ACIP COVID-19 Vaccines Work Group

Dr. Matthew F. Daley, Work Group Chair

July 22, 2021
COVID-19 Pandemic Update

- After a period of decline, COVID-19 cases increasing
  - Rise in proportion of cases due to the Delta variant

As of July 21, 2021:

339 million vaccine doses administered

**Fully vaccinated:**
- >161 million people
- 57% of population ≥12 years of age

https://covid.cdc.gov/covid-data-tracker/#trends_dailytrendscases
https://covid.cdc.gov/covid-data-tracker/#vaccinations
COVID-19 Vaccine Safety Monitoring

- COVID-19 vaccines monitored under the most intensive vaccine safety monitoring in U.S. history
- Ongoing safety surveillance monitored through multiple systems from 6 federal agencies
- Monitoring systems have demonstrated that hundreds of millions of people have safely received COVID-19 vaccines

Focus of today’s presentations:

VAERS is the Nation’s Early Warning System for Vaccine Safety

http://vaers.hhs.gov
Vaccine Adverse Event Reporting System

Key strengths:
- Rapidly detects potential safety problems
- Can detect rare adverse events
- National in scope

Key limitations:
- Inconsistent quality and completeness of information
- Reporting biases
- Generally, cannot determine cause and effect

VAERS accepts all reports from everyone regardless of the plausibility of the vaccine causing the event or the clinical seriousness of the event.
Vaccine Safety Datalink (VSD)

- 9 participating integrated healthcare organizations
- Data on over 12 million persons per year

Types of information in VSD

- Enrollment and demographics
- Immunization records
- Outpatient and clinic visits
- Birth and death certificate information and family linkage
- Procedure codes
- Hospital discharge diagnosis codes
- Emergency room visits
- Charts and electronic health records

Linked by study IDs
Rare Serious Adverse Events Detected After COVID-19 Vaccination

- Thrombosis with thrombocytopenia syndrome (TTS) after Janssen COVID-19 vaccine
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- Myocarditis after mRNA COVID-19 vaccines

https://www.cdc.gov/mmwr/volumes/70/wr/mm7017e4.htm
https://www.cdc.gov/mmwr/volumes/70/wr/mm7027e2.htm
Thrombosis with thrombocytopenia syndrome (TTS) after Janssen COVID-19 vaccine

Myocarditis after mRNA COVID-19 vaccines

Guillain-Barré Syndrome (GBS) after Janssen COVID-19 vaccine

Today’s discussion

Use of COVID-19 vaccines after reports of GBS in Janssen vaccine recipients

https://www.cdc.gov/mmwr/volumes/70/wr/mm7017e4.htm
https://www.cdc.gov/mmwr/volumes/70/wr/mm7027e2.htm
Guillain-Barré Syndrome (GBS)

- Rare neurological disorder in which the immune system damages nerves, causing muscle weakness and sometimes paralysis.

- Estimated 3,000-6,000 cases reported annually in the United States, typically triggered by a gastrointestinal or respiratory infection.

- Most people fully recover from GBS, but some have permanent nerve damage.

- Risk for GBS is highest in males and persons over 50 years of age.
Although rare, GBS reported at a higher than expected rate in the 42 days after Janssen vaccination

Warning added to FDA’s Emergency Use Authorization (EUA) fact sheets

No GBS safety signal identified for mRNA vaccines
GBS After Other Vaccines

- **Influenza:**
  - Increased risk identified with 1976 swine influenza vaccine (~10 GBS cases per 1 million doses administered)
  - Mixed findings with subsequent influenza seasons, but magnitude of any potential increased risk is less than GBS risk due to natural influenza infection

- **Zoster (SHINGRIX):**
  - Causal relationship has not been established, but warning added to package insert due to ~3-6 excess GBS cases per 1 million doses administered to persons ≥65 years in the 6 weeks after vaccination

- No increased risk of GBS observed for other vaccines

https://www.fda.gov/media/108597/download
# Over 30 Other Prespecified Outcomes Monitored Through Safety Surveillance for COVID-19 Vaccines

<table>
<thead>
<tr>
<th>Outcome</th>
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ACIP Response to Reports of Adverse Events After Vaccination

- Vaccine Safety Technical Subcommittee (VaST) reviews data from U.S. government safety systems and other sources

- COVID-19 Vaccines Work Group reviews data and discusses benefit/risk balance

- Public ACIP meeting to review data, discuss benefit/risk assessment, and discuss recommendations for use of COVID-19 vaccines
COVID-19 Work Group Activities – July 2021

- Meets weekly

- Topics covered:
  - Review of GBS cases after Janssen COVID-19 vaccination
  - Discussion of benefit-risk balance for COVID-19 vaccines
  - Review of data and considerations for additional COVID-19 vaccine doses in immunocompromised persons
COVID-19 Work Group Activities – July 2021

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Updated CDC Clinical Considerations for Immunocompromised People

- Immunocompromised people and their close contacts should be vaccinated against COVID-19

- Reduced immune responses to vaccination have been observed in some immunocompromised people
  - Serologic testing to assess immune response to vaccination not recommended

- Immunocompromised people should be counseled to continue all current prevention measures
  - Examples: wearing mask, staying 6 feet apart, avoiding crowds

- Clinical guidance for additional COVID-19 vaccine doses will be updated pending regulatory allowance from FDA

Today’s ACIP Meeting

- Discussion around cases of GBS after Janssen COVID-19 vaccination
- Review of data and considerations for additional COVID-19 vaccine doses in immunocompromised persons
Today's Agenda
Thursday, July 22, 2021

- Guillain-Barré Syndrome (GBS) after Janssen COVID-19 vaccine: Vaccine Adverse Event Reporting System (VAERS)
  Dr. Meghna Alimchandani (FDA)

- Guillain-Barré Syndrome (GBS) after Janssen COVID-19 vaccine: Vaccine Safety Datalink (VSD)
  Dr. Nicola Klein (Kaiser Permanente Northern California)

- VaST assessment
  Dr. Grace Lee (ACIP, VaST Chair)

- Public Comment

- COVID-19 vaccines: benefit-risk discussion
  Dr. Hannah Rosenblum (CDC)

- Work Group interpretation and next steps
  Dr. Sarah Mbaeyi (CDC)

- Review of data and considerations for additional COVID-19 vaccine doses in immunocompromised persons
  Dr. Sara Oliver (CDC)
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 (primary), Kelsey Young (alternate)
- 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
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.

For more information, contact CDC
1-800-CDC-INFO (232-4636)