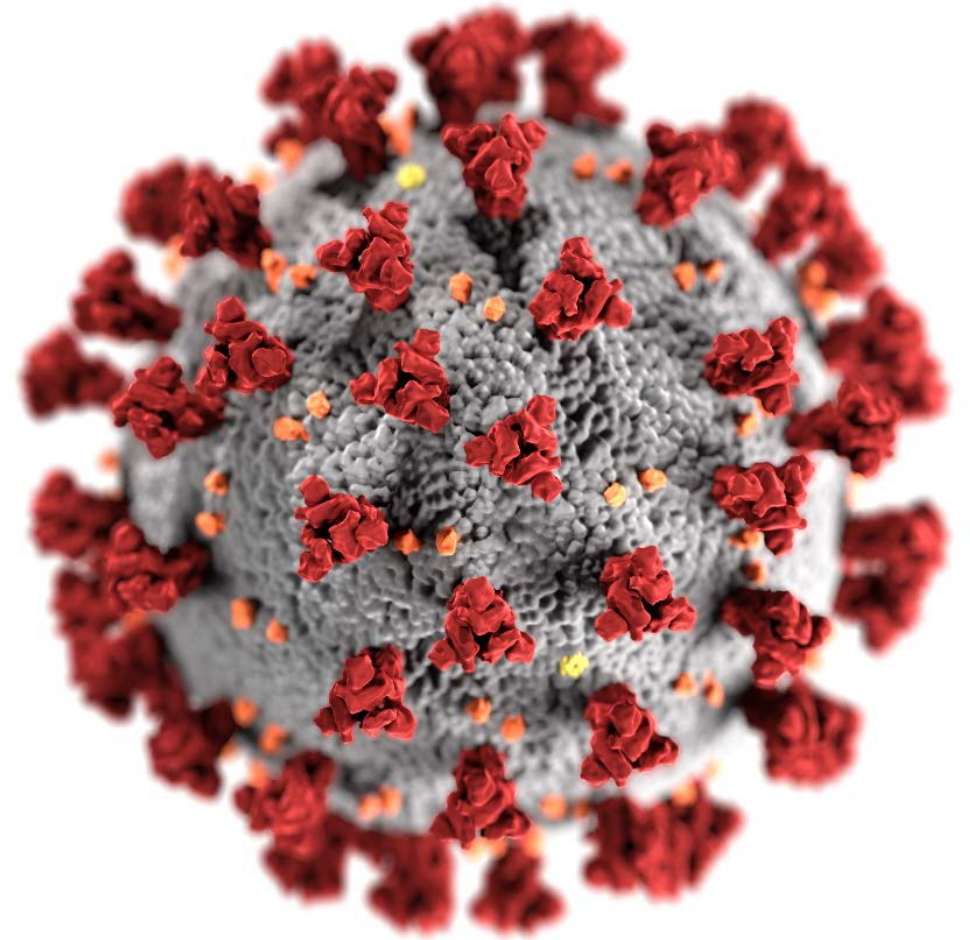


# ACIP COVID-19 Vaccines Work Group

Dr. Matthew F. Daley, Work Group Chair

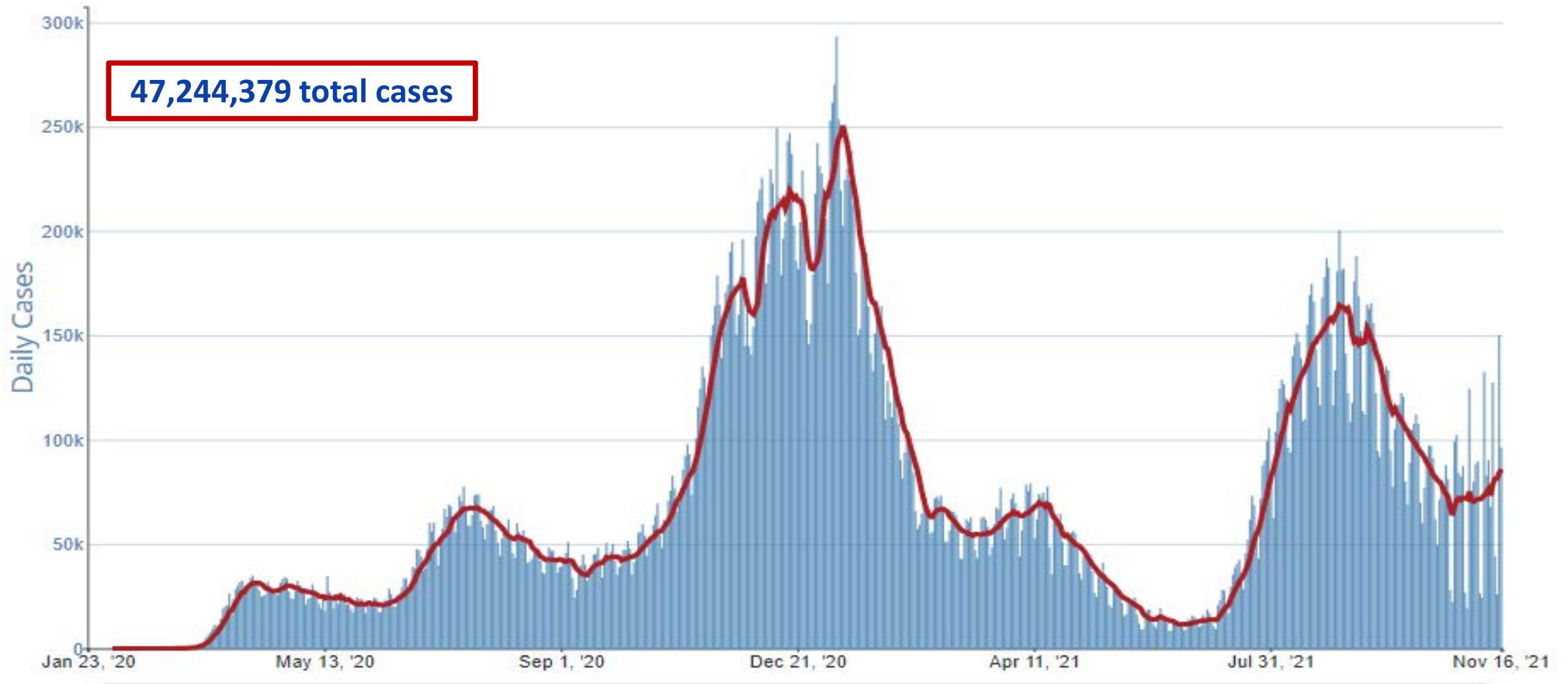
November 19, 2021



[cdc.gov/coronavirus](https://cdc.gov/coronavirus)

# Trends in COVID-19 cases in the United States

January 23, 2020 – November 16, 2021



# COVID-19 Work Group activities – November 2021

- Reviewing updated data for booster doses of COVID-19 vaccines
  - Pfizer-BioNTech clinical trial for booster doses
  - Safety updates for booster doses
  - GRADEing of evidence
  - Updates to Evidence to Recommendations Framework
  - Discussion of booster dose policy options

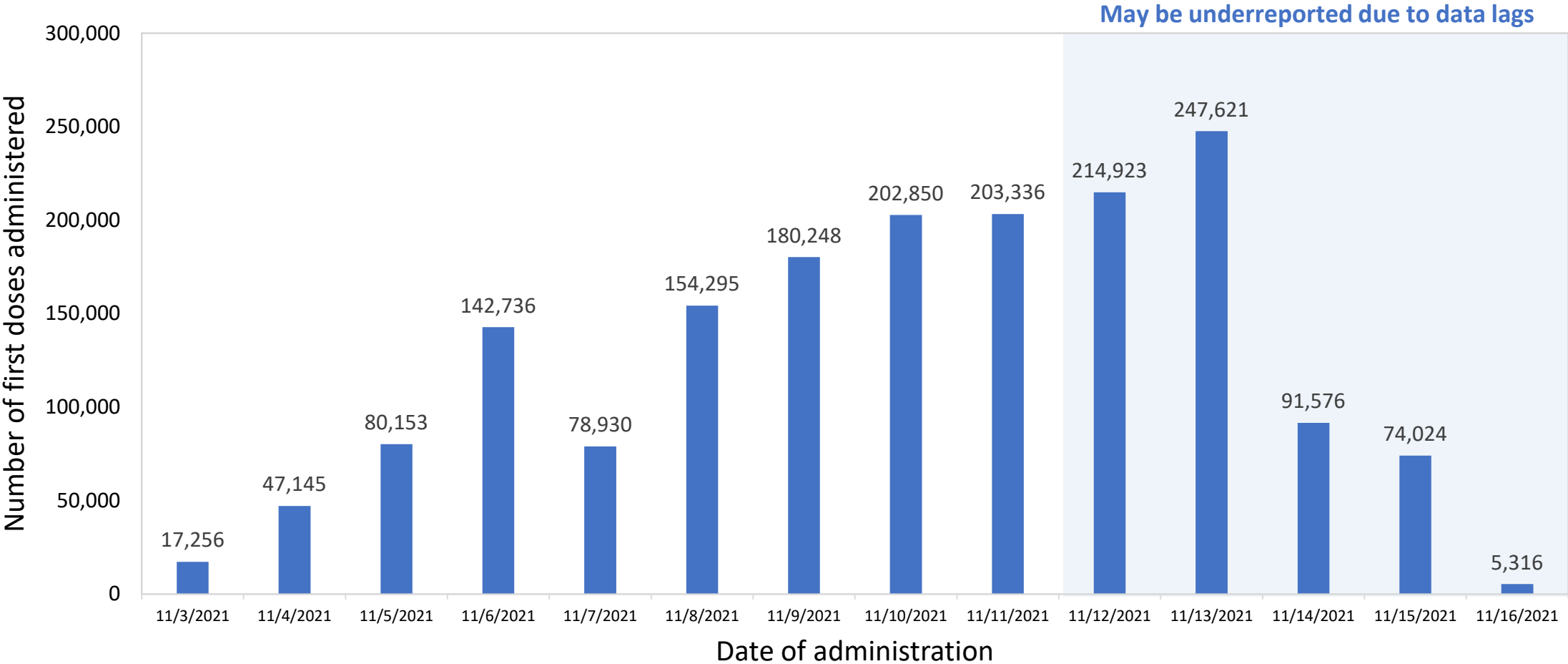
# FDA expands Emergency Use Authorization (EUA) of the Pfizer-BioNTech and Moderna COVID-19 vaccines

- Use of a single booster dose in individuals 18 years of age and older at least 6 months after completion of primary vaccination with any FDA-authorized or approved COVID-19 vaccine
- EUA allows for the use of each available COVID-19 vaccine as heterologous (or “mix and match” booster dose in eligible individuals following completion of primary vaccination with a different COVID-19 vaccine
  - The dosing interval for the heterologous booster dose is the same as that authorized for a booster dose of the vaccine used for primary vaccination.

# COVID-19 vaccines among children 5–11 years of age

- **1,970,760** first doses have been administered to children ages 5–11 through November 17
- **6.2%** of children 5–11 years of age have received a first dose of Pfizer-BioNTech COVID-19 vaccine
- Ongoing review of safety data

# Number of COVID-19 vaccine first doses administered Ages 5-11 Years, starting November 03, 2021



**Notes:** CDC received reports of children who either are or through recoding appear to be <12-years-old and have received COVID-19 vaccination prior to the Emergency Use Authorization for pediatric vaccination. These reports included **203,019** first doses and **127,737** dose completions. These reports could be the result of any of the following: (1) data reporting errors (2) participation in a clinical trial (3) 12-years-old children miscategorized as 11-years-old due to recoding of incomplete birth dates submitted (e.g., year of birth only). Of those children receiving at least the first dose and of those completing the series, 94% and 97% respectively of those coded as being <12-years-old are coded as being 11-years-old. The most recent five days of reporting may be underreported due to delays in reporting. All reported numbers might change over time as historical data are reported to CDC.

**Source:** Immunization Data Lake. Data as of November 17, 2021, 0600AM.

# Emergency Use Instructions: COVID-19 vaccine by Pfizer-BioNTech

- On November 17, 2021, CDC issued Emergency Use Instructions (EUI) about use of the COVID-19 vaccine by Pfizer-BioNTech approved by the Food and Drug Administration (FDA)
- approved by the Food and Drug Administration (FDA) to prevent COVID-19 in people aged  $\geq 16$  years
- The EUI authority\* allows CDC to create and issue EUI to permit emergency use of FDA-approved medical products
  - EUI are provided as fact sheets for healthcare providers and recipients
  - Include information about such products' approved, licensed, or cleared conditions of use

\*2013 Pandemic and All-Hazards Preparedness Reauthorization Act

# Allowed uses of the Pfizer-BioNTech COVID-19 vaccine under EUI

- EUI cover use in people who completed primary vaccination with a **non-FDA authorized or -approved COVID-19 vaccine**:
  - Certain people vaccinated outside the United States with a COVID-19 vaccine listed for emergency use by the World Health Organization
  - Certain participants in COVID-19 vaccine clinical trials within or outside the United States
- EUI provide information about use as:
  - An additional primary dose in certain moderately or severely immunocompromised persons\* aged  $\geq 12$  years
  - A single booster dose in certain adults\* aged  $\geq 18$  years

\*Refer to CDC's Interim Clinical Considerations for additional information on moderately or severely immunocompromised persons recommended for an additional primary dose and populations recommended for a booster dose <https://www.cdc.gov/vaccines/covid-19/clinical-considerations/covid-19-vaccines-us.html>



# Emergency Use Instructions (EUI) Fact Sheets for Healthcare Providers and for Recipients and Caregivers

## ***Emergency Use Instructions for Healthcare Providers: Pfizer-BioNTech COVID-19 vaccine for Additional Primary and Booster Doses in Certain Persons Who Completed Primary Vaccination with Vaccines Not Approved/Authorized in the United States***

The Centers for Disease Control and Prevention (CDC) is issuing Emergency Use Instructions (EUI) to provide information about the use of the formulation of the COVID-19 vaccine by Pfizer-BioNTech which is approved (licensed) by the Food and Drug Administration (FDA) for the prevention of COVID-19 in individuals 16 years of age and older.<sup>1</sup> These EUI provide information about the use of the COVID-19 vaccine by Pfizer-BioNTech as an additional primary dose in certain immunocompromised persons aged  $\geq 12$  years and as a booster dose in certain adults aged  $\geq 18$  years after completion of primary vaccination with ~~certain non-FDA authorized or~~ **approved** COVID-19 vaccines<sup>2</sup>.

These EUI for healthcare providers contain key information regarding t specific to this use. For additional information about the COVID-19 vaci to the [Comirnaty](#) package insert or the [Full Emergency Use Authorizati](#) to CDC's [Interim Clinical Considerations](#) for detailed recommendations relevant information is contained under the headings "People who rec United States" and "People who received COVID-19 vaccine as part of :

### ***Emergency Use Instructions (EUI) Fact Sheet for Recipients and Caregivers: Pfizer-BioNTech COVID-19 vaccine for Additional Primary and Booster Doses in Certain Persons Who Completed Primary Vaccination with Vaccines Not Approved/Authorized in the United States***

You may be eligible for COVID-19 vaccine by Pfizer-BioNTech as an additional primary dose (if aged  $\geq 12$  years) or a single booster dose (if aged  $\geq 18$  years) after completing a primary series vaccination with a **certain** COVID-19 vaccine **not authorized or approved** by the Food and Drug Administration (FDA). For example, people who were vaccinated outside the United States or from clinical trial participation (such as the AstraZeneca COVID-19 vaccine, the Novavax COVID-19 vaccine, or the Sinopharm COVID-19 vaccine) may be eligible to receive an additional primary dose and/or a booster dose.

The additional primary and booster doses of COVID-19 vaccine by Pfizer-BioNTech are described in these Emergency Use Instructions (EUI), which are issued by the Centers for Disease Control and Prevention (CDC) and are further explained in this Fact Sheet. |

# Agenda: Tuesday November 19 2021

- Efficacy and safety of BNT162b2 booster dose
- Update from Moderna

Dr. Perez (Pfizer)

Dr. Das (Moderna)

*Break*

- PUBLIC COMMENT
- COVID-19 vaccine booster dose safety
- VaST summary
- Updates to the EtR Framework:  
Pfizer-BioNTech and Moderna COVID-19 vaccine booster doses

Dr. Shimabukuro (CDC)

Dr. Talbot (VaST Chair)

Dr. Oliver (CDC)

- VOTE

# 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
- NIH: Chris Roberts
- IHS: Thomas Weiser, Uzo Chukwuma
- DOD: Bryan Schumacher
- CMS: Jeff Kelman
- BARDA: Christine Oshansky
- HHS: David Kim

## CDC Leads

- Sara Oliver

## Liaisons

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- AAP: Sean O’Leary
- ACOG: Denise Jamieson (primary),  
Laura Riley (alternate)
- ACP: Jason Goldman
- 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
- CSTE: Susan Lett (primary),  
Christine Hahn (alternate)
- IDSA: Jeff Duchin (primary),  
Carol Baker (alternate)

## Liaisons, cont’d

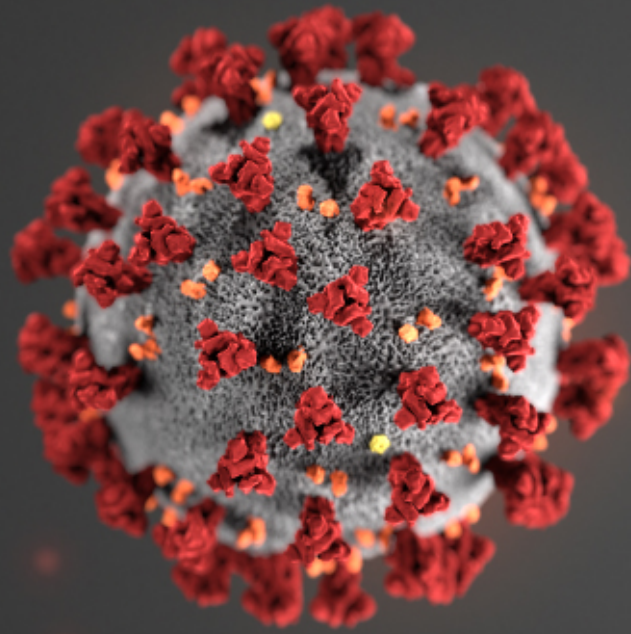
- NACCHO: Matt Zahn (primary),  
Jeff Duchin (alternate)
- NACI: Matthew Tunis
- NFID: Bill Schaffner (primary),  
Marla Dalton (alternate)
- NMA: Patricia Whitley-Williams
- SHEA: Marci Drees

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- Jose Romero
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- Dana Meaney-Delman
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- Sam Graitcer
- Lisa Grohskopf



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

