

Exhibit 238

CDC Emails on Child COVID-19 Deaths

<https://www.documentcloud.org/documents/23226912-cdc-emails-on-child-covid-19-deaths>

Fact Check: Covid as a leading cause of death in children

<https://www.covid-georgia.com/pediatric-news/fact-check-covid-is-a-leading-cause-of-death-in-children/>

From: I
Sent: Sun, 19 Jun 2022 15:22:51 +0000
To: Fleming-Dutra, Katherine E. (CDC/DDID/NCIRD/DBD)
Subject: Flawed data

Why are you spreading fake data with regard to childhood deaths from SARS-CoV-2?

Please correct immediately.

<https://www.covid-georgia.com/pediatric-news/fact-check-covid-is-a-leading-cause-of-death-in-children>

Sent: Sat, 11 Jun 2022 20:42:52 +0000
To: Havers, Fiona (CDC/DDID/NCIRD/DVD); Taylor, Christopher A. (CDC/DDID/NCIRD/DVD); Cardemil, Cristina (NIH/NIAID) [E]
Subject: FW: burden of COVID-19 in infants

Hi Fiona and Cristina,

I wanted to connect you with Cristina Cardemil (now at NIH) who is working on a study looking immune response in mothers and infants following COVID-19 vaccination during pregnancy and postpartum. She is looking for more information on the burden of COVID-19 disease in infants <6 months of age.

Cristina, Fiona and Chris lead COVID-NET, and

From: Siegel, David A. (CDC/DDNID/NCCDPHP/DCPC) <irn3@cdc.gov>
Sent: Wednesday, June 8, 2022 9:05 PM
To: Cardemil, Cristina (NIH/NIAID) [E] <crisrina.cardemil@nih.gov>
Cc: Fleming-Dutra, Katherine E. (CDC/DDID/NCIRD/DBD) <ftu2@cdc.gov>
Subject: RE: burden of COVID-19 in infants

Hi Cristina—thanks for reaching out—hope you are doing well. I pasted a summary below that was shared with me—it is an uncleared, informal summary of literature that was created around January. Looping in Katherine here in case she has anything else—Katherine, are you looking at burden of disease in ages <6months, or only 6 months and older for your work with ACIP?

Thanks,
David

David Siegel, MD, MPH
Clinical Disease and Health Systems Team
Epi TF
CDC COVID-19 response

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404-831-4935 (M)

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From: Cardemil, Cristina (NIH/NIAID) [E] <cristina.cardemil@nih.gov>
Sent: Wednesday, June 8, 2022 11:04 AM
To: Siegel, David A. (CDC/DDNID/NCCDPHP/DCPC) <irn3@cdc.gov>
Subject: burden of COVID-19 in infants

Hi David,

Hope you are well. I am working on an NIH-funded [prospective cohort study](#) on the immune response in mothers and infants following COVID-19 vaccination during pregnancy and postpartum and am seeking more information on the burden of COVID-19 disease in infants <6 months of age. I saw the below NCHS data presented by Sara Oliver at ACIP recently and have reviewed the nice MMWRs with COVID-NET data. I am wondering if you could connect me with someone and/or resources (papers, websites) to further understand what we know about these COVID-19 infections in infants <6 months of age. For example, are there higher-risk groups within the 0-6 month age group for severe disease, are all of the deaths following transmission after pregnancy or are some considered related to congenital infection, are these primarily previously healthy infants with community exposure or do a high proportion have other comorbidities, etc. Having additional data on the burden in early infancy will allow us to understand better the case for vaccination during pregnancy to afford protection for both mom and baby in the first few months of life.

Thanks in advance for any assistance you may provide.

Best
Cristina

Cristina Cardemil, MD MPH
Medical Officer/CDR, United States Public Health Service
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Sent: Thu, 9 Jun 2022 15:59:24 +0000
To: Oliver, Sara Elizabeth (CDC/DDID/NCIRD/DVD)
Subject: FW: burden of COVID-19 in infants

FYI—Cristina Cardemil at NIH reached out asking for

From: Cardemil, Cristina (NIH/NIAID) [E] <cristina.cardemil@nih.gov>
Sent: Thursday, June 9, 2022 10:54 AM
To: Fleming-Dutra, Katherine E. (CDC/DDID/NCIRD/DBD) <ftu2@cdc.gov>; Siegel, David A. (CDC/DDNID/NCCDPHP/DCPC) <irn3@cdc.gov>
Subject: RE: burden of COVID-19 in infants

Hi Katherine, great to hear from you also!

We are pending submission for the first batch of interim data from our study, and we are also currently planning for subsequent testing and analyses, so primarily using the data at this point to inform prioritization of analyses and publications from our study. In the future, we may also cite published data. Anything that is unpublished or not available on public websites will of course keep confidential.

I agree that meeting would be helpful. This is actually a good time as if you have data analysis priorities to help inform future policy for maternal vaccination we can discuss and see where we may be able to support each other. We have a really great team of maternal immunization policy and academic experts who have worked for years on similar questions (eg, Tdap and influenza vaccination during pregnancy). We could potentially do a quick touch base with you and I to determine goals, but also expand to include others if that would be helpful. I am meeting with the team tomorrow and can run this by them. I am guessing you are probably swamped with ACIP prep, so just let me know what format and timing would work best for you.

Best
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Hi Cristina!

It is great to hear from you! I hope you are doing well. Thanks David for connecting us. I have compiled some updated data on infants 0-5 months, although not yet systematically. Our current push is for infants and children 6 months and older to support ACIP recommendations for that age group. However, the next pediatric considerations will be around infants <6 months.

Cristina, when do you need this and what format do you need? How will you be using and sharing the data? I can share the data I have compiled, but first I should let the SMEs who provided the data know. Also, I would love to talk more with you as we prepare for potential vaccine policy for maternal vaccination.

Best,
Katherine

Katherine E. Fleming-Dutra, MD (*she/her/hers*)
Detailed to:
COVID-19 Vaccine Policy Unit
National Center for Immunization and Respiratory Diseases
Centers for Disease Control and Prevention
404-639-4243 | ftu2@cdc.gov

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Sent: Thu, 9 Jun 2022 18:32:01 +0000
To: Oliver, Sara Elizabeth (CDC/DDID/NCIRD/DVD)
Subject: FW: burden of COVID-19 in infants

FYI—one my EIS classmates is now at NIH working on maternal COVID vaccination. I will find a time to talk with her probably after ACIP. Would you want to join an initial call with her? Otherwise, I can and then follow up with you afterwards.

I will share the information I have pulled together from COVID-NET, NCHS and NVSN, but will give the teams a quick heads up as well. That will likely be next week.

Thanks!
Katherine

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From: Duchin, Jeff
Sent: Sat, 18 Jun 2022 19:59:06 +0000
To: Oliver, Sara Elizabeth (CDC/DDID/NCIRD/DVD); Fleming-Dutra, Katherine E. (CDC/DDID/NCIRD/DBD)
Cc: Lee, Grace M; Matt Daley
Subject: Pedi Covid Deaths

Great work today, as always.

No doubt you've seen this and similar critiques of the mortality data presented. Will there be a response from CDC?

<https://www.covid-georgia.com/news/fact-check-covid-is-a-leading-cause-of-death-in-children/>
Jeff

Jeffrey S. Duchin, MD (he/him)

Health Officer and Chief, Communicable Disease Epidemiology & Immunization Section

Public Health - Seattle and King County

Professor in Medicine, Division of Infectious Diseases, University of Washington

Adjunct Professor, School of Public Health

401 5th Ave, Suite 1250, Seattle, WA 98104

Tel: (206) 296-4774; Direct: (206) 263-8171; Fax: (206) 296-4803

E-mail: jeff.duchin@kingcounty.gov

From: Twentyman, Evelyn Rebecca Ford (CDC/DDID/NCIRD/DVD)
Sent: Tue, 14 Jun 2022 12:38:51 +0000
To: Matthew.F.Daley@kp.org; Oliver, Sara Elizabeth (CDC/DDID/NCIRD/DVD)
Subject: Revised intro slides -- new death ranks, new flu content
Attachments: 01_COVID_Daley_2022 June 17_14Jun22.pptx, 01_COVID_Daley_2022 June 18_Twentyman.pptx

Good morning, and happy VRBPAC day 1! 😊

Thanks so much for your time yesterday in discussing these slides. Please find a revised slide deck for June 17 attached. A few notes:

- On the cause of death rankings:
 - It makes a difference whether one cites the cumulative incidence or annualized incidence of each cause of death. Therefore, I added this cumulative incidence basis to both the bullet itself and the reference footnote.
 - In a way it does not matter among infectious diseases—COVID is the leading cause of death secondary to infectious disease either way. However, this makes for clean context that applies across the entire slide.
 - We broke out all cause mortality for both:
 - children ages 0-19, for which COVID is #7;
 - children ages 1-4, for which COVID is #5.
- On the flu vaccine slides:
 - I thought that if we're framing this as pretty acceptable to parents of young children, we might start with the consistently high vaccine coverage in this age group (slide 7).
 - Averted illnesses/hospitalizations/deaths are now limited to children 6 months—4 years, and placed in context of substantial disease burden, variable vaccine efficacy, and the consistent vaccine coverage just presented.
 - These have been approved by our flu vaccine folks.

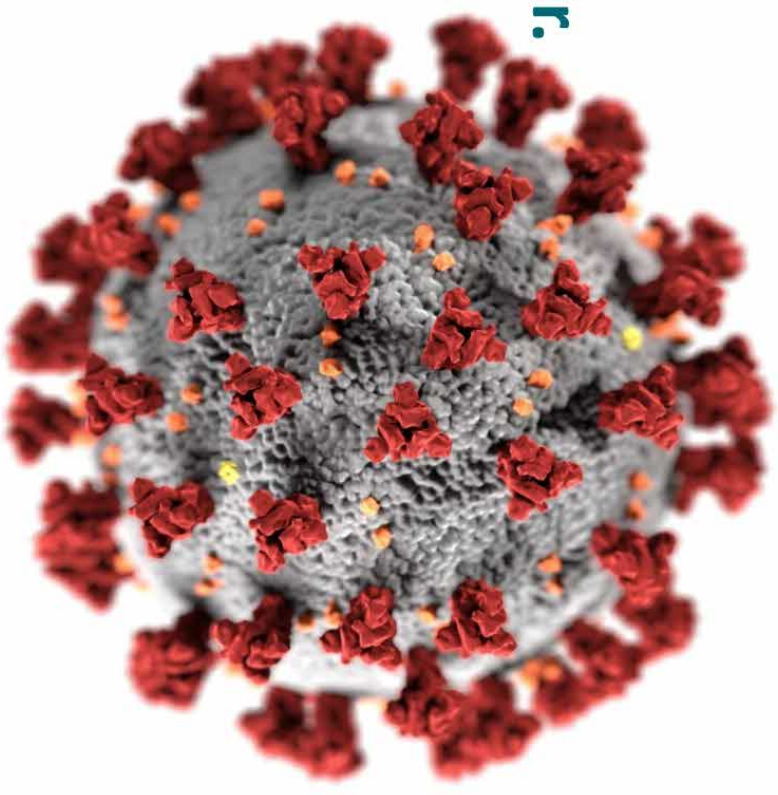
I'm also attaching draft slides for June 18 – I realized we never even broached them yesterday. I don't think there's too much to discuss on these, but definitely let us know if you have any questions/concerns or want anything revised!

Thanks so much, and have a wonderful day!

Evelyn

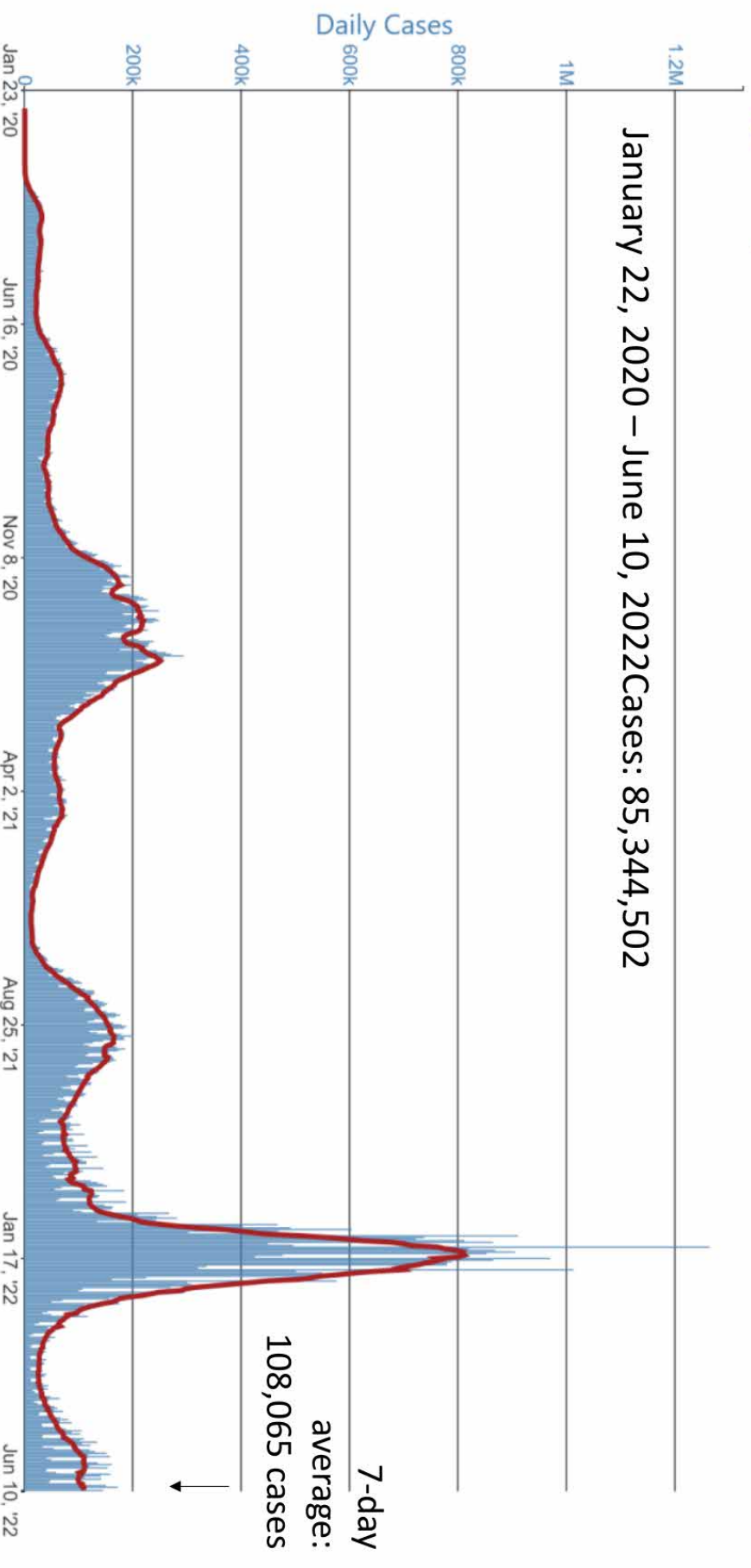
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ACIP COVID-19 Vaccines Work Group
**Dr. Matthew F. Daley, Work Group
Chair**
June 17, 2022



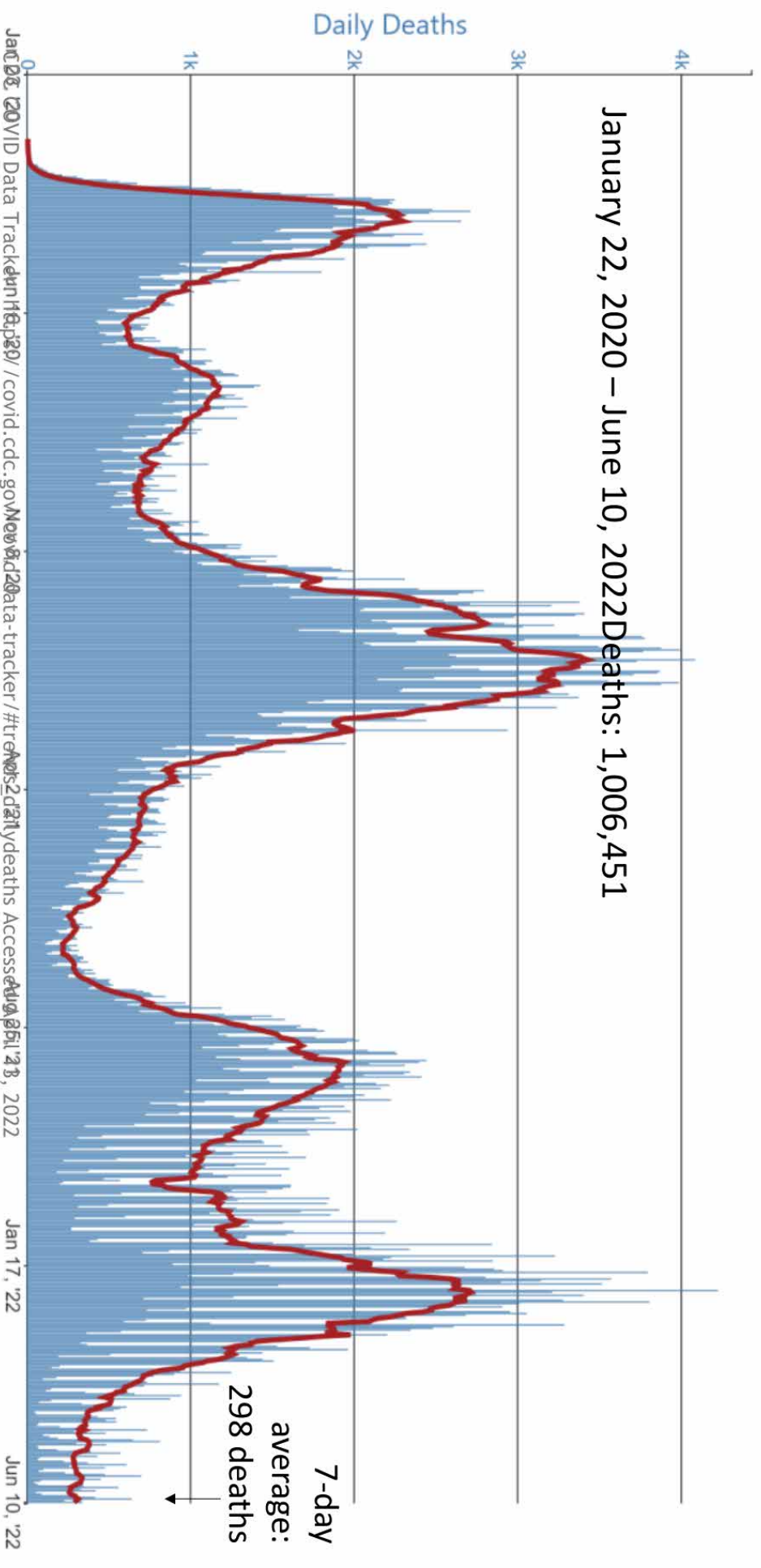
cdc.gov/coronavirus

Trends in number of COVID-19 cases in the United States among all persons



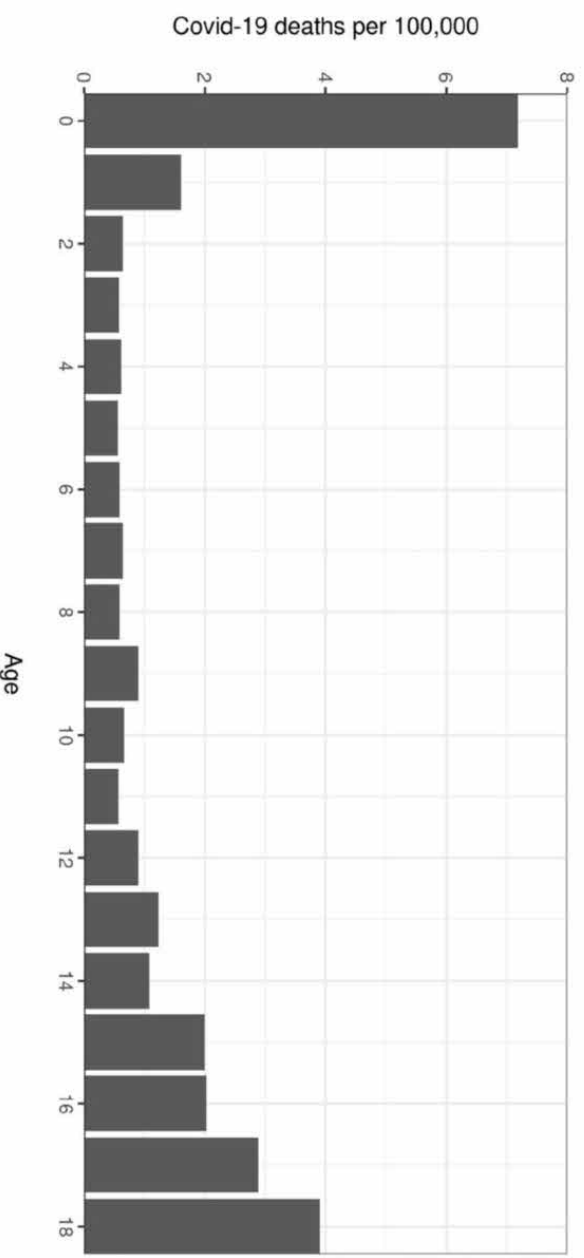
Source: COVID Data Tracker, https://covid.cdc.gov/covid-data-tracker/#trends_dailytrendscases, accessed June 11 2022

Daily Trends in Number of COVID-19 Deaths, United States



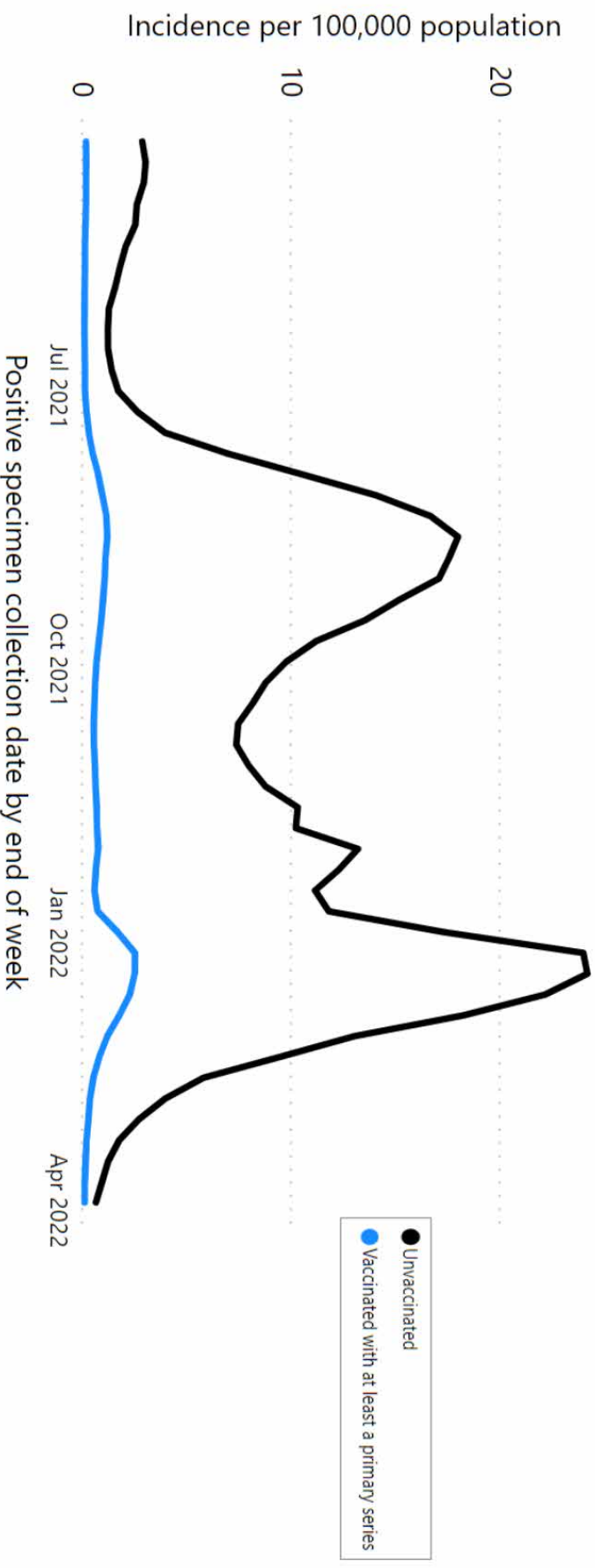
COVID-19 death rate among children by age, United States, March 1, 2020—April 30, 2022

- Based on cumulative total incidence, COVID-19 is the leading cause of death among infectious diseases for people ages 0-19 COVID-19 is the seventh most common of all causes of death for people ages 0-19 Among people ages 1-4, COVID-19 is the fifth most common of all causes of death



Based on death certificate data from the National Center for Health Statistics. COVID-19 based on cumulative total incidence of COVID-19 deaths from March 1, 2020-April 30, 2022. Source: Preprint: Flaxman S, Whittaker C, Semenova E et al. Covid-19 is a leading cause of death in children and young people ages 0-19 years in the United States. medRxiv 2022.05.23.22275458; doi: <https://doi.org/10.1101/2022.05.23.22275458>

Rates of COVID-19 deaths by vaccination status in people ages ≥5 years, United States, April 4, 2021—April 2, 2022



Unvaccinated people ages ≥5 years had **10X** the risk of dying from COVID-19 through March compared to people vaccinated with at least the primary series.

<https://www.cdc.gov/covid-data-tracker/#rates-by-vaccine-status>. Accessed June 12, 2022.

Pediatric vaccine preventable diseases:

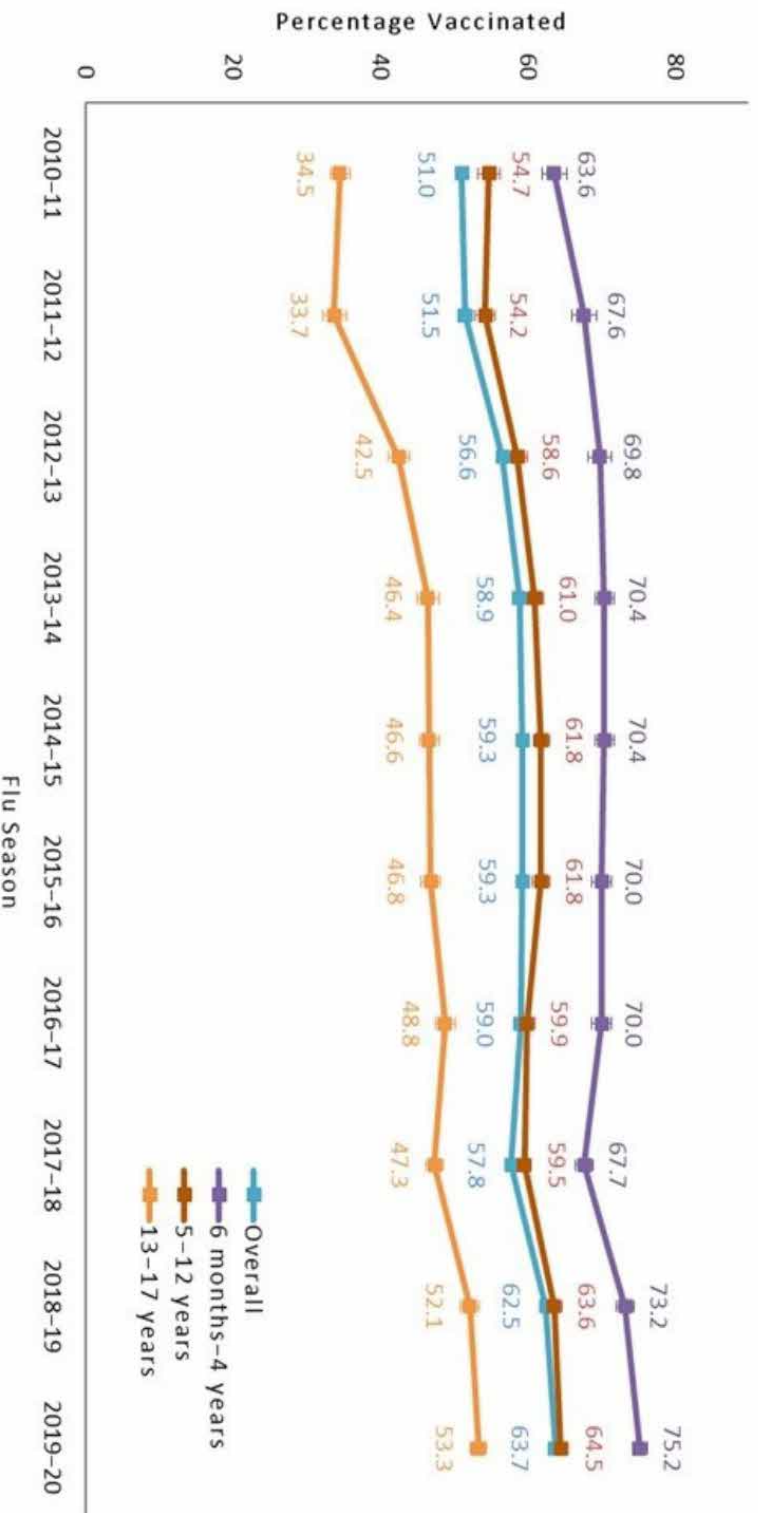
Deaths per year in the United States prior to recommended vaccines

	Hepatitis A ¹	Meningococcal (ACWY) ²	Varicella ³	Rubella ⁴	Rotavirus ⁵	COVID-19 ⁶
Age	<20 years	11–18 years	5–9 years	All ages	<5 years	6 months – 4 years
Time period	1990–1995	2000–2004	1990–1994	1966–1968	1985–1991	Jan 2020–May 2022
Average deaths per year	3	8	16	17	20	86

¹Vogt TM, Wise ME, Bell BP, Finelli L. Declining hepatitis A mortality in the United States during the era of hepatitis A vaccination. *J Infect Dis* 2008; 197:1282–8. ²National Notifiable Diseases Surveillance System with additional serogroup and outcome data from Enhanced Meningococcal Disease Surveillance for 2015–2019. ³Meyer PA, Seward JF, Jurnan AO, Wharton M. Varicella mortality: trends before vaccine licensure in the United States, 1970–1994. *J Infect Dis*. 2000;182(2):383–390. doi:10.1086/3157144Roush SM, Murphy TV. Historical comparisons of morbidity and mortality for vaccine-preventable diseases in the United States. *JAMA* 2007; 298:2155–63.

⁴ Glass RI, Kilgore PE, Holman RC, et al. The epidemiology of rotavirus diarrhea in the United States: surveillance and estimates of disease burden. *J Infect Dis*. 1996 Sep;174 Suppl 1:S5–11. ⁵<https://data.cdc.gov/NCHS/Provisional-COVID-19-Deaths-Counts-by-Age-In-Years/3apk-4u4f/data>.

Flu Vaccination Coverage by Age Group, Children 6 months—17 years, United States, 2010—2020



Data Source: National Immunization Survey-Flu (NIS-Flu)
 Error bars represent 95% confidence intervals around the estimates.

Estimated influenza illnesses, medical visits, hospitalizations and deaths averted by seasonal flu vaccine among children ages 6 months—4 years in the United States, 2010—2020

Among children ages 6 months—4 years, seasonal flu vaccines have averted 1-2: 4.3-20.1 million illnesses 2.9-15.5 million visits 32,000-164,000 hospitalizations 160-2350 deaths



In the context of: Substantial disease burden
Seasonal incidence of about 5-20%
Variable vaccine efficacy
(VE)
Vaccine efficacy estimates ranging from 19-60% from 2010—2020
In the setting of ongoing viral mutations, and need to determine vaccine composition ahead of flu season
Consistent vaccine coverage

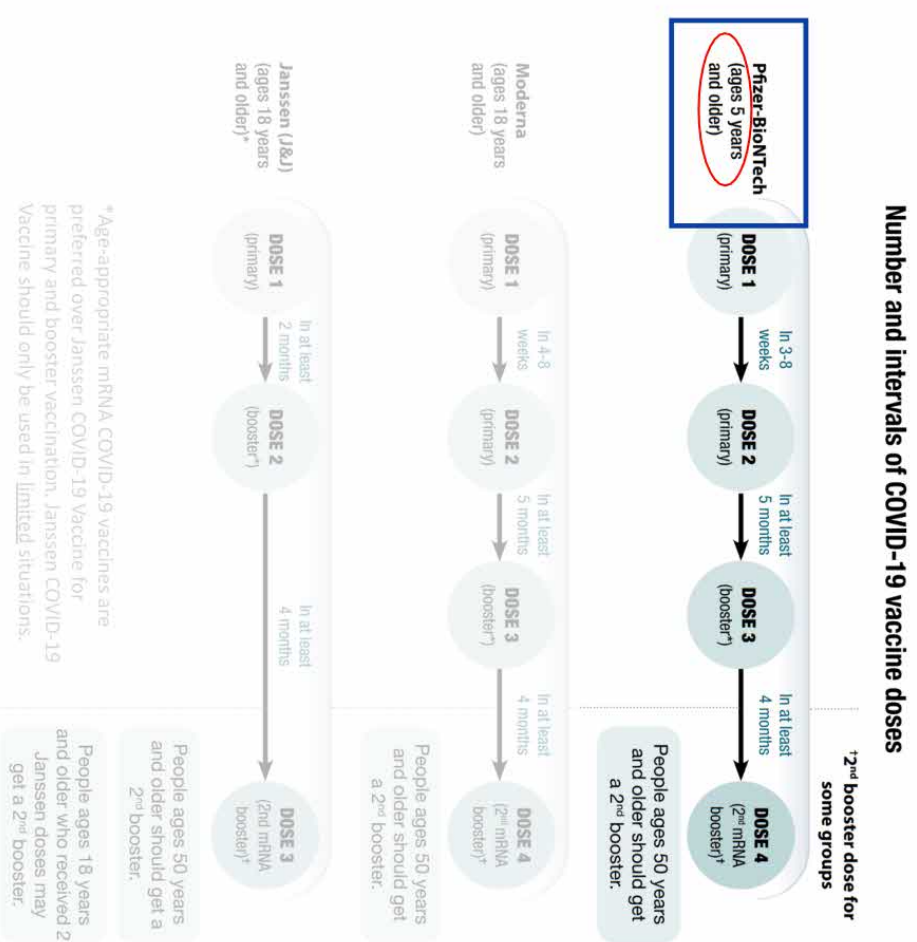
63.6-75.2% flu vaccine coverage

among children 6 months—4 years

1. Rolles MA, Flannery B, Chung JR, et al.; US Influenza Vaccine Effectiveness (Flu VE) Network; Influenza Hospitalization Surveillance Network; Assessment Branch, Immunization Services Division, Centers for Disease Control and Prevention. Effects of influenza vaccination in the United States during the 2017–2018 influenza season. *Clin Infect Dis* 2019;69:1845–53. 10.1093/cid/ciz075 2. www.cdc.gov/flu/about/burden-averted/2019-2020.htm. Accessed June 13, 2022. 3. Jerpome I Tokars, Sonia J Olsen, Carrie Reed, Seasonal Incidence of Symptomatic Influenza in the United States. *Clinical Infectious Diseases*, Volume 66, Issue 10, October 15, 2018. <https://doi.org/10.1093/cid/ciy211>. Accessed June 13, 2022. 5. National Immunization Survey—Flu. <https://www.cdc.gov/flu/fluavaxview/coverage-1920estimates.htm>. Accessed June 13, 2022.

Current recommendations for COVID-19 vaccines

- There is no COVID-19 vaccine currently authorized for use in children less than 5 years of age Only the Pfizer-BioNTech vaccine is currently authorized for use in children ages 5—17 years



FDA update

Convenings of the Vaccines and Related Biological Products Advisory Committee (VRBPAC)

- June 14, 2022: VRBPAC meeting to review the request for EUA for the Moderna COVID-19 vaccine in children and adolescents ages 6—17 yearsJune 15, 2022: VRBPAC meeting to review requests for EUA for: The Moderna COVID-19 vaccine in children ages 6 months—5 yearsThe Pfizer-BioNTech COVID-19 vaccine in children ages 6 months—4 years

COVID-19 vaccine Work Group activities

Late May- Early June 2022

Reviewed and discussed:

- Vaccine safety, immunogenicity and efficacy data—including both immunobridging and laboratory-confirmed direct efficacy—for the Moderna COVID-19 vaccine for children and adolescents ages 6 months—5 years and 6—17 years. Vaccine safety, immunogenicity and efficacy data—including both immunobridging and laboratory-confirmed direct efficacy—for the Pfizer-BioNTech COVID-19 vaccine for children and adolescents ages 6 months—4 yearsCOVID-19 epidemiology and outcomes in children ages 6 months—5 yearsPost-authorization vaccine effectiveness of COVID-19 vaccines in children and adolescents ages 5—17 years Grading of Recommendations, Assessment, and Evaluation (GRADE) and Evidence to Recommendations Frameworks for both Moderna and Pfizer-BioNTech COVID-19 vaccines for children ages 6 months—5 years

Agenda: Friday June 17, 2022

- **Epidemiology of COVID-19 in young children** **Dr. Fleming-Dutra (CDC)**
COVID-19 vaccine effectiveness in children and adolescents **Dr. Link-Gelles (CDC)**
BreakSafety and immunogenicity of Moderna 2-dose primary series **Dr. Das (Moderna)**
in children ages 6 months—5 years**Safety and immunogenicity of BNT 162b2 3-dose primary**
series **Dr. Gruber (Pfizer)**
in children ages 6 months—4 years**mRNA COVID-19 vaccines in young children:**
Dr. Oliver (CDC)
Summary and Work Group interpretation **PUBLIC COMMENT**

Work Group members

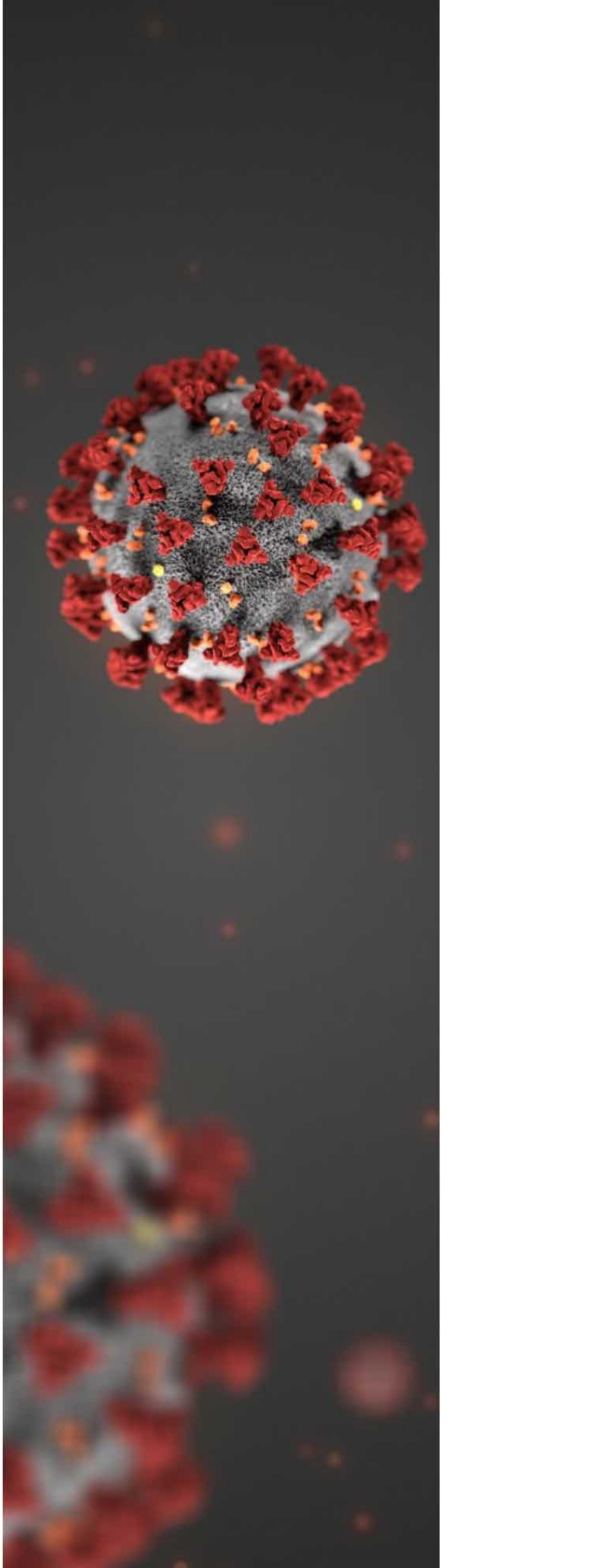
ACIP members
Matthew Daley (chair)
Beth Bell
Grace Lee
Keipp Talbot
Oliver Brooks
EX-officio/government members
FDA: Doran Fink,
Rachel Zhang, Lucia Lee
NIH: Chris Roberts
IHS: Uzo Chukwuma
DOD: Bryan Schumacher
CMS: Jeff Kelman
BARDA: Christine Oshansky
HHS: David Kim
CDC Lead
Sara Oliver
Evelyn Twentyman

Liaisons
AAFP: Jonathan Temte
AAP: Sean O'Leary
ACOG: Denise Jamieson (primary),
Laura Riley (alternate)
ACP: Jason Goldman
ADS: Emily Kahn
AGS: Ken Schmader
AIM: Rob Shechter (primary),
Jane Zucker (alternate)
AMA: Sandra Fryhofer
ANA: Kendra McMillan (primary),
Ruth Francis (alternate)
APhA: Michael Hogue
ASTHO: Marcus Plescia
ASTE: Susan Lett, Paul Cieslak, Christine Hahn
IDSA: Jeff Duchin (primary)

Liaisons, cont'
DNACCHO: Matt Zahn (primary),
Jeff Duchin (alternate)
NACI: Matthew Tunis (primary),
Kelsey Young (alternate)
NFD: Bill Schaffner (primary),
Marla Dalton (alternate)
NMA: Patricia Whitley-Williams
SHEA: Marci Drees
Consultants
Ed Belongia
Kathy Kinlaw
Dayna Matthew
Kathleen Neuzil
Stanley Perlman
Peter Szilagyi
Jose Romero
Hank Bernstein

CDC participants

- Sarah MeyerEvelyn
TwentymanTara
AndersonAmy BlainMary
ChamberlandKatherine
Fleming-DutraMonica
GodfreySusan
GoldsteinStephen
HadlerElisha HallValerie
MorelliDanielle
Moujialauren RoperEdwin
ShanleyMegan Wallace
- JoEllen WolickiAmanda
CohnJessica MacNeilElfriede
AgyemangKaren
BroderAllison CieslaKathleen
DoolingAshley
FowlkesSamuel
GraitcerRebecca Greco
KoneKatherine GrusichRita
HelfandJoy HsuTerri
HydeJefferson Jones
- Cynthia JorgensenAndrew
KrogerRuth Link-GellesLauri
MarkowitzKristen
NordlundTamara
PilishviliHeather ScobieTom
ShimabukuroJohn SuNatalie
ThornburgMelinda
WhartonRyan Wiegand Janet
WrightPatricia YuYon Yu



For more information, contact CDC
1-800-CDC-INFO (232-4636)
TTY: 1-888-232-6348 www.cdc.gov

Thank you!

The findings and conclusions in this report are those of the authors and do not necessarily represent the official position of the Centers for Disease Control and Prevention.



From: Freedman, Megan (CDC/DDID/NCIRD/OD)
Sent: Sat, 18 Jun 2022 22:06:44 +0000
To: Oliver, Sara Elizabeth (CDC/DDID/NCIRD/DVD); Fleming-Dutra, Katherine E. (CDC/DDID/NCIRD/DBD); Twentyman, Evelyn Rebecca Ford (CDC/DDID/NCIRD/DVD)
Cc: Grusich, Katherina (Kate) (CDC/DDID/NCIRD/OD)
Subject: Re: ACIP slide deck

Love it - thank you for sending!!!

Get [Outlook for iOS](#)

From: Oliver, Sara Elizabeth (CDC/DDID/NCIRD/DVD) <yxo4@cdc.gov>

Sent: Saturday, June 18, 2022 3:16:04 PM

To: Freedman, Megan (CDC/DDID/NCIRD/OD) <ksu8@cdc.gov>; Fleming-Dutra, Katherine E. (CDC/DDID/NCIRD/DBD) <ftu2@cdc.gov>; Twentyman, Evelyn Rebecca Ford (CDC/DDID/NCIRD/DVD) <ydj2@cdc.gov>

Cc: Grusich, Katherina (Kate) (CDC/DDID/NCIRD/OD) <yhb3@cdc.gov>

Subject: RE: ACIP slide deck

Meg:

Just FYI- this is the response I sent to Kristen N about the same question. This woman appears

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but these are my thoughts 😊. Just in case we continue to get questions. I'm sure you guys can make it sound prettier, but something like this would be how I would respond. And the general sentiment that "even 1 death from COVID that's preventable is too many, regardless of how you count them"

(b)(5)

From: Freedman, Megan (CDC/DDID/NCIRD/OD) <ksu8@cdc.gov>
Sent: Saturday, June 18, 2022 1:14 PM
To: Fleming-Dutra, Katherine E. (CDC/DDID/NCIRD/DBD) <ftu2@cdc.gov>; Twentyman, Evelyn Rebecca Ford (CDC/DDID/NCIRD/DVD) <ydj2@cdc.gov>; Oliver, Sara Elizabeth (CDC/DDID/NCIRD/DVD) <yxo4@cdc.gov>
Cc: Grusich, Katherina (Kate) (CDC/DDID/NCIRD/OD) <yhb3@cdc.gov>
Subject: RE: ACIP slide deck

Katherine,

I forwarded this to Kate Grusich in public affairs (cc'd). The below appears not to be a member of the media, but a person with a web page or blog who is claiming that one of your ACIP slides is wrong. So first, you/the other the SMEs would need to determine if there's any validity to the complaint. And if so, determine next steps, if any (e.g., pull the slide, add a footnote, etc.). When that's determined, we in comms can help determine if there's an appropriate response that should be shared back.

How does that sound?

Meg Freedman, MPH
Health Communications Specialist
Vaccine Policy Unit Liaison | Vaccine Coordination Unit
Centers for Disease Control and Prevention
ksu8@cdc.gov | 303-949-3375

From: Freedman, Megan (CDC/DDID/NCIRD/OD)
Sent: Saturday, June 18, 2022 9:46 AM
To: Fleming-Dutra, Katherine E. (CDC/DDID/NCIRD/DBD) <ftu2@cdc.gov>; Twentyman, Evelyn Rebecca Ford (CDC/DDID/NCIRD/DVD) <ydj2@cdc.gov>; Oliver, Sara Elizabeth (CDC/DDID/NCIRD/DVD) <yxo4@cdc.gov>
Subject: RE: ACIP slide deck

I'll forward to public affairs (Kate Grusich) and we'll go from there!

Meg Freedman, MPH
Health Communications Specialist
Vaccine Policy Unit Liaison | Vaccine Coordination Unit
Centers for Disease Control and Prevention
ksu8@cdc.gov | 303-949-3375

From: Fleming-Dutra, Katherine E. (CDC/DDID/NCIRD/DBD) <ftu2@cdc.gov>
Sent: Saturday, June 18, 2022 9:41 AM
To: Twentyman, Evelyn Rebecca Ford (CDC/DDID/NCIRD/DVD) <ydj2@cdc.gov>; Freedman, Megan (CDC/DDID/NCIRD/OD) <ksu8@cdc.gov>; Oliver, Sara Elizabeth (CDC/DDID/NCIRD/DVD) <yxo4@cdc.gov>
Subject: FW: ACIP slide deck

Hi Meg, Sara and Evelyn,

I am not sure who this should go through. Does this go to the COVID-19 response media? Let me know what I need to do.

Thank you,
Katherine

From: kelley@covid-georgia.com <kelley@covid-georgia.com>
Sent: Saturday, June 18, 2022 11:25 AM
To: Fleming-Dutra, Katherine E. (CDC/DDID/NCIRD/DBD) <ftu2@cdc.gov>
Subject: ACIP slide deck

Dr. Fleming-Dutra,

I am concerned about some very misleading data in the slide deck you put together for the VRBPAC and ACIP meetings last week. The pre-print from the UK about Covid as a leading cause of death has some serious flaws that seem to have been overlooked, and even exacerbated, by the presentation of rankings in the slide deck. I wanted to give you an opportunity to read my fact check of the data, and see if you had a response.

<https://www.covid-georgia.com/news/fact-check-covid-is-a-leading-cause-of-death-in-children/>

Thank you,

Kelley Krohnert
kelley@covid-georgia.com

www.covid-georgia.com
Twitter: <https://www.twitter.com/kelleykga>

From: Cardemil, Cristina (NIH/NIAID) [E]
Sent: Fri, 10 Jun 2022 13:21:39 +0000
To: Fleming-Dutra, Katherine E. (CDC/DDID/NCIRD/DBD)
Subject: RE: burden of COVID-19 in infants

Thanks Katherine, that sounds good.

Best
Cristina

Cristina Cardemil, MD MPH
Medical Officer/CDR, USPHS
DMID/NIAID/NIH

From: Fleming-Dutra, Katherine E. (CDC/DDID/NCIRD/DBD) <ftu2@cdc.gov>
Sent: Thursday, June 9, 2022 2:37 PM
To: Cardemil, Cristina (NIH/NIAID) [E] <crisrina.cardemil@nih.gov>
Subject: RE: burden of COVID-19 in infants

Hi Cristina,

We will be presenting peds epi data at VRBPAC next week, and what we have on infants <6 months I can share. I can pull it together probably mid next week. Would that work?

Also, I am currently detailed into this position, so let me talk with the team about who would be best to join the initial call.

In the meantime, you might find these papers useful:

Delahoy MJ, Ujamaa D, Taylor CA, et al. [Comparison of influenza and COVID-19-associated hospitalizations among children < 18 years old in the United States-FluSurv-NET \(October-April 2017-2021\) and COVID-NET \(October 2020-September 2021\)](#). Clin Infect Dis. 2022 May 20:ciac388. doi: 10.1093/cid/ciac388.

Flaxman S, Whittaker C, Semenova E et al. Covid-19 is a leading cause of death in children and young people ages 0-19 years in the United States. medRxiv 2022.05.23.22275458; doi: <https://doi.org/10.1101/2022.05.23.22275458>

[Multisystem Inflammatory Syndrome in Infants <12 months of A... : The Pediatric Infectious Disease Journal \(lww.com\)](#)

I will look forward to catching up! If you need anything sooner, just let me know.

Best,
Katherine

Katherine E. Fleming-Dutra, MD (*she/her/hers*)
Detailed to:
COVID-19 Vaccine Policy Unit
National Center for Immunization and Respiratory Diseases
Centers for Disease Control and Prevention
404-639-4243 | ftu2@cdc.gov

From: Cardemil, Cristina (NIH/NIAID) [E] <cristina.cardemil@nih.gov>
Sent: Thursday, June 9, 2022 10:54 AM
To: Fleming-Dutra, Katherine E. (CDC/DDID/NCIRD/DBD) <ftu2@cdc.gov>; Siegel, David A. (CDC/DDNID/NCCDPPH/DCPC) <irn3@cdc.gov>
Subject: RE: burden of COVID-19 in infants

Hi Katherine, great to hear from you also!

We are pending submission for the first batch of interim data from our study, and we are also currently planning for subsequent testing and analyses, so primarily using the data at this point to inform prioritization of analyses and publications from our study. In the future, we may also cite published data. Anything that is unpublished or not available on public websites will of course keep confidential.

I agree that meeting would be helpful. This is actually a good time as if you have data analysis priorities to help inform future policy for maternal vaccination we can discuss and see where we may be able to support each other. We have a really great team of maternal immunization policy and academic experts who have worked for years on similar questions (eg, Tdap and influenza vaccination during pregnancy). We could potentially do a quick touch base with you and I to determine goals, but also expand to include others if that would be helpful. I am meeting with the team tomorrow and can run this by them. I am guessing you are probably swamped with ACIP prep, so just let me know what format and timing would work best for you.

Best
Cristina

Cristina Cardemil, MD MPH
Medical Officer/CDR, United States Public Health Service
Division of Microbiology and Infectious Diseases
National Institute of Allergy and Infectious Diseases
National Institutes of Health
5601 Fishers Lane
Rockville, Maryland
cristina.cardemil@nih.gov

From: Fleming-Dutra, Katherine E. (CDC/DDID/NCIRD/DBD) <ftu2@cdc.gov>
Sent: Thursday, June 9, 2022 9:38 AM
To: Cardemil, Cristina (NIH/NIAID) [E] <cristina.cardemil@nih.gov>; Siegel, David A. (CDC/DDNID/NCCDPHP/DCPC) <irn3@cdc.gov>
Subject: RE: burden of COVID-19 in infants

Hi Cristina!

It is great to hear from you! I hope you are doing well. Thanks David for connecting us. I have compiled some updated data on infants 0-5 months, although not yet systematically. Our current push is for infants and children 6 months and older to support ACIP recommendations for that age group. However, the next pediatric considerations will be around infants <6 months.

Cristina, when do you need this and what format do you need? How will you be using and sharing the data? I can share the data I have compiled, but first I should let the SMEs who provided the data know. Also, I would love to talk more with you as we prepare for potential vaccine policy for maternal vaccination.

Best,
Katherine

Katherine E. Fleming-Dutra, MD (*she/her/hers*)
Detailed to:
COVID-19 Vaccine Policy Unit
National Center for Immunization and Respiratory Diseases
Centers for Disease Control and Prevention
404-639-4243 | ftu2@cdc.gov

From: Cardemil, Cristina (NIH/NIAID) [E] <cristina.cardemil@nih.gov>
Sent: Thursday, June 9, 2022 9:29 AM
To: Siegel, David A. (CDC/DDNID/NCCDPHP/DCPC) <irn3@cdc.gov>
Cc: Fleming-Dutra, Katherine E. (CDC/DDID/NCIRD/DBD) <ftu2@cdc.gov>
Subject: RE: burden of COVID-19 in infants

Thanks David, these are very helpful. This is a great summary and adds context. Please do let me know if other data are or become available.

Best
Cristina

Cristina Cardemil, MD MPH
Medical Officer/CDR, United States Public Health Service
Division of Microbiology and Infectious Diseases
National Institute of Allergy and Infectious Diseases
National Institutes of Health

5601 Fishers Lane
Rockville, Maryland
cristina.cardemil@nih.gov

From: Siegel, David A. (CDC/DDNID/NCCDPHP/DCPC) <irn3@cdc.gov>
Sent: Wednesday, June 8, 2022 9:05 PM
To: Cardemil, Cristina (NIH/NIAID) [E] <cristina.cardemil@nih.gov>
Cc: Fleming-Dutra, Katherine E. (CDC/DDID/NCIRD/DBD) <ftu2@cdc.gov>
Subject: RE: burden of COVID-19 in infants

Hi Cristina—thanks for reaching out—hope you are doing well. I pasted a summary below that was shared with me—it is an uncleared, informal summary of literature that was created around January. Looping in Katherine here in case she has anything else—Katherine, are you looking at burden of disease in ages <6months, or only 6 months and older for your work with ACIP?

Thanks,
David

David Siegel, MD, MPH
Clinical Disease and Health Systems Team
Epi TF
CDC COVID-19 response

Phone:
770-488-4426 (W)
404-831-4935 (M)

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From: Cardemil, Cristina (NIH/NIAID) [E] <cristina.cardemil@nih.gov>
Sent: Wednesday, June 8, 2022 11:04 AM
To: Siegel, David A. (CDC/DDNID/NCCDPHP/DCPC) <irn3@cdc.gov>
Subject: burden of COVID-19 in infants

Hi David,

Hope you are well. I am working on an NIH-funded [prospective cohort study](#) on the immune response in mothers and infants following COVID-19 vaccination during pregnancy and postpartum and am seeking more information on the burden of COVID-19 disease in infants <6 months of age. I saw the below NCHS data presented by Sara Oliver at ACIP recently and have reviewed the nice MMWRs with COVID-NET data. I am wondering if you could connect me with someone and/or resources (papers, websites) to further understand what we know about these COVID-19 infections in infants <6 months of age. For example, are there higher-risk groups within the 0-6 month age group for severe disease, are all of the deaths following transmission after pregnancy or are some considered related to congenital infection, are these primarily previously healthy infants with community exposure or do a high proportion have other comorbidities, etc. Having additional data on the burden in early infancy will allow us to understand better the case for vaccination during pregnancy to afford protection for both mom and baby in the first few months of life.

Thanks in advance for any assistance you may provide.

Best

Cristina

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National Institute of Allergy and Infectious Diseases
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5601 Fishers Lane
Rockville, Maryland
cristina.cardemil@nih.gov

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From: Havers, Fiona (CDC/DDID/NCIRD/DVD)
Sent: Thu, 16 Jun 2022 12:25:38 +0000
To: Cardemil, Cristina (NIH/NIAID) [E]
Cc: Fleming-Dutra, Katherine E. (CDC/DDID/NCIRD/DBD); Taylor, Christopher A. (CDC/DDID/NCIRD/DVD)
Subject: RE: burden of COVID-19 in infants

Hi Cristina,

Sounds good. Please feel free to touch base when you get back if you do need anything further from us. Enjoy your leave!

Fiona

From: Cardemil, Cristina (NIH/NIAID) [E] <crisrina.cardemil@nih.gov>
Sent: Wednesday, June 15, 2022 6:04 PM
To: Havers, Fiona (CDC/DDID/NCIRD/DVD) <wja7@cdc.gov>
Cc: Fleming-Dutra, Katherine E. (CDC/DDID/NCIRD/DBD) <ftu2@cdc.gov>; Taylor, Christopher A. (CDC/DDID/NCIRD/DVD) <iyq3@cdc.gov>
Subject: RE: burden of COVID-19 in infants

Hi! Great to hear from you also. I am about to go on leave, but wanted to send a quick reply before I go. We are finally (?) settling in to our new lives –pandemic move had its challenges but being close to family is really great and I am enjoying my new position at NIH. The COVID-NET data have been fantastic, thanks to you and Chris and team for all of your continued efforts on that surveillance system!

We recently submitted the first batch of [interim data](#) from our study for publication, and we are also currently planning for subsequent testing and analyses. We have several hundred mom-infant dyads who received COVID-19 vaccination during pregnancy or postpartum with sera and BM collected at multiple timepoints, and so are primarily using any available burden data in 0-6 month age group at this point to inform prioritization of testing, analyses and publications from our study. I had initially reached out to see if there had been additional data breaking down the 0-6 month age group—the summary provided by David was helpful and Katherine sent a link to a preprint with mortality data from NCHS (thanks again!). Further data in this age group will be informative, as they are related to policy questions for maternal immunization. While I always love to see more data especially pediatric, and I certainly wouldn't turn down anything that you have that is pre-existing or already planned, I don't know that we have a specific need for your team to pull additional COVID-net data at this time, and I know how busy we all are! Likely, data (especially burden) that are summarized for the next push to support maternal immunization and the immune response in the 0-6 month age group will be informative, and Katherine has already kindly offered to provide a summary of information to date.

Our study team meets weekly and now that we are connected (again) can definitely be in touch if more questions arise that may help to guide our analyses.

Best
Cristina

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From: Havers, Fiona (CDC/DDID/NCIRD/DVD) <wja7@cdc.gov>
Sent: Monday, June 13, 2022 11:42 AM
To: Fleming-Dutra, Katherine E. (CDC/DDID/NCIRD/DBD) <ftu2@cdc.gov>; Taylor, Christopher A. (CDC/DDID/NCIRD/DVD) <iyq3@cdc.gov>; Cardemil, Cristina (NIH/NIAID) [E] <cristina.cardemil@nih.gov>
Subject: RE: burden of COVID-19 in infants

Hi Cristina,

How are you? It is nice to see a familiar name on the email! I hope you are enjoying your job at NIH and your family has settled into DC after your move from Atlanta.

How can we be helpful in terms of burden data for infants <6 months of age? What do you need the data for? COVID-NET can get population-based rates for that age group if you like. Also, we recently published an MMWR specifically on children <5, which breaks out the <6 mo age group in some of the data.

- Marks KJ, Whitaker M, Agathis NT, et al. Hospitalization of Infants and Children Aged 0–4 Years with Laboratory-Confirmed COVID-19 — COVID-NET, 14 States, March 2020–February 2022. MMWR Morb Mortal Wkly Rep 2022;71:429–436.
DOI: <http://dx.doi.org/10.15585/mmwr.mm7111e2external icon>

It looks like from earlier in the thread, you have likely seen these data. Please let us know what you think would be useful. We have complete clinical data, including underlying medical conditions, on basically all children hospitalized through COVID-NET. If you give us more detail about the kind of information that you are looking for, we are happy to help.

Best,
Fiona

Fiona Havers, MD, MHS, FIDSA
Medical Officer, Division of Viral Diseases

National Center for Immunizations and Respiratory Diseases
Centers for Disease Control and Prevention
Work cell: 770-596-3550
Email: fhavers@cdc.gov

From: Fleming-Dutra, Katherine E. (CDC/DDID/NCIRD/DBD) <ftu2@cdc.gov>
Sent: Monday, June 13, 2022 8:28 AM
To: Havers, Fiona (CDC/DDID/NCIRD/DVD) <wja7@cdc.gov>; Taylor, Christopher A. (CDC/DDID/NCIRD/DVD) <iyq3@cdc.gov>; Cardemil, Cristina (NIH/NIAID) [E] <cristina.cardemil@nih.gov>
Subject: FW: burden of COVID-19 in infants

Hi Fiona and Cristina,

I wanted to connect you with Cristina Cardemil (now at NIH) who is working on a study looking immune response in mothers and infants following COVID-19 vaccination during pregnancy and postpartum period. She is looking for more information on the burden of COVID-19 disease in infants <6 months of age.

Cristina, Fiona and Chris lead COVID-NET, which (as you probably know) conducts population-based surveillance for COVID-19 associated hospitalization.

Best,
Katherine

Katherine E. Fleming-Dutra, MD (*she/her/hers*)
Detailed to:
COVID-19 Vaccine Policy Unit
National Center for Immunization and Respiratory Diseases
Centers for Disease Control and Prevention
404-639-4243 | ftu2@cdc.gov

From: Siegel, David A. (CDC/DDNID/NCCDPHP/DCPC) <irn3@cdc.gov>
Sent: Wednesday, June 8, 2022 9:05 PM
To: Cardemil, Cristina (NIH/NIAID) [E] <cristina.cardemil@nih.gov>
Cc: Fleming-Dutra, Katherine E. (CDC/DDID/NCIRD/DBD) <ftu2@cdc.gov>
Subject: RE: burden of COVID-19 in infants

Hi Cristina—thanks for reaching out—hope you are doing well. I pasted a summary below that was shared with me—it is an uncleared, informal summary of literature that was created around January. Looping in Katherine here in case she has anything else—Katherine, are you looking at burden of disease in ages <6months, or only 6 months and older for your work with ACIP?

Thanks,

David

David Siegel, MD, MPH

Clinical Disease and Health Systems Team

Epi TF

CDC COVID-19 response

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770-488-4426 (W)

404-831-4935 (M)

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From: Cardemil, Cristina (NIH/NIAID) [E] <cristina.cardemil@nih.gov>
Sent: Wednesday, June 8, 2022 11:04 AM
To: Siegel, David A. (CDC/DDNID/NCCDPHP/DCPC) <irn3@cdc.gov>
Subject: burden of COVID-19 in infants

Hi David,

Hope you are well. I am working on an NIH-funded [prospective cohort study](#) on the immune response in mothers and infants following COVID-19 vaccination during pregnancy and postpartum and am seeking more information on the burden of COVID-19 disease in infants <6 months of age. I saw the below NCHS data presented by Sara Oliver at ACIP recently and have reviewed the nice MMWRs with COVID-NET data. I am wondering if you could connect me with someone and/or resources (papers, websites) to further understand what we know about these COVID-19 infections in infants <6 months of age. For example, are there higher-risk groups within the 0-6 month age group for severe disease, are all of the deaths following transmission after pregnancy or are some considered related to congenital infection, are these primarily previously healthy infants with community exposure or do a high proportion have other comorbidities, etc. Having additional data on the burden in early infancy will allow us to understand better the case for vaccination during pregnancy to afford protection for both mom and baby in the first few months of life.

Thanks in advance for any assistance you may provide.

Best

Cristina

Cristina Cardemil, MD MPH
Medical Officer/CDR, United States Public Health Service
Division of Microbiology and Infectious Diseases
National Institute of Allergy and Infectious Diseases
National Institutes of Health
5601 Fishers Lane
Rockville, Maryland
cristina.cardemil@nih.gov

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From: Twentyman, Evelyn Rebecca Ford (CDC/DDID/NCIRD/DVD)
Sent: Thu, 16 Jun 2022 16:59:58 +0000
To: Matthew Daley; Oliver, Sara Elizabeth (CDC/DDID/NCIRD/DVD)
Subject: RE: Daley slides

Can do! Anything that helps clarify the status of these vaccines sounds good to me. I'll need a few minutes, but will send a revised version ASAP. Thanks!!

From: Matthew Daley <Matthew.F.Daley@kp.org>
Sent: Thursday, June 16, 2022 12:52 PM
To: Twentyman, Evelyn Rebecca Ford (CDC/DDID/NCIRD/DVD) <ydj2@cdc.gov>; Oliver, Sara Elizabeth (CDC/DDID/NCIRD/DVD) <yxo4@cdc.gov>
Subject: Daley slides

Hi again Evelyn,

Hope you are well. Apologies for the string of minor (hopefully not nit-picky!) comments.

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M

From: Twentyman, Evelyn Rebecca Ford (CDC/DDID/NCIRD/DVD) <ydj2@cdc.gov>
Sent: Tuesday, June 14, 2022 12:45 PM
To: Matthew Daley <Matthew.F.Daley@kp.org>; Oliver, Sara Elizabeth (CDC/DDID/NCIRD/DVD) <yxo4@cdc.gov>
Subject: RE: Revised intro slides -- new death ranks, new flu content

Thank you so much Matt.

Slides are revised attached – thank you! Happy to keep changing things, too; please let us know what you think.

Yes, public comment is last Friday.

June 18th – gave a shot at summarizing some concerns we might hear – see what you think. Also hoping Sara can advise if we are limited in our ability to do this for any reason.

Thank you both!!

Evelyn

From: Matthew Daley <Matthew.F.Daley@kp.org>

Sent: Tuesday, June 14, 2022 1:02 PM

To: Twentyman, Evelyn Rebecca Ford (CDC/DDID/NCIRD/DVD) <ydj2@cdc.gov>; Oliver, Sara Elizabeth (CDC/DDID/NCIRD/DVD) <yxo4@cdc.gov>

Subject: RE: Revised intro slides -- new death ranks, new flu content

These look great. Thanks so much.

(b)(5)

(b)(5)

Public comment is last on Friday?

For the June 18th slides, those look good.

(b)(5)

(b)(5)

Thanks

Matt

PS.

From: Twentyman, Evelyn Rebecca Ford (CDC/DDID/NCIRD/DVD) <ydj2@cdc.gov>

Sent: Tuesday, June 14, 2022 6:39 AM

To: Matthew Daley <Matthew.F.Daley@kp.org>; Oliver, Sara Elizabeth (CDC/DDID/NCIRD/DVD) <yxo4@cdc.gov>

Subject: Revised intro slides -- new death ranks, new flu content

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Good morning, and happy VRBPAC day 1! 😊

Thanks so much for your time yesterday in discussing these slides. Please find a revised slide deck for June 17 attached. A few notes:

- On the cause of death rankings:
 - It makes a difference whether one cites the cumulative incidence or annualized incidence of each cause of death. Therefore, I added this cumulative incidence basis to both the bullet itself and the reference footnote.
 - In a way it does not matter among infectious diseases—COVID is the leading cause of death secondary to infectious disease either way. However, this makes for clean context that applies across the entire slide.
 - We broke out all cause mortality for both:
 - children ages 0-19, for which COVID is #7;
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 - Averted illnesses/hospitalizations/deaths are now limited to children 6 months—4 years, and placed in context of substantial disease burden, variable vaccine efficacy, and the consistent vaccine coverage just presented.
 - These have been approved by our flu vaccine folks.

I'm also attaching draft slides for June 18 – I realized we never even broached them yesterday. I don't think there's too much to discuss on these, but definitely let us know if you have any questions/concerns or want anything revised!

Thanks so much, and have a wonderful day!

Evelyn

(b)(6)

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From: Oliver, Sara Elizabeth (CDC/DDID/NCIRD/DVD)
Sent: Fri, 10 Jun 2022 14:54:50 +0000
To: Fleming-Dutra, Katherine E. (CDC/DDID/NCIRD/DBD)
Subject: RE: FW (Non-urgent): burden of COVID-19 in infants

Katherine:

Sounds good. I agree it would be helpful for us to have a talk. I want to be super collaborative, while also not getting too far ahead of where ACIP is and what we have shared with them. So lets hold off on sharing a ton of stuff that's not publicly available quite yet and figure out the best next steps.

Agree that it would be helpful if we can sync the week of June 27th and not the next 2 weeks, but I would love to coordinate overall on this (and love for YOU to do a lot of that coordination!!)

Thanks!
Sara

From: Fleming-Dutra, Katherine E. (CDC/DDID/NCIRD/DBD) <ftu2@cdc.gov>
Sent: Friday, June 10, 2022 10:25 AM
To: Oliver, Sara Elizabeth (CDC/DDID/NCIRD/DVD) <yxo4@cdc.gov>
Subject: FW (Non-urgent): burden of COVID-19 in infants

Hi Sara,

One my EIS classmates, Cristina Cardemil, is now at NIH working on maternal COVID vaccination. She reached out asking for data on epi of infants <6 months. I can share the information I have pulled together from COVID-NET, NVSN, MIS-C, and NCHS, and I will give the teams a quick heads up before doing that as well. That will likely be next week.

Also, I think it would be helpful to have a call to discuss where we can synergize efforts. That can be after the Little Peds push. I can coordinate, if that would work for you.

She said: This is actually a good time as if you have data analysis priorities to help inform future policy for maternal vaccination we can discuss and see where we may be able to support each other. We have a really great team of maternal immunization policy and academic experts who have worked for years on similar questions (eg, Tdap and influenza vaccination during pregnancy).

Thanks!
Katherine

From: Cardemil, Cristina (NIH/NIAID) [E] <cristina.cardemil@nih.gov>
Sent: Thursday, June 9, 2022 10:54 AM
To: Fleming-Dutra, Katherine E. (CDC/DDID/NCIRD/DBD) <ftu2@cdc.gov>; Siegel, David A. (CDC/DDNID/NCCDPHP/DCPC) <irn3@cdc.gov>
Subject: RE: burden of COVID-19 in infants

Hi Katherine, great to hear from you also!

We are pending submission for the first batch of interim data from our study, and we are also currently planning for subsequent testing and analyses, so primarily using the data at this point to inform prioritization of analyses and publications from our study. In the future, we may also cite published data. Anything that is unpublished or not available on public websites will of course keep confidential.

I agree that meeting would be helpful. This is actually a good time as if you have data analysis priorities to help inform future policy for maternal vaccination we can discuss and see where we may be able to support each other. We have a really great team of maternal immunization policy and academic experts who have worked for years on similar questions (eg, Tdap and influenza vaccination during pregnancy). We could potentially do a quick touch base with you and I to determine goals, but also expand to include others if that would be helpful. I am meeting with the team tomorrow and can run this by them. I am guessing you are probably swamped with ACIP prep, so just let me know what format and timing would work best for you.

Best
Cristina

Cristina Cardemil, MD MPH
Medical Officer/CDR, United States Public Health Service
Division of Microbiology and Infectious Diseases
National Institute of Allergy and Infectious Diseases
National Institutes of Health
5601 Fishers Lane
Rockville, Maryland
cristina.cardemil@nih.gov

From: Fleming-Dutra, Katherine E. (CDC/DDID/NCIRD/DBD) <ftu2@cdc.gov>
Sent: Thursday, June 9, 2022 9:38 AM
To: Cardemil, Cristina (NIH/NIAID) [E] <cristina.cardemil@nih.gov>; Siegel, David A. (CDC/DDNID/NCCDPHP/DCPC) <irn3@cdc.gov>
Subject: RE: burden of COVID-19 in infants

Hi Cristina!

It is great to hear from you! I hope you are doing well. Thanks David for connecting us. I have compiled some updated data on infants 0-5 months, although not yet systematically. Our current push is for

infants and children 6 months and older to support ACIP recommendations for that age group. However, the next pediatric considerations will be around infants <6 months.

Cristina, when do you need this and what format do you need? How will you be using and sharing the data? I can share the data I have compiled, but first I should let the SMEs who provided the data know. Also, I would love to talk more with you as we prepare for potential vaccine policy for maternal vaccination.

Best,
Katherine

Katherine E. Fleming-Dutra, MD (*she/her/hers*)
Detailed to:
COVID-19 Vaccine Policy Unit
National Center for Immunization and Respiratory Diseases
Centers for Disease Control and Prevention
404-639-4243 | ftu2@cdc.gov

From: Cardemil, Cristina (NIH/NIAID) [E] <cristina.cardemil@nih.gov>
Sent: Thursday, June 9, 2022 9:29 AM
To: Siegel, David A. (CDC/DDNID/NCCDPHP/DCPC) <irn3@cdc.gov>
Cc: Fleming-Dutra, Katherine E. (CDC/DDID/NCIRD/DBD) <ftu2@cdc.gov>
Subject: RE: burden of COVID-19 in infants

Thanks David, these are very helpful. This is a great summary and adds context. Please do let me know if other data are or become available.

Best
Cristina

Cristina Cardemil, MD MPH
Medical Officer/CDR, United States Public Health Service
Division of Microbiology and Infectious Diseases
National Institute of Allergy and Infectious Diseases
National Institutes of Health
5601 Fishers Lane
Rockville, Maryland
cristina.cardemil@nih.gov

From: Siegel, David A. (CDC/DDNID/NCCDPHP/DCPC) <irn3@cdc.gov>
Sent: Wednesday, June 8, 2022 9:05 PM
To: Cardemil, Cristina (NIH/NIAID) [E] <cristina.cardemil@nih.gov>

Cc: Fleming-Dutra, Katherine E. (CDC/DDID/NCIRD/DBD) <ftu2@cdc.gov>

Subject: RE: burden of COVID-19 in infants

Hi Cristina—thanks for reaching out—hope you are doing well. I pasted a summary below that was shared with me—it is an uncleared, informal summary of literature that was created around January. Looping in Katherine here in case she has anything else—Katherine, are you looking at burden of disease in ages <6months, or only 6 months and older for your work with ACIP?

Thanks,
David

David Siegel, MD, MPH

Clinical Disease and Health Systems Team

Epi TF

CDC COVID-19 response

Phone:

770-488-4426 (W)

404-831-4935 (M)

(b)(5)

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From: Cardemil, Cristina (NIH/NIAID) [E] <cristina.cardemil@nih.gov>
Sent: Wednesday, June 8, 2022 11:04 AM
To: Siegel, David A. (CDC/DDNID/NCCDPHP/DCPC) <irn3@cdc.gov>
Subject: burden of COVID-19 in infants

Hi David,

Hope you are well. I am working on an NIH-funded [prospective cohort study](#) on the immune response in mothers and infants following COVID-19 vaccination during pregnancy and postpartum and am seeking more information on the burden of COVID-19 disease in infants <6 months of age. I saw the below NCHS data presented by Sara Oliver at ACIP recently and have reviewed the nice MMWRs with COVID-NET data. I am wondering if you could connect me with someone and/or resources (papers, websites) to further understand what we know about these COVID-19 infections in infants <6 months of age. For example, are there higher-risk groups within the 0-6 month age group for severe disease, are all of the deaths following transmission after pregnancy or are some considered related to congenital infection, are these primarily previously healthy infants with community exposure or do a high proportion have other comorbidities, etc. Having additional data on the burden in early infancy will allow us to understand better the case for vaccination during pregnancy to afford protection for both mom and baby in the first few months of life.

Thanks in advance for any assistance you may provide.

Best

Cristina

Cristina Cardemil, MD MPH
Medical Officer/CDR, United States Public Health Service
Division of Microbiology and Infectious Diseases
National Institute of Allergy and Infectious Diseases
National Institutes of Health
5601 Fishers Lane
Rockville, Maryland
cristina.cardemil@nih.gov

(b)(5)

From: Nordlund, Kristen (CDC/OD/OADC)
Sent: Sat, 18 Jun 2022 21:09:28 +0000
To: Oliver, Sara Elizabeth (CDC/DDID/NCIRD/DVD); Fleming-Dutra, Katherine E. (CDC/DDID/NCIRD/DBD)
Subject: RE: Reporters asking about criticism of ACIP slides saying COVID is a "leading cause of death" in children

Thanks Sara!

(b)(5)

(b)(5)

And

really, I think the bottom line (which lots of ACIP members said today) is any death in a child (regardless of where it ranks on a list) is one too many.

Many thanks,
Kristen

From: Oliver, Sara Elizabeth (CDC/DDID/NCIRD/DVD) <yxo4@cdc.gov>
Sent: Saturday, June 18, 2022 5:05 PM
To: Fleming-Dutra, Katherine E. (CDC/DDID/NCIRD/DBD) <ftu2@cdc.gov>; Nordlund, Kristen (CDC/OD/OADC) <hok4@cdc.gov>
Subject: RE: Reporters asking about criticism of ACIP slides saying COVID is a "leading cause of death" in children

Kristen:

(b)(5)

Hope that helps? Happy to discuss further if needed-

Sara

From: Fleming-Dutra, Katherine E. (CDC/DDID/NCIRD/DBD) <ftu2@cdc.gov>
Sent: Saturday, June 18, 2022 4:44 PM
To: Oliver, Sara Elizabeth (CDC/DDID/NCIRD/DVD) <yxo4@cdc.gov>
Subject: Fwd: Reporters asking about criticism of ACIP slides saying COVID is a "leading cause of death" in children

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From: Nordlund, Kristen (CDC/OD/OADC) <hok4@cdc.gov>
Sent: Saturday, June 18, 2022 4:38:45 PM
To: Fleming-Dutra, Katherine E. (CDC/DDID/NCIRD/DBD) <ftu2@cdc.gov>
Cc: Launi, Lori (ATSDR/OAD/OD) <lwe8@cdc.gov>; CDC IMS 2019 NCOV Response Epi TF Communications Team <eocevent101@cdc.gov>
Subject: Reporters asking about criticism of ACIP slides saying COVID is a "leading cause of death" in children

Hi Katherine,

I hope all is well! Lena Sun at the Washington Post reached out about what appears to be some criticism of the data that you showed at VRBPAC and ACIP about COVID being a leading cause of death in young children (I have a feeling you've received follow up about it too). Below is what was sent to the Post and a tweet from a UK researcher.

<https://twitter.com/apsmunro/status/1538138493741850633?s=21&t=75nu8fq2ODMlIQ6inATuYg>

Do you know if the study authors are saying anything about the data or if NCHS has? I'm happy to reach out to NCHS if that's helpful.

Thanks,
Kristen

Kristen Nordlund

Acting Deputy Branch Chief

News Media Branch

o: 404-639-7387 | c: 404-956-0336 | e-mail: hok4@cdc.gov

Begin forwarded message:

From: kelley@covid-georgia.com
Date: June 18, 2022 at 3:17:27 PM EDT
To: "Jan, Tracy" <Tracy.Jan@washpost.com>
Subject: Covid as a "leading cause of death" in children

CAUTION: EXTERNAL SENDER

Tracy,

I saw today's article about the approval of the vaccine for young children, and replied to your tweet, but I wanted to follow up via email as well. The slide that claimed Covid was a top 5 leading death for children of all age groups was based on a severely flawed pre-print from the UK. I wrote up a detailed fact check explaining the issues, which has been shared widely. The study and corresponding slide have also been called out by numerous experts, both in the US and the UK. Please consider updating the article, and perhaps writing a new article about the poor quality of data used.

<https://www.covid-georgia.com/news/fact-check-covid-is-a-leading-cause-of-death-in-children/> [covid-georgia.com]

<https://twitter.com/apsmunro/status/1538138493741850633> [twitter.com]

<https://twitter.com/BallouxFrancois/status/1538222423241261056> [twitter.com]

Thank you,

Kelley Krohnert

kelley@covid-georgia.com

www.covid-georgia.com [covid-georgia.com]

Twitter: <https://www.twitter.com/kelleykga> [twitter.com]

Sent: Sat, 18 Jun 2022 20:49:38 +0000
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(b)(5)

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Kristen Nordlund

*Acting Deputy Branch Chief
News Media Branch*

o: 404-639-7387 | c: 404-956-0336 | e-mail: hok4@cdc.gov

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<https://www.covid-georgia.com/news/fact-check-covid-is-a-leading-cause-of-death-in-children/> [[covid-georgia.com](https://www.covid-georgia.com)]

<https://twitter.com/apsmunro/status/1538138493741850633> [twitter.com]

<https://twitter.com/BallouxFrancois/status/1538222423241261056> [twitter.com]

Thank you,

Kelley Krohnert

kelley@covid-georgia.com

www.covid-georgia.com [[covid-georgia.com](http://www.covid-georgia.com)]

Twitter: <https://www.twitter.com/kelleykga> [[twitter.com](https://www.twitter.com/kelleykga)]

From: Oliver, Sara Elizabeth (CDC/DDID/NCIRD/DVD)
Sent: Tue, 14 Jun 2022 21:31:21 +0000
To: Matthew Daley; Twentyman, Evelyn Rebecca Ford (CDC/DDID/NCIRD/DVD)
Subject: RE: Revised intro slides -- new death ranks, new flu content

I also reached out to Jessica to see if there's any thing we can provide about the docket as well, even if it's that thousands of comments have been submitted before and each have been reviewed, or something. We'll see what she thinks we could do and let you know!

From: Matthew Daley <Matthew.F.Daley@kp.org>
Sent: Tuesday, June 14, 2022 5:26 PM
To: Twentyman, Evelyn Rebecca Ford (CDC/DDID/NCIRD/DVD) <ydj2@cdc.gov>; Oliver, Sara Elizabeth (CDC/DDID/NCIRD/DVD) <yxo4@cdc.gov>
Subject: RE: Revised intro slides -- new death ranks, new flu content

Excellent, thanks Evelyn. A few added comments/suggestions:

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As for the June 18th slides,

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M

From: Twentyman, Evelyn Rebecca Ford (CDC/DDID/NCIRD/DVD) <ydj2@cdc.gov>
Sent: Tuesday, June 14, 2022 12:45 PM
To: Matthew Daley <Matthew.F.Daley@kp.org>; Oliver, Sara Elizabeth (CDC/DDID/NCIRD/DVD) <yxo4@cdc.gov>
Subject: RE: Revised intro slides -- new death ranks, new flu content

Thank you so much Matt.

Slides are revised attached – thank you! Happy to keep changing things, too; please let us know what you think.

Yes, public comment is last Friday.

June 18th – gave a shot at summarizing some concerns we might hear – see what you think. Also hoping Sara can advise if we are limited in our ability to do this for any reason.

Thank you both!!
Evelyn

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To: Twentyman, Evelyn Rebecca Ford (CDC/DDID/NCIRD/DVD) <ydj2@cdc.gov>; Oliver, Sara Elizabeth (CDC/DDID/NCIRD/DVD) <yxo4@cdc.gov>
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(b)(5)

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Matt
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 - These have been approved by our flu vaccine folks.

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Thanks so much, and have a wonderful day!

Evelyn

(b)(6)

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COVID-19 in Georgia



Fact Check: Covid as a Leading Cause of Death in Children

Fact Check, Pediatric News / By Kelley

In the CDC ACIP meeting on June 17 to discuss childhood Covid vaccines, a table was presented showing Covid was a leading cause of death in US children as part of a [slide deck on the epidemiology of Covid-19 in children and adolescents](#) by Dr. Katherine Fleming-Dutra. The source was a [pre-print written by a group of academics from the UK](#), including [Dr. Seth Flaxman](#) and [Dr. Deepti Gurdasani](#), who is well-known on Twitter for her strong views on Covid. I later learned that [a very similar slide was also presented at the beginning of the FDA VRBPAC meeting earlier in the week](#), as were other slides citing this “top 5 cause of death” claim.

The slide was shared on Twitter by [Dr. Katelyn Jetelina](#) (“Your Local Epidemiologist”), and retweeted by many influential people including [Jerome Adams](#), [Julia Raifman](#) (tweet now deleted), [Gregg Gonsalves](#), and [Leana Wen](#). Only problem? **It’s completely and utterly false.** The pre-print it’s based on includes significant errors that invalidate the results. And the slide makes additional errors on top of the pre-print. It’s really disturbing that data this poor made its way into the meetings to discuss childhood Covid, and that it took me less than a few minutes to find a major flaw (and then I found many more as I looked deeper).

On Friday, June 17, I contacted the study’s corresponding author, Dr. Flaxman, who originally said he’d get back to me on Monday, but responded early Sunday morning to get more information about the source of the Underlying Cause of Death data I used for Covid (the [CDC WONDER database](#), Provisional Mortality Statistics, 2018-present). He later [posted on Twitter to say that an updated pre-print would be available soon](#).

UPDATE: A [revised pre-print](#) taking into account my critique was posted on June 28. The rankings are now for every age group, but the authors did some other questionable things to exaggerate Covid deaths in children, including changing the time period for the Covid deaths to the worst 12 month period in the pandemic. I posted a quick Twitter thread to [review of the revised pre-print](#).

COVID-19 is a leading cause of death among children ages 0–19 years

March 1, 2020–April 30, 2022

Age group	Rank of COVID-19 among causes of death
<1 year	4
1–4 years	5
5–9 years	5
10–14 years	4
15–19 years	4

Based on death certificate data from the National Center for Health Statistics. COVID-19 based on cumulative total incidence of COVID-19 deaths from March 1, 2020-April 30, 2022.

Source: Flaxman S, Whittaker C, Semenova E et al. Covid-19 is a leading cause of death in children and young people ages 0-19 years in the United States. medRxiv 2022.05.23.22275458; doi: <https://doi.org/10.1101/2022.05.23.22275458>

There are two major errors with this data, along with some other problems, so I'll go through them individually. The two major errors are of such consequence that I believe this study should be fully retracted.

Underlying Causes of Death

The first major issue I noticed was that they downloaded Covid numbers from NCHS. This source includes deaths where Covid is listed anywhere on the death certificate, not just the underlying cause of death. Death certificates include a single underlying cause of death, along with potentially several contributing causes of death. The NCHS data includes both, which overcounts Covid deaths because it includes death that had a different underlying cause.

What is officially counted as a COVID-19 death?

- Deaths are attributed to COVID-19 when Coronavirus Disease 2019, COVID-19, or other similar term(s) are reported as a *cause* or *contributing cause* of death on the death certificate.
 - When COVID-19 is reported by the certifier as a cause of death, it is coded to the *International Classification of Diseases, 10th Revision* (ICD-10) code for mortality for COVID-19, which is **U07.1**.
 - **NCHS counts of deaths due to COVID-19 include only deaths that have U07.1 as a cause or contributing cause of death.**

<https://www.cdc.gov/nchs/covid19/faq.htm>

The pre-print states “we only consider Covid-19 as an underlying (and not contributing) cause of death” but **this is false**. It also states “In children and young people (CYP) aged 0-19 years, data from the National Center for Health Statistics (NCHS) indicate there were **1,433** deaths for which Covid-19 was the underlying cause of death (March 1, 2020-April 30, 2022).” However, this includes deaths where Covid was NOT, in fact, the underlying cause of death. According to **CDC WONDER**, underlying deaths from Covid for this age group and time period actually totaled **1,088** deaths.

This is a major problem, because the pre-print adds Covid to a ranking of the top **underlying** causes of death from 2019 from CDC WONDER. **The WONDER data they used is specifically Underlying Cause of Death data**. This significantly overcounts Covid deaths compared to the other causes of death listed.

This is basically **the same error that I addressed recently with Jeremy Faust’s blog post comparing pediatric deaths from Covid and the flu**. After I called out this error, Dr. Faust posted a follow-up blog post where he admitted it was wrong to compare multiple CoD data with underlying CoD data.

Cumulative vs Annualized Covid Deaths

The second major issue with the pre-print are the time periods for the deaths. The underlying cause of death data is for a single year – 2019 (more on that later). However, the rankings of Covid deaths by age group in the pre-print include both cumulative (**over 26 months**) AND annualized deaths for some strange reason. That means Covid is inexplicably ranked *twice* for each age group.

Below is the table ranking leading causes of death for 15-19 year olds. Notice that Covid is listed both as the 4th AND the 6th leading cause of death. This is non-sensical and extremely misleading. It is completely inappropriate to compare the cumulative number of Covid deaths over 26 months to deaths from other causes over a one year period. The only way to make a fair comparison is to use an annualized number. There’s no good reason the cumulative number of Covid deaths over 26 months should be included on this list at all.

To make matters worse, **CDC used the rankings for the cumulative Covid-19 deaths** on their slide, further overcounting Covid deaths compared to the other causes of death listed.

Table 1(e)			
Age: 15-19 year olds			
Leading Causes of Death	Crude Rate (per 100,000)	Deaths	Rank
#Accidents (unintentional injuries) (V01-X59,Y85-Y86)	16.8	3537	1
#Intentional self-harm (suicide) (*U03,X60-X84,Y87.0)	10.5	2210	2
#Assault (homicide) (*U01-*U02,X85-Y09,Y87.1)	8.9	1877	3
Covid-19 (cumulative)	3.2	701	4
#Malignant neoplasms (C00-C97)	2.8	589	5
Covid-19 (annualized)	1.5	324	6
#Diseases of heart (I00-I09,I11,I13,I20-I51)	1.4	288	7
#Congenital malformations, deformations and chromosomal abnormalities (Q00-Q99)	0.9	188	8
#Influenza and pneumonia (J09-J18)	0.3	71	9
#Chronic lower respiratory diseases (J40-J47)	0.3	60	9
#Diabetes mellitus (E10-E14)	0.3	59	9

Table 1. Leading causes of death for children and young people aged 0-19 years in 2019 in the US ranked, compared to Covid-19 deaths either as the cumulative total incidence of Covid-19 deaths for March 1, 2020-April 30, 2022 or as annualized figures. Deaths, crude rates per 100,000, and ranks are shown for ages < 1 year (a), 1-4 years (b), 5-9 years (c), 10-14 years (d), 15-19 years (e). In all cases, Covid-19 is a leading cause of death.

Corrected Data

I recreated the results from the pre-print using CDC WONDER to obtain deaths where Covid-19 is listed as the underlying cause of death in the time period listed, and annualized the results. The revised rankings are shown below, alongside the incorrect rankings used on the CDC slide. I also show the annualized number of deaths when using deaths with Covid as the underlying cause of death only, instead of the underlying or contributing cause of death.

Age Group	CDC Ranking	Corrected Ranking
<1 year	4	9
1-4 years	5	8 (in a 4-way tie)
5-9 years	5	8 (in a 4-way tie)

10-14 years	4	8 (in a 2-way tie)
15-19 years	4	6

Age Group	Annualized NCHS Deaths (Underlying or Contributing COD)	Annualized WONDER Deaths (Underlying COD Only)
<1 year	124	79
1-4 years	62	48
5-9 years	62	49
10-14 years	90	66
15-19 years	324	260

Issues using Rankings for Pediatric Covid Deaths

Even given the corrected rankings above, there are also issues with the entire concept of showing the impact of Covid deaths in children using rankings. Rankings overstate the impact of Covid, because the top few causes of death far outweigh the causes further down the list. For example, in ages 1-4, accidents account for almost 25 times as many deaths as Covid-19 on an annualized basis. Furthermore, for each of the 4 age groups covered by the CDC slide, the very broad “accidents” is the leading cause of death. If we break that down further, causes of death like drownings, vehicle crashes, drug overdoses, would be individual causes of death greater than Covid in various age groups. Actuary Mary Pat Campbell explains this well in a couple of blog posts on pediatric Covid deaths:

- [Childhood Mortality Trends, 1999-2021 \(provisional\), Ages 1-17](#)
- [Pools are more dangerous than Covid to small children](#)

The study authors incorrectly posit that the way the cause of death rankings are grouped, the ranking for Covid is “conservative” since it is a single cause rather than a group of causes (like accidents). However, this makes no sense when you consider that some of the subgroups under accidental deaths would alone be greater than Covid.

Additional Thoughts

I have some additional thoughts on this study that I would like to delve into more at a later time. For example, why did they use data from 2019 and not 2020 or 2021, when aspects of our Covid response affected some of the leading causes of death? Also, why did a group of UK researchers analyze US deaths, for which they apparently did not understand the data well, instead of using deaths from their own country? Could it be because US counts Covid deaths very generously, so our data made it easier to present Covid as a leading cause of death in children? In addition, why did they inflate the counts by include 18 and 19 year olds in the data, when the pediatric population is generally accepted to be 0-17?

On the CDC side, how did Dr. Katherine E. Fleming-Dutra, MD at the CDC, a pediatrician and doctor of emergency medicine, not realize this data was seriously flawed and out of line with all other data about the impact of Covid on pediatric mortality? How did a pre-print get used in an ACIP and FDA presentation with such little oversight without the quality of the data being fully vetted? How did I uncover these issues, instead of them being identified by someone whose job it is to evaluate this kind of data? I am a mother who reviews this data on my personal time, and yet I seem to be much more knowledgeable about Covid deaths in children than most academics and public health officials working with Covid-19. We are forced to believe that the CDC researchers who put this data together are either incompetent or liars, and when all the mistakes go in the same direction, it certainly seems like the CDC uses whatever data they can find to push their agenda without any consideration to its veracity.

This is a national disgrace (and an international one, considering the paper came from the UK). I'm appalled at the low quality of the data presented and the fact that it was amplified in such an influential way when discussing the approval of vaccines in young children. The CDC and much of the academic and public health community have utterly failed the American public when it comes to accurately assessing the risk to children (among other things).

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