounts of calcium in the patterns range from 93 to 98 percent of the RDA for girls ages 4 to 18 years. Amounts of iron are marginally low for girls ages 4 to 8 years (89 percent of RDA). Magnesium is 94 percent of the RDA for girls ages 14 to 18 years, and 96 to 97 percent of the RDA for males ages 14 to 50 years and 87 percent of the RDA for men ages 51 years and older. It is important to note that the percentages of the RDA described are calculated for the lowest energy level assigned to these age-sex groups—the level applicable for a sedentary or less active physical activity level. In comparison to EARs, which are the appropriate targets for assessment of adequate intakes in populations, amounts in all patterns meet the EARs for calcium, iron, and magnesium.

The nutrients for which adequacy goals are not met in almost all patterns are vitamin D, vitamin E, and choline. Additionally, iron goals are not met for young girls ages 4 to 8 years (89 percent RDA), women of reproductive age, specifically adult women ages 19 to 50 years (75 to 78 percent RDA), and women who are pregnant (approximately 50 to 70 percent RDA). Vitamin D amounts in the patterns range from 38 to 75 percent of the RDA. Vitamin E amounts are low, ranging between 62 to 82 percent RDA for most age-sex groups except for boys ages 4 to 8 years where Vitamin E amounts are closer to the RDA goal. Choline amounts range from 69 percent to 89 percent of the AI for all age-sex groups except for females 31 to 50 (84 percent AI) and boys ages 4 to 8 years where choline goals are met (104% AI). Unlike when the 2015

Committee examined the patterns, potassium levels are generally above 90 percent of the AI in the patterns due to the 2019 update of the DRI for potassium, which lowered the AI for the age groups examined in this chapter.¹¹ The sodium DRI was changed from a UL to a CDRR value in the 2019 DRI update.

The patterns also meet nearly all of the nutrient goals for moderation. The patterns at the 3 highest energy levels (2,800 to 3,200 kcal) provide sodium in amounts approaching the CDRR of 2,300 mg (2,237 to 2,288 mg) but less than mean intakes from data collected using 24-hour dietary recalls (4,107 mg for males ages 20 years and older for whom these energy-levels would apply). Saturated fat ranges from 7 percent to 8 percent of energy, with most patterns providing 7percent of energy from saturated fat including the solid fats available as “remaining calories for other uses.” For analysis and discussion related to added sugars see ***Part D. Chapter 12: Added Sugars.***

Table D14.1. Healthy U.S.-Style Food Pattern: Comparison of select nutrients to nutrient goals for select energy levels per age-sex groups¹

Energy Level		1,000	1,200	1,400	1,600	1,600	1,800	1,800	1,800	2,000	2,000	2,200	2,200	2,400
Age-sex group for comparison		M/F 1 to 3	F 4 to 8	M 4 to 8	F 9 to 13	F 51+	M 9 to 13	F 14 to 18	F 31 to 50	F 19 to 30	M 51+	M 14 to 18	M 31 to 50	M 19 to 30
Macronutrients														
Protein	%RDA	331%	307%	359%	241%	181%	254%	188%	191%	199%	164%	189%	179%	190%
Protein	%kcal	17%	19%	19%	20%	21%	19%	19%	20%	18%	18%	18%	18%	18%
Carbohydrate	%RDA	104%	122%	146%	159%	159%	183%	183%	183%	201%	201%	224%	223%	242%
Carbohydrate	%kcal	54%	53%	54%	52%	51%	53%	53%	53%	52%	52%	53%	53%	52%
Fiber, total dietary	14g/ 1000kcal	99%	103%	105%	109%	109%	111%	111%	111%	106%	106%	111%	111%	108%
Total lipid (fat)	%kcal	31%	30%	29%	30%	30%	30%	30%	30%	32%	32%	31%	31%	32%
Saturated fat	%kcal	8%	7%	7%	7%	7%	7%	7%	7%	8%	8%	8%	7%	8%
Cholesterol	%DG	28%	40%	51%	63%	61%	64%	64%	62%	70%	70%	77%	75%	82%
Minerals														
Calcium	%RDA	110%	98%	102%	93%	100%	96%	96%	125%	126%	105%	102%	132%	135%
Iron	%RDA	105%	89%	108%	154%	149%	176%	94%	75%	78%	175%	152%	202%	220%
Magnesium	%RDA	224%	174%	202%	130%	101%	141%	94%	109%	117%	87%	96%	97%	107%
Potassium	%AI	88%	95%	107%	128%	121%	130%	141%	132%	140%	107%	126%	117%	120%
Sodium	%CDRR	65%	77%	88%	83%	55%	91%	71%	61%	63%	63%	80%	69%	75%
Vitamins														
Vitamin E	%RDA	82%	84%	94%	75%	56%	82%	60%	62%	70%	70%	75%	77%	83%
Vitamin D	%RDA	38%	40%	44%	53%	66%	54%	54%	67%	68%	68%	57%	70%	72%
Choline	%AI	87%	89%	104%	85%	81%	89%	83%	84%	90%	69%	71%	75%	79%

1: Energy and macronutrients are displayed along with nutrients or food components that were identified as shortfall or nutrients of public health concern or special challenges in any age-sex group. See online Food Pattern Modeling Report (<https://www.dietaryguidelines.gov/2020-advisory-committee-report/food-pattern-modeling/FPM-2-and-older>) for complete list of nutrients and energy levels.

Women Who Are Pregnant or Lactating

The Healthy U.S.-Style Food Pattern is expected to meet nutrient needs for women who are pregnant or lactating, with the exception of iron during pregnancy, vitamin A during lactation, and vitamin E, vitamin D, and choline for both life stages. Estimated energy needs and the total anticipated nutrient composition of the patterns for women who are pregnant or lactating are described in the online Food Pattern Modeling report (<https://www.dietaryguidelines.gov/2020-advisory-committee-report/food-pattern-modeling/FPM-2-and-older>). The Food Patterns at energy levels estimated for women who are pregnant or lactating meet or exceed nutrient needs for most nutrients, as shown in Table D14.2A, B and C. For women who have higher estimated energy requirements, higher energy Patterns may come closer to providing the RDA or AI for nutrients through dietary sources.

The anticipated nutrient composition of the patterns provides between 50 and 72 percent of the RDA for iron for women who are pregnant. The RDA for iron assumes 75 percent of iron is from heme iron sources. The iron requirement for women consuming a vegetarian diet with non-heme iron sources is approximately twice that of women consuming a non-vegetarian diet. Careful choices of foods high in iron should be considered during pregnancy to meet a larger proportion of iron from dietary sources. Some women may need an iron supplement and should consult with their health care provider. Iron needs are in general lower during lactation than during non-pregnant or pregnant women if menstruation has not resumed, which varies based on exclusivity of breast-feeding. Women who resume menstruation sooner may have higher iron needs than reflected in the DRI for women who are lactating.

The anticipated nutrient profile of the patterns contributes between 78 and 82 percent of RDA for Vitamin A for women who are lactating. The anticipated nutrient composition of the patterns generally falls in the range of 71 to 79 percent of the AI for choline during lactation and 74 to 101 percent of the AI during pregnancy. The patterns modeled for the third trimester and generally those at higher energy levels during pregnancy, provide approximately 90 percent or more of the AI for choline.

Dietary supplements used by women who are pregnant or lactating contribute towards most of these nutrients, except choline that is not present in high amounts in prenatal supplements. For that reason, careful choices of choline-rich foods (e.g. eggs and legumes) may be warranted during pregnancy and lactation to help achieve nutrient goals.

Table D14.2A U.S. Healthy-Style Pattern comparison to goals for women who are pregnant or lactating, ages 14 to 18 years

Age Group Energy Level		14 to 18 years				
Life stage group for comparison		1,800	2,200	2,400	2,200 lactating	2,200 lactating
		pregnant (1st trimester) 14 to 18	pregnant (2nd trimester) 14 to 18	pregnant (3rd trimester) 14 to 18	(0-6 mo post part) 14 to 18	(7-12 mo post part) 14 to 18
Macronutrients						
Protein	%RDA	122%	139%	147%	139%	139%
Protein	%kcal	19%	18%	17%	18%	18%
Carbohydrate	%RDA	136%	166%	180%	139%	139%
Carbohydrate	%kcal	53%	53%	53%	53%	53%
Fiber, total dietary	14g/ 1000kcal	111%	114%	115%	114%	111%
Total lipid (fat)	%kcal	30%	31%	32%	31%	31%
Minerals						
Calcium	%RDA	96%	102%	104%	102%	102%
Iron	%RDA	52%	62%	68%	167%	167%
Magnesium	%RDA	85%	98%	103%	109%	109%
Potassium	%AI	125%	145%	149%	151%	151%
Sodium	%CDRR	71%	80%	86%	80%	80%
Vitamins						
Vitamin A	%RDA	117%	131%	135%	82%	82%
Vitamin E	%RDA	60%	75%	80%	59%	59%
Vitamin D	%RDA	54%	57%	60%	57%	57%
Choline	%AI	74%	86%	91%	71%	71%
Folate, DFE	% RDA	84%	101%	109%	121%	121%

Table D14.2B U.S. Healthy-Style pattern comparison to goals for women who are pregnant or lactating, ages 19 to 30 years

Age Group Energy Level		19 to 30 years				
Life stage group for comparison		2,000	2,400	2,600	2,400 lactating	2,400 lactating
		pregnant (1st trimester) 19 to 30	pregnant (2nd trimester) 19 to 30	pregnant (3rd trimester) 19 to 30	(0-6 mo post part) 19 to 30	(7-12 mo post part) 19 to 30
Macronutrients						
Protein	%RDA	129%	150%	157%	150%	150%
Protein	%kcal	18%	18%	17%	18%	18%
Carbohydrate	%RDA	149%	180%	197%	150%	150%
Carbohydrate	%kcal	52%	52%	53%	52%	52%
Fiber, total dietary	14g/ 1000kcal	106%	111%	118%	111%	108%
Total lipid (fat)	%kcal	32%	32%	32%	32%	32%
Minerals						
Calcium	%RDA	126%	135%	140%	135%	135%
Iron	%RDA	52%	65%	72%	195%	195%
Magnesium	%RDA	104%	123%	133%	139%	139%
Potassium	%AI	125%	141%	152%	146%	146%
Sodium	%CDRR	63%	75%	80%	75%	75%
Vitamins						
Vitamin A	%RDA	122%	136%	148%	81%	81%
Vitamin E	%RDA	70%	83%	91%	66%	66%
Vitamin D	%RDA	68%	72%	73%	72%	72%
Choline	%AI	85%	97%	101%	79%	79%
Folate, DFE	% RDA	86%	108%	121%	129%	129%

Table D14.2C U.S. Healthy-Style Pattern comparison to goals for women who are pregnant or lactating, ages 31 to 50 years

Age Group Energy Level		31 to 50 years				
Life stage group for comparison		1,800	2,200	2,400	2,200 lactating	2,200 lactating
		pregnant (1st trimester) 31 to 50	pregnant (2nd trimester) 31 to 50	pregnant (3rd trimester) 31 to 50	(0-6 mo post part) 31 to 50	(7-12 mo post part) 31 to 50
Macronutrients						
Protein	%RDA	124%	141%	150%	141%	141%
Protein	%kcal	20%	18%	18%	18%	18%
Carbohydrate	%RDA	136%	166%	180%	138%	138%
Carbohydrate	%kcal	53%	53%	52%	53%	53%
Fiber, total dietary	14g/ 1000kcal	111%	114%	115%	115%	111%
Total lipid (fat)	%kcal	30%	31%	32%	31%	31%
Minerals						
Calcium	%RDA	125%	132%	135%	132%	132%
Iron	%RDA	50%	60%	65%	179%	179%
Magnesium	%RDA	97%	113%	119%	127%	127%
Potassium	%AI	119%	137%	141%	142%	142%
Sodium	%CDRR	61%	69%	75%	69%	69%
Vitamins						
Vitamin A	%RDA	119%	132%	136%	78%	78%
Vitamin E	%RDA	62%	77%	83%	61%	61%
Vitamin D	%RDA	67%	70%	72%	70%	70%
Choline	%AI	80%	92%	97%	75%	75%
Folate, DFE	% RDA	83%	100%	108%	120%	120%

Pattern Variations

The Food Pattern variations included as part of the 2015 Committee's review included Healthy Vegetarian and Healthy Mediterranean-Style Patterns. The development of these patterns is described in detail in Appendix E-3-7 of the 2015 report.¹⁰ These patterns were adopted by the 2020 Committee and updated using the nutrient profiles for the population ages 2 and older described previously in this chapter. Table D14.3 provides a comparison of the food groups and subgroups of the 3 updated USDA Food Patterns at the 2,000-kcal level. Table D14.4 provides a comparison to nutrient goals at the 2,000-kcal level using females ages 19 to 30 years as an example. The online Food Pattern Modeling report provides food groups and comparison to goals for all age-groups and energy levels

(<https://www.dietaryguidelines.gov/2020-advisory-committee-report/food-pattern-modeling/FPM-2-and-older>).

Table D14.3. Comparison of food groups and subgroups between the 3 USDA Food Patterns at the 2,000-kcal level

FOOD GROUP^[1] (units)^[2]	Healthy U.S.- Style 2,000	Vegetarian 2,000	Mediterranean- Style 2,000
FRUITS (cup eq/day)	2	2	2.5
VEGETABLES (cup eq/day)	2.5	2.5	2.5
Subgroups	Vegetable Subgroup Amounts in Cup Eq per Week		
Dark green (cup eq/week)	1.5	1.5	1.5
Red Orange (cup eq/week)	5.5	5.5	5.5
Legumes (cup eq/week)	1.5	1.5	1.5
Starchy (cup eq/week)	5	5	5
Other (cup eq/week)	4	4	4
GRAINS (oz eq/day)			
Whole grains (oz eq/ day) ^[3]	3	3.5	3
Refined grains (oz eq/ day)	3	3	3
PROTEIN FOODS (oz eq/day)	5.5	3.5	6.5
Subgroups	Protein Foods Subgroup Amounts in Oz Eq per Week		
Meats and Poultry (oz eq/week)	23		23
Eggs (oz eq/week)	3	3	3
Seafood (oz eq/week)	8		15
Legumes as protein (Vegetarian) (oz eq/week)		6	
Nuts, Seeds and Soy (oz eq/week)	5	15	4.5
DAIRY^[4] (cup eq/day)	3	3	2
OILS (grams/day)	27	27	27
Remaining Calories for Other Uses (kcal) ^{[5],[6]}	243	252	240

[1] Foods in each group and subgroup are:

Vegetables

- Dark-green vegetables: All fresh, frozen, and canned dark-green leafy vegetables and broccoli, cooked or raw: for example, broccoli; spinach; romaine; kale; collard, turnip, and mustard greens.
- Red and orange vegetables: All fresh, frozen, and canned red and orange vegetables or juice, cooked or raw: for example, tomatoes, tomato juice, red peppers, carrots, sweet potatoes, winter squash, and pumpkin.

- Legumes (beans and peas): All cooked from dry or canned beans and peas: for example, kidney beans, white beans, black beans, lentils, chickpeas, pinto beans, split peas, and edamame (green soybeans). Does not include green beans or green peas.

- Starchy vegetables: All fresh, frozen, and canned starchy vegetables: for example, white potatoes, corn, green peas, green lima beans, plantains, and cassava.

- Other vegetables: All other fresh, frozen, and canned vegetables, cooked or raw: for example, iceberg lettuce, green beans, onions, cucumbers, cabbage, celery, zucchini, mushrooms, and green peppers.

Fruits

- All fresh, frozen, canned, and dried fruits and fruit juices: for example, oranges and orange juice, apples and apple juice, bananas, grapes, melons, berries, and raisins.

Grains

- Whole grains: All whole-grain products and whole grains used as ingredients: for example, whole-wheat bread, whole-grain cereals and crackers, oatmeal, quinoa, popcorn, and brown rice.

- Refined grains: All refined-grain products and refined grains used as ingredients: for example, white breads, refined grain cereals and crackers, pasta, and white rice. Refined grain choices should be enriched.

Dairy

- All milk, including lactose-free and lactose-reduced products and fortified soy beverages (soymilk), yogurt, frozen yogurt, dairy desserts, and cheeses. Most choices should be fat-free or low-fat. Cream, sour cream, and cream cheese are not included due to their low calcium content.

Protein Foods

- All seafood, meats, poultry, eggs, soy products, nuts, and seeds. Meats and poultry should be lean or low-fat and nuts should be unsalted. Legumes (beans and peas) can be considered part of this group as well as the vegetable group, but should be counted in 1 group only.

[2] Food group amounts shown in cup-(c) or ounce-equivalents (oz-eq). Oils are shown in grams (g). Quantity equivalents for each food group are:

- Vegetables and fruits, 1 cup-equivalent is: 1 cup raw or cooked vegetable or fruit, 1 cup vegetable or fruit juice, 2 cups leafy salad greens, ½ cup dried fruit or vegetable.

- Grains, 1 ounce-equivalent is: ½ cup cooked rice, pasta, or cereal; 1 ounce dry pasta or rice; 1 medium (1 ounce) slice bread; 1 ounce of ready-to-eat cereal (about 1 cup of flaked cereal).

- Dairy, 1 cup-equivalent is: 1 cup milk, yogurt, or fortified soymilk; 1½ ounces natural cheese such as cheddar cheese or 2 ounces of processed cheese.

- Protein Foods, 1 ounce-equivalent is: 1 ounce lean meat, poultry, or seafood; 1 egg; ¼ cup cooked beans or tofu; 1 Tbsp peanut butter; ½ ounce nuts or seeds.

[3] Amounts of whole grains in the Patterns for children are less than the minimum of 3 oz-eq in all Patterns recommended for adults.

[4] Regardless of energy level, the Dairy Food group (inclusive of calcium-fortified soy beverages) is 2 cup-eq for children ages 2 to 3 years, 2.5 cup-eq for children ages 4 to 8 years, and 3 cup-eq for children ages 9 to 18 years.

[5] All foods are assumed to be in nutrient-dense forms, lean or low-fat and prepared without added fats, sugars, refined starches, or salt. If all food choices to meet food group recommendations are in nutrient-dense forms, a small number of kcals remain within the overall energy limit of the Pattern (i.e., limit on kcals for other uses). The number of these kcals depends on the overall energy limit in the Pattern and the amounts of food from each food group required to meet nutritional goals.

[6] Values are rounded.

Table D14.4. Comparison to goals between the 3 USDA Food Patterns at the 2,000-kcal level

Energy Level		Healthy US-Style 2,000 ¹	Vegetarian 2,000 ¹	Mediterranean-Style 2,000 ²
Age-sex group for comparison		Female 19 to 30 yr	Female 19 to 30 yr	Female 19 to 30 yr
Macronutrients				
Protein	%RDA	200%	174%	196%
Protein	%kcal	18%	16%	19%
Carbohydrate	%RDA	199%	214%	193%
Carbohydrate	%kcal	52%	56%	53%
Fiber, total dietary	14g/1000kcal	107%	125%	110%
Total lipid (fat)	%kcal	32%	31%	31%
Saturated fat	%kcal	8%	8%	7%
Cholesterol	%DG	75%	39%	75%
Minerals				
Calcium	%RDA	128%	134%	99%
Iron	%RDA	79%	91% (51% ³)	80%
Magnesium	%RDA	115%	123%	113%
Phosphorus	%RDA	236%	230%	217%
Potassium	%AI	130%	126%	130%
Sodium	%CDRR	72%	65%	67%
Vitamins				
Vitamin E	%RDA	69%	73%	70%
Vitamin D	%RDA	50%	37%	50%
Vitamin B-12	%RDA	260%	164%	266%
Choline	%AI	83%	71%	83%

1: Includes 3 cup eq Dairy; 2: Includes 2 cup eq Dairy.

3: RDA assumes 75% of iron from heme sources. The RDA is 1.8 higher for vegetarians because they obtain iron predominantly from non-heme sources. The percent of the RDA for iron provided by the Vegetarian Pattern using the RDA (i.e., 91%) and 1.8 times the RDA (i.e., 51%).

See online food pattern modeling report (<https://www.dietaryguidelines.gov/2020-advisory-committee-report/food-pattern-modeling/FPM-2-and-older>) for complete list of nutrients.

Healthy Vegetarian Pattern

Although vegetarian dietary patterns are associated with positive health outcomes, their description in the literature often focuses on foods that are not consumed, rather than on the foods that represent the pattern. For the 2015 Committee's process, the USDA Healthy Vegetarian Pattern was informed by reported dietary intakes of self-identified vegetarians using NHANES 2007-2010. Self-identified vegetarian status is not collected in more recent NHANES survey years, so this analysis was not undertaken by the 2020 Committee. In previous analyses, more than 90 percent of self-identified vegetarians consumed dairy products on the

day of the NHANES survey, and 65 percent consumed eggs.¹² Thus, the Healthy Vegetarian Pattern was modeled as a lacto-ovo vegetarian pattern. Nutrient adequacy of the Healthy Vegetarian Patterns aims to meet the same nutrient standards met by the Healthy U.S.-Style Patterns.

The updated Healthy Vegetarian Pattern generally meets nutrient needs (<https://www.dietaryguidelines.gov/2020-advisory-committee-report/food-pattern-modeling/FPM-2-and-older>). Like the Healthy U.S.-Style, the Healthy Vegetarian Pattern does not meet intake recommendations for vitamin E, vitamin D, and choline for adult women and young men, and iron for women ages 14 and older. Bioavailability of iron from non-heme sources found in vegetarian diets is lower than that from heme sources (i.e., animal products). The RDA for iron assumes 75 percent of iron is from heme iron sources, which is unlikely in a typical vegetarian diet. The iron requirement for individuals consuming a vegetarian diet is 1.8 times higher than that of individuals consuming a non-vegetarian diet. The Committee did not specifically address the iron bioavailability for any of the Patterns, as absorption rates are known to differ based on intake of calcium, zinc, and phytates in the diet.

The Healthy Vegetarian Pattern contains some differences in food group amounts compared to the Healthy U.S.-Style Pattern. The major difference is the lack of meat, poultry, or seafood subgroups in the Healthy Vegetarian Pattern. Using the 2,000 kcal level as reference, the Healthy Vegetarian Pattern is higher in soy products (particularly tofu and other processed soy products), legumes, nuts and seeds, and whole grains compared to the Healthy U.S.-Style Pattern. The remaining food group components match that of the Healthy U.S.-Style Pattern.

The 2,000 kcal Healthy Vegetarian Pattern provides less protein (12 g), less fat (1 g), less dietary cholesterol (96 mg), more carbohydrate (19 g), and more dietary fiber (5 g), than the 2,000 kcal Healthy U.S.-Style Pattern. For micronutrients, the Healthy Vegetarian Pattern provides less potassium, vitamin A, vitamin D, sodium, and choline than the Healthy U.S.-Style Pattern. Amounts of fiber, magnesium, and folate are higher in the Healthy Vegetarian Pattern, primarily due to the increased quantity of legumes and nuts and seeds. Calcium also is slightly higher in the Healthy Vegetarian Pattern due to the higher quantity of processed soy products, including tofu, which often contains a calcium salt, as well as the calcium from dairy and other food groups.

The 2,000-kcal Healthy Vegetarian Pattern meets goals and recommendations for most nutrients, although some gaps remain. For women ages 19 to 30 years, the Healthy Vegetarian Pattern provides 91 percent of RDA for iron through an increase of legumes, whole grains, and soy products, compared with 79 percent of RDA in the Healthy U.S.-Style Pattern; however,

given the lower bioavailability of iron from non-heme sources this likely reflects an overestimation of how much iron the Vegetarian pattern provides. Both the Healthy Vegetarian Pattern and the Healthy U.S.-Style Pattern exceed the RDA for magnesium and AI for potassium. Similar to the Healthy U.S.-Style Pattern, the Healthy Vegetarian Pattern does not provide adequate amounts of vitamin E, vitamin D, and choline to meet the RDA and AI. At the 2,000-kcal level, the Healthy Vegetarian Pattern provides 73 percent of RDA for vitamin E, 37 percent of RDA for vitamin D, and 71 percent of AI for choline.

Healthy Mediterranean Style

The Healthy Mediterranean-Style Eating Pattern was developed as part of the 2015 Committee's review and is characterized by food group amounts similar to the diets characterized by research as "Mediterranean," particularly Mediterranean-diet (Med-diet) indexes. It was adapted from the Healthy U.S.-Style pattern to include food categories associated with positive health outcomes vs focusing on meeting specific nutrient goals. The major difference between the 2 patterns is that the Healthy Mediterranean-Style Pattern contains more fruits and seafood and less dairy. Although the development of the pattern was focused on health outcomes vs nutrient adequacy, the adequacy of the Healthy Mediterranean-Style pattern has been compared to the same nutrient standards as the Healthy U.S.-Style Pattern.

The updated Healthy Mediterranean-Style Pattern meets most RDA and AI goals, nearly matching the Healthy U.S.-Style Pattern. The food group and subgroup amounts for this Pattern are described in the online Food Pattern Modeling report (<https://www.dietaryguidelines.gov/2020-advisory-committee-report/food-pattern-modeling/FPM-2-and-older>). The Healthy Mediterranean-Style Pattern provides calcium, vitamin A, and sodium in lower amounts than the Healthy U.S.-Style Pattern. This reflects the lower amount of dairy in the Healthy Mediterranean-Style Pattern for adults: 2 cup-equivalents (cup-eq) compared to 3 cup-eq in the Healthy U.S.-Style Pattern. Calcium is a nutrient of public health concern and thus, the amounts of dairy included in the pattern for children are intended to provide adequate calcium to meet the RDA. Regardless of energy level, the Dairy Food group (inclusive of calcium-fortified soy beverages) is 2 cup-eq for children ages 2 to 3 years, 2.5 cup-eq for children ages 4 to 8 years, and 3 cup-eq for children ages 9 to 18 years.

Using the 2,000-kcal level as reference, the Healthy Mediterranean-Style Pattern includes more fruits (2.5 vs 2.0 cup-eq) and protein foods (6.5 vs 5.5 ounce-equivalents [oz-eq]) compared to the Healthy U.S.-Style Pattern. The higher amount of protein foods comes directly

from an increase in seafood (15vs. 8 oz-eq per week) in the Healthy Mediterranean-Style Pattern. The remaining food group components match that of the Healthy U.S.-Style Pattern. The 2,000-kcal Healthy Mediterranean-Style Pattern (using 2 cup-eq of dairy) provides less calcium (-289 mg), less phosphorous (-135 mg), less sodium (-121 mg) and more omega-3 eicosapentaenoic acid (EPA) (+52 mg) and more omega-3 docosahexaenoic acid (DHA) (+107 mg) than the 2,000-kcal Healthy U.S.-Style Pattern (using 3 cup-eq of dairy).

If Nutrient Needs Are Not Met, Is There Evidence to Support Supplementation and/or Consumption of Fortified Foods to Meet Nutrient Adequacy?

The USDA Food Patterns are designed to meet most or all nutrient recommendations. However, in cases where natural sources of the nutrient are limited (e.g., vitamin D) or when the reference value is above what can be accommodated within an energy range (e.g., iron during pregnancy), fortified foods are recommended and dietary supplements may need to be considered.. Fortification, as defined by the U.S. Food and Drug Administration (FDA), is the deliberate addition of 1 or more essential nutrients to a food, whether or not it is normally contained in the food. Fortified foods, such as ready-to-eat cereals, are included in food pattern modeling in proportion to their consumption in that age group. However, no special emphasis is placed on fortified foods within the food pattern modeling exercises.

Vitamin D presents a unique case for the USDA Food Patterns because it is not present in most foods commonly consumed by Americans. The majority of vitamin D intake comes from fortified foods and supplements. To meet vitamin D recommendations while following the food group recommendations of the USDA Food Patterns, careful selection of specific foods within each food group would be needed, to include natural sources of and foods fortified with vitamin D (see 2015 Dietary Guidelines Advisory Committee Report,¹ Appendix E-3.3 Meeting Vitamin D Recommended Intakes in USDA Food Patterns).

Women of reproductive age should carefully consider choices of foods high in iron, especially during pregnancy, so as to obtain a larger proportion of iron from dietary sources given the higher bioavailability. Prenatal dietary supplements provide iron in amounts sufficient to meet needs of most women during pregnancy, and should be discussed with a healthcare provider.

During the periconceptual time period, folic acid has been shown to reduce the risk for the occurrence or reoccurrence of neural tube defects.^{13,14} It also may reduce other poor pregnancy outcomes among women of reproductive age (see ***Part D. Chapter 2: Food, Beverage, and Nutrient Consumption During Pregnancy***). Efforts to encourage inclusion of folic acid in the diet from fortified foods or dietary supplements among women with low intakes are warranted.

Folic acid intakes are critical in the first trimester of pregnancy to reduce the risk of neural tube defects therefore the Committee supports folic acid supplementation as the standard of care before and during pregnancy.

Choline also is a challenge because an RDA is not established, which makes it difficult to determine whether it is a nutrient of public health concern and therefore developing guidance is problematic. Choline is not currently part of most dietary supplements that Americans typically consume,¹⁵ nor is it fortified in any products known to the Committee. More research is needed, particularly for women of reproductive age, around the health consequences of low levels of choline intake.

Vitamin E has consistently been identified as a shortfall nutrient in the American diet but it is not considered a nutrient of public health concern based on biomarker information from previous NHANES cycles that did not indicate low vitamin E status. Thus, the Committee did not consider evaluating whether fortification or supplementation is warranted.

For additional details on this body of evidence, visit:

<https://www.dietaryguidelines.gov/2020-advisory-committee-report/food-pattern-modeling/FPM-2-and-older>

DISCUSSION

Since the 2015 review of food patterns, when the Healthy U.S.-Style, Healthy Vegetarian, and Healthy Mediterranean-Style Patterns were developed and tested for provision of nutrient recommendations, the literature related to healthy dietary intake patterns and a range of associated outcomes has significantly expanded as demonstrated by the systematic reviews completed by the Committee (see **Part D. Chapter 8: Dietary Patterns**). The growth in this field of research (and subsequent literature base) reinforces the conclusion that for now, the primary Healthy U.S.-Style pattern and its variations are generally representative of high-quality dietary intakes that meet nutrient recommendations; “high-quality” refers to the most nutrient-dense form of a food with the least amount of added sugars, sodium, and saturated fat. A general consensus has emerged from the Committee based on systematic review about the core components to encourage and those to limit. Therefore, the goal going forward is to help the public achieve these healthy dietary intakes more consistently over the lifespan.

The 3 USDA Food Patterns provide an adequate amount of most nutrients while minimizing amounts of sodium, solid fats, and added sugars—all of which increase the risk of chronic

disease. Furthermore, the recommended patterns provide the combinations of foods to meet nutrient recommendations while maintaining an appropriate energy intake based on life stage, sex, and physical activity level. However, this work demonstrates that careful choices must be made to consume nutrient-dense forms of foods, lower in foods with sodium, added sugars, and saturated fat within a given energy level. Similarly, the modeling exercises also demonstrates that choosing less nutrient-dense foods (i.e. typical choices) will fail to meet the nutrient adequacy targets, while potentially providing higher-than-needed energy intake. This type of pattern is, unfortunately, typical of a significant proportion of Americans' current intake, as shown on Healthy Eating Index scores, which reflect alignment with the Healthy U.S.-Style Pattern (see **Part D. Chapter 1: Current Intakes of Foods, Beverages, and Nutrients**). None of the work of this Committee evaluated the cost of these proposed patterns; however, the USDA routinely publishes such data within its USDA Food Plans.¹⁶

As highlighted in the *2015-2020 Dietary Guidelines for Americans*, most Americans would benefit from shifting current food choices to healthy, nutrient-dense foods and beverages across and within all food groups.¹⁰ The need for the shifts are demonstrated by the under- and overconsumption of certain food components identified in this report (see **Part D. Chapter 1**), together with high rates of overweight and obesity suggesting excess energy intakes and or low physical activity. Some shifts that are needed are minor—primarily requiring a different type of food choice or food preparation. For example, choosing a more nutrient-dense snack option of nuts or seeds rather than potato chips or pretzels would provide similar amounts of energy based on serving size, but would help to increase intake of a broad range of nutrients. Baking rather than frying, or alternating food preparation techniques may be considered a small shift that would be beneficial over time. However, other changes or shifts in the diet are likely to require a concerted effort to include foods that may be underconsumed and/or displacing foods and beverages that are overconsumed. One example of this is increasing daily vegetable intake even if the taste of vegetables is not preferred by an individual.

Opportunities for improving the dietary quality of Americans can be gleaned by analyzing intake patterns across life stages. As noted in **Chapter 1**, dietary quality is highest in the youngest populations, with notably lower quality in adolescents and early to middle-aged adults. In this instance, the opportunity for improvement centers on retaining dietary quality from one life stage to the next, while continuing to make incremental improvements along the way. Although the Committee acknowledges that NHANES data are not longitudinal in nature, it is still relevant to highlight some differences in intake by life stage that may be actionable. For example, maintaining the intake of dairy in the form of fluid milk or calcium-fortified soy

beverages, rather than replacing these choices with sweetened beverages as children age could be a key focus for improving dietary quality while also aiding in the development of peak bone mass.¹⁷ Retaining diet and nutrient quality may become increasingly important as dietary guidance emphasizes building health-promoting eating patterns early in life.

Even though the recommended Food Patterns have not appreciably changed with the 2020 Committee's review, the results of food pattern modeling point to some important conclusions and lessons learned. Some of these findings are a result of the life-stage approach used to achieve a focused assessment of dietary intakes and nutrient needs by age-sex subgroups. Updating the food item clusters with relevant intakes of foods by life stage revealed some interesting observations that may provide insight on strategies that might help influence Americans to continue improving dietary quality. For example, it is notable that certain forms of foods appear in differing proportions across age groups. The differences in intake proportions and food groups by life stage suggest that these differences could be driven by the lifestyle and socialization patterns for each age group.^{18,19} School aged-children may be structurally exposed to different food options than working adults or older, retired adults. These differences in socialization and lifestyle patterns may become evident in the food choices and preferences at various stages in life. A better understanding of the influence of these lifestyle patterns that are common to a given life stage may provide the opportunity to better support and promote healthy dietary intake. This points to the need for considering a systems science approach to expand food pattern modeling,² incorporating factors that influence food choice and result in more actionable recommendations that would lower the risk of obesity and other nutrition-related chronic health conditions (see **Part D. Chapter 1** and Lee et al.²⁰).

Diet quality is a central theme for the Committee as a result of reviewing data from a variety of sources, including the results of the food pattern modeling analyses. Food pattern modeling highlights the impact of diet quality on the risk of nutrient inadequacy. The USDA Food Patterns consist of high-quality food choices and achieving the nutrient intake targets is dependent on those choices. When diet quality is poor, as indicated by lower intakes of nutrient-dense foods like vegetables, fruit, legumes, or whole grains, then it is unlikely that individuals will achieve the targeted nutrient intakes from foods. When nutrient-dense foods account for a low proportion of the total energy intake, it follows that nutrient-poor but energy-rich foods, such as refined grains and foods and beverages with added sugars and saturated fats, contribute a higher proportion of energy intake, thereby contributing to a higher risk of overweight and obesity and a range of related chronic diseases.

In addition to ensuring high dietary quality, the USDA Food Patterns allow individuals to meet nutrient needs at a target energy level. This ensures that no matter what an individual's energy needs are, total energy does not have to be exceeded to ensure nutrient adequacy. For many Americans, the issue of energy balance is critical because of the high prevalence of overweight and obesity—consuming a poor-quality, energy-dense diet increases the risk of excess weight gain and associated complications. It should be noted that nutrient adequacy can be achieved if one consumes less-than-ideal food choices, but this will typically come at the expense of consuming excess energy. For example, foods that help meet nutrient needs but include significant amounts of added sugars or solid fats, such as fruits canned in heavy syrup, or higher fat meats, provide more energy than comparable foods with lower amounts of added sugars and solid fats. While added sugars and solid fats may enhance palatability and therefore increase intake of some nutrients or food groups that have typically been under consumed, Americans should be aware of how these additions may affect energy balance. Managing energy intake from all foods and beverages is fundamental to maintaining energy balance, and routine behaviors related to food quality have a significant impact on that energy balance. For analysis and discussion related to added sugars see **Part D. Chapter 12: Added Sugars**.

Achieving energy balance and nutrient adequacy are important for promoting optimal health. This is particularly true when considering growth, development, and healthy aging. Early in life, energy intake increases as infants grow and mature. In general, energy intakes should peak for men and women in the young adult stage: ages 19 to 30 years. From there, energy requirements typically decline in middle age and older adults as changes in lean muscle reduce energy needs. These trajectories in terms of energy and associated nutrients are intended to help achieve peak body composition, muscle stores, and bone mass by early adulthood.⁹ For women who are pregnant or lactating, adjustments in energy and associated nutrients are intended to help support growth and development of the offspring while maintaining the health of the mother. In older ages, achieving nutrient intake adequacy can be particularly challenging in circumstances where food intake is inconsistent due to age-related factors or changes in preferences. Shifting energy intake down with older age often requires paying even more attention to portions, dietary quality, and energy density of food choices. Older adults require less food to meet their lower energy needs. Therefore, it is crucial that the foods consumed be nutrient-dense in order to avoid nutrient shortfalls.

Other life stages of note when considering diet quality and nutrient adequacy are pregnancy and lactation. The existing 2015-2020 USDA Healthy U.S-Style Patterns are expected to meet nutrient needs for women who are pregnant or lactating, with the exception of iron during

pregnancy, vitamin A during lactation, and vitamin E, vitamin D, and choline for both life stages. For women who have higher estimated energy requirements, higher energy patterns may come closer to providing the RDA or AI for nutrients through dietary sources. The considerations for diet quality during pregnancy and lactation have implications for the health of the mother and the offspring. This includes ensuring appropriate growth and development of the fetus, avoidance of maternal-fetal complications during pregnancy, and normal growth and development of the infant. The longer-term implications for the mother are notable as well because retention of weight gain after pregnancy or a history of gestational diabetes or hypertensive disorders of pregnancy also increase the risk of chronic diseases. To achieve healthy outcomes, women should follow a nutrient-dense dietary pattern, such as the Healthy U.S.-Style Pattern, during pregnancy and lactation along with guidance from a healthcare provider on appropriate use of dietary supplements to meet nutrient needs not expected to be covered by dietary intake alone, especially iron, iodine, and folic acid. Folic acid should be consumed preconception and at least through the first trimester.

The food pattern modeling review has several important implications for the development of the *2020-2025 Dietary Guidelines for Americans*. The Committee's food pattern modeling work also offers a few key caveats. Most notably, the food pattern modeling process does not include beverages that are not contributors to the USDA food groups or subgroups, meaning that many of the commonly consumed beverages, such as sweetened beverages and alcoholic beverages, are not included in the patterns presented. Therefore, if individuals choose to include these types of energy-containing beverages in excess of the remaining energy allotted in a pattern on a routine basis, then they would need to account for that energy by reducing intakes of other foods and beverages to ensure energy balance without sacrificing the nutrient adequacy that the Healthy U.S.-Style Pattern provides (see **Part D. Chapter 12: Added Sugars**). Future work is needed to understand how to incorporate beverages into the food pattern modeling process.

As alluded to previously, one consideration with food pattern modeling is that it can identify gaps in nutrient intake and options to meet those needs, but this process does not specify how to change food intake behaviors. It would be valuable to continue food pattern modeling analyses by life stage as well as to employ the socio-ecological model systems approach, such as that identified by the *2015-2020 Dietary Guidelines for Americans*, to identify strategies that promote and advance broad public health change engaging multiple sectors, as delineated by the Socioecological Framework.^{10,19}

Another aspect of food pattern modeling that this Committee discussed is how to apply DRI recommendations for individuals more broadly at the population level. To advance this goal, the food pattern modeling approach would need to be adjusted appropriately and subsequently evaluated against the EAR, not the RDA that is used for individual planning. As noted in the 2017 NASEM report,² techniques such as linear programming or stochastic modeling may be useful in food pattern modeling as applied to food preferences, geographic or cultural factors, as well as nutrient recommendations as model parameters.²¹

Lastly, food pattern modeling identifies the food groups and subgroups needed to meet nutritional goals. It does not specify the specific foods to be consumed, as menu planning would. However, food pattern modeling does provide the framework to build menu planning and then allows individuals to tailor the recommended USDA Food Patterns to specific tastes and preferences. Ultimately, individuals who would benefit from guidance need support to help them make ideal food choices within their own personal dietary preferences to ensure that nutritional goals are met with high-quality foods.

SUMMARY

The recommended USDA Food Patterns for Americans, which achieve healthy dietary intake and meet nutritional goals and energy balance, include the Healthy U.S.-Style, the Healthy Vegetarian, and the Healthy Mediterranean-Style Patterns. No additional food patterns were developed during the work of this Committee, confirming the guidance on Patterns issued from this and previous Committees (see **Part D. Chapter 8: Dietary Patterns**). Although these 3 Food Patterns have some key differences that allow for tailoring to individual preferences, they share some core components, including obtaining the majority of energy from plant-based foods, such as fruits, vegetables, legumes, whole grains, nuts and seeds, and obtaining protein and fats from nutrient-rich food sources, while limiting intakes of added sugars, solid fats, and sodium.

The 2020 Committee looked at ways to implement recommendations from the 2017 NASEM report on updating the process for the *Dietary Guidelines for Americans*.² Food pattern modeling was one tool identified by the NASEM report. The Committee sought to use food pattern modeling across life stages to increase the applicability of food pattern modeling for individuals. The focus on life stages has provided interesting insights into opportunities for tailoring recommendations for food intake to meet nutrient needs across the life course. Future Committees should be encouraged to expand upon this tailored approach, where more refined

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dietary guidance for each life stage may be developed to promote optimal health and aging within and across each life stage.

Food pattern modeling helps to affirm the recommended dietary patterns by demonstrating their impact on nutrient adequacy. Food pattern modeling highlights the impact that diet composition and quality have on nutrient intakes. Consumption of the optimal balance of energy and nutrients has always been a key concern of the Committee because under- and overconsumption of certain nutrients and food components are associated with an increased risk of chronic disease. Indeed, food components of public health concern have been identified by the Committee based on inadequate intakes of key nutrients that have biomarkers that indicate increased disease risk (see **Part D Chapter 1**). Food pattern modeling provides a means to transition from a nutrient level focus to a dietary pattern level of focus, whereby the individual can address nutrient needs within a food plan. By evaluating how diet composition and quality affect nutrient intakes, food pattern modeling provides an important understanding of how to consume combinations of foods to address those shortfalls or excesses. This moves the focus from nutrient intakes to foods and dietary patterns over a period of time. Ultimately, the negative health risks of a low-quality dietary pattern can be mitigated or largely avoided when one of the recommended USDA Food Patterns is consumed at the energy level to maintain a healthy weight.

Strong evidence shows the types of foods individuals should primarily be consuming, and this has been reaffirmed by the work of this Committee (see **Part D. Chapter 8: Dietary Patterns** and **Chapter 12: Added Sugars**). Additionally, general consensus exists around what types of foods should be limited, as they contribute high amounts of energy with minimal contribution to the nutrients needed to promote optimal health and avoid chronic disease. Even though some needs have important variations across life stages, the foods that individuals should eat over the lifespan are remarkably consistent. If healthy eating patterns can be established early in life and sustained thereafter, the impact on the prevalence of chronic disease could be significant (see **Part D. Chapter 7: USDA Food Patterns for Children Younger than Age 24 Months**). Because the risk of chronic disease begins early in life, taking steps to apply the best understanding of healthy dietary intakes in the earliest days of life can support lifelong chronic disease risk reduction and improved quality of life.

Food pattern modeling begins to illustrate some opportunities for engagement with the public in continuing to shift dietary intakes in healthy directions. Identifying subtle changes in intakes and preferences over the life course signals opportunities to help maintain healthy intakes early in life and build on those behaviors over time. It is also possible to identify life

stage transition points when the potential for changes are likely to be detrimental or lead to higher risk dietary patterns. If these “at risk” periods are anticipated over the life course, public health strategies can be considered that may help to decrease the adoption of poor dietary habits that may become engrained into lifestyle patterns over the long term. The Committee strongly recommends the Departments of Agriculture and of Health and Human Services make it a priority to direct Federal resources and research toward implementing effective behavior change strategies to achieve the recommendations outlined in this report. As explored by the 2015 Committee and recommended by the *2015-2020 Dietary Guidelines for Americans*, employing a systems-based approach and the Socioecological Model may lead to behavior change strategies that can be used to favorably affect a range of health-related outcomes and to enhance the effectiveness of interventions.

To facilitate shifting American dietary intakes toward healthier directions, access to healthy food options is critical. The Committee recognizes that several barriers and facilitators affect access and influence consumers’ dietary behaviors beyond nutritional considerations, including food costs and food security status. The Committee recommends that the Departments of Agriculture and of Health and Human Services continue to assess how food costs and food security status influence food intake and resulting nutritional status in the American public. The Departments have done a significant amount of work on understanding the cost of the recommended Food Plans. The Healthy U.S.-Style Pattern described in this chapter will serve as the foundation for updating the USDA Food Plans that calculate market basket costs of a healthy eating pattern at 4 levels: the Thrifty Food Plan (i.e., minimal cost), Low Cost, Moderate Cost, and Liberal Food Plans. These Food Plans demonstrate that healthy eating does not need to be cost-prohibitive. However, little information exists on how food insecurity, which is the limited or uncertain availability of nutritionally adequate and safe foods or limited or uncertain ability to acquire acceptable foods in socially acceptable ways, affects food purchasing behaviors. Approximately 11 percent of U.S. households experienced food insecurity in 2018.²² Future research is needed to understand how food security status interacts with food costs to shape dietary behaviors.

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PART E. FUTURE DIRECTIONS

A valuable outcome of the extensive review of scientific evidence undertaken by the Committee is a keen awareness of additional work that must be done. The Committee drafted Future Directions to highlight research recommendations that could advance knowledge in nutrition science and support future activities related to the Dietary Guidelines, both within and outside the Federal government. A number of topics require additional research or data, and these gaps in evidence should be communicated to those who fund and conduct primary research and surveillance data projects. The Committee also has insight into some of the methodological limitations and inconsistencies that pervaded the available evidence and provided suggestions to improve research design and methods and to help the research community better understand how these issues affect the confidence with which systematic review conclusions may be drawn. The Committee encourages mechanisms, including journal articles, workshops, or other approaches, to communicate the research recommendations to the audiences they target. The Committee's Future Directions described herein include support for Federal data, needs for updated Dietary Reference Intakes, and other related activities, as well as research recommendations and topics for consideration by future Committees.

SUPPORT FOR FEDERAL DATA, DIETARY REFERENCE INTAKES, AND RELATED ACTIVITIES

Support for Federal Data

The data generated in the National Health and Nutrition Examination Survey (NHANES), including What We Eat in America (WWEIA), are essential for the development of the Committee's report. The inclusion of the age group birth to 24 months, women who are pregnant or lactating, plus the lifespan approach for the Dietary Guidelines require the availability of relevant data to adequately assess food and nutrient intake and health status for these population groups. The Committee identified several specific types of data needs:

- Ensure national surveillance systems expand diversity and sample size of underreported populations. This should include those individuals in *underrepresented life stages*, such as women who are pregnant or lactating and infants and children younger than age 24 months, as well as those in *underrepresented populations*, such as Native Americans, Pacific Islanders, and Native Hawaiians. USDA databases also should be expanded by analyzing and incorporating additional foods and beverages from diverse populations. Further, national surveillance systems should incorporate survey questions that query participants on

food and beverage intake in the context of socioeconomic status, food security status, cultural food traditions, and religious or ethnic food “rules.”

Rationale: All aspects of the population should be represented in the data considered and used to inform national guidance.

- Include biomarker data that are national in scope to adequately describe the nutritional status of Americans, particularly those who are currently underrepresented in national data (i.e., infants and toddlers, reproductive-aged females, women who are pregnant or lactating, and certain race and ethnic groups). For example, include biomarkers of iodine and zinc status in nutrition surveys, especially for women who are pregnant or lactating, and infants and children younger than age 24 months.

Rationale: Very limited biomarker data are available in recent survey years. This Committee, in some instances, had to rely on biomarker data from NHANES 2003-2006 or older to inform decisions on contemporary nutritional status.

In several chapters, concerns were raised about potential underconsumption of iodine by women who are pregnant or lactating and infants and children younger than age 24 months. Very little to no data are available on urinary iodine for children younger than age 24 months, so the extent of the problem is unknown. Iodine deficiency has been documented in other high-income countries (e.g., Norway). Only 53 percent of table salt sold at retail level in the United States in 2009 was iodized,¹ and the iodine content of cow milk in the United States is highly variable.² Underconsumption of iodine during infancy has important potential consequences for brain development, especially if maternal intake was also low during pregnancy.³

For zinc, lack of biomarker data in nutrition surveys limits the judgments that can be made about risk of inadequacy. Zinc status of older infants fed human milk is of particular interest (see **Part D. Chapter 5: Foods and Beverages Consumed During Infancy and Toddlerhood**). Therefore, surveys should be designed to include stratification by milk source. For children from birth to age 24 months, very little information on nutritional status is available in national surveys due to inadequate sample size and the NHANES policy of not taking blood samples for infants younger than age 1 year. Efforts are underway to conduct a pilot study on the feasibility of conducting blood draws from infants through NHANES.⁴ The Committee supports these efforts.

- Improve dietary assessment methods that can more accurately estimate energy intakes feasible for use in Federal surveillance and monitoring.

Rationale: All existing dietary assessment methods are subject to under-reporting of energy intakes in most population subgroups. Because excess energy intakes without concomitant increases in energy expenditures can lead to weight gain, more accurate assessment tools are needed. Energy intake estimates among infants are of particular concern because they appear to exceed needs for growth and development, and may result from care provider over-reporting dietary intakes.

- Harmonize the Federal sampling framework with the Dietary Reference Intakes (DRI) age groups, and develop clear definitions of life stages.

Rationale: The Committee took a life-stage approach to address the role of nutrition and health; however, a lack of consistency in terms used to define life stage exists. Furthermore, the sampling frameworks and age groupings do not align with the DRI age groupings, complicating data analysis and interpretation.

- Implement surveillance systems to gather more information about the contextual aspects of food and beverage intake, such as the frequency and/or timing of food and beverage consumption.

Rationale: This information is important to fully understand how individuals consume specific foods and beverages to better align with nutrient requirements and changes in meal and snacking occasions across life stages.

- Continue the ongoing Federal initiative to expand research on human milk composition and how it relates to maternal and infant health.⁵ Update USDA databases to establish a reference or standard human milk composition profile that incorporates data from diverse populations and across lactation, with consideration of how milk composition may be influenced by maternal diet and other factors. The ultimate goal is an accurate and current database of representative values for the energy and nutrient composition of human milk across the full course of lactation, including beyond 1 year of life. The milk samples should be collected from diverse groups of individuals and linked to dietary intake and other metadata (e.g., age, parity).

Rationale: Human milk composition was last analyzed and updated in USDA databases in 1976. Analytical methods for human milk composition have significantly advanced over the past 4 decades and some components, such as human milk oligosaccharides, are not in the current database. In addition, the human milk samples were not collected from diverse populations of women and were not linked to metadata regarding maternal diet, supplement use, genetics (e.g., secretor status), or other factors that could influence milk composition. In addition, little information is available on milk composition during extended lactation, which limited the Committee's food pattern modeling activities for infants older than age 12 months who consume human milk. The Committee made many assumptions about the energy and nutrient composition of human milk. Much more research is needed to develop an accurate database of representative values that reflects the dynamic changes in milk composition based on the age of the infant and maternal characteristics.

- Enhance surveillance systems to enable linkage of parent-child or other family member intakes within surveys.

Rationale: Parents play an important role in shaping children's eating habits and food preferences by serving as gatekeepers for food entry into the home and by modeling eating behaviors. The ability to link parental and care provider dietary intake data to that of their children would strengthen the ability to determine how parental and care provider dietary practices affect child health and development.

- Link surveillance systems that collect data about infant feeding and health outcomes.

Rationale: Despite the importance of the questions that examined relationships between human milk and/or infant formula consumption and long-term health outcomes in

offspring, the available evidence for many questions was insufficient to form conclusion statements. Generally, much more evidence exists about shorter-term outcomes (e.g., in infancy and early childhood) than for long-term outcomes (into adulthood), because studies of the latter require such a long timeframe. Large datasets, especially those that follow participants longitudinally, and in particular link children with siblings and parents, would be very useful for more robustly assessing associations and providing more confidence in conclusions regarding causality.

Dietary Reference Intakes

The DRIs are essential resources for evaluating the nutritional quality of current dietary patterns for the American public, and the Committee has identified where updates are needed for the DRIs to be relevant in the Dietary Guidelines process.

- Updates to existing DRIs are urgently needed for many nutrients for all age-sex groups and life stages to better characterize potential risk of dietary inadequacy and excess.

Rationale: Intake of choline is below the Adequate Intake (AI) for several segments of the population, and it is important to understand if this level of intake presents a public health concern for certain age-sex groups. Further progress on understanding the essentiality of choline and recommended intakes is needed. Older adults may benefit from protein intakes above existing DRI recommendations given the high prevalence of sarcopenia, and may have differential energy and nutrient needs based on presence of chronic disease, polypharmacy, changes in oral health and tooth loss, among a myriad of other potential factors that influence needs. Therefore, reassessing protein and macronutrient requirements across the lifespan is warranted. In situations in which it is difficult to meet the Recommended Dietary Allowances (RDA) in food patterns, but the specific public health concern associated with current intakes is not clear (e.g., vitamins A and E), more research and a better understanding is needed about the basis of the DRIs and the implications for underconsumption of the nutrient.

- Update and strengthen the DRI values for infants and children younger than age 24 months, as well as women during pregnancy and lactation, ideally all at once, with careful attention to new data on human milk composition.

Rationale: Especially among infants, a limited set of Estimated Average Requirement reference values exist. As described in **Part D. Chapter 7: USDA Food Patterns for Children Younger Than Age 24 Months**, most of the DRI values for ages 7 to 12 months are AI values, with RDA available only for iron, zinc, and protein for older infants. Several of the AI values may be overestimates, which makes food pattern modeling difficult. Moreover, the AI values at ages 7 to 12 months are generally based on expected intakes of nutrients from human milk, plus the estimated contribution from complementary foods and beverages. However, the nutrient values for human milk used for those estimates have serious weaknesses, as described elsewhere.⁶ A NASEM Committee has evaluated these limitations,⁷ and their findings will help set the stage for next steps. At ages 1 to 3 years, RDA values have been established for most nutrients,

but for some nutrients only an AI is available (e.g., potassium, choline) and some of these may be overestimates. Some DRI values have discrepancies with other published nutrient reference values for ages 6 to 24 months,⁸ which warrants attention. This should include evaluation of Tolerable Upper Intake Levels (UL), as some of them have been challenged as being too low during this age range.⁹ It should be noted that the World Health Organization has embarked on a review of nutrient reference values for this age range, starting with calcium, zinc, and vitamin D.¹⁰ The Committee recommends coordination of efforts toward updating and harmonizing DRIs for infants and children younger than age 24 months, in conjunction with similar efforts for updating the DRIs for women who are pregnant or lactating.

- Update the *Dietary Reference Intakes for Energy, Carbohydrate, Fiber, Fat, Fatty Acids, Cholesterol, Protein, and Amino Acids*.¹¹

Rationale: The growing interest in low carbohydrate diets as well as the need to understand metabolic responses to different fatty acids indicates the importance of updating the DRIs for macronutrients. In addition, the availability of the Chronic Disease Risk Reduction Intake (CDRR) framework for the DRIs will be useful in examining appropriate recommendations for all of the macronutrients and subcategories within each classification.

Support for Activities Related to the Dietary Guidelines

The Committee was asked to address questions on diet and health to inform food-based dietary guidance for the general public. The Committee offers support for related activities to complement the Committee's review:

- Identify collaborative efforts across the Federal government, such as convening a multidisciplinary ad-hoc Advisory Committee, to integrate systems science approaches, including consideration of dietary patterns, in treating and managing diet-related conditions and disorders, such as type 2 diabetes, obesity, and cardiovascular disease (CVD).

Rationale: The public comments reviewed by the Committee demonstrate a strong interest in the development of dietary patterns for individuals with diet-related chronic diseases, including strategies for weight loss, to aid in the management and treatment of these conditions. In addition, such a concern also may exist for individuals with disabilities.

Given that overweight and obesity can occur early in life and persist and increase risk of diet-related chronic conditions across the lifespan, future collaborative efforts across the Federal government must address primary preventative *and* secondary treatment strategies related to these conditions. The Committee was not charged with treatment strategies. Furthermore, although conditions such as obesity, type 2 diabetes, and CVD are related to diet, diet alone is not solely responsible for the complex, multifactorial nature of these conditions, as other genetic, biological, behavioral, socioeconomic, and environmental factors have been identified. Thus, the Committee recommends

approaches be identified, such as establishing a multidisciplinary ad-hoc Advisory Committee to integrate systems science approaches with existing socioecological frameworks to focus on this issue.

- Develop tools and technologies to help individuals manage weight and analyze and plan their diets. Develop simulation models for public use for different nutrient and food group patterns (e.g., how much added sugars can be consumed within a particular macronutrient distribution, alcohol intake level, weight maintenance).

Rationale: Without continued funding for national monitoring and surveillance (i.e., NHANES and all data sources used within **Part D. Chapter 1: Current Intakes of Foods, Beverages, and Nutrients**), and without consumer resources for tracking diet and physical activity (i.e., SuperTracker), it is unlikely that Americans will be able to reduce obesity and chronic disease. Without such resources, it is difficult for individuals to follow the Dietary Guidelines.

- Include a review of public health-based strategies that have been successful in promoting higher quality dietary intakes, especially in key populations that are at high risk and/or disadvantaged, including strategies that affect the price, availability, and marketing of various foods and beverages.

Rationale: Dietary intakes have never aligned with the Dietary Guidelines recommendations. Although the Committee can identify areas in which Americans need to make improvements, the Committee was not tasked with examining how to change behaviors to improve intakes. A need exists to tailor specific messaging on how to achieve energy balance to maintain a healthy weight and improve or maintain nutrient intakes in population-specific ways across the lifespan.

- Support efforts to consider the Dietary Guidelines in relation to sustainability of the food system.

Rationale: The achievability and maintenance of healthy food and beverage intakes is dependent on a complex number of factors that influence food access, availability, and cost. Long-term maintenance of healthy intakes requires long-term support of associated food systems. The 2017 National Academies of Sciences, Engineering, and Medicine (NASEM) report, *Redesigning the Process for Establishing the Dietary Guidelines*¹² recommended the need for research to develop a systems approach that is relevant to the Dietary Guidelines.

- Promote and support systems-based approaches to increase breastfeeding initiation and lengthen duration, with a focus on disparities by geography, income, education, and race and ethnicity.

Rationale: Breastfeeding initiation and duration rates vary by race and ethnicity, with notably lower rates among non-Hispanic Blacks, and by infant birthweight (i.e., low birth weight infants are less likely to be fed human milk). Given the numerous health benefits to both the child and mother, understanding the barriers to breastfeeding and developing context-specific strategies to facilitate breastfeeding are needed.

- Review existing guidance relevant to high-income countries about both *what* to feed and *how* to feed infants and toddlers, to complement the Committee's reviews about *what* to feed infants and toddlers.

Rationale: The Committee's reviews did not include topics related to *how* to feed infants and toddlers, such as feeding human milk at the breast compared to by bottle, repeated exposure to foods, and care provider feeding practices such as responsive feeding. USDA and HHS should provide some guidance on these issues, which are of critical importance with regard to outcomes such as eating behaviors, food acceptance, and obesity. Regarding *what* to feed, the Committee's reviews did not cover all possible child and maternal outcomes, so a review of existing relevant guidance would complement the conclusions reached by the Committee.

- Reexamine issues related to the iron content of infant formulas. Further characterize if and when iron intakes may be too high by evaluating the iron content of infant formulas in the U.S. marketplace and estimated iron intakes (and status) of infants consuming infant formulas with varying levels of iron as sole source nutrition and in combinations with complementary foods and beverages. Conduct consumer research to better understand care provider decisions for selection of formula based on iron content, and clinical research to evaluate potential risks of high iron intake.¹³

Rationale: For infants ages 6 to 12 months, consuming infant formula (with 1.8 milligrams [mg] iron/100 kilocalories [kcal]; 12.3 mg iron/liter [L]) and 0.5 ounce equivalents (oz eq) of fortified infant cereal (with 15.7 mg iron/oz eq) would result in the potential for excess intakes of iron of up to about 2 times the RDA. Though this level does not exceed the UL for iron (40 mg), if infant formula were consumed containing the allowable maximum level (i.e., 3.0 mg/100 kcal)¹⁴ in combination with iron-fortified cereal, the UL could be exceeded. Internationally, regulations regarding the iron content of infant formula vary, with debate over both the amount and the rationale. The latter has primarily focused on preventing iron deficiency and iron deficiency anemia with less consideration of potential implications of risk of excess intakes.¹⁵

FUTURE DIRECTIONS FOR THE DIETARY GUIDELINES PROCESS

As the Departments look ahead to support future Dietary Guidelines Advisory Committees, the Committee offers the following support for future directions to the process and topic areas that are emerging for consideration by future Committees:

- Investigate a process to identify topics that can be carried forward into a future cycle of the Dietary Guidelines without additional review by the Advisory Committee.

Rationale: Certain issues have been included sporadically in the Dietary Guidelines and, while not covered by each Committee, should be represented in public health messaging. In some cases these topics may reflect links to related areas that are relevant to diet and nutrition (e.g., food safety, oral health, physical activity), and in other cases they may reflect nutritional issues (e.g., *trans* fatty acids, reduction in sodium

intake) that remain of public health importance but do not need additional review from a Federal Advisory Committee because of existing, current guidance from other authoritative sources. Such a process would maintain the integrity of the Dietary Guidelines while enabling the Federal Advisory Committee to focus its attention on topics of highest priority for scientific review.

- Continue reviewing the scientific evidence on nutrition and health on an ongoing basis. Conduct systematic reviews and consider meta-analysis for appropriate questions on a continuous process, including between Committees.

Rationale: Dietary Guidelines Advisory Committees are time limited. To increase the scope of what future Committees can address, Federal agencies should continue to identify and review scientific evidence on nutrition and health between Advisory Committee cycles. This would enable Advisory Committees to focus on the most current literature and cover a wider range of topics. For example, the relationship between dietary patterns and health outcomes should be examined using a continuous model to identify and evaluate evidence as it is published in an effort to more efficiently document and update the state of the science on dietary patterns and health. Presently, Dietary Guidelines Advisory Committees are convened and the Dietary Guidelines for Americans are updated on an every-5-year cycle. As suggested by the NASEM report, *Redesigning the Process for Establishing the Dietary Guidelines*,¹² this approach may not allow for the adaptability and flexibility needed to recognize the rapidly changing environment of diet and health. Conducting systematic reviews using a continuous model would allow NESR to better document the current state of science on high-priority topics, particularly those that serve as the foundation for the Dietary Guidelines. A more continuous model would be beneficial for a number of reasons, as outlined in the NASEM report. Not only would it enhance continuity between each cycle, it would allow for increased engagement from a range of subject-matter experts, as well as other stakeholders and the general public.

- Conduct research to implement systems approaches into the Dietary Guidelines process.

Rationale: Improvements in developing the Committee's report were implemented in response to the NASEM report on the Dietary Guidelines process, to make the process more transparent, inclusive, and science-driven. The Committee encourages future research to apply a systems approach into the Dietary Guidelines process. Such an approach would examine multilevel social ecologic determinants such as the large array of determinants of food choice (e.g., food palatability, food cost, convenience, advertising, and exercise patterns) and the contribution of the food environment (e.g., household factors such as cultural practices, community factors like food store availability, and food policies) on food and beverage intake.

- Develop a systematic approach to examine dietary drivers of overweight and obesity across the lifespan.

Rationale: Given that overweight and obesity are such critical public health problems and underlie multiple health outcomes of interest, for future Dietary Guidelines Advisory Committees, this outcome should be addressed in a focused, systematic way. For example, one Subcommittee could focus on dietary drivers of obesity across the

lifespan, or Subcommittees could develop a systematic approach to considering overweight and obesity, sorting between weight-related impacts and dietary influences independent of weight.

- Consider the role of the gut microbiome in future guidelines.

Rationale: Diet is one of the key moderators of the composition and function of the microbiome. Dysbioses have been associated with many of the same chronic and immune-mediated diseases that are associated with less healthy dietary patterns. These findings suggest that the microbiota may mediate or moderate some diet-disease associations. Advances in understanding of the role of the microbiome in health outcomes could inform future dietary guidance.

- Examine the relationship between nutrition and immune function.

Rationale: As the epidemic caused by COVID-19 has evolved, those at most risk of the most serious outcomes of COVID-19, including hospitalization and death, are people afflicted by non-communicable diseases (e.g. obesity, type 2 diabetes, and CVD). This association indicates the importance of understanding how the dietary patterns most associated with risk of these chronic diseases also may affect immune response and response to infectious diseases. Additionally, as many nutrients are involved in immune function, the 2025 Committee should examine associations between nutrient status and immune function. Because of the disparities across race and socioeconomic status in dietary intake and rates of non-communicable diseases, research should focus on underserved populations.

- Consider the role of genetics and epigenetics in future guidelines (e.g., single nucleotide polymorphisms (SNPs) for fatty acid metabolism; folate metabolism).

Rationale: SNPs may alter how people absorb, transport, synthesize, or metabolize nutrients. Folate has two methylenetetrahydrofolate reductase (MTHFR) gene variants, called C677T and A1298C, which are common. In the United States, about 25 percent of people who are Hispanic, and 10 to 15 percent of people who are non-Hispanic White have two copies of C677T. Other SNPs have been associated with a higher risk of having an infant with a neural tube defect.

Epigenetic factors may also influence the effect of dietary fats on CVD risk factors. Dietary and environmental factors can change the expression of genes. Early in life, the plasticity of the epigenome in response to the diet is thought to be important for health, but empirical data are needed. The underlying relationship of diet in early life and its influence on epigenetics requires further study. In early infancy, the preferred single food source is human milk with its very specific fatty acid profile that is eventually complemented at approximately 6 months with fats found in complementary foods and beverages.

RESEARCH RECOMMENDATIONS AND CONSIDERATIONS FOR FUTURE COMMITTEES RELATED TO THE TOPICS AND QUESTIONS

The Committee identified research needs as well as considerations for future Committees related to the topics and questions examined in its review. The Committee encourages *funders* to use this information when prioritizing research to support and *researchers* to consider these topics and recommendations when conducting research. The Committee encourages the next Committee and the Departments to carefully consider all the research recommendations listed below when developing any future questions or topics for the next Dietary Guidelines Advisory Committee. This section begins with overarching methodological considerations and follows with more specific research needs and considerations for future Committees that have been identified by chapter. In addition to the research recommendations provided in the report, the Committee identified specific research recommendations for systematic reviews conducted with support from USDA's Nutrition Evidence Systematic Review (NESR) team. These research recommendations can be found in each of the 2020 Committee's systematic reviews, which are available on NESR's website at nesr.usda.gov/2020-dietary-guidelines-advisory-committee-systematic-reviews.

Overarching Methodological Considerations

- Broadly consider diverse populations with varying age groups and different racial, ethnic, and socioeconomic backgrounds. Consider diversity in multiple areas of future diet and health research as well as consideration of socioeconomic factors, such as food security and access to healthy foods.

Rationale: Lack of data inhibits the scientific community from being able to assess health and develop guidance for diverse populations. This information is needed to inform relevant guidance for all Americans and to support more effective public health strategies.

- Consider the degree to which a reported dietary exposure reflects true customary intake over the timeframe of a prospective cohort trial.

Rationale: A strength of prospective cohort studies is their ability to assess the impact of a dietary exposure (e.g., a dietary pattern, nutrient intake) on health outcomes over a long time period in a large number of people. However, it is well known that dietary exposures change over the lifespan. Consequently, it is not clear whether an exposure at one time point adequately reflects the customary intake of the individual (or population) at another time point over an extended time period (e.g., years to decades). If the nature or strength of exposure changes over the follow-up period, the predictive value of the exposure assessment at baseline may be incorrect, leading to less than accurate estimates of the importance of the dietary exposure and any recommendations that may stem from it. Thus, it is strongly recommended that the dietary exposure be

assessed regularly over the follow-up period to establish the degree to which dietary intake remains stable within and between individuals. Not only should dietary exposures be reassessed regularly, but the degree to which they confirm the validity of the baseline assessment or indicate changes may have occurred should be included in published reports. An attempt to administer the prospective cohort trial's dietary collection method systematically over the lifespan of the cohort would assist with addressing this potential shortfall.

- Develop strategies to classify dietary habits and behaviors from existing assessment methods.

Rationale: Many decisions were made in the work of the Committee to classify individuals' dietary behaviors based on one 24-hour dietary recall. For example, the Committee classified infants into human milk-fed and formula-fed and mixed-fed groupings based on 1 report, which may or may not accurately reflect habitual patterns. Similarly, the Committee examined the number of eating occasions and how that related to dietary intakes, based on 1 report, which may or may not reflect usual meal and snack patterns or the timing of consumption.

The addition of recommendations for all stages of the lifespan is important for the Dietary Guidelines. For such guidelines to be effective and science-based, research knowledge on these dietary habits and behaviors is essential.

- Use validated and reliable age-appropriate outcome assessment methods for children that do not rely only on parental report, particularly for developmental domains, when conducting research on dietary intake and neurocognitive development among children. Include accurate reporting of adverse and detrimental effects.

Rationale: Existing neurocognitive assessment tools and what they measure vary greatly, thereby limiting ability to compare results across studies. Determining standardized, validated, and commonly used assessment tools in this field need to be identified and linked with the relevant dietary data. Culturally specific and age-appropriate assessment tools are needed as well as better methods for parental report of outcomes. Use of validated assessment tools would allow comparison of results across studies and strengthen the evidence base.

- When examining CVD outcomes, conduct studies to determine how diet affects risk of stroke vs risk of coronary heart disease (CHD) and CHD mortality.

Rationale: The dietary factors that affect risk of stroke appear to differ from those related to CHD and CHD mortality. Further research is needed to inform nutrition recommendations that reduce the risk of all forms of CVD.

Current Dietary Intakes Through the Life Course

Chapter 1: Current Intakes of Foods, Beverages, and Nutrients

- Collect nationally representative longitudinal data to inform future Dietary Guidelines.

Rationale: To understand how early life nutritional exposures relate to risk of chronic disease, including obesity, taste preferences, and shaping of dietary patterns, longitudinal data with multiple assessments of dietary intake over time in the same population are needed. With this type of research, a better understanding could be gained of how to tailor initial dietary patterns to foster taste and acceptance of fruits, vegetables, and whole grains, echoing the *Dietary Guidelines* recommendations. Longitudinal data will enhance understanding of life transitions and how these relate to diet and health. Transitions are not only age-specific (e.g., starting school, career, retirement) but can also be contextual (e.g., food security), or biological (e.g., perimenopause to menopause).

- Develop a dietary pattern scoring system, such as the Healthy Eating Index (HEI), for infants and children from birth to age 24 months, considering findings from this report and future dietary guidance.

Rationale: Comparisons of diet quality are not possible from birth to less than 24 months of age, as HEI recommendations do not exist.

- Investigate approaches to better quantify and describe existing contemporary dietary patterns in national survey data.

Rationale: Existing dietary patterns have been compared with the HEI. As dietary patterns are not aligned with the HEI, a better quantitative assessment of existing dietary patterns in the United States is needed (aside from the HEI). The nature of this assessment illustrates discrepancies between the recommendations inherent in the HEI and actual dietary patterns; however, it does not define the existing contemporary dietary patterns. Being able to define these existing patterns can be useful to encourage changes to improve dietary quality. Previous NHANES survey years included questions about self-reported patterns, such as vegetarian, that would aid future research in this area.

- Examine how overall income and food security status interact to predict dietary intakes and the resulting diet quality.

Rationale: The *2015-2020 Dietary Guidelines* includes a socio-ecological model to illustrate the many complex factors that affect food choices, including food security. Although the 2020 Committee did not review evidence in this area, it recognized that food security and access to healthy food choices are significant factors that affect the ability of individuals and households to follow recommendations in the *Dietary Guidelines for Americans*. Research is necessary to understand the impact of these factors on diet quality so that recommendations reflect an understanding of these factors in encouraging better quality diets for all Americans. Taste and cost have been reported as primary drivers of food choice; future work should address these dimensions.

- Examine the interaction between the nutrition status of the mother and the health of the child. Risk of iron deficiency anemia among pregnant women and how that affects infant iron stores and cognitive development should be an area of priority.

Rationale: Most breastfed infants do not meet iron requirements from the diet alone and may depend on innate iron stores early in life that vary based on many factors identified in relation to the birth to 24 months age group, such as delayed cord clamping.

- Examine how the diets of women who are pregnant or lactating shape dietary preferences of offspring.

Rationale: Maternal diet during pregnancy and lactation may provide the earliest opportunity to positively influence child food acceptance. A systematic review conducted as part of the Pregnancy and Birth to 24 Months project¹⁶ concluded that limited but consistent evidence suggested that some flavors originating from the maternal diet during pregnancy can transfer to and flavor amniotic fluid, and that fetal flavor exposure increases acceptance of similarly flavored foods when re-exposed during infancy and potentially childhood.¹⁷ Additional research is needed because existing findings may not generalize to all foods and beverages and the relationship between mothers' diet during either pregnancy or lactation and children's *overall dietary intake* has not been examined. Further investigation would benefit the birth to age 24 months population and beyond.

- Develop research methodologies to determine diet quality that can be used to compare diets with the HEI.

Rationale: For some questions the Committee examined, the Committee was unable to measure diet quality with the HEI relative to specific dietary components because the component was a part of the HEI. Added sugars is one example.

- Examine optimal dietary factors to support healthy aging, including preventing age-related cognitive decline.

Rationale: Various food components, such as vitamin B₁₂, have been related to cognitive function. Although the Committee did not specifically address cognitive health data and biomarker data from NHANES, 8 percent of older women have low dietary intakes of vitamin B₁₂. Future Committees may wish to examine optimal nutritional intake for prevention of cognitive decline, focusing on a wide range of food components and dietary patterns.

Diet and Health Relationships: Pregnancy and Lactation

Overarching Research Recommendations

- Strengthen research designs for studies conducted during pregnancy and lactation to support future recommendations.
 - Begin the study design process with dietary questions in mind so that appropriate dietary assessment tools and timing of assessment to exposure can be used.
 - Conduct additional well designed and sufficiently powered RCTs to expand the evidence base, which currently relies on cohort studies.

- Conduct meta-analyses on questions related to key nutrients and food groups.
- Develop and validate novel dietary assessment tools to accurately capture the complexity of dietary habits.
- Future research should use standardized outcomes (e.g., birthweight adjusted for gestational age and sex, standardized neurocognitive tests conducted at specific times, inclusion of length with growth data) to enable valid comparisons between studies.

Rationale: The use of a standardized birth size measure would enable valid comparisons between and within countries.

- Foster collaborative efforts across different regions and populations so that dietary patterns can be consistently scored, compared, and reproduced across studies.

Rationale: The inclusion of participants from diverse cultures and geographical locations will enhance knowledge about the generalizability of the data on dietary patterns during pregnancy and lactation and enable specific approaches to the dietary patterns observed in diverse populations

- Broaden the consideration and control of confounding variables when conducting studies with women who are pregnant or lactating, particularly for confounders such as prepregnancy body mass index (BMI), gestational weight gain (total and rate of gain), and postpregnancy BMI.

Rationale: These confounding variables significantly influence the outcomes measured in studies on diet during pregnancy and lactation. The validity of such studies depends on appropriate inclusion and control of these variables.

Chapter 2: Food, Beverage, and Nutrient Consumption During Pregnancy

- Investigate how preconception nutrition and diet, including BMI and metabolic health, are related to maternal and child outcomes.

Rationale: Include women before and during pregnancy and design studies to determine whether dietary patterns and other nutrition exposures, including supplements, are more critical during certain time periods than others, for maternal and child outcomes.

- Evaluate the relative contribution of nutrients from all sources of foods and beverages, including fortified foods and supplements among women who are pregnant, with a focus on omega-3 fatty acids, folate, iron, vitamin D, choline, and iodine. Identify strategies to help women attain sufficiency and avoid excess to balance intake from foods, including fortified foods, and supplements.

Rationale: For iron and folate/folic acid, a potential exists for excess intake. Therefore any research on health outcomes should consider intake from all sources (food folates, folic acid fortification, and folic acid supplementation) before developing guidance for women who are pregnant. Research should focus on refining the understanding of the recommended levels of folate fortification of foods and folic acid consumed as a dietary

supplement, both individually and in combination, in pregnant women, including the potential for masking vitamin B₁₂ deficiency.

- Build upon the existing research to identify how maternal dietary patterns, including beverages and foods, as well as specific components, including intakes of seafood, omega-3 fatty acids, choline, iodine, iron, and folate, are related to child development (i.e., child language and physical development, autism spectrum disorder, cognitive development, social emotional development, academic performance, attention deficit disorder/attention deficit hyperactivity disorder [ADD/ADHD], anxiety and depression).

Rationale: Some evidence exists on the relationship of omega-3 supplementation to these outcomes, yet much less is available on choline, iodine, and folate. All of these nutrients and foods are important for brain development and need to be considered jointly when considering these outcomes.

- Identify dietary patterns (including frequency of eating and beverages in addition to foods) that support recommended gestational weight gain (GWG), prevent excess postpartum weight retention, and reduce maternal morbidity and mortality, especially among high-risk women (e.g., those with high BMI before pregnancy, history of adverse pregnancy outcomes).

Rationale: Current evidence is insufficient to explain the relationship between multiple important aspects of dietary patterns and the significant diet-related health outcomes of GWG, postpartum weight retention, and morbidity and mortality in pregnant women.

- Evaluate the role of meal frequency and macronutrient composition during pregnancy on measures of maternal and child metabolic health (gestational diabetes mellitus, small for gestational age, and large for gestational age).

Rationale: The 1990 *Nutrition During Pregnancy*¹⁸ included guidance to eat 3 meals and 2 snacks daily, but this guidance lacked a clear evidence base. The 2009 *Weight Gain During Pregnancy: Reexamining the Guidelines*¹⁹ did not extend this guidance. However, the Academy of Nutrition and Dietetics has similar guidance (“3 meals and 2 or more snacks helps to distribute carbohydrate intake and reduce postprandial blood glucose elevations”) for women who have gestational diabetes. For macronutrient composition, the DRIs recommend a minimum of 175 grams (g) of carbohydrate, 71 g of protein (or 1.1 g/kg/d protein) and 28 g fiber per day for women who are pregnant, including those who have gestational diabetes. The Academy of Nutrition and Dietetics concurs with this guidance, and recommends individualized amounts and types of carbohydrate, with an emphasis on controlling carbohydrate intake at breakfast to improve postprandial blood glucose for women who have gestational diabetes. Additionally, no clear consensus on recommended macronutrient intakes has been established for women with gestational diabetes. For example, national guidance on the percent of energy coming from carbohydrate ranges from 33 to 60 percent (e.g., American College of Obstetricians and Gynecologists recommends 33 to 40 percent; American Diabetes Association none; Academy of Nutrition and Dietetics about 37 to 60 percent; Endocrine Society 35 to 45 percent; International Federation of Gynecology and Obstetrics 35 to 45 percent). This evaluation is important to inform development of dietary guidelines.

- **For the next Committee:** Examine a question on the dietary determinants of maternal iodine status (in both pregnancy and lactation) and the relationship between maternal iodine intake and maternal and child outcomes, including child development.

Rationale: Low iodine intake is of public health concern among women who are pregnant, based on biomarker data that suggest low nutrient status (see **Part D. Chapter 1**). Prenatal iodine deficiency may lead to irreversible neurocognitive defects and lower childhood IQ. In addition, food values for iodine need to be included in the USDA database, so that intakes across the lifespan can be estimated.

- **For the next Committee:** Examine questions on the relationship between maternal dietary supplement and/or fortified food intake of vitamins B₁₂, vitamin D, iron, and choline and maternal and child outcomes.

Rationale: Given the importance of these nutrients to achieve optimal pregnancy outcomes, and the fact that they are all nutrients of concern among females of reproductive age, additional attention should be given to these nutrients by future Dietary Guidelines Advisory Committees.

- **For the next Committee:** Examine a question on the relationship between omega-3 fatty acid supplements consumed before and during pregnancy and pregnancy outcomes.

Rationale: The Committee did not assess the effect of omega-3 fatty acid supplements consumed before or during pregnancy and pregnancy outcomes. However, seafood emerged as a component that was higher in dietary patterns associated with a reduced risk of excessive GWG, gestational diabetes, hypertensive disorders during pregnancy, and preterm birth. Although seafood contain nutrients other than omega-3 fatty acids, systematic reviews have associated omega-3 supplements with preventing early or any preterm delivery.^{20,21} Less evidence is available for other pregnancy outcomes. However, relevant trials are underway, and future Committees should have available evidence to consider both seafood and omega-3 supplementation on pregnancy and longer-term infant outcomes.

Chapter 3: Food, Beverage, and Nutrient Consumption During Lactation

- Evaluate the relative contribution of nutrients from all sources of foods and beverages, including fortified foods and supplements among women who are lactating, with a focus on omega-3 fatty acids, folate, iron, vitamin B₁₂, vitamin D, choline, and iodine. Identify strategies to help women attain sufficiency and avoid excess to balance intake from foods, including fortified foods, and supplements.

Rationale: For iron and folate/folic acid, a potential for excess intake exists. Therefore, any research on health outcomes should consider intake from all sources before developing guidance for women who are lactating. Research should focus on refining the understanding of the recommended levels of folate fortification of foods and folic acid consumed as a nutrient supplement both individually and in combination, in women who are lactating.

- Develop research in women who are lactating that focuses on an examination of maternal dietary intake patterns and child development (child language development, autism spectrum disorder, cognitive development, social emotional development, academic performance, ADD/ADHD, anxiety, and depression) emphasizing foods rich in key nutrients for which a relationship between maternal intake and human milk composition has been established (e.g., seafood and/or polyunsaturated fatty acids, choline, iodine, and B vitamins in relation to brain development).

Rationale: Human milk is the preferred single source of nutrition for infants during a critical period of brain development. Insufficient evidence is available to determine the relationship between maternal dietary intake patterns, the presence of nutrients in human milk that play a key role in central nervous system development, and multiple diverse cognitive and behavioral developmental outcomes in breastfed infants and children.

- Conduct studies that consider the duration and intensity of human milk feeding (proportion of milk feedings coming from human milk) when assessing the relationship between maternal dietary patterns, including frequency of eating, and postpartum weight loss (PPWL), and assess PPWL/postpartum weight retention (PPWR) at multiple time points, rather than just a onetime measure.

Rationale: Maternal obesity is both a risk factor for, and a consequence of, excessive GWG and/or excessive postpartum weight retention. The majority of women with overweight or obesity exceed GWG recommendation^{22,23} and fewer than half of women revert to pregravid weights following pregnancy²⁴⁻²⁸ and postpartum weight retention results in about 1 in 7 women moving from a normal weight classification prepregnancy to an overweight classification.²³ Energy requirements during lactation account for mobilization of adipose stores; therefore, the duration and intensity of human milk feeding has the potential to reduce postpartum weight retention and reduce obesity risk of the mother.

- Identify optimal intake of fatty acids during lactation to attain optimal levels of fatty acids in human milk with respect to infant outcomes.

Rationale: It is known that maternal dietary intake affects fatty acids in human milk and fatty acid intake of the infant is related to development. However, the optimal intake of fatty acids by the mother is still unknown.

Diet and Health Relationships: Birth to 24 Months

Chapter 4: Duration, Frequency, and Volume of Exclusive Human Milk and/or Infant Formula Feeding

- **For the next Committee:** Review evidence about human milk feeding and *maternal* health outcomes (e.g., postpartum weight loss, diabetes) to complement reviews about human milk feeding and *offspring* health outcomes.

Rationale: HHS and USDA should include maternal health outcomes within the evidence base underlying its recommendations about human milk and/or infant formula consumption, such as the optimal duration of exclusive human milk feeding and of any human milk feeding. The cumulative duration of lactation over a woman's lifetime is a key exposure to examine with regard to certain long-term maternal health outcomes. Recommendations regarding feeding of infants and toddlers younger than age 2 years should ideally take into account the benefits and risks of all relevant outcomes, which includes outcomes in mothers who are lactating as well as their offspring.

- **For the next Committee:** Consider examining relationships between infant milk-feeding practices and infant mortality, infectious diseases, and child development.

Rationale: An examination of infant mortality, infectious diseases, and child development will enable the next Committee to strengthen the advice provided to the HHS and USDA by this Committee related to human milk and/or infant formula consumption. For example, evidence about infant mortality (e.g., Sudden Infant Death Syndrome [SIDS]) could strengthen the foundational advice provided by this Committee to recommend human milk consumption. U.S. data about SIDS may be available to provide important and relevant evidence for the next Committee. This Committee was unable to examine child neurobehavioral outcomes. Child development and infectious diseases (e.g., gastrointestinal, respiratory, and ear infections) are important childhood outcomes, and examining them could allow the next Committee to provide stronger advice about human milk and/or infant formula consumption, and perhaps to advise the HHS and USDA about the consumption of human milk beyond age 12 months.

- Investigate how the patterns and proportions of human milk feeding across the day and night and within each feeding, in the context of mixed feeding, are related to health outcomes in offspring.

Rationale: Despite the high prevalence of mixed feeding in the U.S. population, the Committee was unable to make recommendations about how much human milk an infant should consume relative to infant formula due to the paucity of evidence.

- Conduct studies to examine the relationship between consuming human milk by bottle vs from the breast and health outcomes in offspring.

Rationale: Very little evidence was available for the Committee to review the consequences of feeding human milk by bottle vs from the breast. The composition of human milk varies during the day and within a feeding, which may affect the infant's physiology²⁹; bottle-feeding human milk may modify these patterns. In addition, some evidence suggests that the feeding dynamics of breast- and formula-feeding mothers and their infants differ, which also deserves further investigation.

- Conduct studies that examine outcomes related to extended human milk consumption (e.g., durations longer than 12 months) in comparison to shorter durations, and study the duration of any human milk consumption among infants fed human milk (i.e., assess infants who were never fed human milk separately from infants who were fed human milk).

Rationale: To provide the USDA and HHS with stronger recommendations about the optimal duration of human milk consumption, the next Committee will need more

evidence that includes infants fed human milk longer than 1 year. Studies that group infants who were never fed human milk with infants who were fed human milk for short durations, and compare them with infants who were fed human milk for longer durations, make it difficult to interpret whether a difference in a health outcome relates to the initiation or the duration of human milk consumption.

- Conduct research that clarifies any unique contributions of the duration of exclusive human milk feeding and the timing of the introduction of complementary foods and beverages on health outcomes.

Rationale: Current literature that examines the duration of exclusive human milk feeding (which may terminate with complementary feeding) and the timing of the introduction of complementary foods and beverages (which may immediately follow a period of exclusive human milk feeding) may overlap substantially. However, the degree of overlap is difficult to ascertain. Infant feeding research does not often specify whether exclusive human milk feeding is followed by complementary feeding or formula feeding or both, and complementary feeding research does not often specify whether complementary foods and beverages are introduced to infants fed human milk exclusively or fed infant formula in some amount. Future researchers should be mindful about this potential ambiguity when designing and conducting research about the duration of exclusive human milk feeding or the timing of the introduction of complementary foods and beverages and strive to clarify any unique contributions of each of the 2 feeding practices on health outcomes.

- Conduct RCTs of breastfeeding promotion (like the Promotion of Breastfeeding Intervention Trial, or PROBIT), especially in populations that have the lowest rates of breastfeeding in the United States. Also conduct observational studies about human milk and/or infant formula consumption and health outcomes in offspring that are designed to reduce bias from confounding factors as much as possible, such as sibling-pair studies, and studies that use instrumental variables, such as Mendelian randomization approaches.

Rationale: Infant-feeding research can be prone to bias from confounding because infant feeding is strongly socially patterned. Randomization mitigates confounding, but it is unethical to randomize infants to feeding conditions. RCTs of breastfeeding promotion (such as the PROBIT trial in Belarus) can be useful for studying relationships between infant feeding and health outcomes if they achieve substantial differences in duration or exclusivity of breastfeeding between intervention groups. Sibling-pair studies reduce bias from confounding because siblings share genetic and environmental factors. Few such studies exist, and they tend to have much smaller sample sizes than other types of observational studies. Large sibling-pair studies are needed, and such studies need to examine siblings that differ in terms of the duration of human milk consumption (e.g., <6 months, ≥6 months) and not just with respect to ever vs never consuming human milk. Observational studies need to pay careful attention to minimizing confounding, and using instrumental variables, such as Mendelian randomization, may be beneficial.

- Consider effect modification and biological mechanisms when designing studies that examine relationships between infant feeding and health outcomes.

Rationale: Different biological or environmental factors may modify the relationships between infant feeding and health outcomes, and may be important to consider when developing dietary guidance. For example, the relationship between human milk feeding and child overweight may differ between infants of mothers with high vs low BMI. Inclusion of maternal and child characteristics that relate to potential biological mechanisms for the associations between infant feeding and health outcomes can provide insight into subgroups that could be targeted for specific guidance. For example, assessment of human milk composition (e.g., nutrients, immune components and human milk oligosaccharides) as well as maternal and infant intestinal microbiota composition may reveal host-microbe-nutrition interactions in the pathogenesis of atopic diseases.

- Identify ways to study large, prospective, representative U.S. samples from the period of infant feeding into adulthood, such as accessing electronic medical record data and create funding opportunities to examine existing data sources from vanguard national child studies.

Rationale: Scant evidence examined the relationships between human milk and/or infant formula consumption and outcomes in offspring beyond childhood, such as type 2 diabetes and CVD. Studies from representative U.S. samples is especially important because the United States has a higher prevalence of type 2 diabetes and CVD than some of the other countries that conduct long-term studies, and so the evidence from such non-U.S. studies may have limited generalizability in the United States.

- Evaluate the most useful biomarkers of nutrient status for infants and children younger than age 2 years, and cutoff values appropriate for identifying both deficiency and excess in this age group. Nutrients of interest include those addressed by the 2020 Committee (iron, zinc, iodine, vitamin B₁₂, vitamin D, and fatty acids), but may also include some that were not addressed (e.g., choline, iodine).

Rationale: Heterogeneity in the methods used to assess nutrient status in the systematic reviews about infant feeding and nutrient status exist, in part, because of uncertainty about the most appropriate biomarkers to use in this age group. During infancy, in the average values of certain biomarkers change profoundly between birth and 12 months, such as hemoglobin and markers of iron status, due to normal physiological changes. This makes the identification of appropriate cutoff values challenging. Serum zinc is useful as a marker of zinc status at the population level, but has serious limitations for use at the individual level. For fatty acid status, interpretation of results may differ depending on whether serum/plasma values or red blood cell values are assessed, whether samples are collected in a fed or fasted state, and on how the results are expressed (e.g., as percentage of total fatty acids, or as concentrations).

Chapter 5: Foods and Beverages Consumed During Infancy and Toddlerhood

- **For the next Committee:** Review evidence about *how* to feed infants and toddlers to complement reviews about *what* to feed infants and toddlers. Important topics may include feeding human milk at the breast compared to by bottle, repeated exposure to foods, and care provider feeding practices, such as responsive feeding.

Rationale: Little evidence is currently available on the *how* of feeding infants and toddlers. Such evidence could help USDA and HHS in providing guidance on how, as

well as what, to feed infants and toddlers. Both aspects of feeding are of critical importance with regard to outcomes such as eating behaviors, food acceptance, and obesity.

- Conduct research investigating the relationships between the consumption of sugar-sweetened beverages and juice during the complementary feeding period and obesity in childhood and other measures of growth, size, and body composition.

Rationale: The systematic reviews that examined types and amounts of complementary foods and beverages and growth, size, and body composition identified limited evidence about intakes of sugar-sweetened beverages and juices and their relationship with growth, size, and body composition. This relationship is important to examine to strengthen existing dietary guidance regarding beverages for this age group.

- Conduct RCTs to examine the relationships between complementary feeding and key outcomes. For example, conduct RCTs to examine specific types of foods consumed during infancy and toddlerhood and risk of developing atopic disease, and the timing of the introduction of complementary foods and beverages and child development.

Rationale: With 2 notable exceptions (i.e., peanut intake and food allergy to peanut, egg intake and food allergy to egg), the systematic review that examined types and amounts of complementary foods and beverages and food allergy and atopic allergic diseases identified insufficient evidence or limited evidence that examined the relationships between most food types and atopic disease outcomes. Similarly, insufficient evidence existed to draw conclusions about the timing of introduction of complementary foods and beverages and child development. Some of the available evidence had methodological limitations that are important to address in future studies.

Chapter 6: Nutrients from Dietary Supplements and Fortified Foods During Infancy and Toddlerhood

- Evaluate how best to identify and treat infants who become iron deficient before 6 months of age, including populations with racial and ethnic diversity, and investigate the biological mechanisms by which iron supplementation during infancy may affect growth, including potential effects on morbidity, the microbiome, zinc and copper status, and oxidative stress or lipid peroxidation.

Rationale: Evidence suggesting slower growth among infants given iron supplements suggests that routine iron supplementation of all breastfed infants may not be advisable. An alternative could be to screen for iron deficiency among higher-risk infants younger than age 6 months, and provide iron supplements only to those with biomarkers indicating iron deficiency, but more research is needed to ensure the proper identification and treatment of such infants.

- Investigate how much (if any) vitamin D supplementation is needed for breastfed infants when the mother is taking high doses of vitamin D, and when the infant has short periods of sun exposure in certain latitudes. Future studies should be appropriately powered, include

racially and ethnically diverse samples, and report baseline vitamin D status, human milk vitamin D content, and sun exposure.

Rationale: The body of evidence the Committee reviewed does not provide a basis for recommending vitamin D supplementation above 400 IU per day during infancy (the current AAP recommendation).³⁰ Additional research can help guide future decisions about whether and how much vitamin D from supplements is necessary for breastfed infants under specific conditions.

Chapter 7: USDA Food Patterns in Infants and Children Younger than Age 24 Months

- **For the next Committee:** Use tools, such as linear programming, for food pattern modeling. This is particularly important for ages 6 to 24 months given the challenges of meeting nutritional goals during this age range.

Rationale: Using tools such as linear programming and other types of optimization modeling allows for incorporation of multiple nutritional constraints and food sources of nutrients simultaneously, to identify combinations of foods and beverages that meet all nutritional goals. These analyses should be designed to take into account nutrient bioavailability (especially iron, zinc, and calcium) from various food sources, including human milk. The 2017 NASEM report, *Redesigning the Process for Establishing the Dietary Guidelines*,¹² recommended that food pattern modeling should be enhanced “to better reflect the complex interactions involved, variability in intakes, and range of possible healthful diets.” In future work, the Committee also should consider models that allow for amounts of individual foods to vary within each food group, not just the current nutrient profiles approach using representative nutrient-dense foods selected based on current intake patterns in the United States.

- **For the next Committee:** Using tools such as linear programming, develop food patterns for infants and toddlers fed human milk.

Rationale: The 2020 Committee was not able to develop food patterns for these subgroups because of uncertainties regarding DRI values and challenges presented by using the nutrient profiles approach for food pattern modeling. The Committee presented example combinations of foods and beverages that meet most nutritional goals for infants and toddlers fed human milk, but these are not formal USDA Patterns. With tools such as linear programming, as described above, and ideally with updated DRI values for the key limiting nutrients, the next Committee will be in a strong position to continue work on developing food patterns for these subgroups.

- Investigate whether advice to not add salt to complementary foods and beverages puts certain infants or toddlers at risk of iodine or sodium inadequacy.

Rationale: Infant feeding guidance usually recommends that salt not be added to foods for infants. This has implications not only for adequacy of sodium intake, but also adequacy of iodine intake, as iodized salt is a key contributor to the latter. If infants are fed some prepared foods to which salt has been added, sodium intakes may not be low,

but if the recommendation to avoid added salt were fully implemented, underconsumption may be a concern. Insufficient information is currently available to judge whether iodine intakes are adequate among infants not consuming iodine-fortified infant formula, and among toddlers in general.

- Conduct analyses to determine whether the vegetarian pattern for toddlers supports adequate iron and zinc status.

Rationale: Most of the iron in the Vegetarian-Style Pattern developed for toddlers comes from whole grains, soy products, nuts and seeds, and legumes, from which bioavailability of iron is likely to be low due to relatively high levels of phytate and absence of heme iron (IOM 2001).³¹ Zinc absorption also is affected by high phytate levels. Further work is needed to evaluate whether the foods and beverages in this pattern can adequately support iron and zinc status during the second year of life.

- Conduct research to determine the proportion of toddlers ages 12 to 24 months who continue to receive human milk, and in what amounts.

Rationale: Little information is available on the amounts of human milk consumed after age 12 months. This information is needed for food pattern modeling in this age range. Methods using stable isotopes (dose to the mother) can be used to obtain this information. In addition, little information is available on human milk composition after 12 months postpartum.

Diet and Health Relationships: Ages Two Years and Older

Chapter 8: Dietary Patterns

- Develop a standard definition of low-carbohydrate diets, with gradations at specified cut-offs for all macronutrients, to inform the systematic assessment of diets based on macronutrient distribution where proportions fall sufficiently outside of the Acceptable Macronutrient Distribution Range (AMDR).

Rationale: No standardized cut-offs below the AMDR have been established to define what level of carbohydrate proportion is considered to be “low” or “very-low.” Although a growing body of evidence suggests benefits of a carbohydrate-restricted diet, the lack of a standard definition makes it difficult to systematically assess whether diets restricting carbohydrate levels may aid in the treatment of chronic diseases. Based on the Committee’s reviews, which comprehensively examined any evidence with regard to carbohydrate levels below the AMDR, regardless of how extreme, insufficient or limited evidence was available to support diets with carbohydrate levels below the AMDR in the context of disease prevention. However, additional research in this topic area is needed and should be guided by a universal understanding of the AMDR cut-offs considered to be “low” and very-low” carbohydrate.

- Conduct additional research examining a constant dietary pattern (i.e., describes the foods and beverages consumed and controls for diet quality) that varies by macronutrient distributions with carbohydrate below 25 percent of energy to determine whether a

relationship exists between “low-carbohydrate” dietary patterns and the prevention of diseases, such as obesity, CVD, and type 2 diabetes.

Rationale: Few studies that examine diets based on macronutrient distribution do so with a relatively constant dietary pattern between groups that would isolate the effects of the macronutrient distribution from the variation in the foods and/or beverages (i.e., diet quality) consumed. Specific dietary patterns with carbohydrate levels below 25 percent of energy may be detrimental to long-term health if they are poor in diet quality, whereas higher quality dietary patterns with carbohydrate levels below 25 percent of energy may be beneficial. However, this relationship is not currently known. Conducting this research could expand knowledge in this area and inform whether the public may benefit by consuming specific dietary patterns with varied macronutrient levels.

- Expand knowledge about the relationship between dietary patterns and bone health by examining additional outcomes and dietary factors beyond calcium and vitamin D that may affect bone health.

Rationale: Currently available studies are lacking information on a broad spectrum of bone health outcomes across the lifespan, as well as data on the effect of complete dietary intake on bone health. This may be due to limited data on bone health outcomes in younger populations. The few studies that are available indicate that consumption of a healthy diet is significantly related to reduced fractures in the older population. Continued broad research would allow for this relationship to be further understood and provide guidance on beneficial dietary intake for positive bone health outcomes.

- Study dietary patterns within the context of confounding variables, such as weight status, physical activity, biomarkers, racial or ethnic background, and socioeconomic status to understand additional factors influencing health outcomes.

Rationale: The influence of confounding variables on outcomes compared to the influence of dietary patterns on outcomes is not well understood and less commonly studied. A better understanding of which confounding variables may have stronger influences on outcomes than dietary patterns would provide further insight into risk of chronic diseases, and thus, preventive measures.

- Design studies with sufficient detail and differentiation of the types and amounts of foods and beverages consumed, including inadequate or excessive intake, to inform an overall assessment of diet quality in the study of dietary patterns and/or diets based on macronutrient proportion.

Rationale: Studies often lack or provide limited information on the type and amount of foods and beverages consumed by participants, and this may be due to inconsistency in dietary instruments used to collect data on dietary intake. When information is limited or inconsistent, it is difficult to draw strong conclusions for what types and amounts of foods and beverages to consume or avoid, such as, “processed meat” vs “red and processed meat” vs “meat.” More information would allow more detailed guidance to be developed.

- Collect diet information at multiple time points in the course of study follow-up, beginning early in life, to strengthen the evidence on dietary patterns and health outcomes over the lifespan.

Rationale: The currently available literature features many observational studies with dietary data collected once at baseline, which fails to reflect changes in dietary intake throughout follow-up. Without accounting for change in dietary intake over time, the dietary intake reflected in studies may be far from accurate, and may miss changes in intake that result based on a change in health status or based on medical recommendations. Collecting data at multiple time points would encourage a new standard for observational studies that use dietary intake data and provide greater accuracy in the data used to determine relationships between dietary intake and health outcomes.

- Conduct additional dietary patterns research with well-designed, sufficiently powered RCTs that include standardized assessments of dietary intake to strengthen the evidence for health outcomes, including sarcopenia, neurocognitive health, cancer, bone health, overweight and obesity, CVD, and type 2 diabetes in populations of various racial and ethnic backgrounds across life stages particularly childhood and adolescence.

Rationale: Few studies evaluate the relationships between dietary patterns and health outcomes with RCTs and adequate sample size in diverse populations. Though many chronic health outcomes are observed in middle-aged and older adults, it is unclear if dietary intake across the lifespan affects these outcomes both in childhood and adolescence and into adulthood. Many observational studies indicate a significant relationship between dietary patterns and health outcomes, but RCTs are needed to confirm this relationship with reproducible results.

Chapter 9: Dietary Fats and Seafood

Dietary Fats

- Conduct longitudinal research to understand how early life dietary exposures, specifically types and ratios of dietary fatty acids, affect cardiovascular health across the lifespan.

Rationale: Limited longitudinal studies exist assessing the relationship between types and ratios of fatty acids consumed early in childhood and long-term CVD outcomes. Serial cross-sectional studies have suggested associations, but stronger study designs that better control for confounding are needed. This evidence could inform dietary recommendations and help communicate the importance of establishing healthy dietary patterns in childhood.

- Examine the effects of replacing saturated fats with other macronutrients, including different types/sources of carbohydrate (complex vs refined) on CVD-related outcomes in children and adults. Conduct research to provide quantitative data to show effects of replacing saturated fats with different types of carbohydrates on blood lipids. Conduct studies to determine whether replacement of saturated fats with different type of carbohydrates affects low density lipoprotein cholesterol (LDL-C) particle size and the impact of LDL-C particle size on risk of atherosclerosis.

Rationale: If energy intake remains constant, reducing 1 macronutrient is associated with a corresponding increase in other macronutrients. Thus, research needs to examine how replacement of saturated fats with other macronutrients affects blood lipids and CVD risk. Although multiple studies have examined replacement of saturated fats with carbohydrates, few have distinguished among types or sources of carbohydrates. Foods containing complex carbohydrates, which also tend to be high in dietary fiber, appear to be associated with more favorable changes in blood lipids, especially triglycerides, compared to foods containing refined carbohydrates.

The mechanism by which different types of carbohydrates influence blood lipids is not yet fully understood. Diets high in carbohydrate are often associated with elevated levels of triglycerides and very low-density lipoprotein cholesterol. Some research suggests that this may shift the distribution of LDL-C particles to smaller, cholesterol-depleted LDL-C particles. Researchers are studying whether atherogenicity differs by LDL-C particle size. However, measures of overall LDL-C that do not differentiate between particle size are currently considered sufficient to monitor atherogenic risk and response to therapeutic intervention. More research is needed on CVD biomarkers that may provide increased specificity for predicting risk compared to LDL-C.

- Examine the effects of different food sources of saturated fats, including animal (e.g., butter, lard) and plant (e.g., palm vs coconut oils) sources, different food matrices that encompass saturated fats (e.g., saturated fats in cheese vs yogurt), and different production techniques (e.g., refined deodorized bleached vs virgin coconut oil) on health outcomes.

Rationale: Dietary fats are found in a wide variety of foods. Animal fat sources tend to have higher amounts of saturated fats and cholesterol, while plant sources tend to be higher in polyunsaturated fats and monounsaturated fats, and lower in saturated fats. These fatty acids differ in their atherogenicity. Although multiple studies have been conducted to examine types of fats in relation to CVD risk, very limited data exist on how different food sources of dietary fats, the food matrices they are found within, and the techniques used to produce them affect health outcomes. This information could help refine dietary guidance.

- Examine how puberty and sex hormones and male-female differences modify the effect of dietary fats on blood lipids and other CVD risk factors.

Rationale: Males and females differ with respect to CVD risk, and the impact of diet on blood lipids differs by sex. Growth and sex steroid hormones appear to modulate risk of onset and severity of CVD, resulting in differential incidence of CVD, but how diet and sex hormones interact to affect CVD risk across the lifespan is largely unknown.

- Conduct feeding trials isolating the effect of dietary cholesterol on blood lipids and other CVD risk factors, controlling for baseline blood cholesterol levels and BMI.

Rationale: Dietary cholesterol comes from animal source foods that also are high in saturated fats, with the exception of eggs and shellfish. Limited data elucidate the specific effect of dietary cholesterol independent of saturated fat on CVD risk. This is especially salient given that both dietary intake of dietary cholesterol and blood cholesterol levels have decreased over time, complicating interpretation of the seminal

research indicating a strong association between dietary cholesterol and blood cholesterol.

- Conduct studies to determine whether the substantial reduction of *trans* fat in the American diet has influenced responsiveness of CVD biomarkers to changes in saturated fat consumption.

Rationale: Strong scientific evidence demonstrating the association of *trans* fat with blood lipids and CVD risk has resulted in the removal of partially hydrogenated oils from the food supply. Thus, a need exists to understand how dietary fats, particularly saturated fat, affect CVD risk in the current context of minimal *trans* fat consumption.

Seafood

- Conduct longitudinal research on seafood intake during pregnancy and lactation, and impact on infant and childhood neurocognitive development outcomes to establish the evidence base for impact across life stages.

Rationale: The lack of sufficient, evidence-based research documenting causal influences of maternal diet on infant and childhood neurocognitive development outcomes curtails preventive efforts. The Committee established criteria for studies to draw scientifically meaningful conclusions on the questions developed by the USDA and HHS. No studies of maternal diet during lactation that reported on neurocognitive outcomes of the nursing infant during childhood met the criteria for inclusion. Additionally, no studies reported on clinical outcomes of subsequent development of ADD/ADHD or neurocognitive health (e.g., dementias, cognitive decline, anxiety and depression) in adulthood. Longitudinal studies with repeated measurements over time are needed to document associations of seafood intake, as well as other dietary factors, with neurocognitive outcomes during critical windows of development, including puberty. Studies designed to assess the long-term effect of diets on health are needed, specifically those on developmental milestones, including the underlying physiology associated with onset and progression of puberty.

- Establish and use standard methods to assess seafood intake or exposures. Use validated, standardized diet assessment methods to quantify seafood intake (e.g., amount, frequency, type, and preparation method). Control for baseline levels of seafood and non-seafood intakes, adjust for and report approach on how dietary compliance was achieved. Control for potential seafood-specific confounders and mediators in dietary seafood studies. Conduct research to assess levels of environmental toxins in seafood consumed and provision of results both adjusted and unadjusted. Encourage the use of standardized methods across studies.

Rationale: No standard methods have been developed to assess fish intake or exposures. All existing dietary assessments, such as food frequency questionnaires, have limitations, specifically as it relates to episodically consumed foods, such as seafood. Validated questionnaires and/or biomarkers are needed. Standardized diet assessment methodology is key to investigating cross-comparisons within cohorts over the lifespan. No currently available studies adequately controlled for non-fish exposure for omega-3 polyunsaturated fats and few controlled for race and ethnicity, infant feeding mode, environmental contaminants, and concentration/ratio of the fatty acids, which vary

greatly among fish. Use of standardized methods and controlling for key confounders allows meaningful comparison of results across studies and strengthens the evidence base.

- Conduct mechanistic studies to understand relationships between seafood and neurocognitive development and neurocognitive health.

Rationale: More definitive data from RCTs are needed, such as trials that address diet or nutrient related mechanisms underlying suspected associations on neurocognitive development and neurocognitive health through the lifespan. More research is needed to look at all nutrient components of seafood, not just fatty acids. Fish protein may be different than other animal protein. Unique properties of fish may affect neurocognitive development and health. Research to understand the mechanisms which modulate neurocognitive outcomes are needed.

- Determine at what stage in the lifespan maternal seafood intake is most critical (before pregnancy, prenatal, postpartum) and at what stage the child's seafood intake is most critical in determining health outcomes. Identify potential biomarkers signaling when the child's own dietary intake more strongly influences biological measures, including blood pressure, blood lipids, and other physiologic and neurodevelopmental health outcomes.

Rationale: This type of research would allow for a better understanding of when the impact of a child's own dietary intake (e.g., intake of complementary foods) supersedes the impact of maternal intake during pregnancy and lactation for various outcomes, including neurocognitive outcomes. This would inform not only pregnancy and lactation dietary recommendations but also infant and early childhood feeding recommendations.

- Review effects of food sources of omega-3 fatty acids other than from seafood (e.g., algae, flax seeds, walnuts, soy oil) in relation to neurocognitive health, and examine the optimal ratio of docosahexaenoic acid and eicosapentaenoic acid.

Rationale: More research continues to become available on these topics and should be monitored to inform refined guidance related to types of dietary fats and health.

Chapter 10-12: Beverages, Alcoholic Beverages, and Added Sugars

- Study beverage patterns alone and in conjunction with overall dietary patterns to better understand the impact of the pattern of beverage consumption on health during all stages of life.

Rationale: Many studies have examined dietary patterns and their impact on health but few have assessed patterns of beverage consumption and health or have combined dietary and beverage patterns to create a comprehensive view of overall intake. Studies are needed to tease apart the relationship between beverages and health outcomes, the association between beverage patterns (including alcohol) and dietary patterns that in turn affect health outcomes, and how combined beverage and dietary patterns are associated with health outcomes. Prospective research studies with strong experimental designs are needed that delve deeply into beverage patterns, including: 1) the time of

day consumed, 2) number of times a day consumed, 3) times consumed alone versus with food, 4) time of consumption relative to eating events, 5) volume consumed at each of the time points, 6) consumption of energy and non-energy yielding beverages including water, 7) contribution of beverages to total energy intake, 8) differences across population sub-groups (e.g., sex, age, BMI categories), 9) caffeinated vs non-caffeinated, 10) macronutrient content (protein, carbohydrate, fat), 11) beverage size, 12) consumption in relation to planned exercise, and 13) beverage use as a supplement or meal replacement.

Studies should specifically examine beverages' effect on health versus the effect of components contained within those beverages (e.g., sugar, fat, electrolytes, phytochemicals). Studies examining the relationship between beverage consumption and health outcomes need longer experimental timeframes: Even existing studies with strong experimental designs are often too short in duration to fully measure the effect on outcomes of interest and generally; these studies lack control for many key confounders. Studies also are needed that compare one type of beverage to another (e.g., sugar-sweetened beverages to water) or one type of beverage to none.

Understanding the effect of certain beverage intake patterns on health vs simply the effect of individual types of beverages on health will be critical to understanding of the role of the beverage vs its pattern of use on health and the subsequent development of accurate messages about beverage consumption in future Dietary Guidelines.

- Design well-controlled RCTs that examine the relationship between consumption of beverages during pregnancy and birth weight independent of gestational weight gain.

Rationale: More studies are needed on beverage consumption during pregnancy and its effect on birthweight. Currently, the evidence is insufficient to make any recommendations. Studies are needed that compare one type of beverage to another (e.g., sugar-sweetened beverages to water) or one type of beverage to none as well as variations in fat and sweetener content within beverage types. These studies further need to determine, through careful study designs, whether effects of certain beverage types are due to the beverage itself or one or more components contained within the beverage. Study also are needed on whether broader patterns of beverage consumption during pregnancy are associated with birthweight. Studies of individual beverage types do not adequately account for how increased or decreased consumption of one beverage type affects consumption of all other beverage types, and understanding replacement of one beverage type with another is needed to fully understand the role beverages play in birthweight. Existing research has a high risk of bias; does not consistently adjust for gestational age, sex, and total maternal energy intake; has high rates of attrition, poor generalizability, inconsistent exposure definitions and assessment timing; and inconsistent results. Understanding the effect of beverage consumption during pregnancy on birthweight will be very important for providing guidance to expectant mothers in the Dietary Guidelines themselves as well as in programs that assist pregnant mothers, such as the Special Supplemental Program for Women, Infants, and Children (WIC).

- Examine the effects of the physical form of food (e.g., whether it is consumed by eating or drinking) on various health outcomes.

Rationale: The physical form of food may affect eating behaviors and physiological responses, which may in turn influence various health outcomes and could help inform dietary guidance.

- Assess the effects of caffeine contained in beverages on health using methods that isolate the effect of caffeine from that of the beverage in question.

Rationale: Studies examining the relationship between beverage consumption and health outcomes should distinguish between caffeinated and decaffeinated or caffeine-free versions of the same beverage (e.g., caffeinated vs decaf coffee) to isolate the effects of caffeine from the effects of the beverage in which it is consumed. Many U.S. government programs limit or do not allow beverages with caffeine to be available or sold to children, including school meal programs, competitive foods, and summer meal programs. More knowledge about the effects of caffeine vs the effects of beverages that contain caffeine will better inform the nutrition standards these programs use as well as provide dietary guidance for vulnerable populations, such as children and women who are pregnant.

- Accurately quantify water intake and use this information to better study the associations between water consumption and health during all stages of life.

Rationale: Better information about water intake is needed, including: 1) quantity consumed, 2) tap vs bottled water consumption, 3) whether it is filtered, carbonated, or flavored, and 4) proportion of total water in the diet from drinking water vs consuming water-containing products. The information is rarely found in food frequency questionnaires, individuals often do not report water intake on 24-hour recalls, and interviewers may not consistently probe for this information. Studying the effects of water consumption on health would be more feasible with this greater specificity. Currently, the effects of plain water consumption on health vs water consumed in other beverages and foods is not well understood, making it difficult to develop specific evidence-informed recommendations to consume water.

- Measure alcoholic beverage intake and consumption patterns with greater accuracy and determine their effect on human health through all appropriate life stages using more consistent and improved definitions, controls, and research methods.

Rationale: More studies are needed on alcohol intake and health outcomes using stronger research designs, including RCTs, Mendelian randomization studies, and non-randomized intervention studies. Mendelian randomization studies of alcohol are often more practical than RCTs and are an emerging area of the literature that will likely expand during the next 5 to 10 years. Research on alcohol consumption and health should use multiple measures of intake over time, distinguish between lifelong never drinkers and either very low level consumers or former drinkers who refer to themselves as never drinkers, better control for key confounders, use longer study duration, and enroll younger study participants (as 40 percent of alcohol-attributable deaths occur by age 50 years). Additional research is needed on patterns of consumption, including health outcomes in relation to the frequency and usual amount of alcohol consumed during drinking days. This research could help disentangle effects of average (i.e., total) consumption vs the usual number of drinks consumed on days or occasions when

alcohol is actually consumed, including the maximum number of drinks consumed during a particular recall period. Although increasing attention is being paid in the research literature to the effects of alcohol consumption patterns (i.e., how much is consumed and how often), more evidence is needed on this topic with respect to mortality outcomes, and all-cause mortality in particular. Finally, more research is needed about how alcohol consumption across different levels and patterns of consumption is associated with dietary patterns and overall diet quality.

- Examine associations between neurocognitive health and consumption of non-alcoholic beverages, added sugars, and alcohol in order to build the level of evidence necessary to make recommendations for future Dietary Guidelines.

Rationale: Understanding these associations is critical for dietary guidance, especially during lactation and in older populations. Programs such as the Child and Adult Care Food Program and the Elderly Nutrition Program rely on the Dietary Guidelines to develop their standards. Before future Committee review, researchers should conduct RCTs and high quality longitudinal cohort studies, adjusting for key confounding variables, examining diet and neurocognitive health including questions related to beverage consumption (sugar-sweetened beverages, milk, juice, water, alcoholic beverages, beverage patterns) and consumption of added sugars. This should include research conducted on alcohol consumption during lactation and neurocognitive health of the infant. Use of existing cohorts for which appropriate design elements are available (e.g., appropriate measurements of exposure, outcomes and potential confounders) could be useful.

- Investigate how the consumption of specific non-alcoholic beverages and beverage consumption patterns affect growth, size, body composition, CVD, and type 2 diabetes across the lifespan.

Rationale: The Committee was not able to assess the relationship between all beverage types and growth, size, body composition, and risk of overweight and obesity. Additionally, for the beverage types that were examined (milk, 100% juice, sugar-sweetened beverages and low- and no-calorie sweetened beverages), evidence was limited. Studies on beverages and body composition that use the most sensitive, accurate and precise methods available could provide valuable information on this relationship. Reliance on self-reported data is discouraged. Consistent measures would assist future Committees in developing conclusions. Studies also need more specificity and consistency in the definition of exposure, consistent and validated measures of beverage intake, more control for potential confounders, longer study durations, larger sample sizes, objective methods for assessing compliance in RCTs, methods that avoid high attrition, consistency in comparator beverages, and more generalizable populations.

Studies should also assess whether certain beverages and beverage patterns have beneficial associations with risk of obesity, adiposity, CVD, and type 2 diabetes.

For studies specifically related to dairy milk and growth, size and body composition, in addition to studies comparing milk to other beverages like water, evidence comparing different levels of fat within the milk category and comparisons of flavored to non-flavored milk is needed. The issue extends to comparisons of low- and no-calorie

sweetened beverages vs sugar-sweetened beverages for children, where evidence is insufficient to make a recommendation. For adults, only limited evidence of no association is available. Well-conducted studies of the effect of 100% fruit juice on adiposity also are needed. Obesity prevention programs need to understand how beverage consumption affects body composition measures. This additional research will aid in these efforts.

- Investigate how alcohol consumption affects growth, size, body composition, and risk of overweight and obesity.

Rationale: Alcoholic beverages contain substantial energy but contribute little to nutrient intake. Understanding the impact of alcohol consumption on adiposity could help inform future evidence-based guidance on alcohol consumption.

- Conduct research assessing how frequency and quantity of exposure to added sugars across the lifespan influences the preferred level of sweetness in foods and beverages.

Rationale: Promoting decreased added sugars consumption is challenging given personal and cultural taste preferences. Evidence suggests that preference for high-fat and high-salt foods is related to frequency of exposure to these food components.^{32,33} Two large clinical trials are currently underway to assess whether and how frequency of exposure to added sugars influences preference for sweetness and these will add to this body of literature. Future Committees should review this evidence to examine the relationship between quantity, frequency, and timing across the lifespan of added sugars exposure and food habits and preferences. Conducting this review could inform future recommendations to limit frequency of added sugars exposure as well as practical recommendations to shift to foods and beverages lower in added sugars.

Chapter 13: Frequency of Eating

- Standardize terms used in frequency of eating research.

Rationale: Multiple definitions of frequency of eating and health exist. Studies vary in their definition of an eating occasion. This Committee defined eating occasions as any ingestive event including eating and drinking energy yielding and non-energy yielding foods and beverages. Some studies define eating occasions based on the energy value of eating occasions (e.g., any ingested substance including water and non-energy-yielding beverages, > 50 kcals, >100 kcals), the minimal time between eating occasions to consider them distinct, as well as food form (e.g., include or exclude various categories of beverages). Some studies also differ on whether only meals or meals and snacks are counted as eating occasions. No widely accepted definition of these eating occasions exists in the scientific community. All of these factors can influence physiological mechanisms that can moderate a range of health outcomes of importance across the lifespan. Thus, a critical need exists to establish consensus-based definitions of eating occasions.³⁴

- Collect and report all ingestive events occurring within a 24-hour period over multiple days and time periods.

Rationale: A large body of evidence exists that includes 24-hour intake data over multiple days and time periods. However, most of these RCTs were not primarily focused on eating frequency and thus did not report the number of ingestive events (of any kind) across the day. In addition, many other studies focusing on specific eating occasions and/or timing of eating occasions (e.g., breakfast, snacking, late night eating) also did not collect and/or report eating occasions over a full day to allow for accurate assessment of usual eating frequency patterns. This resulted in the exclusion of these trials for the Committee's review because it was not possible to assess the degree to which eating and drinking compensation at a later time point(s) may have occurred in these excluded trials. Lastly, the published studies that directly manipulate eating frequency across days and weeks (e.g., intermittent fasting, time-restricted feeding), did not collect and/or report eating frequency on non-fasting days or during feeding periods, again limiting the ability to assess the impact of eating frequency on the outcomes of interest. The Committee required the reporting of eating frequency on at least three, 24-hour periods and, for intervention studies, on 2 separate occasions. The 3, 24-hour period criterion was chosen as an attempt to capture customary eating frequency patterns that can vary significantly across days. The additional criteria for intervention studies of collecting ingestive event information on more than 1 period of time allows for the documentation of baseline (usual) eating frequency pattern to determine whether a change in pattern occurred as a result of the intervention, whereas the second occasion identifies eating frequency as a result of the intervention. Adequate collection and reporting of 24-hour ingestive event data is necessary for all future studies on frequency of eating and health. Additionally, the Committee recommends the reporting of key confounders to adequately assess the main effect.

- Conduct research on the relationships between timing and frequency of eating and diet quality.

Rationale: Understanding the context of eating is an important strategy to target behavior change. The timing of eating occasions appears to affect diet quality. Very little data on chrono-nutrition exists. Previous research has associated temporal dietary patterns, or the distribution of energy and intake of food components over time, with diet quality and disease risk. In the Committee's review, late-night eating occasions appear to be associated with intakes of foods or beverages that should be limited (added sugars, saturated fats, sodium, and alcohol). Adolescents and teenagers have notable differences in the timing and frequency of eating occasions. This is a subgroup with a high proportion of low nutrient intakes and who could benefit from future research in frequency of eating and diet quality. In addition, it is not known how the frequency of eating during and after pregnancy affects gestational weight gain and/or postpartum weight loss.

- Report water intake as an eating occasion in research on frequency of eating.

Rationale: Water intake is rarely recorded and reported in the scientific literature. A decision about whether to count water-only as an eating occasion or ingestive event is necessary to determine the frequency of eating over a given time period. Water intake may alter food choice, the timing and frequency of eating occasions, digestive process, metabolism, and if water-only ingestive events are counted, the direct estimate of eating frequency. The lack of reliable data on water intake precluded the Committee from

consistently including water intake in its examination of the effects of frequency of eating on the designated health outcomes. The Committee also recognizes a need for improved methods for quantifying the frequency, amount, and timing of water intake.

- Improve methods for measuring frequency of eating.

Rationale: Nearly all of the published literature on the frequency of eating is based on participant self-report. The validity and reliability of these estimates are untested. Objective measures are needed to validate these self-reports in large epidemiological trials and to more directly quantify eating occasions in clinical trials. Methods capturing the full waking day's ingestive behavior are needed. One promising approach includes the use of minimally invasive biosensors that detect glucose fluctuations in response to eating occasions. Multiple non-invasive devices are being developed and tested, including wearable devices that monitor food and beverage delivery to the oral cavity, chewing, and swallowing as stand-alone or combined indices that may be coupled with image-based tools. Additional work on these approaches, including time and date stamps to verify when eating occasions occur, is central for evaluating the impact of both eating frequency and the timing of eating on health outcomes.

- Conduct well-designed RCTs that examine the relationship between frequency of eating and health.

Rationale: Given the limited evidence available, the Committee was unable to identify the relationship between frequency of eating and health. Thus, long-term RCTs with multi-day, objective assessments of frequency of eating are vitally needed to directly assess whether the number of eating occasions throughout the day influences health.

- Conduct research on how food insecurity fits into hypotheses around frequency of eating and health.

Rationale: The frequency of eating may be under volitional control or determined by external forces. The implications for health may differ under these 2 conditions. Where food is readily available and an individual chooses to adopt a particular eating pattern comprised of healthful foods, body weight and nutritional status goals may be achieved. In contrast, where access to food is limited in amount and quality (e.g., food insecurity), the challenges to health maintenance are greater. The complexity of the latter condition is compounded because food insecurity may vary over time (e.g., beginning versus end of a pay period). The prevalence of food insecurity is high and worsens with economic downturns and limitations to feeding programs. If frequency of eating holds independent effects on health, understanding the implications of food insecurity on the frequency of eating occasions and health outcomes will be essential for dietary guidance. Clarifying the role of food insecurity on the frequency of eating occasions will also aid in future analyses that must determine whether this condition should be incorporated into models as a moderator, mediator, or confounder.

- Examine the timing of eating occasions and health.

Rationale: Continued public interest exists as to whether skipping a morning meal affects health and well-being. Although multiple scientific and medical organizations support the daily consumption of breakfast to reduce the risk of cardiometabolic

diseases, reduce obesity, or to improve diet quality and healthy dietary habits, others have challenged^{35,36} these positions due to limited long-term RCTs^{37,38}. Timing of eating occasions, including late-day/evening eating, snacking, intermittent fasting, and/or time-restricted eating are also of high public interest. Because timing of eating occasions is a sub-component of eating frequency, this topic was within the current scope of this Committee. However, most published studies focusing on breakfast, late day eating, snacking and intermittent fasting, report daily energy and/or macronutrient content but do not assess or document eating occasions across the day and were thus excluded from the analyses. Future questions that specifically address timing of ingestive events separate from frequency of eating may provide helpful guidance when implementing the healthy eating pattern recommendations set within the Dietary Guidelines.

- Continue to address questions on frequency of eating and health.

Rationale: Although this Committee was unable to find sufficient evidence on which to summarize the evidence between frequency of eating and health, frequency of eating remains a growing body of scientific literature that is of great interest to the nutritional status of the American population. Therefore, this Committee urges the next Committee and the Departments to continue to prioritize questions on frequency of eating and health for the 2025 Dietary Guidelines Advisory Committee.

Chapter 14: USDA Food Patterns for Ages 2 Years and Older

- Develop methods to incorporate beverages that are not contributors to the USDA food groups or subgroups, into USDA Food Patterns.

Rationale: Current methods do not incorporate beverages into the USDA Food Patterns and therefore do not account for the calories or nutrients provided by them. Many Americans consume energy-containing beverages and therefore require specific guidance surrounding beverage choices.

- Employ statistical techniques such as linear programming or stochastic modelling to food preferences for individuals and to capture population-level intakes and shortfalls.

Rationale: The 2017 NASEM report, *Redesigning the Process for Establishing the Dietary Guidelines*,¹² recommended that food pattern modeling should be enhanced “to better reflect the complex interactions involved, variability in intakes, and range of possible healthful diets.” Improving and using novel statistical techniques in deriving food patterning could enhance food pattern modeling to help tailor healthy dietary patterns for individuals and populations.

- Develop methods to incorporate diversity into USDA Food Pattern Modeling.

Rationale: The American dietary landscape is very diverse and the Committee observed dietary intake patterns that differed by age, race and ethnicity, and by income. The U.S. continues to become more racially and ethnically diverse, and rates of poverty are high, especially among children. Thus, it is imperative to develop food patterns that are context specific and flexible to fit dietary constraints and choices. By 2055, the United

States will not have a single racial or ethnic majority.³⁹ The percentage of foreign-born individuals will increase from 14 percent (2016) to 19 percent by 2060.³⁹ Immigration from Latin America and Asia is expected to account for most of this change.⁴⁰ The dietary patterns commonly consumed by racial-ethnic and cultural groups often have unique characteristics (such as the lack of dairy intake by some groups) that differ from the Healthy U.S.-Style Pattern. These differences may cause the patterns from these groups to appear inadequate because some of the unique foods consumed in these populations that provide the missing nutrients are not represented in the food item clusters used in food pattern modeling. It is now, and will become even more, imperative that dietary guidance reflect dietary patterns of growing demographic groups, particularly LatinX and Asian populations. In addition, the inclusion of the most nutrient-dense forms of foods that are included in the patterns may be difficult for some populations to obtain, either due to cost or due to low availability as a result of geographic location (e.g., in rural areas or food deserts). How demography shapes food patterns is an important area of scientific inquiry that could be included in the future work of other Committees.

- Develop methods to allow application of DRI recommendations for individuals more broadly at the population level.

Rationale: Currently USDA food pattern modeling methods compare anticipated nutrient intakes from food groups and subgroups to the RDA or the AI when an RDA is not published. The patterns are intended for use by individuals, which provides a rationale for using the RDA. However, the EAR is used when evaluating intakes of a population. Groups that are planning or implementing nutrition programs for populations, such as nutrient-based standards for food pantry offerings, should be able to use food pattern modeling as a means to identify appropriate strategies in their planning efforts that are consistent with healthy dietary patterns. Thus, at the group or population level, the existing patterns should be examined relative to the EAR, and would contribute more toward the recommendations.

- Continue to apply age-sex group specific nutrient profiles to food pattern modeling exercises.

Rationale: Food pattern modeling by life stage is useful for identifying areas of needed improvement in food patterns to achieve nutrient adequacy and maintain energy balance. Such awareness is necessary to use the socio-ecological model systems-based approach, such as that identified by the *2015-2020 Dietary Guidelines for Americans*, to identify strategies that promote and advance public health.

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APPENDIX F-1: GLOSSARY OF TERMS

Added sugars—Sugars that are added during the processing of foods (such as sucrose or dextrose), foods packaged as sweeteners (such as table sugar), sugars from syrups and honey, and sugars from concentrated fruit or vegetable juices. They do not include naturally occurring sugars that are found in milk, fruits, and vegetables.

All-cause mortality—The total number of deaths from any or all causes during a specific time period. This does not include cause-specific mortality (i.e., total number of deaths from a specific disease such as cardiovascular disease or cancer).

Body mass index (BMI)—A measure defining weight in kilograms (kg) divided by height in meters (m) squared. BMI is an indicator of deficient or excess body tissue, both fat and muscle. BMI status categories for individuals ages 2 years and older include underweight, normal weight, overweight, and obese. (Normal weight is often referred to as “healthy” weight.) Overweight and obese describe ranges of weight that are greater than what is considered healthy for a given height, while underweight describes a weight that is lower than what is considered healthy. Because children and adolescents are growing, their BMI is plotted on growth charts for sex and age. The percentile indicates the relative position of the child's BMI among children of the same sex and age. This is generally referred to as a **BMI percentile or z-score**.

Body Weight Category	Children and Adolescents (ages 2 to 19 years) (Sex-Specific BMI-for-Age Percentile Range)	Adults (BMI)
Underweight	Less than the 5th percentile	Less than 18.5 kg/m ²
Normal weight	5th percentile to less than the 85th percentile	18.5 to 24.9 kg/m ²
Overweight	85th to less than the 95th percentile	25.0 to 29.9 kg/m ²
Obese	Equal to or greater than the 95 th percentile	
Obese class I		30.0 to 34.9 kg/m ²
Obese class II		35.0 to 39.9 kg/m ²
Obese class III		40.0 kg/m ² and greater

Calorie— A unit commonly used to measure energy content of foods and beverages as well as energy use (expenditure) by the body. A kilocalorie is equal to the amount of energy (heat) required to raise the temperature of 1 kilogram of water 1 degree centigrade. Energy is required to sustain the body's various functions, including metabolic processes and physical activity.

Carbohydrate, fat, protein, and alcohol provide all of the energy supplied by foods and beverages. If not specified explicitly, references to “calories” refer to “kilocalories.”

Carbohydrates—One type of macronutrient. Carbohydrates include sugars, starches, and fibers:

- **Sugars**—A simple carbohydrate composed of one unit (a monosaccharide, such as glucose and fructose) or two joined units (a disaccharide, such as lactose and sucrose). Sugars include white and brown sugar, fruit sugar, corn syrup, molasses, and honey (see **Added sugars**).
- **Starches**—Many glucose units linked together. Examples of foods containing starch include vegetables, dry beans and peas, and grains (e.g., rice, oats, wheat, barley, corn).
- **Fiber**—Nondigestible carbohydrates and lignin that are intrinsic and intact in plants. Fiber consists of dietary fiber, the fiber naturally occurring in foods, and functional fiber, which are isolated, nondigestible carbohydrates that have beneficial physiological effects in humans.

Cardiovascular disease (CVD)—Heart disease as well as diseases of the blood vessel system (arteries, capillaries, veins) that can lead to heart attack, chest pain (angina), or stroke.

Cholesterol—A natural sterol present in all animal tissues. Free cholesterol is a component of cell membranes and serves as a precursor for steroid hormones (estrogen, testosterone, aldosterone), and for bile acids. Humans are able to synthesize sufficient cholesterol to meet biologic requirements, and there is no evidence for a dietary requirement for cholesterol.

- **Blood cholesterol**—Cholesterol that travels in the serum of the blood as distinct particles containing both lipids and proteins (lipoproteins). Also referred to as serum cholesterol. Two kinds of lipoproteins are:
 - **High-density lipoprotein cholesterol (HDL-C)**—Blood cholesterol often called “good” cholesterol; carries cholesterol from tissues to the liver, which removes it from the body.
 - **Low-density lipoprotein cholesterol (LDL-C)**—Blood cholesterol often called “bad” cholesterol; carries cholesterol to arteries and tissues. A high LDL-C level in the blood leads to a buildup of cholesterol in arteries.

- **Dietary cholesterol**—Cholesterol found in foods of animal origin, including meat, seafood, poultry, eggs, and dairy products. Plant foods, such as grains, vegetables, fruits, and oils, do not contain dietary cholesterol.

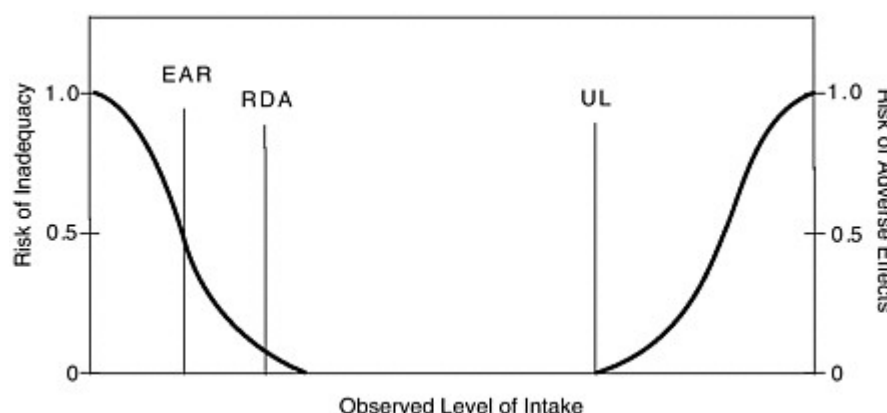
Complementary feeding— The process that starts when human milk or infant formula is complemented by other foods and beverages. The complementary feeding period typically continues to age 24 months as the young child transitions fully to family foods.

Complementary foods and beverages (CFB)—Foods and beverages (liquids, semisolids, and solids) other than human milk or infant formula provided to an infant or young child to provide nutrients and energy.

Cup equivalent (cup eq)—The amount of a food product that is considered equal to 1 cup from the vegetable, fruit, or milk food group. A cup eq for some foods may differ from a measured cup in volume because: (1) the foods have been concentrated (such as raisins or tomato paste), (2) the foods are airy in their raw form and do not compress well into a cup (such as salad greens), or (3) the foods are measured in a different form (such as cheese).

Dietary pattern—The quantities, proportions, variety, or combination of different foods, drinks, and nutrients in diets, and the frequency with which they are habitually consumed.

Dietary Reference Intakes (DRIs)—Nutrient reference values developed by the National Academies of Sciences, Engineering, and Medicine that are specific on the basis of age, sex, and life stage and cover more than 40 nutrient substances. The DRIs provide reference values for vitamins, minerals, and other nutrients that: 1) indicate daily intake amounts that meet the needs of most healthy people, and 2) set intake levels not to exceed to avoid harm. They include the values shown in the graphic (dssl.nlm.nih.gov/dssl/dri.jsp) and are described here.



- **Acceptable Macronutrient Distribution Ranges (AMDR)**—Range of intake for a particular energy source that is associated with reduced risk of chronic disease while providing intakes of essential nutrients. If an individual's intake is outside of the AMDR, there is a potential of increasing the risk of chronic diseases and/or insufficient intakes of essential nutrients.
- **Adequate Intakes (AI)**—A recommended average daily nutrient intake level based on observed or experimentally determined approximations or estimates of mean nutrient intake by a group (or groups) of apparently healthy people. This is used when the Recommended Dietary Allowance cannot be determined.
- **Chronic Disease Risk Reduction Intakes (CDRR)**—The lowest level of intake for which a sufficient strength of evidence exists to characterize a chronic disease risk reduction. This nutrient reference value is currently available only for sodium.
- **Estimated Average Requirements (EAR)**—The average daily nutrient intake level estimated to meet the requirement of half the healthy individuals in a particular life stage and sex group.
- **Recommended Dietary Allowance (RDA)**—The average dietary intake level that is sufficient to meet the nutrient requirement of nearly all (97 to 98 percent) healthy individuals in a particular life stage and sex group.
- **Tolerable Upper Intake Level (UL)**—The highest average daily nutrient intake level likely to pose no risk of adverse health effects for nearly all individuals in a particular life stage and sex group. As intake increases above the UL, the potential risk of adverse health effects increases.

Dietary supplement—A product intended to supplement the diet that contains one or more dietary ingredients (including vitamins, minerals, herbs or other botanicals, amino acids, and

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other substances) intended to be taken by mouth as a pill, capsule, table, or liquid, and that is labeled on the front panel as being a dietary supplement.

Eating occasion—Ingestive event, including a meal, snack or beverage during which any caloric or non-caloric food or beverage is consumed (see **Frequency of eating**).

Essential calories—The energy associated with the foods and beverages ingested to meet nutritional goals through choices that align with the USDA Food Patterns in forms with the least amounts of saturated fat, added sugars, and sodium.

Exclusive human milk feeding—Feeding human milk alone and not in combination with infant formula and/or complementary foods and beverages (including water), except for medications or vitamin and mineral supplements.

Fats—One type of macronutrient (see **Solid fats** and **Oils**).

- **Monounsaturated fat**—Monounsaturated fats have one double bond. They are found in both animal and plant products. Plant sources that are rich in monounsaturated fat include nuts and vegetable oils that are liquid at room temperature (e.g., canola oil, olive oil, high oleic safflower and sunflower oils).
- **Polyunsaturated fat**—Polyunsaturated fats have two or more double bonds and may be of two types, based on the position of the first double bond. Polyunsaturated fats are found in many different plants and some fish sources.
 - **Omega-3 fatty acids**—The three main omega-3 fatty acids are alpha-linolenic acid (ALA), eicosapentaenoic acid (EPA), and docosahexaenoic acid (DHA). Alpha-linolenic acid is required because it cannot be synthesized by humans and, therefore, is considered essential in the diet. Primary sources include soybean oil, canola oil, walnuts, and flaxseed. EPA and DHA are very long chain omega-3 fatty acids that are found in fish and shellfish.
 - **Omega-6 fatty acids**— There are four main omega-6 fatty acids: linoleic acid (LA), arachidonic acid (ARA), gamma linoleic acid (GLA), and conjugated linoleic acid (CLA). Linoleic acid is required because it cannot be synthesized by humans and, therefore, is considered essential in the diet. Primary sources of LA are nuts and liquid vegetable oils, including soybean oil, corn oil, and safflower oil.

- **Saturated fat**—Saturated fats have no double bonds. Major sources include animal products, such as meat and dairy products, and tropical oils such as coconut or palm oils. In general, fats high in saturated fatty acids are solid at room temperature.
- **trans fat**—*Trans* fats are unsaturated fatty acids that contain one or more isolated (i.e., nonconjugated) double bonds in a *trans* configuration. *Trans* fatty acids present in foods that come from ruminant animals (e.g., cattle and sheep). Such foods include dairy products, beef, and lamb.

Food categories—A method of grouping similar foods in their as-consumed forms, for descriptive purposes. The USDA/ARS has created 150 mutually exclusive food categories to account for each food or beverage item reported in What We Eat in America (WWEIA), the food intake survey component of the National Health and Nutrition Examination Survey (for more information, visit: <http://seprl.ars.usda.gov/Services/docs.htm?docid=23429>). Examples of WWEIA Food Categories include soups, nachos, and yeast breads. When food items that contain multiple ingredients are assigned to food categories, they are not disaggregated into their component parts. For example, all pizzas are put into the pizza category (see **Food groups**).

Food environments—Factors and conditions that influence food choices and food availability. These environments include settings such as home, child care (early care and education), school, after-school programs, worksites, food retail stores and restaurants, and other outlets where individuals and families make eating and drinking decisions. The food environment also includes macro-level factors and includes food marketing, food production and distribution systems, agricultural policies, Federal nutrition assistance programs, and economic price structures.

Food groups—A method of grouping similar foods for descriptive and guidance purposes. Food groups in the USDA Food Pattern are defined as fruits, vegetables, grains, dairy, and protein foods. Some of these groups are divided into subgroups, such as dark-green vegetables or whole grains, which may have intake goals or limits (for more information, see **Appendix E3.1 Table A1. USDA Healthy U.S.-Style Food Patterns—Intake Amounts**). When mixed dishes are assigned to food groups, they are disaggregated into their major component parts. For example, pizza may be disaggregated into the grain (crust), dairy (cheese), vegetable (sauce and toppings), and protein foods (toppings) food groups.

Food pattern modeling—The process of developing and adjusting daily intake amounts from food categories or groups to meet specific criteria, such as meeting nutrient intake goals, limiting nutrients or other food components, or varying proportions or amounts of specific food categories or groups.

Food security—A condition in which all people, now and in the future, have access to sufficient, safe, and nutritious food to maintain a healthy and active life.

Fortification—The deliberate addition of one or more essential nutrients to a food, whether or not it is normally contained in the food. Fortification may be used to prevent or correct a demonstrated deficiency in the population or specific population groups; restore naturally occurring nutrients lost during processing, storage, or handling; or to add a nutrient to a food at the level found in a comparable traditional food. When cereal grains are labeled as enriched, it is mandatory that they be fortified with folic acid.

Frequency of eating—The number of daily eating occasions (see **Eating occasion**).

Food components of public health concern—Nutrients and other dietary components that are overconsumed or underconsumed (compared to Dietary Reference Intake recommendations and to biological measures of the nutrient when available) and linked in the scientific literature to adverse health outcomes in the general population or in a subpopulation.

Gestational diabetes—Diabetes occurring during pregnancy in women not previously diagnosed with diabetes.

Gestational weight gain—Weight a woman gains during pregnancy.

Health—A state of complete physical, mental, and social well-being and not merely the absence of disease or infirmity.

Human milk—A mother's own milk provided at the breast (i.e., nursing) or expressed and fed fresh or after refrigeration or freezing.

Human milk feeding—Feeding human milk alone or in combination with infant formula and/or complementary foods and beverages, such as cow milk.

Hypertensive disorders of pregnancy—Disorders occurring during pregnancy that include gestational hypertension, preeclampsia, and eclampsia.

Infant formula—A food that is represented for special dietary use solely as a food for infants by reason of its simulation of human milk or its suitability as a complete or partial substitute for human milk.

Isocaloric—Having the same energy values. For example, two dietary patterns that vary in macronutrient proportions but have the same energy content are isocaloric.

Lean meat—Any meat with less than 10 percent fat by weight, or less than 10 grams of fat per 100 grams, based on USDA and FDA definitions for food label use. Examples include 95 percent lean ground beef, cooked; broiled beef steak, lean only eaten; baked pork chop, lean only eaten; roasted chicken breast or leg, no skin eaten; and smoked/cured ham, lean only eaten.

Life stages—The age groups defined by the NHANES sampling weights or by the DRI age-sex groups.

- Infants and toddlers (birth to less than 24 months)
- Children and adolescents (ages 2 to 19 years)
- Adults (ages 20 to 64 years)
- Pregnant women (20 to 44 years)
- Lactating women (20 to 44 years)
- Older adults (ages 65 years and older)

Macronutrient—A dietary component that provides energy. Macronutrients include protein, fats, and carbohydrates. Alcohol also provides energy but, for purposes of the Committee's report, it is not considered when discussing macronutrients. Diets based on macronutrient distribution were considered as those in which at least once macronutrient proportion was outside of the AMDR (see **Acceptable Macronutrient Distribution Range**). More information on diets based on macronutrient proportions can be found in *Part D. Chapter 2: Food, Beverage, and Nutrient Consumption During Pregnancy*, *Part D. Chapter 3: Food, Beverage, and Nutrient Consumption During Lactation*, and *Part D. Chapter 8: Dietary Patterns*.

Neurocognitive—Having to do with the ability to think and reason, including the ability to concentrate, remember things, process information, learn, speak, and understand.

Neurocognitive development—The maturation during infancy and childhood of the ability to think and reason. Domains include: cognitive development, language and communication development, movement and physical development, and social-emotional and behavioral development. Outcomes that affect, or can be affected by, neurocognitive development include academic performance, attention deficit disorder (ADD) or attention-deficit/hyperactivity disorder (ADHD), anxiety, depression or autism spectrum disorder (ASD).

Nutrient-dense foods—Foods that are naturally rich in vitamins, minerals, and other substances and that may have positive health effects; that are lean or low in solid fats and do not have added solid fats, sugars, starches, or sodium; and that retain naturally-occurring components, such as fiber. All vegetables, fruits, whole grains, fish, eggs, and nuts prepared without added solid fats or sugars are considered nutrient-dense, as are lean or low-fat forms of fluid milk, meat, and poultry prepared without added solid fats or sugars. Nutrient-dense foods provide substantial amounts of vitamins and minerals (micronutrients) and relatively few calories compared to forms of the food that have solid fat and/or added sugars.

Nutrient-Dense Representative Foods—For the purpose of USDA’s food pattern modeling, nutrient-dense representative foods are those within each item cluster in forms with the least amounts of added sugars, sodium, and solid fats.

Nutrition Evidence Systematic Review (NESR)—Formerly known as the Nutrition Evidence Library (NEL), NESR specializes in conducting food- and nutrition-related systematic reviews. NESR systematic reviews are research projects that answer important public health questions by using rigorous and transparent methods to search for, evaluate, analyze, and synthesize the body of scientific evidence on topics relevant to Federal policy and programs. For more information, visit: nesr.usda.gov.

Oils—Fats that are liquid at room temperature. Oils come from many different plants and some fish. Some common oils include canola, corn, olive, peanut, safflower, soybean, and sunflower oils. A number of foods are naturally high in oils, such as: nuts, olives, some fish, and avocados. Foods that are mainly made up of oil include mayonnaise, certain salad dressings, and soft (tub or squeeze) margarine with no *trans* fats. Oils are high in monounsaturated or polyunsaturated

fats, and lower in saturated fats than solid fats. A few plant oils, termed tropical oils, including coconut oil, palm oil and palm kernel oil, are high in saturated fats and for nutritional purposes should be considered as solid fats. Partially-hydrogenated oils that contain *trans* fats should also be considered as solid fats for nutritional purposes (see **Fats**).

Ounce equivalent (oz eq)—The amount of a food product that is considered equal to one ounce from the grain or protein foods food group. An oz eq for some foods may be less than a measured ounce in weight if the food is concentrated or low in water content (nuts, peanut butter, dried meats, flour) or more than a measured ounce in weight if the food contains a large amount of water (tofu, cooked beans, cooked rice or pasta).

Portion size—The amount of a food served or consumed in one eating occasion (see **Eating occasion**).

Postpartum weight loss—Change in weight from baseline during the postpartum period to a later time point during the postpartum period.

Processed meat—Meat, poultry, or seafood products preserved by smoking, curing or salting, or addition of chemical preservatives. Processed meat includes bacon, sausage, hot dogs, sandwich meat, packaged ham, pepperoni, and salami.

Protein—One type of macronutrient. Protein is the major functional and structural component of every animal cell. Proteins are composed of amino acids, nine of which are indispensable, meaning they cannot be synthesized by humans and therefore must be obtained from the diet. The quality of dietary protein is determined by its amino acid profile relative to human requirements as determined by the body's requirements for growth, maintenance, and repair. Protein quality is determined by two factors: digestibility and amino acid composition.

- **Animal protein**—Protein from meat, poultry, seafood, eggs, and milk and milk products.
- **Vegetable protein**—Protein from plants such as dry beans, whole grains, fruit, nuts, and seeds.

Protocol—A plan used by the 2020 Dietary Guidelines Advisory Committee to conduct a systematic review of a scientific question.

Reference Amount Customarily Consumed (RACC)—The serving size listed on a Nutrition Facts Label, which is based on a reference amount of food or beverage that is commonly eaten at a single eating occasion, as determined by the Food and Drug Administration.

Refined grains—Grains and grain products missing the bran, germ, and/or endosperm; any grain product that is not a whole grain. Many refined grains are low in fiber but enriched with thiamin, riboflavin, niacin, and iron, and fortified with folic acid.

Sarcopenia—A progressive and generalized loss of skeletal muscle mass, alone or in conjunction with either or both low muscle strength and low muscle performance.

Seafood—Marine animals that live in the sea and in freshwater lakes and rivers. Seafood includes fish, such as salmon, tuna, trout, and tilapia, and shellfish, such as shrimp, crab, and oysters.

Socioeconomic status—An economic and sociologic measure defined by factors such as income in dollars, income as a percent of the poverty ratio, food security, eligibility for federal assistance programs, or level of education.

Solid fats—Fats that are usually solid at room temperature. Solid fats are found in animal foods except for seafood, and can be made from vegetable oils through hydrogenation. Some tropical oil plants, such as coconut and palm, are considered as solid fats due to their fatty acid composition. Solid fats contain more saturated fats and/or *trans* fats than liquid oils (e.g., soybean, canola, and corn oils), and lower amounts of monounsaturated or polyunsaturated fatty acids. Common fats considered to be solid fats include: butterfat, beef fat (tallow, suet), chicken fat, pork fat (lard), stick margarine, shortening, coconut oil, palm oil and palm kernel oil. Foods high in solid fats include: butter, full-fat cheeses, creams, whole milk, full-fat ice creams, marbled cuts of meats, regular ground beef, bacon, sausages, poultry skin, and many baked goods made using these products (such as cookies, crackers, doughnuts, pastries, and croissants). The fat component of milk and cream (butter) is solid at room temperature (see **Fats**).

Sugar-sweetened beverages—Liquids that are sweetened with various forms of added sugars. These beverages include, but are not limited to, soda (regular, not sugar-free), fruitades, sports

drinks, energy drinks, sweetened waters, and coffee and tea beverages with added sugars. Also called calorically sweetened beverages.

Whole grains—Grains and grain products made from the entire grain seed, usually called the kernel, which consists of the bran, germ, and endosperm. If the kernel has been cracked, crushed, or flaked, it must retain the same relative proportions of bran, germ, and endosperm as the original grain in order to be called whole grain. Many, but not all, whole grains also are sources of dietary fiber.

APPENDIX F-2: PUBLIC COMMENTS

OVERVIEW

The Dietary Guidelines Advisory Committee operates under the Federal Advisory Committee Act (FACA), a law that emphasizes public participation and requires open access to meetings and operations. To further engage the public and ensure input into the process, the U.S. Departments of Agriculture (USDA) and of Health and Human Services (HHS) solicited public comments throughout the Dietary Guidelines Advisory Committee process. Published Federal Register notices alerted the public to written comment collection and their right to provide oral comments during 2 of 5 meetings the Committee held. Per FACA, all meetings of the Committee were open to the public; the meetings were made accessible in person and by webcast. In addition, the Departments updated the DietaryGuidelines.gov website, sent out GovDelivery notices, and posted social media messages on a steady basis to notify the public of opportunities for engagement throughout the Committee's work. Partly due to these expanded efforts to involve the public, comments increased more than 60-fold from 2015 to 2020.

Comments to the Committee covered a wide array of topics. The majority addressed topics under review by the Committee, specifically added sugars, beverages, the birth to age 24 months subpopulation and related topics (e.g., human milk, infant formula), dietary fats, dietary patterns across all ages, and dietary patterns during pregnancy and lactation.

A total of 62,339 comments were posted from March 12, 2019, through June 10, 2020, including 5 submitted by postal mail and uploaded to the Federal Docket Management System (FDMS). Of these, 3,961 were unique and 58,378 were form letters. Of note, interest in the Dietary Guidelines process was far reaching. Although the majority of comments were received from within the United States, they also emanated from Australia, Canada, Denmark, Egypt, France, Germany, India, Ireland, Israel, Italy, Luxembourg, Malaysia, Malta, Mexico, the Netherlands, New Zealand, Northern Ireland, the Philippines, Poland, Portugal, Slovenia, South Africa, Spain, Taiwan (Province of China), United Arab Emirates, and the United Kingdom.

PROCESS

Comments were accepted electronically through Regulations.gov and by paper submissions through the postal mail. A team of Federal staff processed comments using FDMS, a

centralized Docket Management system that provides the ability to search, view, download, and submit comments on Federal notices and Rules. Media and mail campaigns resulted in duplicate comments from individuals and organizations, and these are referred to as form letters. FDMS enabled comment deduplication based on the detection of similarities and differences among comments within each campaign. A threshold for the amount of text constituting a duplicate comment was predetermined, allowing form letters to be easily identified and managed by staff. The efficient processing of public comments using FDMS was of particular importance given the public's growing interest in the work of the Dietary Guidelines Advisory Committee, as evidenced by the numbers of public comments in Table F2.1.

Table F2.1. Number of public comments submitted to Dietary Guidelines Advisory Committees

Dietary Guidelines Advisory Committee	Number of Public Comments
1990	~80
1995	284
2000	165
2005	435
2010	774
2015	972
2020	62,339

Information required from the public comment submitter included the text of the comment (up to 5,000 characters), attachments, if any, and first and last names. Additional information, though not required, could be provided and would be viewable on Regulations.gov, including the submitter's city, state, and country, and organization name, if applicable. Street address, zip code, email address, and telephone and fax numbers also could be provided, but would not be viewable on Regulations.gov except if included in attachments.

All comment submissions were reviewed by trained Federal staff and after being posted were viewable on Regulations.gov. Nearly all public submissions were posted to Regulations.gov without change. The content of public comments was not edited, but in some cases, certain types of personally identifiable information, such as an individual's street address or email address, were redacted. Several comments were withdrawn after notice was given to staff by the commenter that an incomplete comment had been submitted in error. Comments

that contained vulgar language or inappropriate comments were not posted. In total, 27 comments received were not posted due to one of these reasons.

Staff summarized each submitted comment. Committee members were regularly sent comment summaries organized by topic area and were given instructions for searching and reading the full comments on Regulations.gov. When requested, Federal staff also provided Committee members with copies of original public comment submissions and any corresponding attachments. Public comments were discussed and considered by the Committee at Subcommittee and full Committee meetings.

WRITTEN COMMENTS TO THE ADVISORY COMMITTEE

Written public comments to the Committee were continuously submitted from March 12, 2019, through June 10, 2020. The initial collection, which spanned March 12, 2019, through June 17, 2019, was announced in Federal Register notice 84 FR 8840 and comments were collected in Docket FNS-2019-0001-0001. During this time, 515 unique comments and 6,222 form letters were submitted, for a total of 6,737 comments. The next phase of comment collection occurred from June 18, 2019, through June 10, 2020, and was announced in Federal Register notice 84 FR 28266; comments were collected in Docket FNS-2019-0001-6698. During this time period, 3,446 unique comments and 52,156 form letters were submitted, for a total of 55,602 comments. All comments will remain on Regulations.gov and can be accessed and read at any future time by searching for the Docket numbers noted above.

At 4 meetings of the Committee, the Chair requested public comments on the protocols for each scientific question considered by the Committee. For each question, a specific protocol, or plan, was developed to describe how the Committee would apply a methodology, such as the Nutrition Evidence Systematic Review (NESR) methodology, to answer the scientific question. During the second, third, fourth, and fifth Committee meetings, the Chair asked the public to provide comments on the protocols specifically discussed at those meetings. Staff compiled all comments on the protocols and provided them to Committee members, along with directions on accessing and reading comments on Regulations.gov.

ORAL COMMENTS TO THE ADVISORY COMMITTEE

The opportunity to provide oral comments in person at 2 of the full Committee meetings was announced in the Federal Register notice 84 FR 28266, published on June 18, 2019. This was the first time that USDA and HHS offered 2 opportunities for the public to provide oral comments to the Committee. The second opportunity took place in Houston, Texas; this was the first time in decades the public provided oral public comments outside of the Washington, DC metropolitan area. A total of 75 people provided oral comments on July 11, 2019, in Washington, DC and 51 people provided comments on January 24, 2020, in Houston, TX. For the July 11 meeting, 81 people were on the list to provide oral comments (including confirmed and standby commenters), but 6 of those did not attend to give remarks. For the January 24 meeting, 61 people were on the list to provide oral comments (including confirmed and standby commenters); 10 of those did not attend to give remarks. Registration to provide oral comments was completed online and registrants were accepted on a first come, first served basis. Registration was further limited to 1 person per organization. Individuals submitted a brief outline of their oral comments upon registering and were allowed up to 3 minutes in which to deliver their comments to the Committee. Some individuals also submitted written copies of their oral comments through Regulations.gov.

ADDITIONAL COMMENT COLLECTIONS

In addition to soliciting public comments throughout the period of the Committee's work, USDA and HHS asked for public comments at 3 other times.

Before the Committee was established, USDA and HHS asked for public comments on the topics and questions developed for examination by the Committee in their review of the scientific evidence to support the development of the *2020-2025 Dietary Guidelines for Americans*. These topics and questions remain available at DietaryGuidelines.gov. Comments were accepted February 28, 2018, to March 30, 2018; a total of 6,069 public comments in this collection are on Regulations.gov in Docket FNS-2018-0005. Of those comments, some included attachments containing form letters, which accounted for an additional 6,571 comments considered duplicative, bringing the total number of comment submissions to 12,640. Of those, 3,250 were unique comments and 9,390 were form letters covering various topics.

The public also was asked to submit nominations for the Committee. Nominations were collected from September 6, 2018, through October 6, 2018 (see **Part C. Methodology** for additional details).

A final round of public comments directed to USDA and HHS on the Committee's Advisory Report will be received in Docket FNS-2020-0015 on Regulations.gov following the Committee's submission of its Report to the Secretaries of USDA and HHS. The report will be available for the public's review on DietaryGuidelines.gov. This round will encompass both written and oral comments on the Committee's Advisory Report. A Federal Register notice 85 FR 33081, published on June 1, 2020, announced a month-long public comment period on this Report, as well as an opportunity on August 11, 2020, for members of the public to provide oral comments to the Departments about the Report.

SUMMARY

For 15 months, USDA and HHS sought written and oral public comments throughout the Committee's deliberations. The Committee reviewed the comments and greatly appreciated the time, effort, and thought that individuals and organizations put into their submissions. Public involvement is critical to making the Dietary Guidelines process open and transparent.

APPENDIX F-3: BIOGRAPHICAL SKETCHES OF THE 2020 DIETARY GUIDELINES ADVISORY COMMITTEE

Below is brief biographical information for each member of the 2020 Dietary Guidelines Advisory Committee as it relates to the Committee's scope and charge.

Chair: Barbara Schneeman, PhD: Dr. Schneeman served as the Chair of the 2020 Dietary Guidelines Advisory Committee, as well as Chair/Vice Chair Representative on the Dietary Patterns, Beverages and Added Sugars, and Dietary Fats and Seafood Subcommittees and the Data Analysis and Food Pattern Modeling Cross-Cutting Working Group. She provided expertise in dietary patterns, beverages, and types of dietary fat among infants and toddlers and adults. Dr. Schneeman is Professor Emeritus at the University of California, Davis, and former Director of the Office of Nutrition, Labeling, and Dietary Supplements at the U.S. Food and Drug Administration's Center for Food Safety and Applied Nutrition. Her research has focused on outcomes of public health importance, cardiovascular disease, overall health, and other outcomes of public health importance. Dr. Schneeman is a member of the World Health Organization's Nutrition Guidance Expert Advisory Group subgroup on Nutrition and Health. She was on the National Academy of Sciences, Engineering, and Medicine's Committee to Review the Process to Update the *Dietary Guidelines for Americans* and a member of the 1990 and 1995 Dietary Guidelines Advisory Committees.

Vice Chair: Ronald Kleinman, MD: Dr. Kleinman served as Vice Chair of the 2020 Dietary Guidelines Advisory Committee, as well as the Chair/Vice Chair representative on the Pregnancy and Lactation, Birth to 24 Months, and Frequency of Eating Subcommittees. He provided expertise in current dietary intake and nutrients of concern, beverages, and frequency of eating among infants and toddlers, young children, women who are pregnant or lactating. Dr. Kleinman is the Charles Wilder Professor of Pediatrics at Harvard Medical School and a pediatrician at Massachusetts General Hospital, where he serves as Physician-in-Chief and Chair of the hospital's Department of Pediatrics. His research has focused on nutrition adequacy, growth and development, and other outcomes of public health importance. Dr. Kleinman was chair of the NIH Workshop Planning Committee for Dietary Guidelines Birth to 24 Months, and is a founding member and past president of the International Society for Behavioral Nutrition and Physical Activity.

Jamy Ard, MD: Dr. Ard was a member of the 2020 Advisory Committee's Dietary Patterns Subcommittee and the Data Analysis and Food Pattern Modeling Cross-Cutting Working Group. He provided expertise in dietary patterns, beverages, and types of dietary fats across childhood, adolescence, and adulthood. Dr. Ard is Professor of General Internal Medicine and of Epidemiology and Prevention at Wake Forest School of Medicine, Medical Director at Wake Forest Baptist Medical Center, and Director of Participant Clinical Interaction at Wake Forest School of Medicine. His research has focused on cardiovascular disease and obesity. Dr. Ard served as a member of National Academies of Sciences, Engineering, and Medicine committees on the process to establish the *Dietary Guidelines* and on consequences of sodium reduction in populations, and as a member of the NIH Expert Panel on the Identification, Evaluation, and Treatment of Overweight and Obesity in Adults.

Regan Bailey, PhD, MPH, RD: Dr. Bailey was the chair of the Data Analysis and Food Pattern Modeling Cross-Cutting Working Group and a member of the Dietary Fats and Seafood Subcommittee. She provided expertise in nutrients of concern and nutrition data analysis. Dr. Bailey is an Associate Professor at Purdue University and Director of the Purdue Nutrition Assessment Center. She has conducted research to improve the methods of measuring nutritional status to optimize health. Dr. Bailey's research focuses on efforts to understand how to use dietary intakes, dietary patterns, and biomarkers of nutritional status to assess how dietary exposure relate to human health across the lifespan. Previously, Dr. Bailey was a nutrition epidemiologist at the Office of Dietary Supplements at the National Institutes of Health.

Lydia Bazzano, MD, PhD: Dr. Bazzano was a member of the Dietary Patterns and the Birth to 24 Months Subcommittees. She provided expertise is dietary patterns, nutrients of concern, and beverages. Dr. Bazzano is a Lunda B. and H. Leighton Steward Professor in Nutrition Research at Tulane University, Director of Tulane's Center for Lifespan Epidemiology Research, and Staff Physician at the Ochsner Medical Center. She has conducted clinical research with a focus on cardiovascular disease and its risk factors, with an emphasis on the role of cardiometabolic factors, including diet, obesity, lipids, and blood glucose over the lifespan. Dr. Bazzano leads trials on behavioral interventions, including diet, to improve weight and cardio-metabolic risk factors and oversees a longstanding cohort study on cardiovascular disease epidemiology.

Carol Boushey, PhD, MPH, RD: Dr. Boushey was the chair of the Dietary Patterns Subcommittee and a member of the Frequency of Eating Subcommittee. She provided expertise in dietary patterns and frequency of eating across childhood, adolescence, and adulthood. Dr. Boushey is a member of the graduate faculty at the University of Hawaii at Manoa's Department of Human Nutrition, Food, and Animal Sciences and is an Associate Research Professor at the University of Hawaii Cancer Center and Director of the Center's Nutrition Support Shared Resource. She also is an Adjunct Professor at Purdue University's Department of Nutrition Science. Dr. Boushey's research focuses on relationships between diet and disease, specifically cancer and obesity. She is a member of the Dietary Patterns Methods Project, initiated by the National Cancer Institute. Dr. Boushey served as a member of National Academies of Sciences, Engineering, and Medicine committee on the process to establish the *Dietary Guidelines*.

Teresa Davis, PhD: Dr. Davis was a member of the Birth to 24 Months Subcommittee and the Data Analysis and Food Pattern Modeling Cross-Cutting Working Group. She provided expertise in dietary intakes and nutrients of concern. Dr. Davis is a Professor at Baylor College of Medicine's Department of Pediatrics and Associate Director of Baylor's Children's Nutrition Research Center Postdoctoral Fellowship Program. She also is an Adjunct Professor at Texas A&M University's Department of Nutrition and Food Science, as well as its Department of Animal Science. Her work has focused on basic and transitional research related to child growth and development, specifically protein synthesis and muscle growth in infants and toddlers from birth to 24 months. Dr. Davis is a past president of the American Society for Nutrition, current editor-in-chief of *The Journal of Nutrition* and past guest scientific editor for the *American Journal of Clinical Nutrition*.

Kathryn Dewey, PhD: Dr. Dewey was the chair of the Birth to 24 Months Subcommittee and a member of the Pregnancy and Lactation Subcommittee. She provided expertise in current dietary intake and nutrients of concern among infants and toddlers and women who are pregnant or lactating. Dr. Dewey is a Distinguished Professor Emerita at the University of California, Davis and previous Director of the university's Program in International and Community Nutrition. Her research has included the evaluation of interventions to improve nutrition of women who are pregnant or lactating and infants and young children in vulnerable populations. Dr. Dewey has studied iron status of infants and young children, lactation success and breastfeeding difficulties and the influence of feeding practices on infant intake, growth and Scientific Report of the 2020 Dietary Guidelines Advisory Committee

body composition, and subsequent risk of child overweight. She served on a technical expert collaborative of the USDA/HHS Pregnancy and Birth to 24 Months Project. Dr. Dewey is a past president of the Society for International Nutrition Research and of the International Society for Research on Human Milk and Lactation.

Sharon Donovan, PhD, RD: Dr. Donovan was the chair of the Pregnancy and Lactation Subcommittee and a member of the Birth to 24 Months Subcommittee. She provided expertise in current dietary intake and nutrients of concern among women who are pregnant or lactating and infants, toddlers, and young children. She also provided expertise in human milk composition and lactation. Dr. Donovan is Melissa M. Noel Endowed Chair of Diet and Health and Professor of Nutrition at the Department of Food Science and Human Nutrition at the University of Illinois at Urbana-Champaign. She also is an Adjunct Professor in the Department of Pediatrics the University of Illinois' College of Medicine. Her research has focused on pediatric nutrition and the importance for growth, development and long-term functional outcomes, such as cognition and immune response. Dr. Donovan is a past president of the American Society for Nutrition and of the International Society for Research on Human Milk and Lactation.

Steven Heymsfield, MD: Dr. Heymsfield was the chair of the Frequency of Eating Subcommittee and a member of the Dietary Patterns Subcommittee. He provided expertise in energy metabolism, body composition, and obesity. Dr. Heymsfield is Professor of Nutrition at Louisiana State University and Director of the Metabolism and Body Composition Laboratory at the university's Pennington Biomedical Research Center. His research has focused on human obesity, including energy balance regulation, weight loss treatments, co-morbidity effects, and development of related mathematical models. He also has interest in the development of methods for evaluating body composition and application of new technologies to study human metabolism. Dr. Heymsfield is a past president of The Obesity Society, the American Society of Clinical Nutrition, and the American Society of Parenteral and Enteral Nutrition.

Heather Leidy, PhD: Dr. Leidy was a member of the Frequency of Eating and the Beverages and Added Sugars Subcommittees. She provided expertise in frequency of eating and beverage intake among adolescents and adults. Dr. Leidy is an Associate Professor at the University of Texas at Austin in the Department of Nutritional Sciences and the Department of Pediatrics through the Dell Medical School. She conducted research on the effects of dietary protein,

especially at breakfast, on satiety, healthy eating behavior, glycemic control, and weight management in young people. She is the current director of Research Interest Sections for the American Society of Nutrition. Formerly she served as an Associate Professor in the Department of Nutrition Sciences at Purdue University.

Richard Mattes, PhD, MPH, RD: Dr. Mattes was a member of the Frequency of Eating and the Beverages and Added Sugars Subcommittees. He provided expertise in frequency of eating and beverage intake among adults. Dr. Mattes is Distinguished Professor of Nutrition Science at Purdue University, as well as Director of the university's Ingestive Behavior Research Center. He also is Adjunct Associate Professor of Medicine at the Indiana University School of Medicine and an Affiliated Scientist at the Monell Chemical Senses Center. His research has focused on understanding the numerous influences on human ingestive behavior, nutrient utilization, and energy balance in healthy and clinical populations. Dr. Mattes' research also explores the role of various properties of foods and beverages, as well as human characteristics, on eating behavior and health outcomes. He is the current president of the American Society for Nutrition.

Elizabeth Mayer-Davis, PhD, RD: Dr. Mayer-Davis was the chair of the Beverages and Added Sugars Subcommittee and a member of the Dietary Patterns Subcommittee. She provided expertise in dietary patterns and beverage intake among children and adults, including women who are pregnant or lactating. Dr. Mayer-Davis is the Cary C. Boshamer Distinguished Professor of Nutrition and Medicine and Chair of Nutrition at the School of Public Health and School of Medicine of the University of North Carolina (UNC) at Chapel Hill, where she also is Professor of Medicine. She also is an Adjunct Professor at the University of South Carolina's Arnold School of Public Health's Department of Epidemiology and Biostatistics and co-director of the UNC Nutrition Obesity Research Center. Her research has focused on diabetes and the ways in which nutrition can affect the risk of developing diabetes and the risk of type 1 and type 2 diabetes complications.

Timothy Naimi, MD, MPH: Dr. Naimi was a member of the Beverages and Added Sugars Subcommittee and the Data Analysis and Food Pattern Modeling Cross-Cutting Working Group. He provided expertise in beverages, particularly alcoholic beverage intake among adults. Dr. Naimi is a Professor in Boston University School of Medicine's Departments of Medicine and Pediatrics, as well as a Professor in Boston University School of Public Health's Department of Community Health Sciences. He also is a faculty member of Boston Medical Center's Injury

Prevention Center, a clinician-investigator at the center's Section of General Internal Medicine, and a staff physician at the Codman Square Health Center. His research has focused on alcohol and health. Dr. Naimi is on the National Academies of Sciences, Engineering, and Medicine's Committee on Accelerating Progress to Reduce Alcohol-Impaired Driving Fatalities.

Rachel Novotny, PhD, RDN, LD: Dr. Novotny was a member of the Pregnancy and Lactation and the Beverages and Added Sugars Subcommittees. She provided expertise in dietary patterns, beverages, and added sugars across childhood, adolescence, and adulthood. Dr. Novotny is a Professor in the Department of Human Nutrition, Food, and Animal Science at the University of Hawaii at Manoa College of Tropical Agriculture and Human Resources and Professor in the Population Sciences in the Pacific Program at the University of Hawaii Cancer Center. Her research has focused on ethnic differences in diet, physical activity and body size and composition, especially patterns of growth and development. Dr. Novotny's work examines undernutrition and overnutrition and related health risks, including blood pressure, cancer, bone health, obesity, and diabetes. Her research has also examined dietary patterns of underserved populations, especially among Hispanics in their native countries, and Native Alaskans, Native Hawaiians, and Pacific Islanders.

Joan Sabaté, MD, DrPH: Dr. Sabaté was a member of the Dietary Patterns and the Dietary Fats and Seafood Subcommittees. He provided expertise in dietary patterns, dietary fats, and seafood among adults. Dr. Sabaté is Executive Director of the Center for Nutrition, Lifestyle and Disease Prevention in Loma Linda University's School of Public Health. He also is a Professor at the University's School of Public Health and its School of Medicine. His research has focused on the effect of plant-based diets and foods on growth and development, lipids, cardiovascular disease, and cognition. Dr. Sabaté is an investigator on epidemiological studies examining dietary intake with health outcomes among a large cohort of vegetarians. He directs an environmental research program and explores interrelationship between environmental and health impacts of food choices.

Linda Snetselaar, PhD, RDN: Dr. Snetselaar was the chair of the Dietary Fats and Seafood Subcommittee and a member of the Dietary Patterns Subcommittee. She provided expertise in dietary patterns and types of dietary fats across childhood, adolescence, and adulthood. Dr. Snetselaar is Director of the Nutrition Center in the Department of Internal Medicine at the University of Iowa's College of Medicine, where she also is a Professor in the Division of

Endocrinology. She also is Co-Director of the Prevention Intervention Center at the university's School of Public Health and is Professor and Endowed Chair in Preventive Nutrition Education. Dr. Snetselaar's research examines the relationships between diet and cardiovascular disease, neurocognitive health, diabetes, and cancer with an emphasis on dietary patterns and public health community-based research. She serves as editor-in-chief of the *Journal of the Academy of Nutrition and Dietetics*.

Jamie Stang, PhD, MPH, RD: Dr. Stang was a member of the Pregnancy and Lactation Subcommittee and the Data Analysis and Food Pattern Modeling Cross-Cutting Working Group. She provided expertise in dietary intake during pregnancy. Dr. Stang is Chair of the Public Health Nutrition Program at the University of Minnesota School of Public Health's Division of Epidemiology and Community Health, where she is an Associate Professor. She also is Director of the University's Center for Excellence in Maternal and Child Health Education, Science and Practice. Her research has focused on nutrition and weight status in pregnancy, child and adolescent nutrition, behavioral counseling in child obesity, and obesity among women of childbearing age. Dr. Stang is on the Roundtable on Obesity Solutions Workshop Planning Committee for the National Academies of Sciences, Engineering, and Medicine, and formerly a member of a technical expert collaborative of the USDA/HHS Pregnancy and Birth to 24 Months Project.

Elsie Taveras, MD, MPH: Dr. Taveras was a member of the Pregnancy and Lactation and the Birth to 24 Months Subcommittees. She provided expertise in infants and children and women who are pregnant or lactating, with a focus on minority populations. Dr. Taveras is Professor of Pediatrics at Harvard Medical School, where she also is an Investigator in its Nutrition Obesity Research Center, and Professor of Nutrition at Harvard T.H. Chan School of Public Health. At Massachusetts General Hospital, she is Chief of the Division of General Academic Pediatrics, Director of Pediatric Population Health Management, Co-Director of the Raising Healthy Hearts Clinic and Executive Director of the Kraft Center for Community Health. Her research has examined determinants of obesity in women and children and developing interventions across the life course to prevent obesity and chronic diseases, especially in underserved populations. She is a member of the National Collaborative on Childhood Obesity Research External Scientific Panel.

Linda Van Horn, PhD, RDN, LD: Dr. Van Horn was a member of the Dietary Patterns and the Dietary Fats and Seafood Subcommittees. She provided expertise in dietary patterns, added sugars, dietary fats, and seafood across childhood, adolescence, and adulthood and among women pregnant or lactating. Dr. Van Horn is Associate Dean for Faculty Development at Northwestern University's Feinberg School of Medicine and a Tenured Professor at the School of Medicine's Department of Preventive Medicine. Her research has focused on the role of diet in prevention and treatment of cardiovascular disease and obesity across the lifespan. Dr. Van Horn has also examined the importance of diet quality in pregnant and lactating women, with a focus on gestational weight gain. Dr. Van Horn is a member of the American Heart Association Nutrition Committee and the American Cancer Society's Prevention Committee. She was the chair of the 2010 Dietary Guidelines Advisory Committee.

APPENDIX F-4: MEMBERSHIP OF DIETARY GUIDELINES ADVISORY COMMITTEE SUBCOMMITTEES AND WORKING GROUP

SUBCOMMITTEE AND WORKING GROUP STRUCTURE

The 2020 Dietary Guidelines Advisory Committee included 6 Subcommittees and 1 Cross-Cutting Working Group. The purpose of the Subcommittees and Working Group was to review evidence for the topics and questions specified by the Departments of Agriculture and of Health and Human Services. Each group conducted its work between the Committee's meetings and reported on its work to the full Committee at its meetings, all of which were held publicly. At these public meetings, the full Committee discussed and made decisions regarding the Subcommittees' and the Working Group's scientific reviews. The conclusions and advice included in the Committee's report were reached with consensus across the full Committee.

Work structure from Meeting 1 through completion of the report.

Dietary Patterns Subcommittee

Carol Boushey (Chair)
Barbara Schneeman (Chair/Vice Chair Representative)
Jamy Ard
Lydia Bazzano
Steven Heymsfield
Elizabeth Mayer-Davis
Joan Sabaté
Linda Snetselaar
Linda Van Horn

Pregnancy and Lactation Subcommittee

Sharon Donovan (Chair)
Ronald Kleinman (Chair/Vice Chair Representative)
Kathryn Dewey
Rachel Novotny
Jamie Stang
Elsie Taveras

Birth to Age 24 Months Subcommittee

Kathryn Dewey (Chair)
Ronald Kleinman (Chair/Vice Chair Representative)
Lydia Bazzano
Teresa Davis
Sharon Donovan
Elsie Taveras

Beverages and Added Sugars Subcommittee

Elizabeth Mayer-Davis (Chair)
Barbara Schneeman (Chair/Vice Chair Representative)
Heather Leidy
Richard Mattes
Timothy Naimi
Rachel Novotny

Dietary Fats and Seafood Subcommittee

Linda Snetselaar (Chair)
Barbara Schneeman (Chair/Vice Chair Representative)
Regan Bailey
Joan Sabaté
Linda Van Horn

Frequency of Eating Subcommittee

Steven Heymsfield (Chair)
Ronald Kleinman (Chair/Vice Chair Representative)
Carol Boushey
Heather Leidy
Richard Mattes

Data Analysis and Food Pattern Modeling – Cross-Cutting Working Group

Regan Bailey (Chair)
Barbara Schneeman (Chair/Vice Chair Representative)
Jamy Ard
Teresa Davis
Timothy Naimi
Jamie Stang

Subcommittee Chairs Meetings

At various times throughout the Committee's operation, the Chair and Vice Chair held calls with the Subcommittee and Working Group chairs to coordinate work, review the timeline, and discuss cross-cutting issues.

WRITING GROUP STRUCTURE

The Chair and Vice Chair established a writing group to support development of **Part B. Chapter 2: Integrating the Evidence**. This group included representatives from across the Subcommittees and Cross-Cutting Working Group to ensure the chapter captured the major themes of the Committee's work. This chapter was discussed during Subcommittee meetings and reviewed by the members before presentation at the Committee's June 17, 2020, Meeting to discuss the Draft Report.

Writing group structure from March 2020, when the need was identified, through completion of the report.

Integration Writing Group

Barbara Schneeman (Chair)
Ronald Kleinman (Vice Chair)
Jamy Ard
Teresa Davis
Richard Mattes
Jamie Stang
Elsie Taveras
Linda Van Horn

APPENDIX F-5: DIETARY GUIDELINES ADVISORY COMMITTEE REPORT ACKNOWLEDGMENTS

INVITED EXPERT SPEAKER AND/OR CONSULTATION

Eric Decker, PhD
University of Massachusetts

Lauren S. Wakschlag, PhD
Northwestern University

Anita Panjwani, PhD
Purdue University

Federal

Stephanie M. George, PhD, MPH, MA
National Institutes of Health
National Cancer Institute (at the time)
National Institute of Arthritis and Musculoskeletal and Skin Diseases (current)

Daniel J. Raiten, PhD
National Institutes of Health
Eunice Kennedy Shriver National Institute of Child Health and Human Development

Sharon Ross PhD, MPH
National Institutes of Health
National Cancer Institute

Barbara Shukitt-Hale, PhD
USDA Agricultural Research Service
Human Nutrition Research Center on Aging

STAFF, CONTRACT, AND/OR TECHNICAL SUPPORT

Nigel Baker	Dave Herring, MS, RD
Lisa Bente, MS, RD	Mary Herrup, RD
Dennis Bier, MD	Mark Hightower
Melissa Ciampo, RD	Corey Holland, RD
Garth Clark	Jayme Holliday
Susan Cole	Barbara Jirka, PhD
Kevin Conner	Mike Johnson
Carol Dreibelbis, MPH	Mark Lino, PhD
Erica Evans, RD	Hannah Mitchell
Jenna Fahle, MSPH, RD	Angelique Moss
Janie Fleming	Sohyun Park
Amy Frady, RD	Mansy Pullen
Robert Gest	Perry Rainosek
Adam Gillum	Cikena Reid
Rodney Hall	Laurie Wheeler
Brooke Hardison, MPH	Yat Ping Wong, MLS, MPH
Betty Harvey	

Dietary Guidelines and NESR Web Design

Urban Emu

PEER REVIEWERS OF NESR SYSTEMATIC REVIEWS

The following Federal scientists from the Departments of Agriculture, Defense, Health and Human Services, and Veterans Affairs conducted independent peer reviews of the NESR systematic reviews.

David Klurfeld, PhD

Coordinator of Peer Review of NESR Systematic Reviews
Co-Executive Secretary

Lindsay Allen, PhD

David Baer, PhD

Brian Bennett, PhD

Josephine Boyington, PhD

Alison Brown, PhD

Douglas Burrin, PhD

Jay Cao, PhD

Mary Cogswell, PhD

Cindy Davis, PhD

Johanna Dwyer, PhD

Joanne Elena, PhD

Mary Evans, PhD

Lindy Fenlason, MD

Naomi Fukagawa, MD, PhD

Sarah Gebauer, PhD

Kirsten Herrick, PhD

Joseph Hibbeln, MD

Mary Kable, PhD

Laura Kettel-Kahn, PhD

J. Philip Karl, PhD

Claudine Kavanaugh, PhD

Emily Kohls, PhD

Chao-Qiang Lai, PhD

Maren Laughlin, PhD

Harris Lieberman, PhD

Stefano Luccioli, MD

Padma Maruvada, PhD

James McClung, PhD

Robin McKinnon, PhD

Holly Nicastro, PhD

Janet Novotny, PhD

Laurence Parnell, PhD

Matthew Picklo, PhD

Nancy Potischman, PhD

Charlotte Pratt, PhD

Jill Reedy, PhD

James Roemmich, PhD

Barbara Shukitt-Hale, PhD

Charles Stephensen, PhD

Jessica Thomson, PhD

Karen Winer, PhD

Beverly Wolpert, PhD

Jacqueline Wright, DrPH

Essie Yamini, PhD

Lin Yan, PhD

Susan Yanovski, MD