From:

**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] <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)

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,

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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

**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.

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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

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) < <a href="mailto:irn3@cdc.gov">irn3@cdc.gov</a> <a href="mailto:CCC">Cc: Fleming-Dutra, Katherine E. (CDC/DDID/NCIRD/DBD) < <a href="mailto:ftu2@cdc.gov">ftu2@cdc.gov</a> <a href="mailto:script-align: right;">ftu2@cdc.gov</a> <a href="mailto:script-align: right;">right: script-align: right;</a> <a href="mailto:script-align: right;">ftu2@cdc.gov</a> <a href="mailto:script-align: right;">right: script-align: right;</a> <a href="mailto:script-align: right;">right: script-align: right;</a> <a href="mailto:script-align: right;">ftu2@cdc.gov</a> <a href="mailto:script-align: right;">right: script-align: right;</a> <a href="mailto:script-align: right;">ftu2@cdc.gov</a> <a href="mailto:script-align: right;">right: script-align: right;</a> <a href="mailto:script-align: right;">right: script-align: right;<

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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>

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Thanks, David

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(b)(5)	



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<a href="mailto:cristina.cardemil@nih.gov">cristina.cardemil@nih.gov</a>

(b)(5)	

**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

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.

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National Institutes of Health
5601 Fishers Lane
Rockville, Maryland
cristina.cardemil@nih.gov

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:

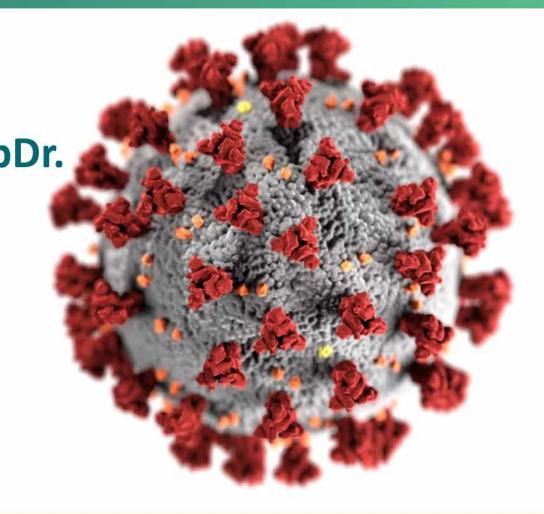
- On the cause of death rankings:
  - It makes a difference whether one cites the cumulative incidence or annualized incidence of each cause of death. Therefore, I added this cumulative incidence basis to both the bullet itself and the reference footnote.
    - In a way it does not matter among infectious 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.
  - O 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!

(b)(6)

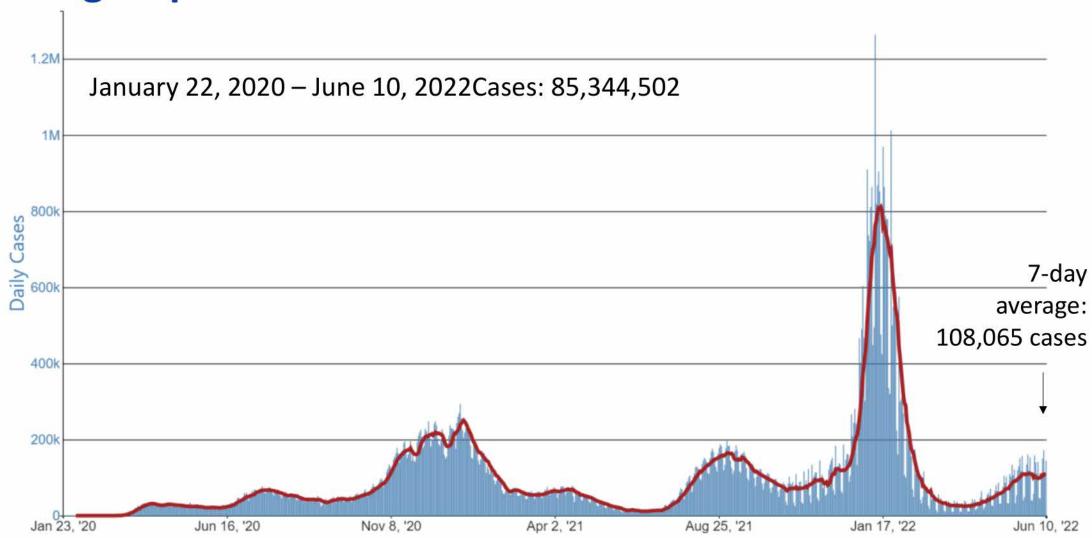
ACIP COVID-19 Vaccines Work GroupDr. Matthew F. Daley, Work Group ChairJune 17, 2022





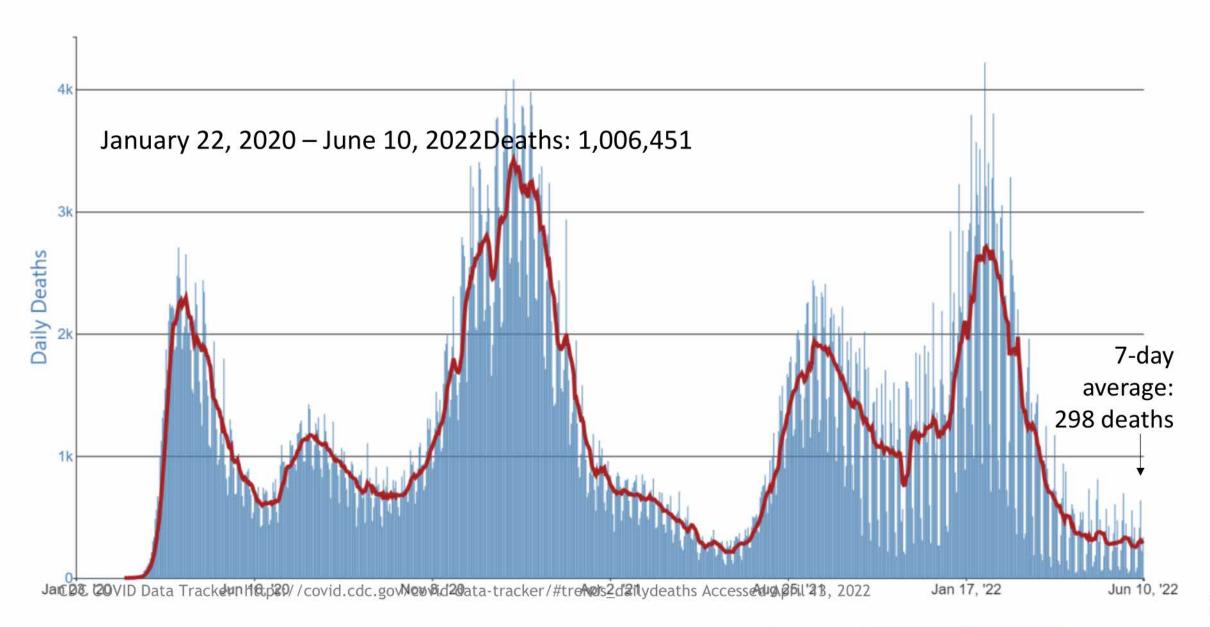
cdc.gov/coronavirus

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



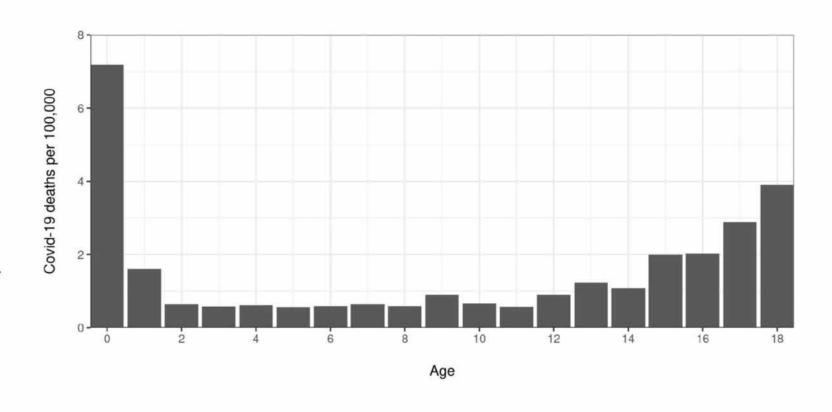
Source: COVID Data Tracker, <a href="https://covid.cdc.gov/covid-data-tracker/#trends\_dailytrendscases">https://covid.cdc.gov/covid-data-tracker/#trends\_dailytrendscases</a>, accessed June 11 2022

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



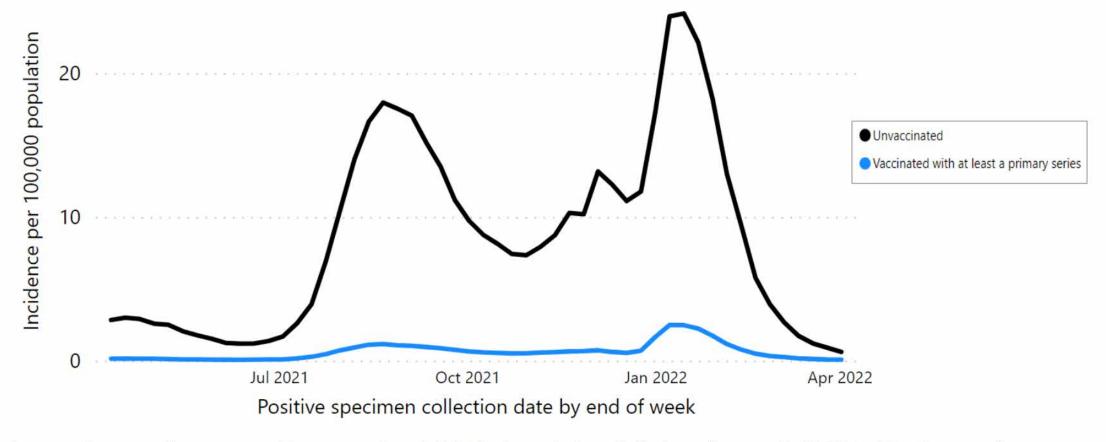
# COVID-19 death rate among children by age, United States, March 1, 2020—April 30, 2022

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 0-19Among 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.

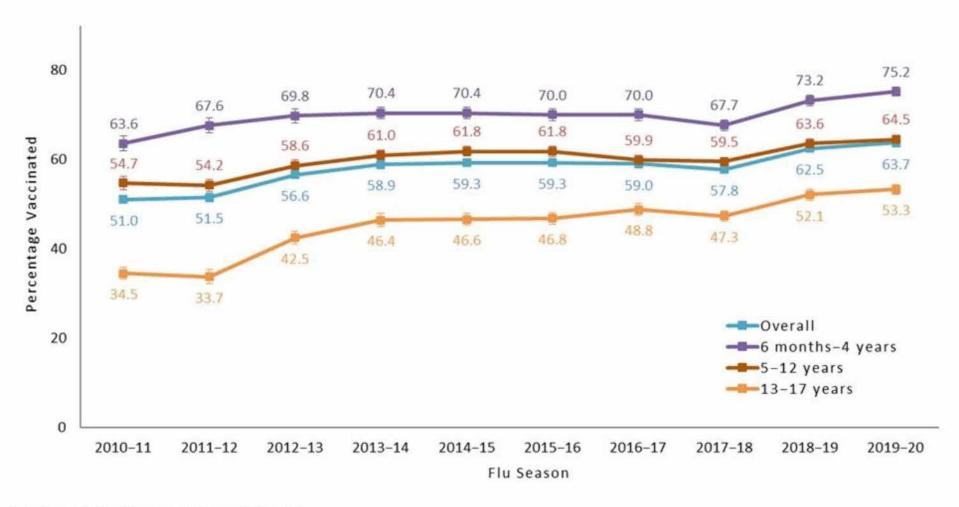
# Pediatric vaccine preventable diseases: Deaths per year in the United States prior to recommended vaccines

	Hepatitis A <sup>1</sup>	Meningococcal (ACWY) <sup>2</sup>	Varicella <sup>3</sup>	Rubella <sup>4</sup>	Rotavirus <sup>5</sup>	COVID-19 <sup>6</sup>
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 Dis2008; 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, Jumaan 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 SW, Murphy TV; Historical comparisons of morbidity and mortality for vaccine-preventable diseases in the United States. JAMA 2007; 298:2155–63.

<sup>5</sup> 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:S5-11.6 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



# 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 averted1-2: 4.3-20.1 million illnesses 2.9-15.5 million visits 32.000-164,000 hospitalizations 150-2350 deaths





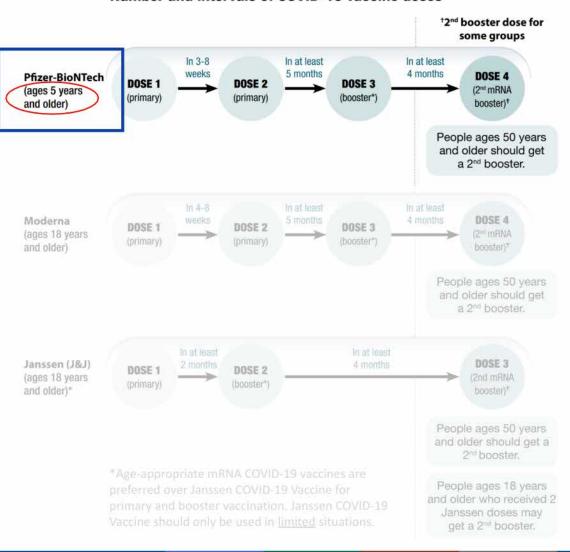
In the context of: Substantial disease burdenSeasonal incidence of about 5-20%3 Variable vaccine efficacy (VE) Vaccine efficacy estimates ranging from 19-60% from 2010-20204 In the setting of ongoing viral mutations, and need to determine vaccine composition ahead of flu seasonConsistent vaccine coverage

1. Rolfes 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 Projection. 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. <a href="https://www.cdc.gov/flu/about/burden-averted/2019-2020.htm">www.cdc.gov/flu/about/burden-averted/2019-2020.htm</a> Accessed June 13, 2022. 3. Jerome I Tokars, Sonja J Olsen, Carrie Reed, Seasonal Incidence of Symptomatic Influenza in the United States, Clinical Infectious Diseases, Volume 66, Issue 10 5 Mp) 2018 Prace 150 1518 OLS. (In 1918 OLS.) The Network Managed William Science and Vertex Managed Village Cines and Vertex

### **Current recommendations for COVID-19 vaccines**

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

#### Number and intervals of COVID-19 vaccine doses



### **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
 COVID-19 vaccine effectiveness in children and adolescents

Dr. Fleming-Dutra (CDC)
Dr. Link-Gelles (CDC)

BreakSafety and immunogenicity of Moderna 2-dose primary series Dr. Das (Moderna) in children ages 6 months—5 yearsSafety and immunogenicity of BNT 162b2 3-dose primary series Dr. Gruber (Pfizer)

in children ages 6 months—4 yearsmRNA COVID-19 vaccines in young children:

Dr. Oliver (CDC)

Summary and Work Group interpretation PUBLIC COMMENT

# **Work Group members**

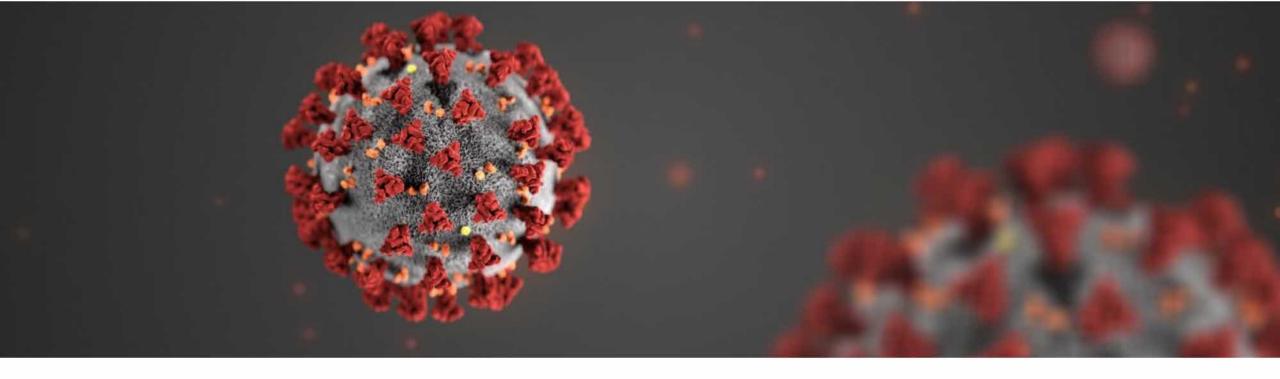
ACIP membersMatthew Daley (chair)Beth Bell Grace LeeKeipp TalbotOliver BrooksEx-officio/government membersFDA: Doran Fink, Rachel Zhang, Lucia LeeNIH: Chris RobertsIHS: Uzo ChukwumaDOD: Bryan SchumacherCMS: Jeff KelmanBARDA: Christine OshanskyHHS: David KimCDC LeadsSara OliverEvelyn Twentyman

LiaisonsAAFP: Jonathan TemteAAP: Sean O'LearyACOG: Denise Jamieson (primary), Laura Riley (alternate)ACP: Jason GoldmanADS: Emily KahnAGS: Ken SchmaderAIM: Rob Shechter (primary), Jane Zucker (alternate)AMA: Sandra FryhoferANA: Kendra McMillan (primary), Ruth Francis (alternate)APhA: Michael HogueASTHO: Marcus PlesciaCSTE: 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)NFID:
Bill Schaffner (primary),
Marla Dalton (alternate)NMA: Patricia
Whitley-WilliamsSHEA: Marci
DreesConsultantsEd Belongia Kathy Kinlaw
Dayna Matthew Kathleen Neuzil Stanley
Perlman Peter SzilagyiJose RomeroHank
Bernstein

# **CDC** participants

- Sarah MeyerEvelyn
   TwentymanTara
   AndersonAmy BlainMary
   ChamberlandKatherine
   Fleming-DutraMonica
   GodfreySusan
   GoldsteinStephen
   HadlerElisha HallValerie
   MorelliDanielle
   MouliaLauren 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.



To:	Oliver, Sara Elizabeth (CDC/DDID/NCIRD/DVD); Fleming-Dutra, Katherine E.
<u> </u>	D); Twentyman, Evelyn Rebecca Ford (CDC/DDID/NCIRD/DVD)
Cc: Subject:	Grusich, Katherina (Kate) (CDC/DDID/NCIRD/OD) Re: ACIP slide deck
Subject.	Ne. Ach slide deck
Love it - thank you for	or sending!!!
Get Outlook for iOS  From: Oliver, Sara Eliza	abeth (CDC/DDID/NCIRD/DVD) <yxo4@cdc.gov></yxo4@cdc.gov>
Sent: Saturday, June 18	SEPANDO SE CITATOR DE LA CARTES DE CARTES DE LA CARTES DE LA CARTES DE CARTES DE CARTES DE CARTES DE CARTES DE
사용 : : : 1 1 1 1 1 1 1 1 1 1 1 1 1 1 1 1	(CDC/DDID/NCIRD/OD) <ksu8@cdc.gov>; Fleming-Dutra, Katherine E.</ksu8@cdc.gov>
71	D) <ftu2@cdc.gov>; Twentyman, Evelyn Rebecca Ford (CDC/DDID/NCIRD/DVD)</ftu2@cdc.gov>
<pre><ydj2@cdc.gov> Cc: Grusich. Katherina</ydj2@cdc.gov></pre>	(Kate) (CDC/DDID/NCIRD/OD) <yhb3@cdc.gov></yhb3@cdc.gov>
Subject: RE: ACIP slide	겠 [ [ [ ] ] [ ] [ ] [ ] [ ] [ ]
Meg:	
Just FYI- this is the re	sponse I sent to Kristen N about the same question. This woman appears
	(b)(6)
and the second of the second o	oughts 😊. Just in case we continue to get questions. I'm sure you guys can
	er, but something like this would be how I would respond. And the general
	1 death from COVID that's preventable is too many, regardless of how
you count them"	
•	
	(b)(5)

Freedman, Megan (CDC/DDID/NCIRD/OD)

From:

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) < hb3@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) < <a href="ftu2@cdc.gov">ftu2@cdc.gov</a>>

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] <cristina.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. <u>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.</u>

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 (Iww.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/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) < <a href="mailto:ftu2@cdc.gov">ftu2@cdc.gov</a>>

Sent: Thursday, June 9, 2022 9:38 AM

To: Cardemil, Cristina (NIH/NIAID) [E] < <a href="mailto:cristina.cardemil@nih.gov">cristina.cardemil@nih.gov</a>; 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) < <a href="mailto:irn3@cdc.gov">irn3@cdc.gov</a> **Cc:** Fleming-Dutra, Katherine E. (CDC/DDID/NCIRD/DBD) < <a href="mailto:ftu2@cdc.gov">ftu2@cdc.gov</a>

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] < <a href="mailto:cristina.cardemil@nih.gov">cristina.cardemil@nih.gov</a> <a href="mailto:cristina.cardemilgo:cristina.cardemilgo:cristina.cardemilgo:cristina.cardemilgo:cristina.cardemilgo:cristina.cardemilgo:cristina.cardemilgo:cristina.cardemilgo:cr

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

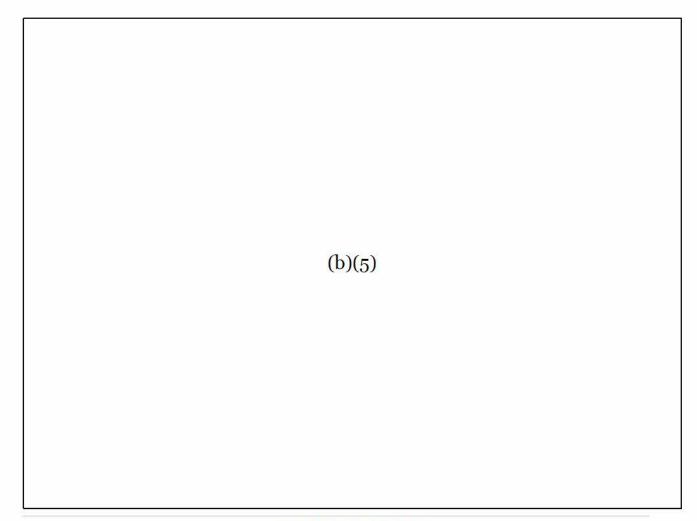
#### David Siegel, MD, MPH

Clinical Disease and Health Systems Team Epi TF CDC COVID-19 response

Phone:

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

(b)(5)	



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 <u>prospective cohort study</u> 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
<a href="mailto:cristina.cardemil@nih.gov">cristina.cardemil@nih.gov</a>

	(b)(5)

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] <cristina.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

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: 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) < <a href="ftu2@cdc.gov">ftu2@cdc.gov</a>; 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) < jyq3@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) < <a href="ftu2@cdc.gov">ftu2@cdc.gov</a>>

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,

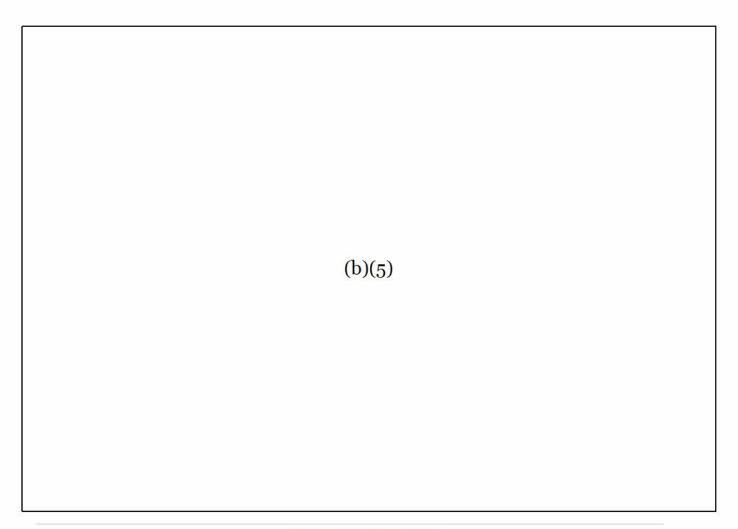
vid	

Epi TF

David Siegel, MD, MPH

Clinical Disease and Health Systems Team

CDC COVID-19 response	
Phone: 770-488-4426 (W) 404-831-4935 (M)	
(b)(5)	



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 <u>prospective cohort study</u> 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

(L)(-)
(b)(5)

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.

(b)(5)

(b)(5)

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 18<sup>th</sup> – 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!!

Eve	lvn

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) < vdj2@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)(r)	
	(b)(5)	
,		

Public comment is last on Friday?

For the June 18<sup>th</sup> slides, those look good. (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

**Caution:** This email came from outside Kaiser Permanente. Do not open attachments or click on links if you do not recognize the sender.

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.
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    - children ages 0-19, for which COVID is #7;
    - children ages 1-4, for which COVID is #5.
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  - 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

(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 27<sup>th</sup> 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) < <a href="ftu2@cdc.gov">ftu2@cdc.gov</a>; 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) < <a href="mailto:ftu2@cdc.gov">ftu2@cdc.gov</a>>

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] < <a href="mailto:cristina.cardemil@nih.gov">cristina.cardemil@nih.gov</a>

Sent: Thursday, June 9, 2022 9:29 AM

**To:** Siegel, David A. (CDC/DDNID/NCCDPHP/DCPC) < <a href="mailto:irn3@cdc.gov">irn3@cdc.gov</a> <a href="mailto:CCC">Cc: Fleming-Dutra, Katherine E. (CDC/DDID/NCIRD/DBD) < <a href="mailto:ftu2@cdc.gov">ftu2@cdc.gov</a> <a href="mailto:scripto:ftu2@cdc.gov">ftu2@cdc.gov</a>

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] < <a href="mailto:cristina.cardemil@nih.gov">cristina.cardemil@nih.gov</a>

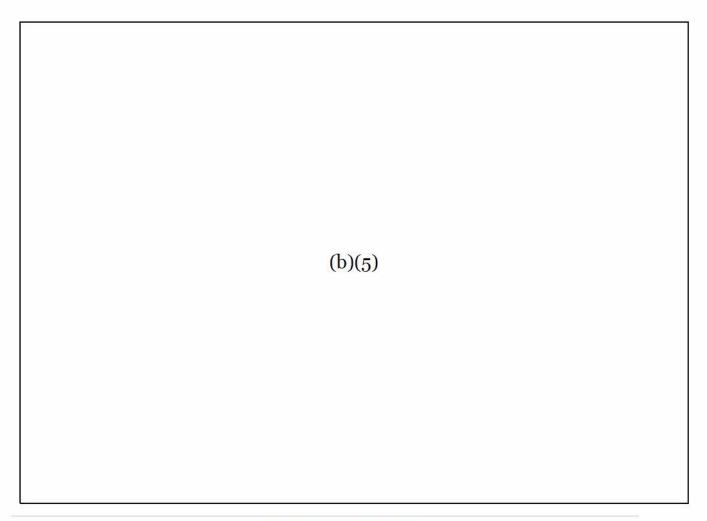
Cc: Fleming-Dutra, Katherine E. (CDC/DDID/NCIRD/DBD) < ftu2@cdc.gov> Subject: RE: burden of COVID-19 in infants Hi Cristina—thanks for reaching out—hope you are doing well. I pasted a summary below that was shared with me—it is an uncleared, informal summary of literature that was created around January. 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)

Page 73

(b)(5)

Page 74

(b)(5)



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 <u>prospective cohort study</u> 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
<a href="mailto:cristina.cardemil@nih.gov">cristina.cardemil@nih.gov</a>

(b)(5)

Thanks Sara!	(b)(5)
really, I think the bottom line ( where it ranks on a list) is one	(b)(5) (which lots of ACIP members said today) is any death in a child (regardless of too many.
Many thanks, Kristen	
Sent: Saturday, June 18, 2022 Fo: Fleming-Dutra, Katherine CDC/OD/OADC) <hok4@cdc< td=""><td>E. (CDC/DDID/NCIRD/DBD) <ftu2@cdc.gov>; Nordlund, Kristen</ftu2@cdc.gov></td></hok4@cdc<>	E. (CDC/DDID/NCIRD/DBD) <ftu2@cdc.gov>; Nordlund, Kristen</ftu2@cdc.gov>
Kristen:	
	(b)(5)

Oliver, Sara Elizabeth (CDC/DDID/NCIRD/DVD); Fleming-Dutra, Katherine E.

Nordlund, Kristen (CDC/OD/OADC)

Sat, 18 Jun 2022 21:09:28 +0000

Hope that helps? Happy to discuss further if needed-

From:

Sent:

(CDC/DDID/NCIRD/DBD)

To:

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

#### Get Outlook for iOS

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) < <a href="mailto:ftu2@cdc.gov">ftu2@cdc.gov</a>

Cc: Launi, Lori (ATSDR/OAD/OD) < <a href="mailto:lwe8@cdc.gov">!we8@cdc.gov">; CDC IMS 2019 NCOV Response Epi TF</a>

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=75nu8fq2ODMllQ6inATuYg

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: <a href="https://www.twitter.com/kelleykga">https://www.twitter.com/kelleykga</a> [twitter.com]

**Sent:** Sat, 18 Jun 2022 20:49:38 +0000

To: Fleming-Dutra, Katherine E. (CDC/DDID/NCIRD/DBD); Nordlund, Kristen

(CDC/OD/OADC)

Subject: RE: Reporters asking about criticism of ACIP slides saying COVID is a "leading

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(b)(5)

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Cc: Launi, Lori (ATSDR/OAD/OD) < <a href="https://www.es.edu.gov">we8@cdc.gov</a>; CDC IMS 2019 NCOV Response Epi TF

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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://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]

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:

(b)(5)

As for the June 18<sup>th</sup> slides, (b)(5)
(b)(5)

M

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

Sent: Tuesday, June 14, 2022 12:45 PM

To: Matthew Daley <<u>Matthew.F.Daley@kp.org</u>>; 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 18<sup>th</sup> – 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)			
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<b>Caution:</b> This email came from outside Kaiser Permanente. Do not open attachments or click on links if you do not recognize the sender.				

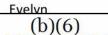
Good morning, and happy VRBPAC day 1!  $\odot$ 

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Thanks so much, and have a wonderful day!



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