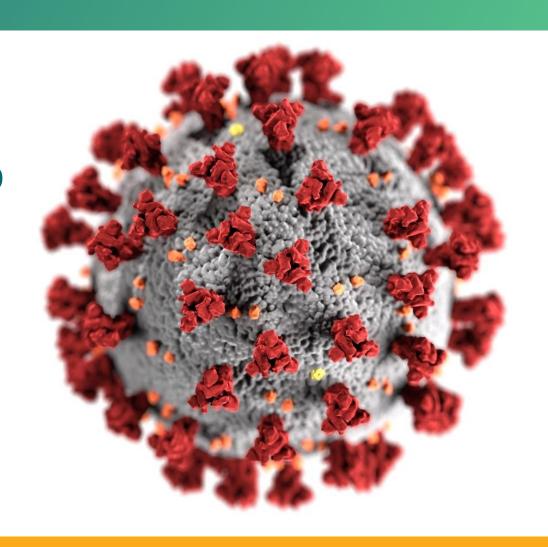
# **ACIP COVID-19 Vaccines Work Group**

Dr. Matt Daley, Work Group Chair June 23, 2021

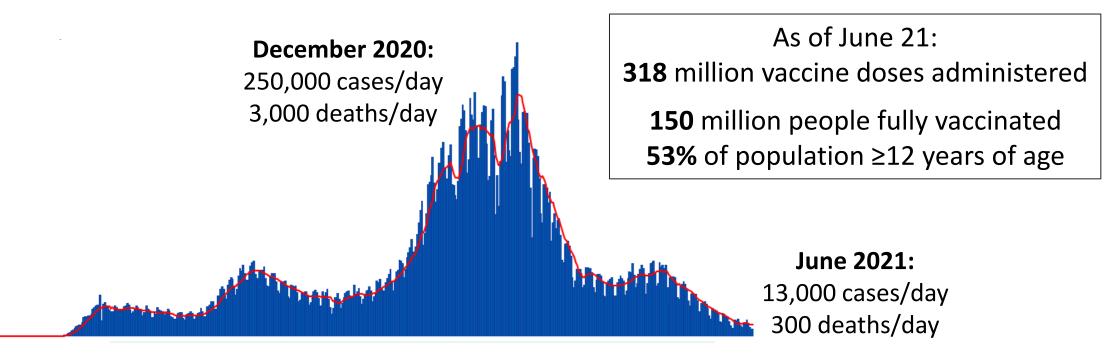




cdc.gov/coronavirus

## **COVID-19 Pandemic and vaccines**

 Since December, three COVID-19 vaccines authorized under EUA and recommended for use in the US



# **COVID-19 Work Group activities – May to June 2021**

Meets weekly

## Topics covered:

- Review of vaccines and SARS-CoV-2 variants
- Data needed to inform discussions around additional doses of COVID-19 vaccines
- Safety updates and review of myocarditis cases
- Discussion of benefit-risk balance for COVID-19 vaccines in adolescents and young adults

# **Today's ACIP meeting**

Discussion around cases of myocarditis/pericarditis after mRNA COVID-19 vaccination

# **Today's ACIP meeting**

Discussion around cases of myocarditis/pericarditis after mRNA COVID-19 vaccination

### **Vaccine Safety**:

Identifying and characterizing rare serious adverse events

Minimizing the occurrence of adverse events whenever possible

Communicating risks to the public, public health officials, and healthcare providers

Discussing known and potential benefits of vaccination with

known and potential harms of vaccination

# Myocarditis Cases Reported After mRNA vaccines in Israel December 2020–May 2021

- 148 myocarditis cases occurring around the time of vaccination
- Mostly reported among younger men aged 16–19, usually after second dose
- Most cases were hospitalized, but 95% considered to be mild cases
- Israel determined a possible link between the second vaccine dose and the onset of myocarditis among young men aged 16 to 30
- Israel determined "risks for complications of coronavirus disease outweigh the risks posed by the vaccine's side effects"
  - "Myocarditis cases observed among teenagers aged 16–19 occurred in low rates and in most cases passed with no complications"

# Myocarditis and Pericarditis Following mRNA COVID-19 vaccination

Since April 2021, there have been increased reports to Vaccine Adverse Event Reporting System (VAERS) of cases of inflammation of the heart happening after mRNA COVID-19 vaccination



# Myocarditis and Pericarditis Following mRNA COVID-19 Vaccination

Updated May 27, 2021 Languages ▼ Print

#### What You Need to Know

- More than 165 million people have received at least one dose of COVID-19 vaccine in the United States, and CDC continues to monitor the safety of COVID-19 vaccines for any health problems that happen after vaccination.
- Since April 2021, there have been increased reports to the Vaccine Adverse Event Reporting System (VAERS) of cases
  of inflammation of the heart—called myocarditis and pericarditis—happening after mRNA COVID-19 vaccination
  (Pfizer-BioNTech and Moderna) in the United States.
- These reports are rare, given the number of vaccine doses administered, and have been reported after mRNA COVID-19 vaccination (Pfizer-BioNTech and Moderna), particularly in adolescents and young adults.
- CDC and its partners are actively monitoring these reports, by reviewing data and medical records, to learn more
  about what happened and to see if there is any relationship to COVID-19 vaccination.
- . Most patients who received care responded well to medicine and rest and quickly felt better.
- · Cases reported to VAERS have occurred:
  - Mostly in male adolescents and young adults age 16 years or older
  - More often after getting the second dose of one of these two COVID-19 vaccines than after the first dose
  - Typically within several days after COVID-19 vaccination
- Patients can usually return to their normal daily activities after their symptoms improve, and they should speak with their doctor about return to exercise or sports.
- CDC continues to recommend <u>COVID-19 vaccination</u> for everyone 12 years of age and older, given the greater risk of COVID-19 illness and related, possibly severe complications.
- Getting vaccinated is the best way to help protect yourself and your family from COVID-19.

# Myocarditis and Pericarditis Following mRNA COVID-19 vaccination ACIP Response

- Vaccine Safety Technical Work Group (VaST) reviewed data from Israel,
   Department of Defense and CDC/FDA safety surveillance systems
- COVID-19 vaccines Work Group reviewed data and discussed benefit/risk balance
- Public ACIP meeting to review data and discuss benefit/risk assessment

# **Today's ACIP meeting**

Discussion around cases of myocarditis/pericarditis after mRNA COVID-19 vaccination

Considerations around need for booster doses of COVID-19 vaccines

## **Booster Doses of COVID-19 vaccines**

Majority of Americans received at least 1 dose of COVID-19 vaccine

- Planning required if booster doses of COVID-19 vaccines needed
  - Discussions around planning need to occur well in advance of future recommendations
  - Planning discussions do not imply booster doses will be recommended

 Discussions today around additional data needed to inform possible future recommendations

# **Today's Agenda**

## Wednesday, June 23

- Overview of myocarditis and pericarditis
   Dr. Matthew Oster (CDC)
- Update on COVID-19 vaccine safety, including myocarditis after mRNA vaccines
   Dr. Tom Shimabukuro (CDC)
- VaST assessment
   Dr. Grace Lee (ACIP, VaST Chair)
- COVID-19 mRNA vaccines in adolescents and young adults: Benefit-risk discussion
   Dr. Megan Wallace (CDC) and Dr. Sara Oliver (CDC)
- Discussion
- Public Comment
- Overview of data to inform recommendations for additional doses of COVID-19 vaccines
   Dr. Sara Oliver (CDC)
- Discussion

## Work group members

#### **ACIP** members

- Matthew Daley (chair)
- Beth Bell
- Grace Lee
- Jose Romero
- Keipp Talbot

### **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 Lead**

Sara Oliver

#### Liaisons

- AAFP: Jonathan Temte
- 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: Oliver Brooks
- SHEA: Marci Drees

#### **Consultants**

- Ed Belongia
- Kathy Kinlaw
- Dayna Matthew
- Kathleen Neuzil
- Stanley Perlman
- Peter Szilagyi

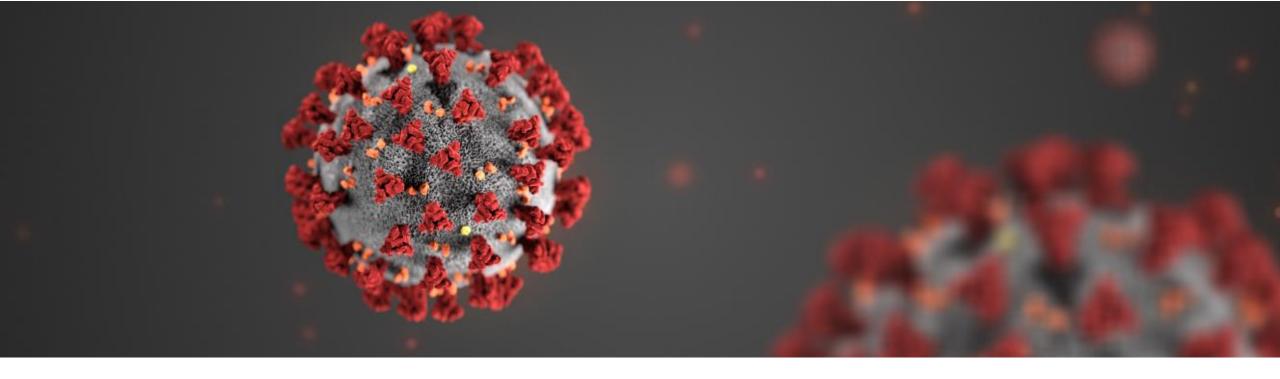
## **CDC** participants

- Doug Campos-Outcalt
- Mary Chamberland
- Thomas Clark
- Amanda Cohn
- Jillian Doss-Walker
- Kathleen Dooling
- Anthony Fiore
- Julia Gargano
- Sue Gerber
- Jack Gersten
- Susan Goldstein
- Monica Godfrey
- Sam Graitcer
- Lisa Grohskopf
- Stephen Hadler

- Rita Helfand
- Terri Hyde
- Cynthia Jorgensen
- Erin Kennedy
- Sarah Kidd
- Ram Koppaka
- Gayle Langley
- Megan Lindley
- Nicole Lindsey
- Ruth Link-Gelles
- Jessica MacNeil
- Lauri Markowitz
- Mona Marin
- Sarah Mbaeyi
- Meredith McMorrow

- Danielle Moulia
- Rebecca Morgan
- Titilope Oduyebo
- Anita Patel
- Nicole Reisman
- Hannah Rosenblum
- Janell Routh
- Stephanie Schrag
- Heather Scobie
- Edwin Shanley
- Tom Shimabukuro
- Heidi Soeters
- Mark Sotir
- Stephanie Thomas
- Natalie Thornburg

- Jennifer Verani
- Megan Wallace
- Cindy Weinbaum
- Melinda Wharton
- Kate Woodworth
- Yon 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.

