

Saving the Babies You Helped Get Here:

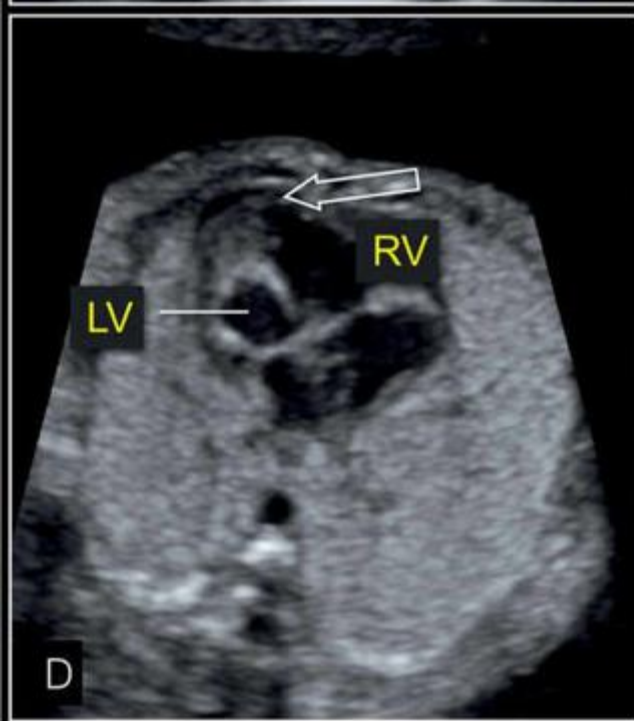
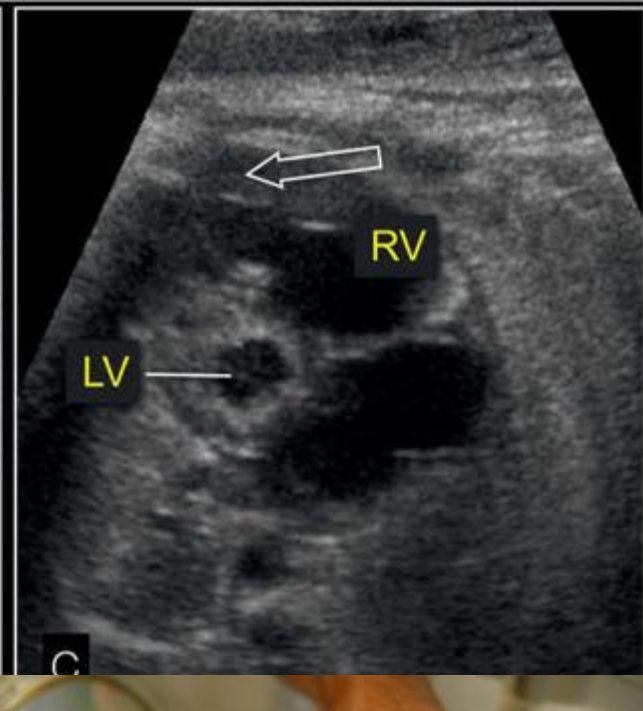
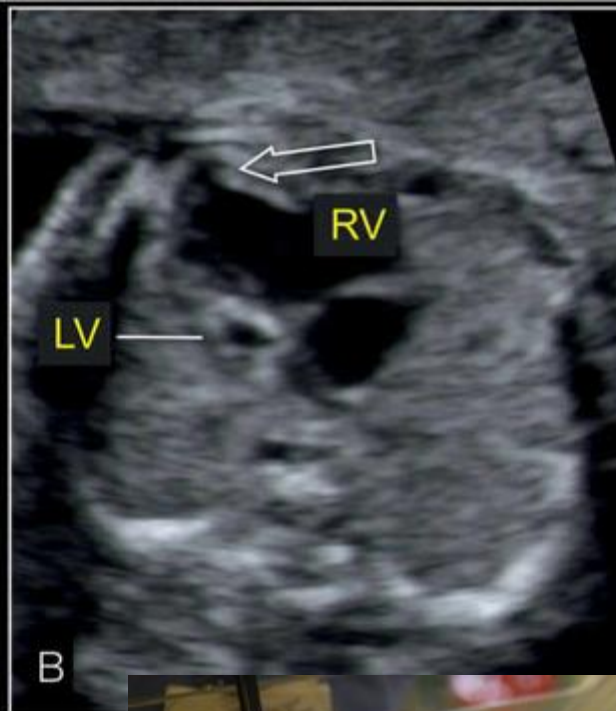
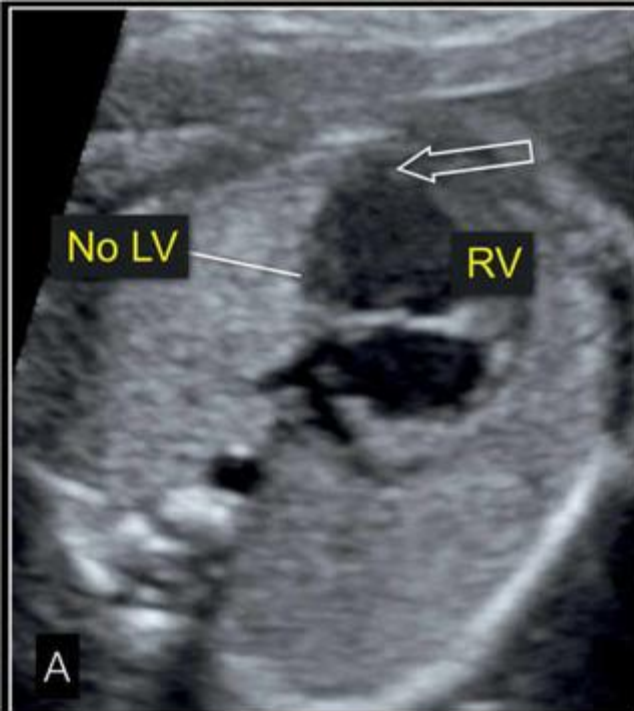
What Every Child Advocate Needs To Know About Safe Infant Sleep



Benjamin Hoffman MD CPST-I

Professor of Pediatrics

President, American Academy of
Pediatrics







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AVERY'S DISEASES *of the* NEWBORN

CHRISTINE A. GLEASON | SANDRA E. JUUL



TENTH EDITION



Objectives

By the end of this talk, you should be able to:

1. Discuss the epidemiology of preventable infant death
2. Describe safe sleep practices and the role of care providers in supporting behaviors
3. Discuss controversies in infant sleep
4. List advocacy and systems approaches to supporting safe parent behaviors

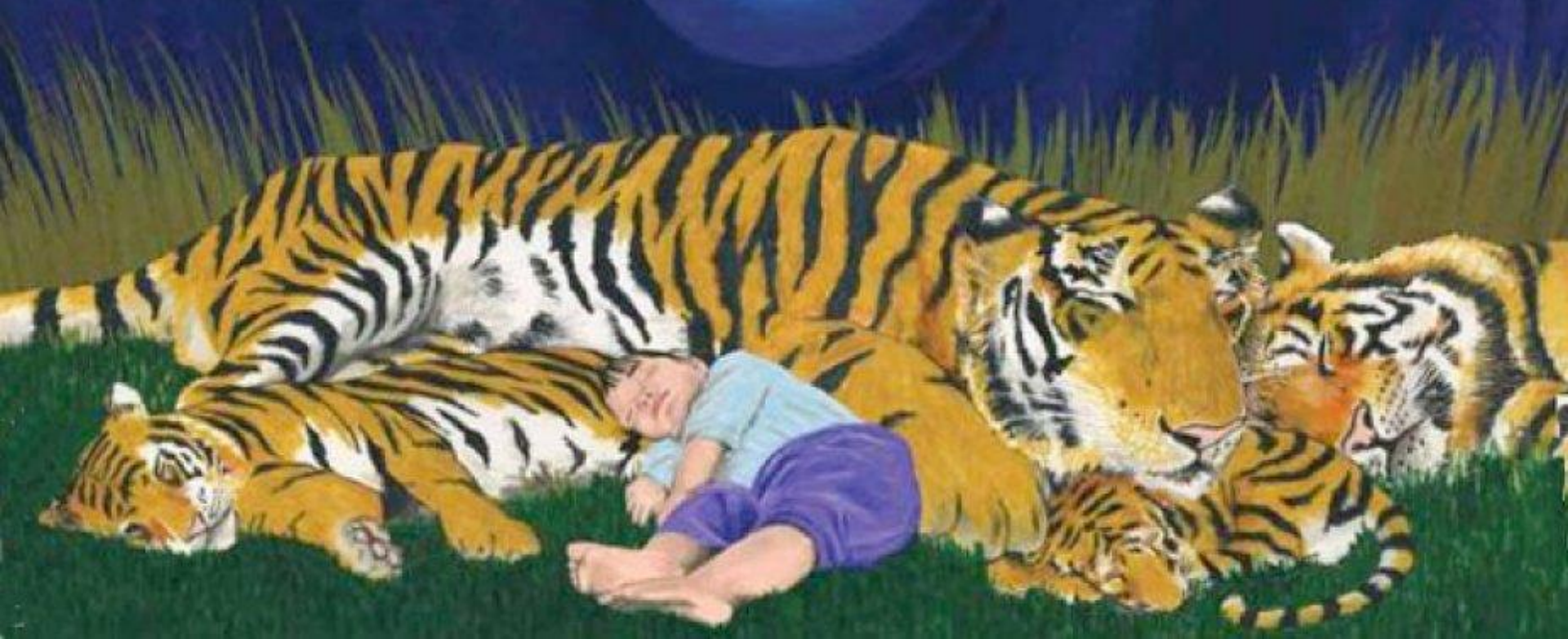


Disclosure Statement

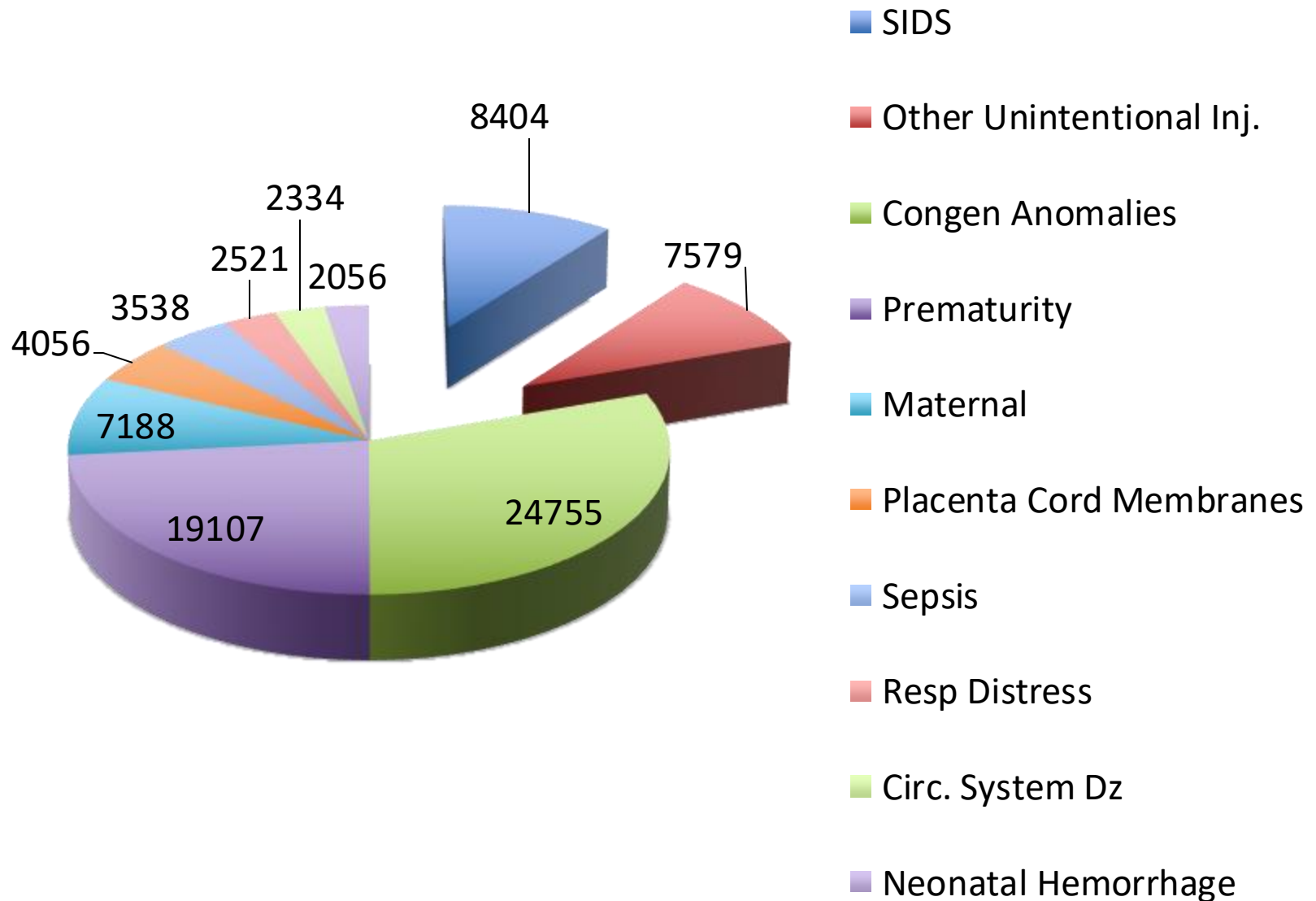
- Ben Hoffman has no relevant financial relationships with the manufacturer(s) of any commercial product(s) and/or provider of commercial services discussed in this session
 - I have served as an expert in legal cases regarding inclined sleepers
- I do not intend to discuss an unapproved/investigative use of a commercial product/device in our presentation.



Go the Fok to Sleep



Deaths 0-1 year 2018-2023



10 Leading Causes of Death, United States

2018 to 2023, All Deaths with drilldown to ICD codes, All Sexes, All Races, All Ethnicities

	<1	1-4
1	Congenital Anomalies 24,755	Unintentional Injury 7,390
2	Short Gestation 19,017	Congenital Anomalies 2,461
3	SIDS 8,404	Homicide 1,875
4	Unintentional Injury 7,579	Malignant Neoplasms 1,735
5	Maternal Pregnancy Comp. 7,188	Heart Disease 710
6	Placenta Cord Membranes 4,056	Influenza & Pneumonia 646
7	Bacterial Sepsis 3,538	Perinatal Period 357

TOTAL

7,579



100.0%

Suffocation

6,410



84.6%

Motor vehicle, traffic

481



6.3%

Drowning (includes water transport)

232



3.1%

Poisoning

121

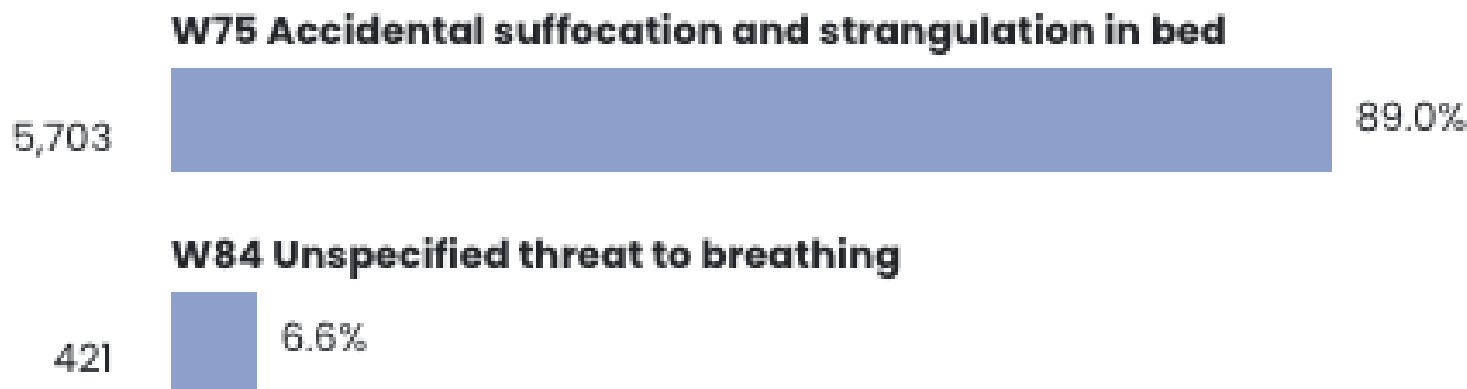


1.6%

Suffocation

#1 Leading Cause of Death

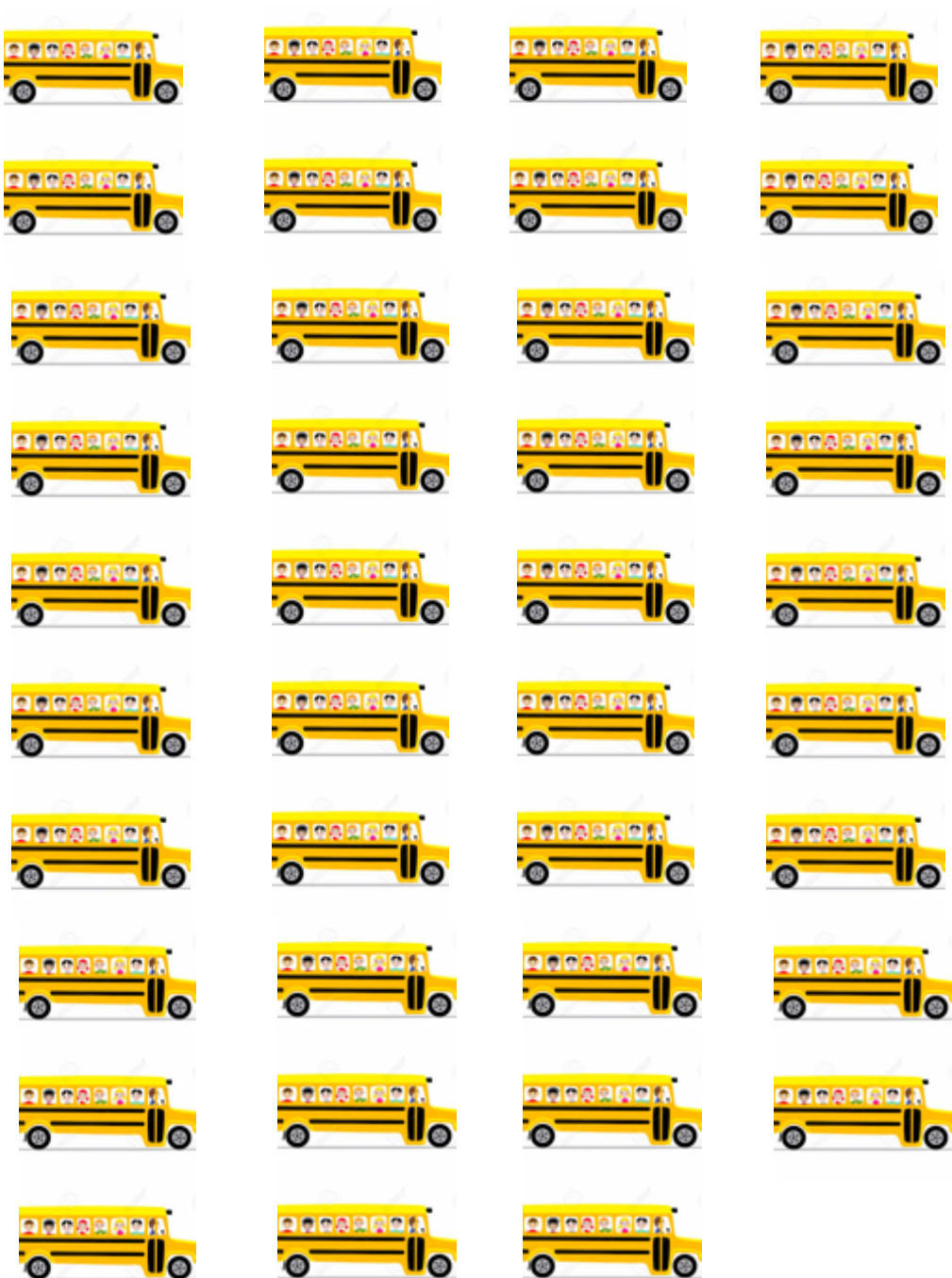
2018 to 2023, All Sexes, All Races



75% of Unintentional Injury Deaths among infants were sleep-related suffocation/strangulation







39 School busses
of infants
DIE IN THEIR
SLEEP
Every Year



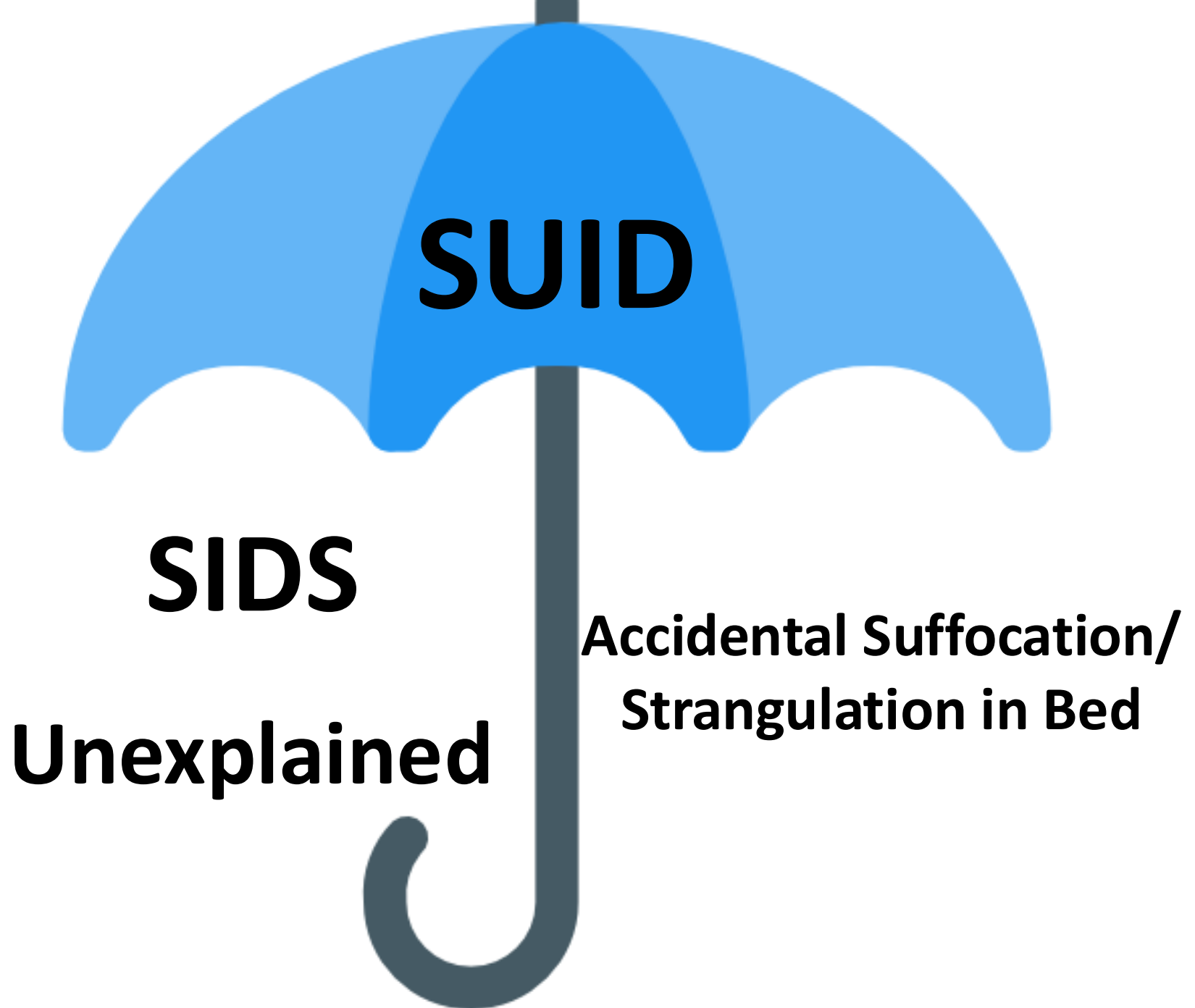






What is SUID?

SUID (Sudden Unexpected Infant Death) is when infants die suddenly of no immediately obvious cause.



SUID

SIDS

Unexplained

**Accidental Suffocation/
Strangulation in Bed**



What is SIDS?

“The sudden death of an infant younger than 1 year of age that remains unexplained after a **thorough case investigation**, including performance of a **complete autopsy**, thorough examination of the **death scene**, and review of the **infant’s and family’s clinical histories.**”

What is SIDS?

90% in infants younger than
6 months



Peaks between 1 and 4 months of age;
however, can occur any time during an infant's
first year.

What is SUID?

SIDS

Unknown Cause

Cannot be explained because a thorough investigation was not conducted and the cause of death could not be determined

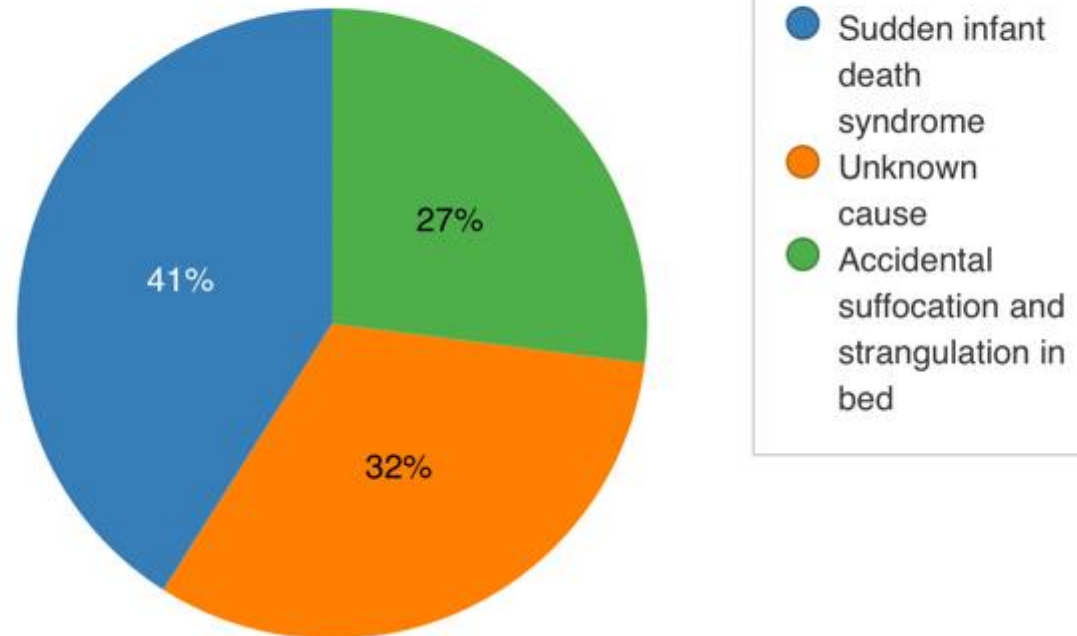


Accidental Suffocation and Strangulation in Bed

Contributing factors may include soft bedding, pillow, overlaying, wedging, entrapment, strangulation

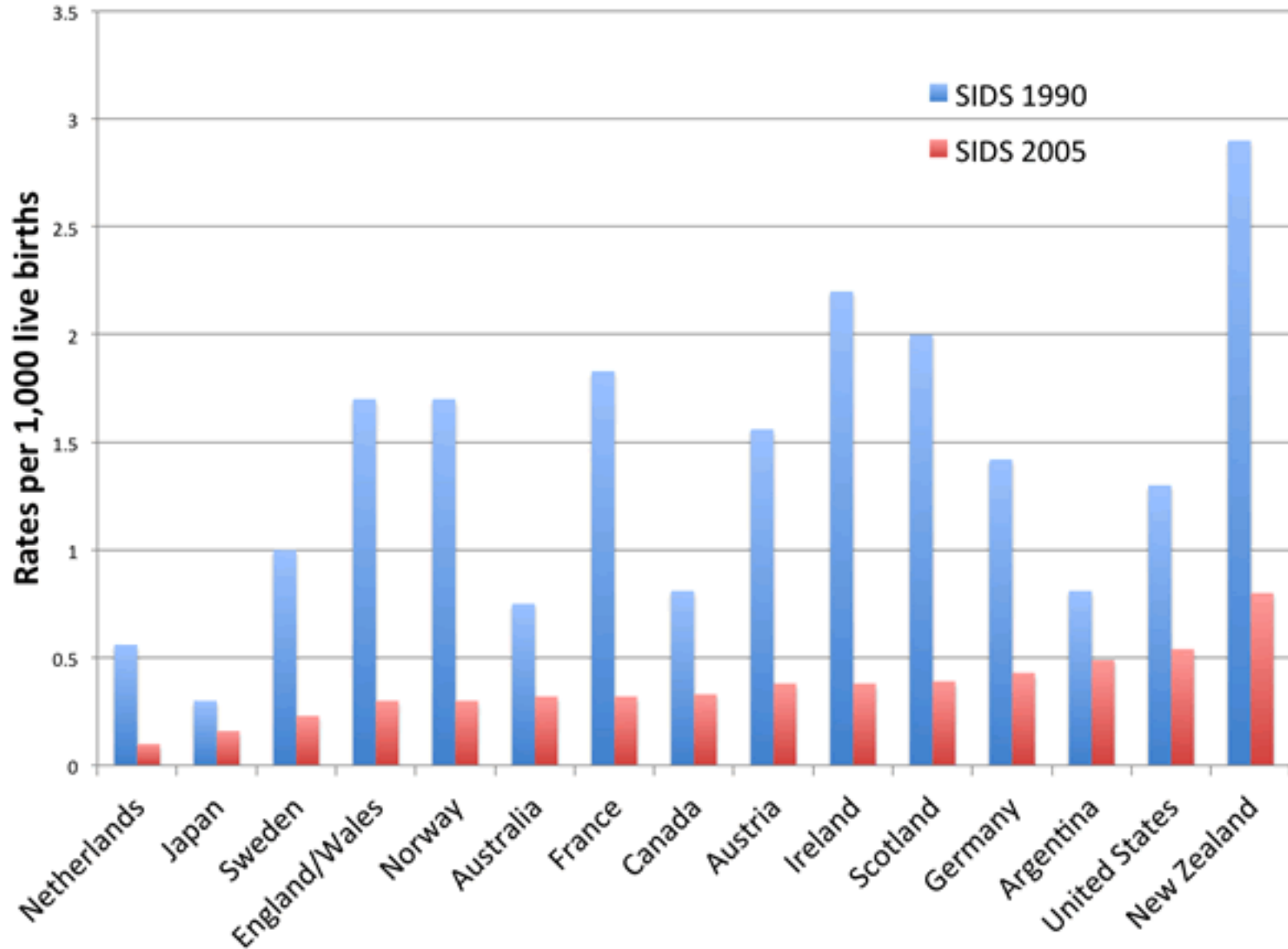
Most Cases of SUID are SIDS

Breakdown of Sudden Unexpected Infant Deaths by Cause, 2020

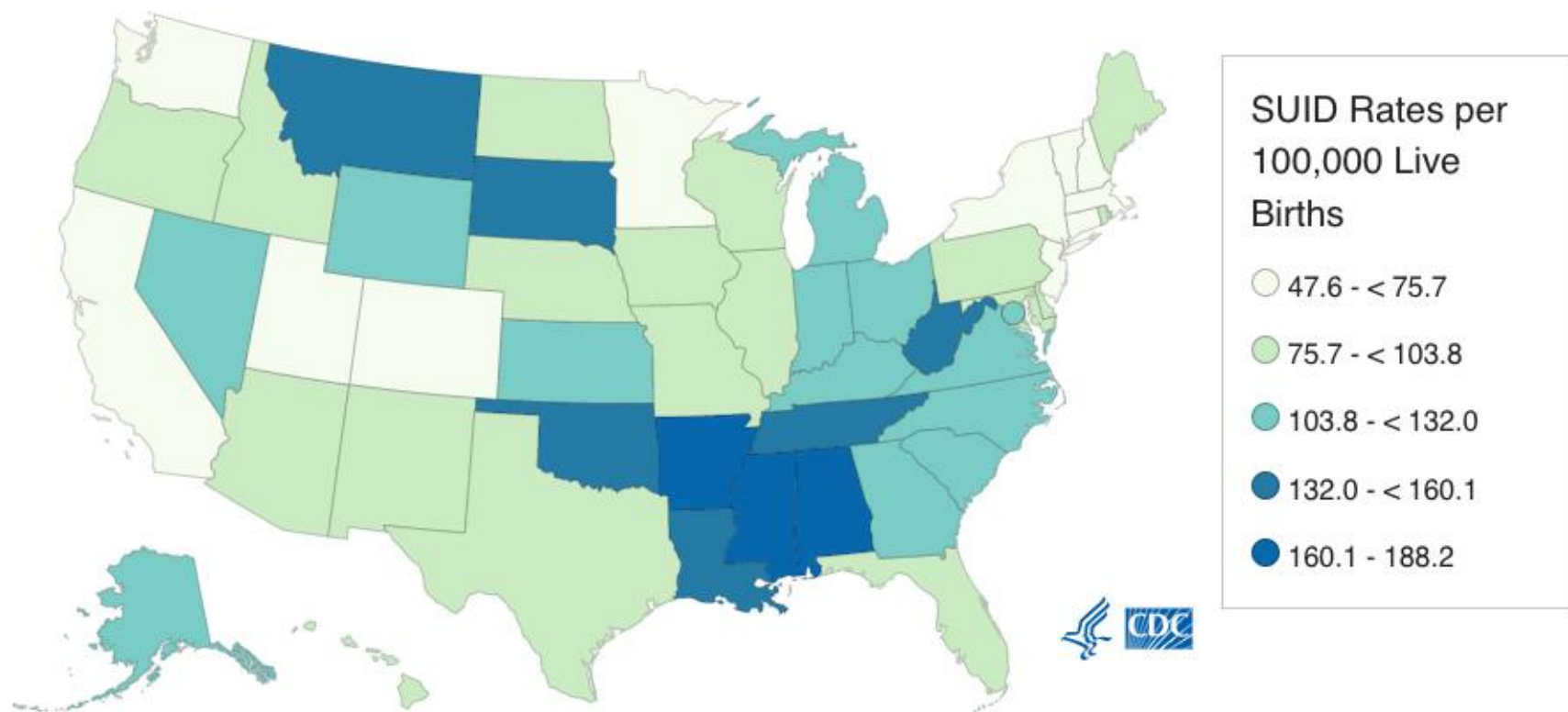


Percentage	
Sudden infant death syndrome	41%
Unknown cause	32%
Accidental suffocation and strangulation in bed	27%

The US has a high SIDS rate



SUID Rates by State, 2016–2020

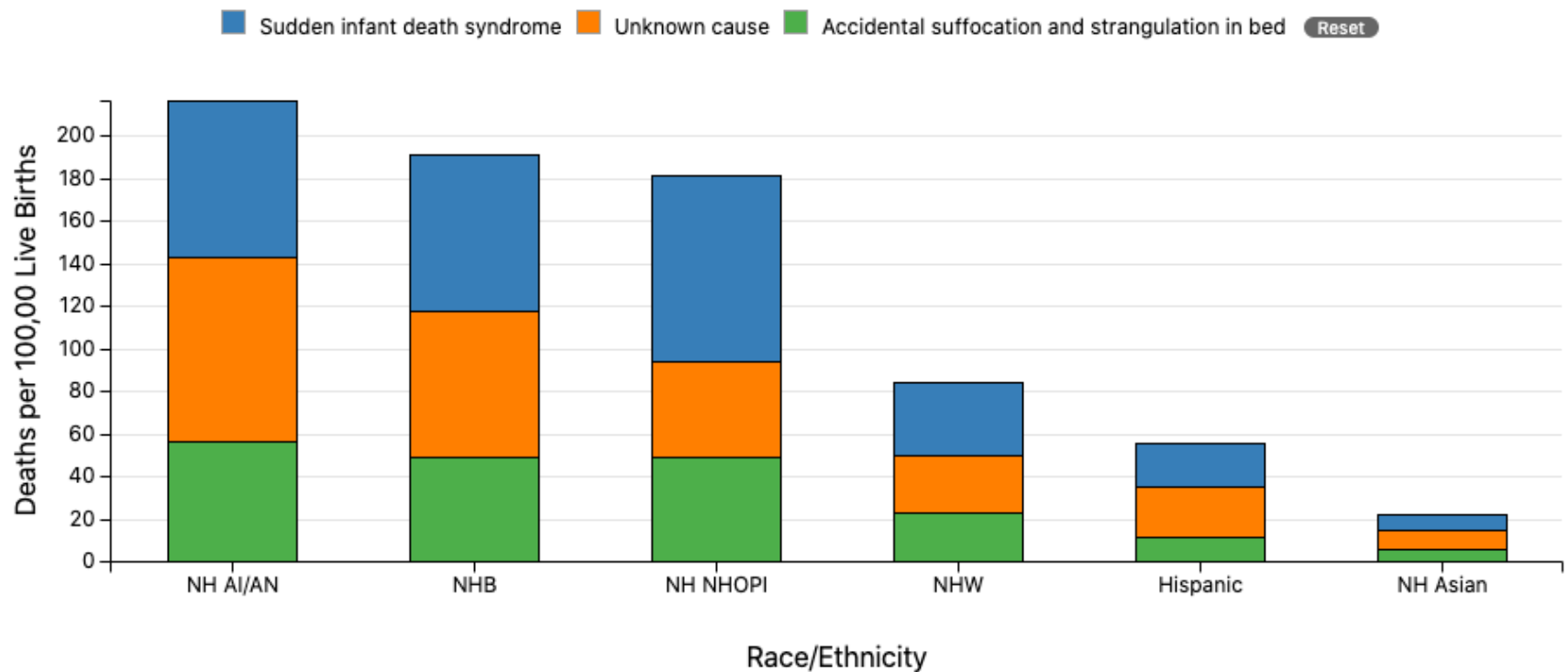


Data Table



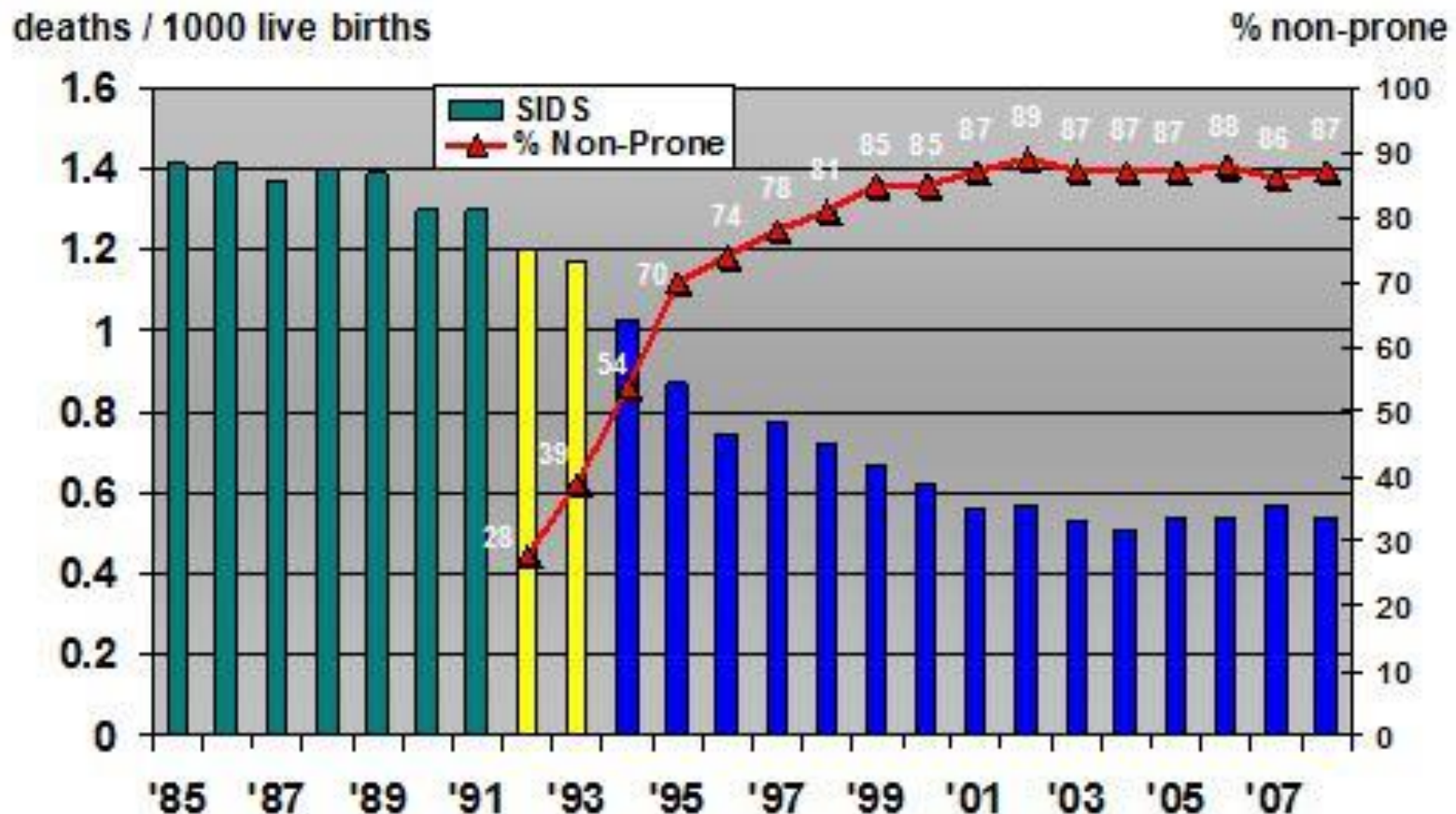
Children of Color have much higher risks

Sudden Unexpected Infant Death by Race/Ethnicity, 2015–2019



NH AI/AN = Non-Hispanic American Indian/Alaska Native; NHB = Non-Hispanic Black; NH NHOPi = Non-Hispanic Native Hawaiian/Other Pacific Islander; NHW = Non-Hispanic White; NH Asian = Non-Hispanic Asian

SIDS Rate and Sleep Position U.S. Infants 1985 - 2008



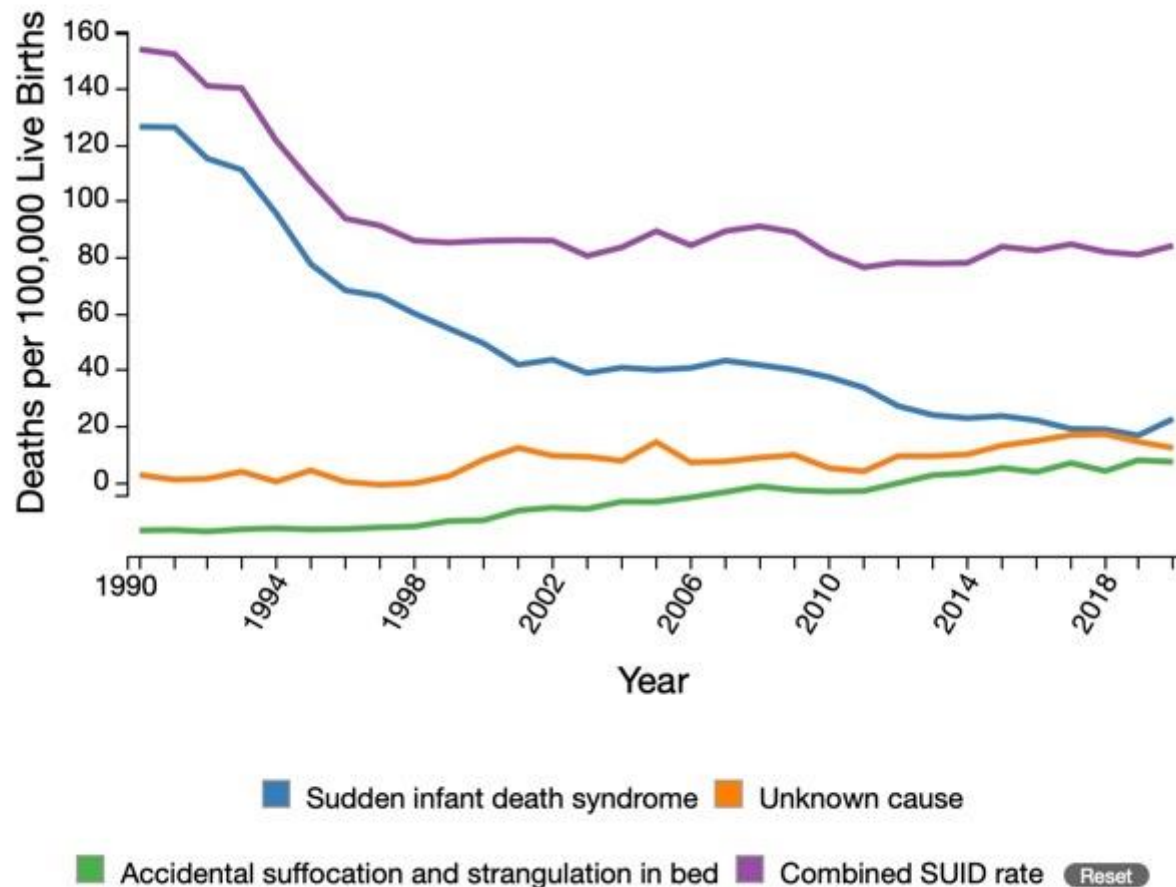
Sleep Position Source: NICHD
NISP Household Survey
SIDS Rate Source: National
Center for Health Statistics, CDC
Updated 05/08/2011

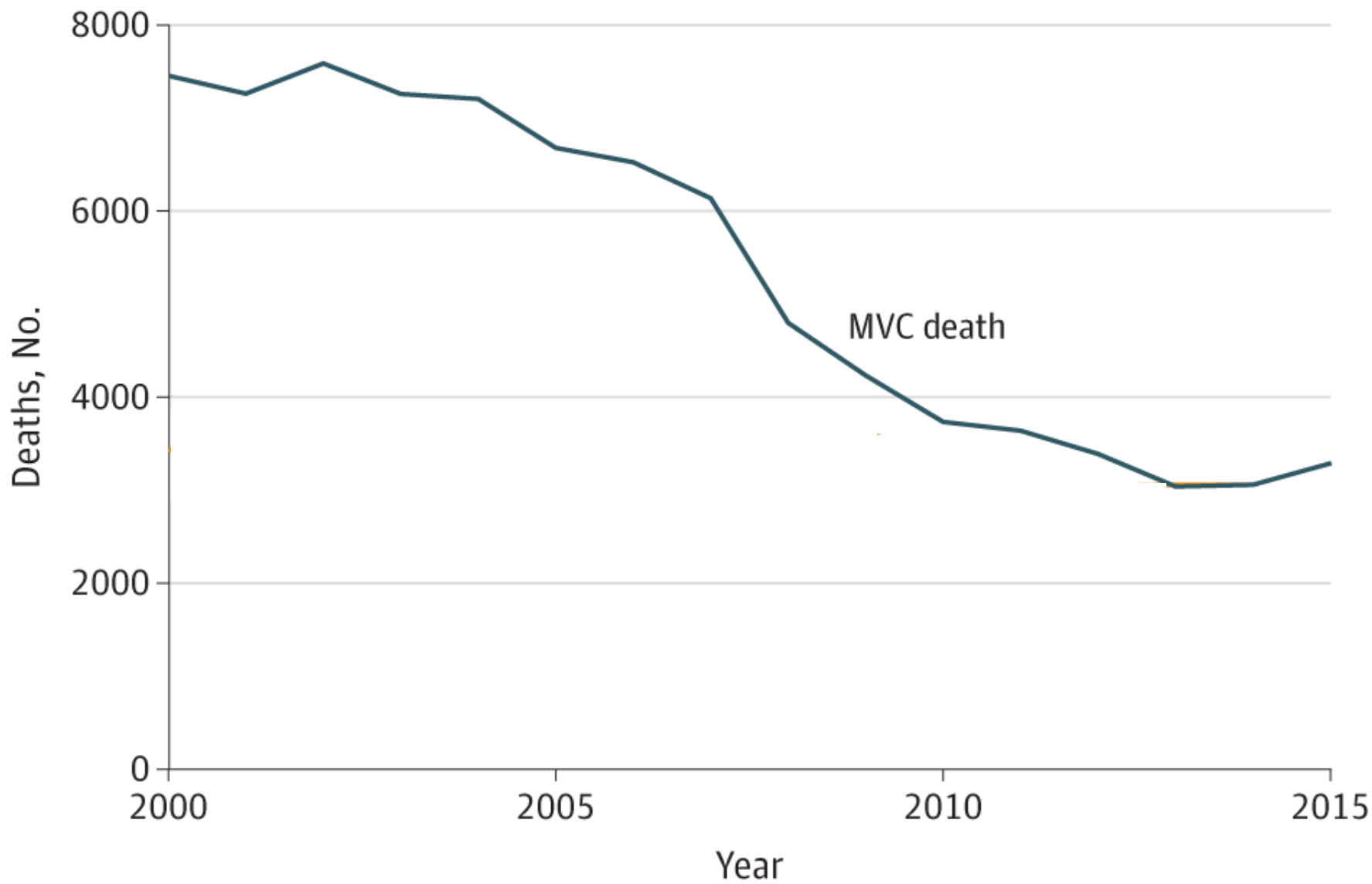
• AAP SIDS Statement 1992

• Back to Sleep Campaign 1994

SIDS has decreased significantly

Trends in Sudden Unexpected Infant Death by Cause, 1990–2020



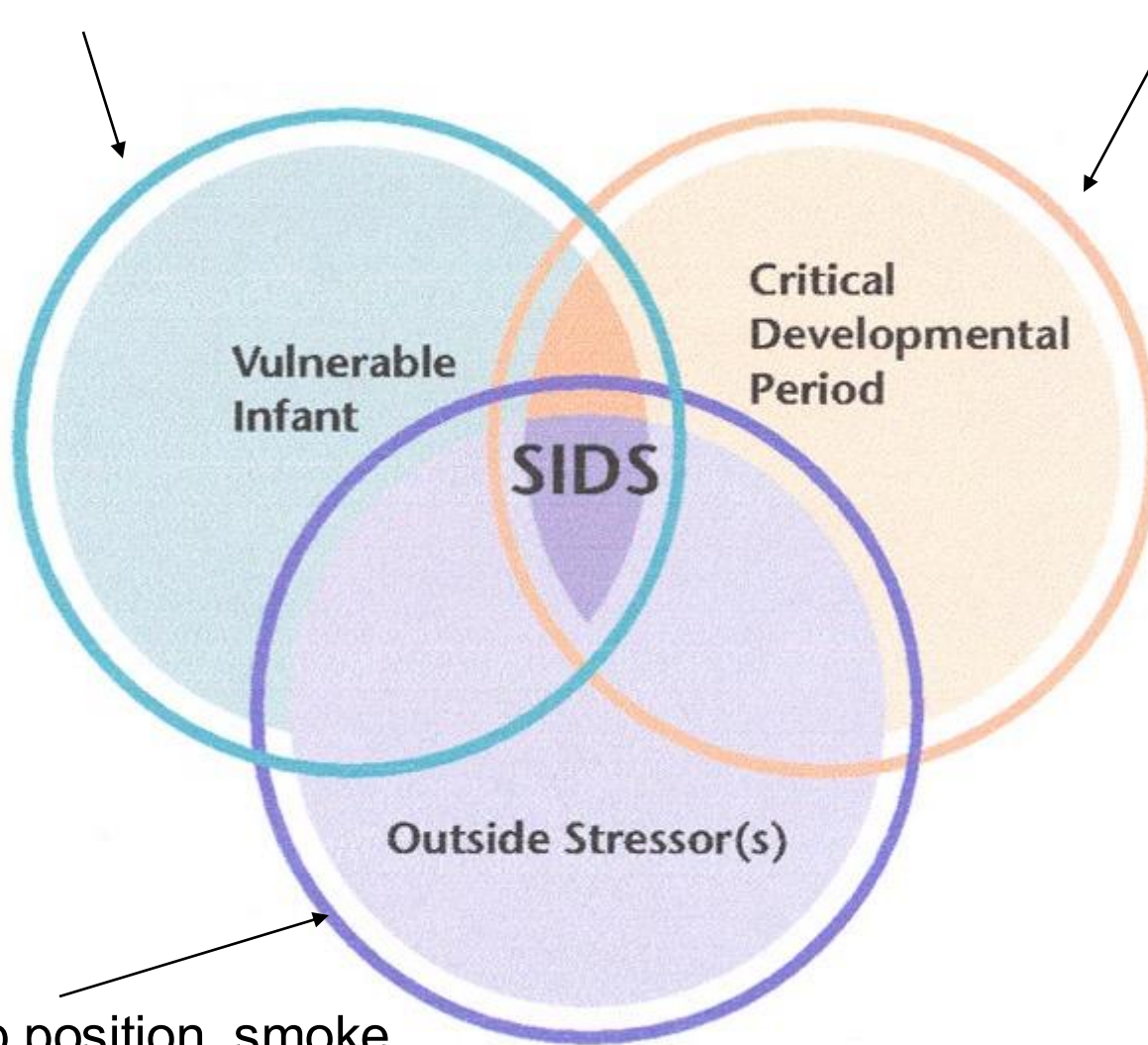


Why is sleep a
risk for infants?



AROUSAL DEFECT:

Highest risk at 1-4 months



Prone sleep position, smoke exposure, soft bedding

Triple Risk Model

Arousability

The background of the slide features a dark blue silhouette of a human head in profile, facing right. Inside the head, a complex, glowing blue neural network is depicted, with numerous bright blue nodes connected by thin, light blue lines. The overall aesthetic is high-tech and scientific, with a color palette dominated by various shades of blue.

- **Abnormalities in autonomic control in the brainstem**
 - **Decreased neurotransmitter (serotonin) binding**
 - Serotonin transporter protein gene polymorphisms
 - **Network dysfunction**
 - **Dysfunctional response to hypercarbia or hypoxia**



A black and white photograph of a baby lying down, crying with its mouth wide open. The baby is wearing a light-colored long-sleeved shirt and a striped bib. A large green arrow points upwards from the bottom left, and a large blue arrow points downwards from the top right. The background is blurred, showing what appears to be a person's hand and part of a face.

Arousability

Asphyxiating Environments

POLICY STATEMENT Organizational Principles to Guide and Define the Child Health
Care System and/or Improve the Health of all Children

American Academy
of Pediatrics



DEDICATED TO THE HEALTH OF ALL CHILDREN™

Sleep-Related Infant Deaths: Updated 2022 Recommendations for Reducing Infant Deaths in the Sleep Environment

Rachel Y. Moon, MD, FAAP,^a Rebecca F. Carlin, MD, FAAP,^b Ivan Hand, MD, FAAP,^c
THE TASK FORCE ON SUDDEN INFANT DEATH SYNDROME AND THE COMMITTEE ON FETUS AND NEWBORN





**Place Baby
on Back for
Naps and
at Night**



Always place baby on
his or her **back to sleep**,
for naps and at night

Choose an approved Crib, Bassinette or
Pack-N-play

**Place Baby
on a Firm
Sleep
Surface**



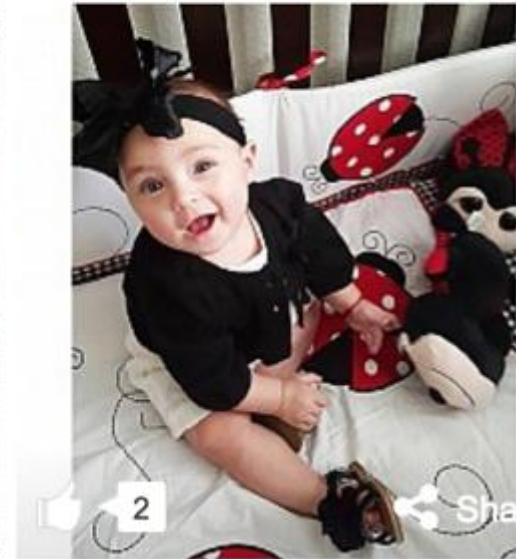
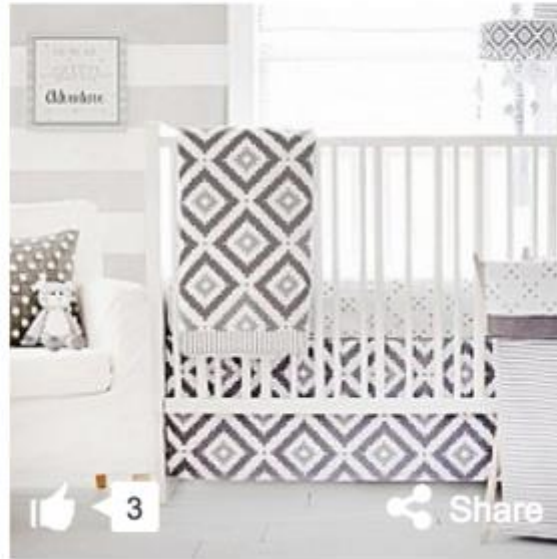
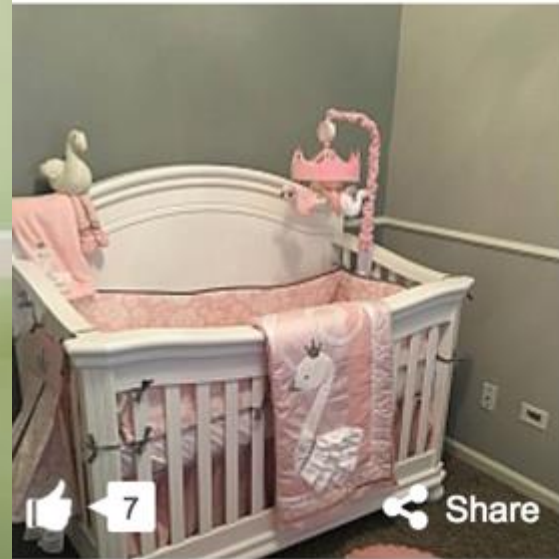


Use a **firm, flat non-inclined sleep surface**, such as a mattress in a safety-approved crib (covered by a fitted sheet) or a bassinet



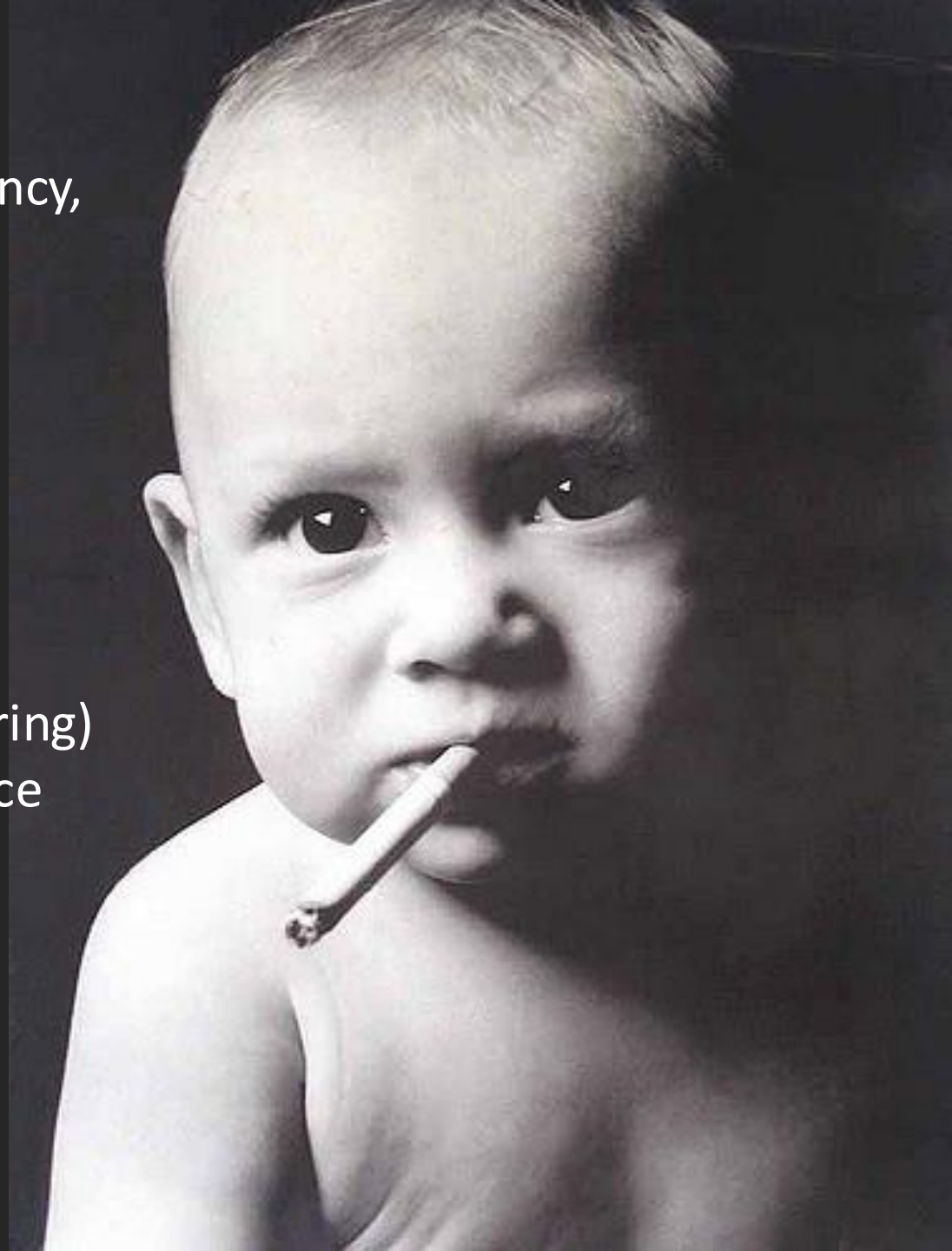
We do not know a safe way for a baby to sleep in bed with a parent!

share your photos [#buybuybaby](#)



Keep soft objects, toys, crib bumpers, loose bedding, pillows, blankets, quilts, sheepskins out of the baby's sleep area

- **Do not smoke** during pregnancy, and do not smoke or allow smoking around your baby
- **Breastfeeding** your baby to reduce the risk of SIDS
- Consider giving your baby a **pacifier** (not attached to a string) for naps and at night to reduce the risk of SIDS



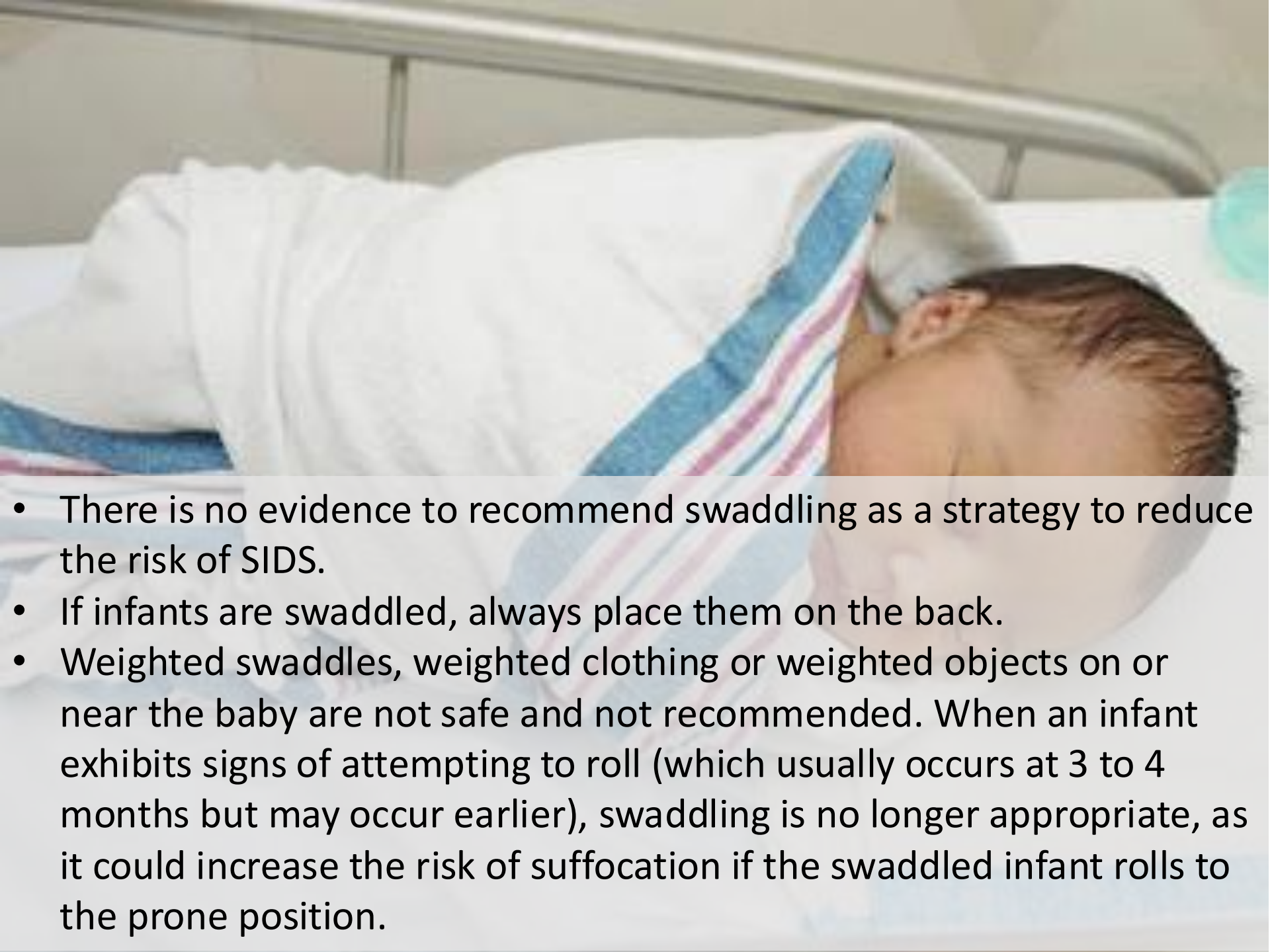


Babies have to be
swaddled!





Swaddling, or wrapping the infant in a light blanket, is often used as a strategy to calm the infant and encourage the use of the supine position. There is a high risk of death if a swaddled infant is placed in or rolls to the prone position.



- There is no evidence to recommend swaddling as a strategy to reduce the risk of SIDS.
- If infants are swaddled, always place them on the back.
- Weighted swaddles, weighted clothing or weighted objects on or near the baby are not safe and not recommended. When an infant exhibits signs of attempting to roll (which usually occurs at 3 to 4 months but may occur earlier), swaddling is no longer appropriate, as it could increase the risk of suffocation if the swaddled infant rolls to the prone position.



VIDEO SHOP **WELLNESS** FOOD CULTURE FAMILY LIVING STYLE ...



NEWSLETTER

Digital Deals on fall fun: 50% off YUMMIE apparel, PURPOSE jewelry and more

WELLNESS — June 21, 2022

New infant sleep guidelines advise against hats and weighted swaddles, blankets





Hands Free Swaddling

Swaddle your baby “HANDS FREE” in one lightweight blanket for their first two months of life.

Babies start to move more around 2 months. If their movement loosens the swaddle then the blanket can be a ***suffocation hazard***.





When you find her
like this, won't you
sleep better knowing
she can BREATHE
FREELY through her
mattress?



Breathable Mattresses make all the difference!



It is safe to bedshare with the right equipment



Ideal for Co-Sleeping/Bed Sharing

With rounded sides, the DockATot helps create a barrier between baby and parents to give your child their own cozy space. When used in an adult bed properly, DockATot offers a better way to co-sleep.



Kourtney Kardashian

"There are a lot of tips that I strongly recommend for co-sleeping safely if you are going to try it. I also recently discovered DockATot™. I have been loving it...Amazing for sleeping in different beds, traveling, etc."



Scott & Marika Foley

"We've found nothing that works better for helping our kids (and us!) get a better nights sleep than the DockATot™. It's portable, washable and we've recommended it to all of our friends with newborns. It's so simple but it truly saved us. This was our first time using the Grand DockATot™. It's a perfect nap spot for our 3 year old son, even his five year old sister loves lounging in it."



Sara Foster

"Omg, this is the greatest product ever! My daughter is 6 days old and this is all I have had her in! I would like to order more for gifts for friends. I love this product so much."



Jeniffer Love Hewitt

"These are awesome loungers for my little ones! They love them and that makes me so happy."



Erika M.

10/23/2019



Being a mom of two has been an adjustment for me, but the dockatot has made it so much easier for me! If my little guy isn't swaddled you he won't sleep unless it's in his dockatot. Life saver! Not to mention, it's ADORABLE!



Spare Cover (Deluxe+) -
Natural Buffalo



Audeena S.

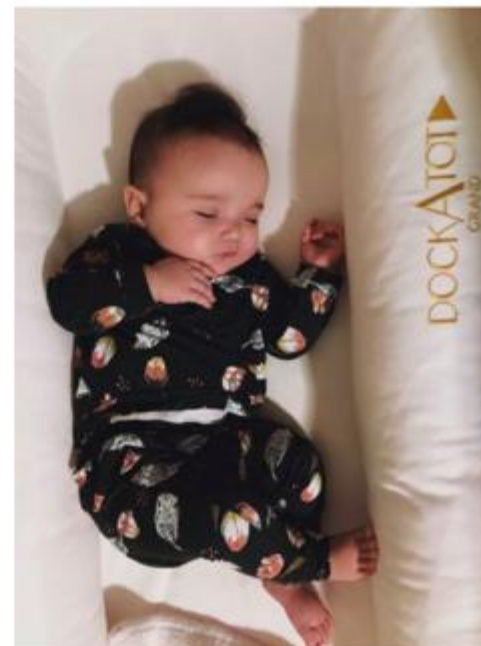
10/21/2019



We love our dock a tot. I wish I would have bought it before I wasted my money on other bassinets and co sleeper options. The only thing I would change is that I expected to get use to around 8 months. My son is 4 months and has outgrown it. Some people offerin the the



Deluxe+ Dock - Pristine
White



Isabel S.

10/16/2019



We love our DockATot! My baby was constantly moving around in her crib, and rolling over so we decided to try the grand, since she loved the DockATot as a baby. It works great she is able to sleep all night. I'm so glad I don't have to worry about her rolling around in her crib now!

More Infant Sleep Products Linked to Deaths, a Consumer Reports Investigation Finds

Government data reveals fatalities associated with in-bed sleepers such as the DockATot and Snuggly Nest

By Rachel Rabkin Peachman
October 21, 2019



In-bed sleepers, including those shown above, have been associated with at least 12 deaths.

Several infant in-bed sleepers meant for bed-sharing with an adult caregiver are linked to at least 12 deaths that occurred between 2012 and 2018, according to a Consumer Reports investigation. The findings are based in part on incident data that CR received from the Consumer Product Safety Commission, which inadvertently disclosed information about the specific products involved in the incidents.

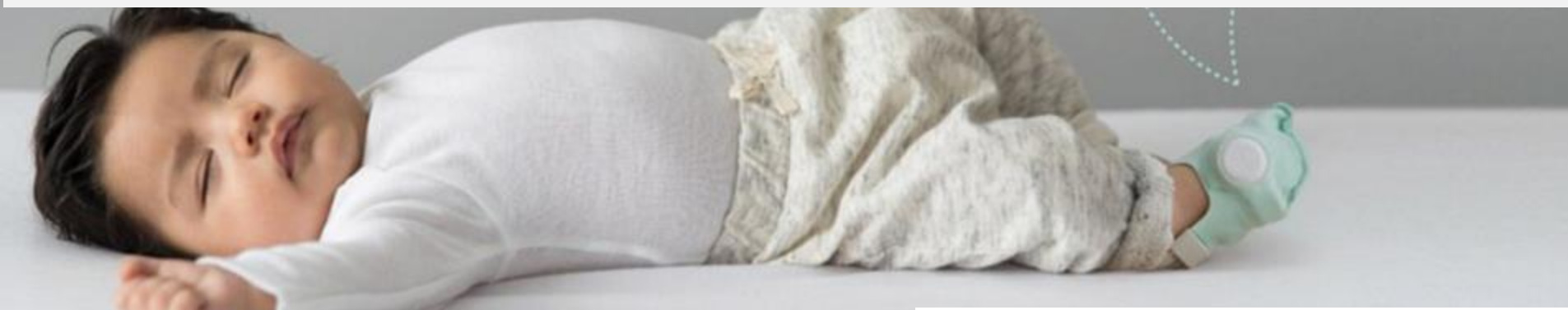
“We know that many parents choose to share a bed with a child, for instance, perhaps to help with breastfeeding or because of a cultural preference or a belief that it is safe.

The evidence is clear that this significantly raises the risk of a baby’s injury or death, however, and for that reason AAP cannot support bed-sharing under any circumstances.”



Huge news at Owlet!

As one of the pioneers for in-home monitoring of infants we felt a big responsibility to provide superior technology and peace of mind for parents. Nearly two years later, we are proud to continue pioneering by being the first in-home health monitor to share its unique data collected from nearly 50,000 newborns. **Our observations have been published in *Global Pediatric Health*, a peer-reviewed medical journal!**



Baby monitors p

Owlet® Dream Duo 2

Smart Baby Monitoring With Personalized
Sleep Support

★★★★★ 4.2 (51)

\$399 *Or \$33.25/month with 

WORLD'S MOST AWARDED BABY BED

snoo
smart sleeper

SNOO Smart Bassinet Sleeper

WE'VE GOT SLEEP...DOWN TO A SCIENCE!™

Karp earnestly compares the \$1,200 bassinet to the advent of penicillin — “I’m not here to promote a product, but I am saying if someone developed penicillin, wouldn’t it be important to tell people about it?” — and insists that it can save lives by stopping babies from rolling into an unsafe position in their sleep. Raising the money for SNOO, Karp drew on his celebrity appeal: Justin Timberlake and Jessica Biel are investors, as are Scarlett Johansson, Gwyneth Paltrow and Zoe Saldana. (Or, as Montée put it, “We have Justin and Jessica and Gwyneth and Scarlett and Zoe.”)



The Snoo is a smart baby bassinet that gently rocks and plays white noise to calm fussy newborns—and, theoretically, gives parents some of their nighttime sleep back.

Photo: John Walsh/Consumer Reports

Update, April 4, 2023: In March 2023, the Food and Drug Administration granted the Snoo “De Novo” approval. De Novo classification means that a novel product is considered a medical device for a particular use: In this case, the Snoo has been approved as a Class II medical device that has been evaluated to safely keep the baby secure on their back while in the Snoo.

Infants who sleep on their back are less likely to die of SIDS (Sudden Infant Death Syndrome) than those who sleep on their side or stomach. However, while the Snoo has been deemed a novel medical device that keeps babies on their back, it has not been approved as a product that prevents SIDS, and the Snoo cannot market itself explicitly as such. The FDA has verified, however, that the Snoo does not increase the likelihood of SIDS/SUID (Sudden Unexpected Infant Death).

According to the FDA, there are no infant sleep systems or positioners that are allowed to market themselves as preventing or reducing the chances of SIDS or SUID.

Elevating the head of the infant's crib is ineffective in reducing gastroesophageal reflux and is not recommended



Sleeping upright reduces GE reflux

Pediatric Gastroesophageal Reflux Clinical Practice Guidelines:
Joint Recommendations of the North American Society for
Pediatric Gastroenterology, Hepatology, and Nutrition
(NASPGHAN) and the European Society for Pediatric
Gastroenterology, Hepatology, and Nutrition (ESPGHAN)

Co-Chairs: *Yvan Vandenplas and †Colin D. Rudolph
Committee Members: ‡Carlo Di Lorenzo, §Eric Hassall, ||Gregory Liptak,
¶Lynette Mazur, #Judith Sondheimer, **Annamaria Staiano, ††Michael Thomson,
‡‡Gigi Veereman-Wauters, and §§Tobias G. Wenzl

**UZ Brussel Kinderen, Brussels, Belgium, †Division of Pediatric Gastroenterology, Hepatology, and Nutrition,
Children's Hospital of Wisconsin, Medical College of Wisconsin, Milwaukee, WI, USA, ‡Division of Pediatric Gastroenterology,
Nationwide Children's Hospital, The Ohio State University, Columbus, OH, USA, §Division of Gastroenterology,
Department of Pediatrics, British Columbia Children's Hospital/University of British Columbia, Vancouver, BC, Canada,
||Department of Pediatrics, Upstate Medical University, Syracuse, NY, USA, ¶Department of Pediatrics, University of Texas Health
Sciences Center Houston and Shriners Hospital for Children, Houston, TX, USA, #Department of Pediatrics, University of Colorado
Health Sciences Center, Denver, CO, USA, **Department of Pediatrics, University of Naples "Federico II," Naples, Italy,
††Centre for Pediatric Gastroenterology, Sheffield Children's Hospital, Western Bank, Sheffield, UK,
‡‡Pediatric Gastroenterology & Nutrition, Queen Paola Children's Hospital-ZNA, Antwerp, Belgium, and
§§Klinik für Kinder- und Jugendmedizin, Universitätsklinikum der RWTH Aachen, Aachen, Germany*

Nordic Epidemiological SIDS Study demonstrated that the odds ratio of mortality from SIDS was more than 10 times higher in prone-sleeping infants and 3 times higher in side-sleeping infants than in supine-sleeping infants

The amount of reflux in supine infants with head elevated is equal to or greater than in infants supine and flat (232,234,238,239). The semisupine positioning as attained in an infant car seat exacerbates GER



Sleeping in a car seat, swing or other sitting/carrying device is fine.

2/3 of Deaths Associated with Sitting/Carrying Devices in Car Seats



Do-Re-Moo-Quack

Laugh & Learn™ Silly Sounds Light-Up Piano >

Bring the best gift to
baby's 1st birthday bash!



Want help choosing good toys
for this age & stage?

[VISIT OUR PLAYTIME GUIDE](#)

The best possible start

With a lot of love and thought, we design toys to reveal all the fun, interesting and wonderful things that kids are into. For more than 80 years, it's been our mission to help families give their kids the best possible start in life, and we take that mission really seriously. Let's keep celebrating what makes every kid unique, and nurture what's in their nature.

[READ OUR STORY >](#)







1

"Best thing that ever happened to infant sleeping! The Fisher Price Rock 'n Play Sleeper was a life saver."

Consumer review
on [fisher-price.com](https://www.fisher-price.com)

**What other
moms say ...**

"Comfortable, easy to take places, and the only way I can shower in the morning."

Consumer review
on [fisher-price.com](https://www.fisher-price.com)

From: Pilarz, Kitty <[REDACTED]@[REDACTED].com>
Sent: Monday, February 09, 2009 11:23 AM
To: Chapman, Linda; Steinwachs, Mike; Taton, Justin; Miller, Jerry
Cc: Pilarz, Kitty
Subject: Hammock

I talked to Dr. Gary Deegear again today to follow up on the question that came up during our preliminary in home - is there any issue having a baby sleep all night every night at this angle, does it cause spine problems etc.?

Dr. Deegear stated pediatricians recommend babies with reflux sleep at 30 degrees, this is just fine, or sleep in a car seat overnight for months or even a year. The Back to sleep campaign places children on their backs, and elevated positions of the head is fine. He is Not aware of research on this. He will do a quick search. I explained that we are also researching this issue.

I also have a call in to a local group of pedestrians to see if they are willing to offer an opinion.

Kitty Pilarz
Director, Mattel Worldwide Product Safety
Fisher-Price

[REDACTED]

[REDACTED]

[REDACTED]



4.7 Million





CPSC Consumer Alert: Caregivers Urged To Use Restraints With Inclined Sleep Products



Release date: May 31, 2018

Release number: 18-171

Release Details

1 of 1 photos



WASHINGTON, D.C. – The U.S. Consumer Product Safety Commission (CPSC) is reminding parents: Always create a safe sleep environment for babies in a crib, bassinet, play yard or inclined sleeper.

In particular, CPSC is alerting consumers to be aware of hazards when infants are not restrained in inclined sleep products.

Inclined sleep products are bassinet-like products with an inclined back to elevate the baby's head and torso. There are many different styles of infant inclined sleep products available for infants and newborns. These can include frame-type, semi-rigid and compact inclined sleep products.

CPSC is aware of infant deaths associated with inclined sleep products. Babies have died after rolling over in these sleep products.

CPSC, therefore, urges consumers: Always use restraints and stop using these products as soon as an infant can roll over.

CPSC ALERT: CPSC and Fisher-Price Warn Consumers About Fisher-Price Rock 'N Play Due to Reports of Death When Infants Roll Over in the Product



Release date: April 5, 2019

Release number: 19-101

Release Details

1 of 1 photos



All models of Fisher Price Rock 'N Play



UPDATE: Fisher-Price Rock 'N Play Sleeper Recalled Due to Reports of Infant Deaths

WASHINGTON, D.C. -- The Consumer Product Safety Commission (CPSC) and Fisher-Price warn consumers about the Fisher-Price Rock 'n Play due to reports of death when infants roll over in the product. According to medical literature, infants typically begin rollover behaviors at 3 months. The CPSC is aware of 10 infant deaths in the Rock 'n Play that have occurred since 2015, after the infants rolled from their back to their stomach or side, while unrestrained. All 10 infants were 3 months or older.

Consumer Reports: Fisher-Price Must Recall the Rock 'n Play Sleeper Immediately

Investigation finds product tied to at least 32 deaths; CR calls for much stronger action by industry, government to ensure safe sleep by infants on a firm, flat surface—not at an incline

Filed under: Policy & Mobilization

Release date 04/08/2019



WASHINGTON, D.C.—Consumer Reports today published the results of an investigation into the safety of the Fisher-Price Rock 'n Play Sleeper—a product designed and marketed for babies to sleep on an incline—and found it is tied to at least 32 infant deaths. The Consumer Product Safety Commission and Fisher-Price issued a warning about the product on April 5, several days after CR asked for comment. In light of its findings, CR said this alert does not do nearly enough to minimize the risk of suffocation by infants, and called for far stronger action.

Media Contacts

David Butler
(202) 462-6262
dbutler@consumer.org

AAP Urges U.S. Consumer Product Safety Commission to Recall Fisher-Price Rock 'n Play Sleeper

4/9/2019

The American Academy of Pediatrics (AAP) calls on the U.S. Consumer Product Safety Commission (CPSC) to issue an immediate recall for the Fisher-Price Rock 'n Play Sleeper, which has been tied to 32 sleep-related infant deaths, according to a new analysis by Consumer Reports.

AAP urges parents to stop using the product immediately. Stores should remove the Rock 'n Play Sleeper from their shelves. A warning issued by the CPSC and Fisher-Price on April 5 did not go far enough to ensure safety and protect infants, according to the AAP.

"This product is deadly and should be recalled immediately," said Kyle Yasuda, MD, FAAP, president of the American Academy of Pediatrics. "When parents purchase a product for their baby or child, many assume that if it's being sold in a store, it must be safe to use. Tragically, that is not the case. There is convincing evidence that the Rock 'n Play inclined sleeper puts infants' lives at risk, and CPSC must step up and take immediate action to remove it from stores and prevent further tragedies."

Last week, the CPSC and manufacturer alerted consumers to stop using the product when the infant reaches 3 months of age or is capable of rolling over, citing 10 infant deaths that occurred in the Rock 'n Play. The Consumer Reports article, published April 8, tied a total of 32 deaths to the Rock 'n Play, including the 10 noted in last week's warning.

Consumer Reports concluded that these 32 deaths, between 2011 and 2018, included babies even younger than the 3-month threshold cited in the initial warning, which is alarming. The cause of death listed for some babies was asphyxia, or the inability to breathe caused by the babies' position. AAP urges parents of children of all ages to immediately stop using the Rock 'n Play.

Shop > Everything Baby > Baby Gear > Sleepers

Sleepers

CATEGORY

< Baby Gear

Bassinets (11)

Sleepers (30)

Baby Bouncers, Rockers & Soothers (49)

Baby Swings (31)

Baby Floor Seats (20)

High Chairs & Booster Seats (37)

Jumperoos & Baby Entertainers (20)

Play Yards & Playpens (7)

Baby Bathtubs & Bath Seats (15)

Potty Chairs & Toilet Seats (13)

Diaper Bags (2)

Nursery Furniture (16)

BRAND

☐ Everything Baby (3)

RATING

☐ ★★★★★ & Up

☐ ★★★★★ & Up

☐ ★★★★★ & Up

☐ ★★★★★ & Up

PRICE

☐ Between \$50 and \$74.99 (11)

☐ Between \$75 and \$99.99 (14)

☐ Between \$100 and \$149.99 (5)

AGE

☐ Baby-on-the-way (17)

☐ Birth - 6 months (22)

☐ 6-12 months (17)

☐ 12-18 months (3)

Related Searches

green portable bassinets

rock n play sleeper

Results 1 - 30 of 30

Sort by Recommended



Premium Auto Rock 'n Play Sleeper with...

RECALL NOTICE



Auto Rock 'n Play™ Sleeper

RECALL NOTICE



Newborn Rock ' Play™ Sleeper - Luminosity

RECALL NOTICE



Safari Dreams Deluxe Newborn Auto Rock 'n...

RECALL NOTICE



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RECALL NOTICE



My Little Snugabunny™ Deluxe Newborn Rock...

RECALL NOTICE



Deluxe Rock 'n Play™ Sleeper

RECALL NOTICE



Newborn Rock ' Play™ Sleeper - Surreal...

RECALL NOTICE



Moonlight Meadow Deluxe Newborn Rock '...

RECALL NOTICE



Newborn Rock 'n Play™ Sleeper - Geo Meadow™

RECALL NOTICE



Premium Auto Rock 'n Play™ Sleeper with...

RECALL NOTICE



Newborn Rock 'n Play™ Sleeper - Pink Ellipse™

RECALL NOTICE



Biomechanical Analysis of Inclined Sleep Products – FINAL Report 09.18.2019

Consumer Product Safety Commission Solicitation Number: [REDACTED]

Principal Investigator: Erin M. Mannen, Ph.D., *Biomechanics Researcher*
Assistant Professor of Orthopaedic Surgery
Director of Translational Orthopaedic Research
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Arkansas Children's Hospital

David B. Bumpass, M.D., *Pediatric Spine Surgeon*
Assistant Professor of Orthopaedic Surgery
University of Arkansas for Medical Sciences
Arkansas Children's Hospital

Brien Rabenhorst, M.D., *Pediatric Orthopaedic Surgeon*
Associate Professor of Orthopaedic Surgery
University of Arkansas for Medical Sciences
Arkansas Children's Hospital

Brandi Whitaker, Ph.D., *Pediatric Psychologist*
Associate Professor of Pediatric Psychology
University of Arkansas for Medical Sciences
Arkansas Children's Hospital

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Postdoctoral Research Fellow
Department of Orthopaedic Surgery
University of Arkansas for Medical Sciences

Safeer F. Siddicky, Ph.D., *Biomechanics Researcher*
Postdoctoral Research Fellow
Department of Orthopaedic Surgery
University of Arkansas for Medical Sciences

Project Time Period:

September 2018 to September 2019



Based on the results of the biomechanical testing, product analysis, and incident report analysis, **none of the Inclined Sleep Products that were tested and evaluated as a part of this study are safe for infant sleep.**

While there were differences in the product designs and the biomechanical results of infants within the products, no product that was examined in this study was found to be safe for infant sleep. **All products in the class of Inclined Sleep Products that were tested and evaluated in this study are unsafe for infants.** If this product class remains, ASTM F3118-17a should be rewritten and implemented as a mandatory standard to mitigate hazards posed by and prevent future incidents with Inclined Sleep Products.

6. ASTM RECOMMENDATIONS

With the findings of the biomechanical study, the product analysis, and the incident report analysis, the team reviewed, analyzed, and interpreted the safety and design of specific Inclined Sleep Products. The project team examined other Inclined Sleep Products per the CPSC's requests to determine whether the design specifications in ASTM F3118-17a are appropriate to prevent accidental deaths. **The team believes that no inclined sleep products that were examined as a part of this study are currently safe for infant sleep. The product category should be completely eliminated, or the ASTM standard significantly modified to ensure a safe environment and mitigate risk.**

Recommendation: An incline angle of 10-degrees is likely safe for an infant Inclined Sleep Product, and an incline of 20-degrees or greater is not safe. In order to determine if angles between 10- and 20-degrees are safe, additional biomechanical testing is required.

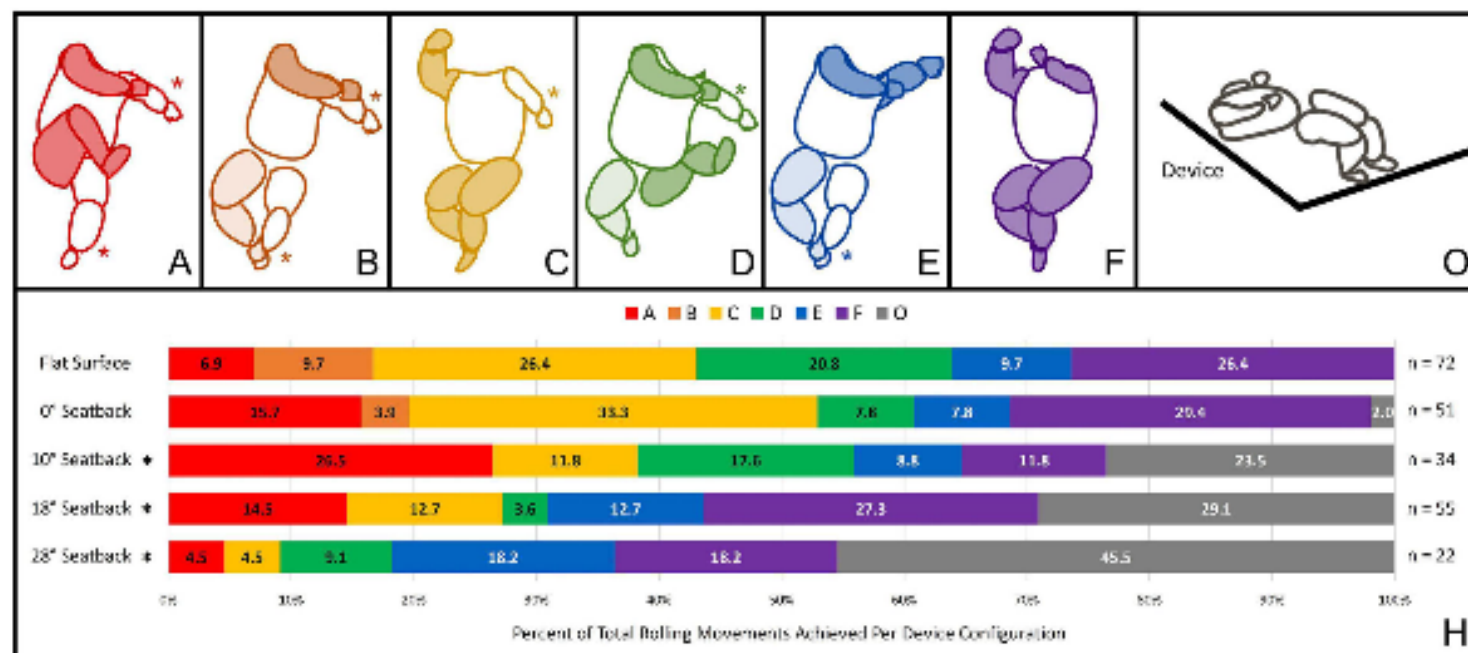


FIGURE 8:

(A-F) Rolling illustrations of the six previously defined coordinated movements.

Illustrations adapted from Kobayashi et al. (2016) with permission. Rolling occurs to the infant's left. The darker limbs initiate the roll, the lighter limbs follow, and limbs marked with an asterisk (*) are stationary. (O) Depiction of the new coordinated movement type only occurring in the different device configurations. (H) Percent of each coordinated movement achieved for each device configuration. Conditions marked with an asterisk (*) were found to have significantly different proportions of coordinated movement chosen when compared to the flat surface ($p < 0.001$).

Public Law 117–126
117th Congress

An Act

May 16, 2022
[H.R. 3182]

To provide that inclined sleepers for infants and crib bumpers shall be considered banned hazardous products under section 8 of the Consumer Product Safety Act, and for other purposes.

Safe Sleep for
Babies Act of
2021.
15 USC 2051
note.

*Be it enacted by the Senate and House of Representatives of
the United States of America in Congress assembled,*

SECTION 1. SHORT TITLE.

This Act may be cited as the “Safe Sleep for Babies Act of
2021”.

15 USC 2057d.
Deadline.

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(a) **IN GENERAL.**—Not later than 180 days after the date of enactment of this Act, inclined sleepers for infants, regardless of the date of manufacture, shall be considered a banned hazardous product under section 8 of the Consumer Product Safety Act (15 U.S.C. 2057).

(b) **INCLINED SLEEPER FOR INFANTS DEFINED.**—In this section, the term “inclined sleeper for infants” means a product with an inclined sleep surface greater than ten degrees that is intended, marketed, or designed to provide sleeping accommodations for an infant up to 1 year old.

15 USC 2057e.
Deadline.

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(b) **CRIB BUMPER DEFINED.**—In this section, the term “crib bumper”—

(1) means any material that is intended to cover the sides of a crib to prevent injury to any crib occupant from impacts against the side of a crib or to prevent partial or complete access to any openings in the sides of a crib to prevent a crib occupant from getting any part of the body entrapped in any opening;

(2) includes a padded crib bumper, a supported and unsupported vinyl bumper guard, and vertical crib slat covers; and

(3) does not include a non-padded mesh crib liner.



UNITED STATES
CONSUMER PRODUCT SAFETY COMMISSION
4330 EAST WEST HIGHWAY
BETHESDA, MD 20814

**JOINT STATEMENT OF CHAIR HOEHN-SARIC AND COMMISSIONERS
TRUMKA AND BOYLE: CPSC REJECTS ATTEMPT TO WEAKEN BASSINET
STANDARD AND INFANT SLEEP RULE**

SEPTEMBER 27, 2022

On Friday, September 23rd, the Commission voted unanimously to protect sleeping babies. We rejected the ASTM revision to a voluntary standard that would have made bassinets less safe and would have allowed firms to end-run the landmark Infant Sleep Products Rule (ISP Rule). With today's vote, we reaffirm our commitment to protecting the most vulnerable among us by

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we cannot allow our safety standards—especially for infants—to be diluted in this way. We must—and we will—reject any attempt to do so.

Our vote today is a victory for consumers and for infant safety.

September is Baby Safety Month and CPSC will continue to reiterate that infants should only sleep on a firm, flat surface, like a crib. A strong bassinet standard and ISP Rule will help to make every day a safe day for babies. We cannot allow otherwise.

Fisher-Price Reannounces Recall of 4.7 Million Rock 'n Play Sleepers; At Least Eight Deaths Occurred After Recall

Share: [f](#) [t](#) [g](#) [p](#) [+](#)



Name of Product:

All models of Rock 'n Play Sleepers

Hazard:

Infant fatalities have occurred in the Rock 'n Play Sleepers, after the infants rolled from their back to their stomach or side while unrestrained, or under other circumstances.

Remedy:

Refund

Recall Date:

January 09, 2023

Units:

About 4.7 million (The original [recall](#) was announced on April 12, 2019.)



The risk of sleep-related death in an inclined sleep environment

Laura R. Sangaré^{1,2*}, Lance Kaufman³, Robert A. Bardwell^{3,4}, Deborah Nichols⁵ and Mersine Bryan^{2,6}

Abstract

Background Unsafe sleep environments are the primary modifiable risk factor for sudden unexpected infant death (SUID). Despite this knowledge, products that deviate from the American Academy of Pediatrics (AAP) safe sleep recommendations continue to be commonplace, such as inclined sleepers. Analyses to estimate risk among these products are lacking, perpetuating their presence in the marketplace. We present a method of comparing risk of SUID in an inclined sleeper to an AAP-recommended sleep environment.

Methods A case-control analysis using publicly available and previously published survey data was conducted for SUID events occurring between January 1, 2018 and April 12, 2019 (the date of the first inclined sleeper recall). SUID deaths were categorized as occurring in an AAP-recommended sleep environments or in an inclined sleeper. Exposure Odds Ratios (OR) are reported as the risk of SUID among infants using inclined sleepers relative to an AAP-recommended sleep environment.

Results During the study period, 4,900,573 births and 4,363 SUID deaths occurred in the US. Control characteristics were similar between previous night users of an AAP-recommended sleep environment (24%) and inclined sleepers (3.8%). Inclined sleepers were associated with a 5-fold (OR: 5.1; 95% CI: 3.2, 7.9) increased risk of SUID among infants < 12 months compared to infants in an AAP-recommended sleep environment. This risk was greatest among infants ≥ 4 months (RR: 10.4; 95% CI: 5.1, 21.5).

Conclusions This novel analysis fills a longstanding gap in risk assessments of inclined infant sleep products. More timely risk analyses may improve the safety of the marketplace.

Keywords SUID, Epidemiology, Infant, Sleep, Asphyxia

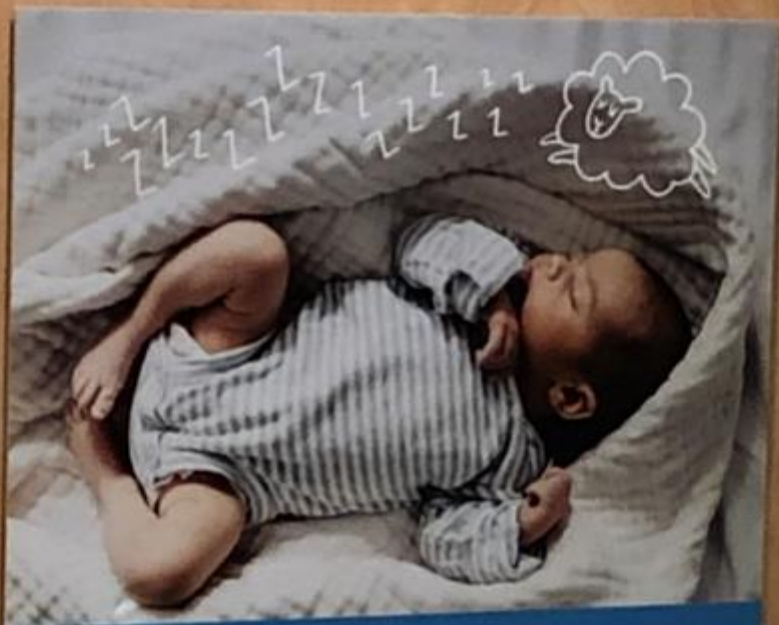
Rule 6B

3. What are the requirements and prohibitions of Section 6(b)?

Section 6(b) prohibits the Commission from disclosing information about a consumer product that identifies a manufacturer or private labeler unless the Commission has taken "reasonable steps" to assure 1) that the information is accurate, 2) that disclosure of the information is fair in the circumstances, and 3) that disclosure of the information is reasonably related to effectuating the purposes of the CPSA and of the other laws administered by the Commission. Before disclosure of such information, the Commission must provide the manufacturer or private labeler with an opportunity to comment on the accuracy of the information. The Commission may not disclose such information for at least 15 days after sending it to the company for comment.

Rule 6B prevents the CPSC from anything that might identify a company without the companies consent

ive Care Unit



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in the country

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Hospital

OHSU

Questions?



Take Home

- Infant sleep is a big deal for families
- SUID claims ~3600 per year
- A baby is safest when they sleep:
 - Alone
 - On their back
 - On a flat, firm surface in an approved crib or bassinet
- Many products marketed for infant sleep represent a real and present danger
- What we say and do matters

AVERY'S DISEASES *of the* NEWBORN

CHRISTINE A. GLEASON | SANDRA E. JUUL



TENTH EDITION

ELSEVIER

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AVERY'S DISEASES *of the* NEWBORN

CHRISTINE A. GLEASON | SANDRA E. JUUL



TENTH EDITION

ELSEVIER

A Box for Every Baby: A New Program Aims to Give Baby Boxes to Parents to Help Combat Ohio's Abysmal Infant Mortality Rate

Posted By Laura Morrison on Thu, Mar 9, 2017 at 9:41 am



Most parents in Finland don't even use the boxes as a baby bed. A recent survey found that just 37 percent of families there used the baby boxes as a sleeping place, Dr. Haataja said. "The box as a sleeping box is a marginal issue; the baby's health is associated with the maternal health care system," she said. "Our [low infant mortality rate](#) is due to free of charge high quality maternal and child health care services and child care guidance."



The Bed Box



\$69.99

Select your pattern:

Boisterous Bunnies

QUANTITY

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Safe Sleep Survival Kit

\$79.99

Safe Sleep Components

Safe Sleep Education



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Cribs for Kids®
Helping every baby sleep safer



COMPONENTS OF THE SAFE SLEEP SURVIVAL KIT

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- Halo SleepSack®
- Graco® Pack 'n Play® Sheet with Safe Sleep message
- 'ABCs of Safe Sleep' Photo Magnet
- Philips Soothie Pacifier
- Safe Sleep Educational Material
- Safe Sleep DVD: 10 minutes
- "Sleep Baby Safe and Snug" Children's Book

AVAILABLE IN ENGLISH AND SPANISH
All patterns subject to change due to availability and will always consist of gender-neutral patterns.



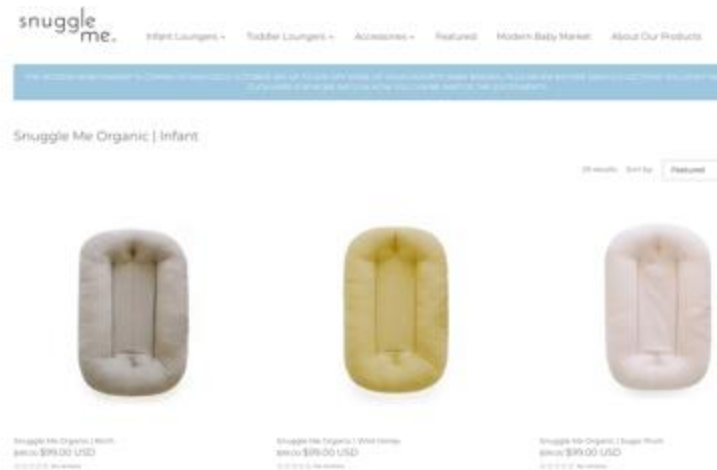
Cribs for Kids®
Helping every baby sleep safer

More Infant Sleep Products Linked to Deaths, a Consumer Reports Investigation Finds

Government data reveals fatalities associated with in-bed sleepers such as the DockATot and Snuggly Nest

By Rachel Rabkin Peachman

October 21, 2019



In-bed sleepers, including those shown above, have been associated with at least 12 deaths.

Several infant in-bed sleepers meant for bed-sharing with an adult caregiver are linked to at least 12 deaths that occurred between 2012 and 2018, according to a Consumer Reports investigation. The findings are based in part on incident data that CR received from the Consumer Product Safety Commission, which



Tweet



Amer Acad Pediatrics ✓
@AmerAcadPeds

Pediatricians @DrBenHoffman and Dr. Rachel Moon testifying at the @USCPSC forum on crib bumpers. @AmerAcadPeds' policy is clear: crib bumpers contribute to an unsafe sleep environment for infants and should be banned.



Tweet your reply



Government Moves Closer to Stopping the Sale of Dangerous Baby Sleep Products

The action includes inclined and in-bed sleepers. Consumer Reports advises caregivers to immediately stop using these products for sleep.

By Rachel Rabkin Peachman

Published May 19, 2021 | Updated June 2, 2021

Update: On June 2, 2021, the Consumer Product Safety Commission voted 3 to 1 to approve a final rule to require that all products sold and marketed for infant sleep meet established safety standards for sleep products.

That includes inclined sleepers, which position babies at an angle of greater than 10 degrees, and in-bed sleepers, which are intended or marketed for parents who want to share their bed with their babies. Together, these kinds of products have been linked to dozens of infant deaths.

Public Law 117–126
117th Congress

An Act

May 16, 2022
[H.R. 3182]

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**IF YOU SEE
SOMETHING,
SAY
SOMETHING.**



Windermere 🏡 @winderm... · 4/12/16 ...

Replying to @DrBenHoffman

@Drbenhoffman Thank you for bringing awareness to this issue. Good thing mom & dad were there to turn the baby over after photo was taken.

1

1

2





TAKING ACTION

Helping hospitals serve as a safe sleep model

Jamie Macklin, M.D., FAAP, PHM, is among the experts with the Ohio AAP who designed the Education and Safe Sleep Environment (EASE) Project. EASE is a quality improvement initiative aimed at increasing safe sleep practices with an emphasis on safe sleep behavior modeling in hospitals. During the first wave of the EASE Project, six Ohio children's hospitals spent 12 months gathering data and implementing safe sleep interventions that drove better behaviors in their individual institutions. After one year, the study found:

45%

increase in patients less than 1 year of age in safe sleep environments (alone, on their back, in a bare crib) during random audits

30%

increase in caregiver reports of receiving safe sleep education during hospital stays

27%

decrease in the presence of loose blankets in patient cribs during observations

100%

of participating hospitals have approval or are updating safe sleep policies to meet AAP recommendations



Hospitals can enroll in an online version of the EASE Project at ohioaap.org/EASEOnline/Register.



How Does a Standard Get Created?



Someone Recognizes the Need for:

- A better test...
- A new specification...
- A safer product...



Task Group: Convene Key Stakeholders

- 6-8 people is ideal
- Register a work item
- Circulate and discuss initial drafts in-person and online



Subcommittee: Bring in More Experts

- E-ballot the draft standard
- Address negative votes and comments
- E-ballot again or advance to main committee



Main Committee (and Society): Widen the Lens

- E-ballot standard
- Address any negatives and comments
- Back to subcommittee, if needed



ASTM International Committee on Standards: Review and Approval

- Process review if necessary (e.g., handling of negatives)



Online and Print Publication

- ASTM International staff formats final draft



Marketplace Use*

- Manufacturers
 - Governments
 - Trade associations
 - Consumers
 - ASTM develops related services as needed
- *ASTM publicizes purpose and availability of the standard.

www.astm.org/join

- Sets **VOLUNTARY STANDARDS** for products
- **Weighted towards industry and Manufacturers**



- Establishes **Mandatory Standards**
- Led by scientists/experts at CPSC
- Can be slow and not transparent until comment/review periods
- Depends on current leadership at the agency

CPSC RISK MANAGEMENT PROCESS



