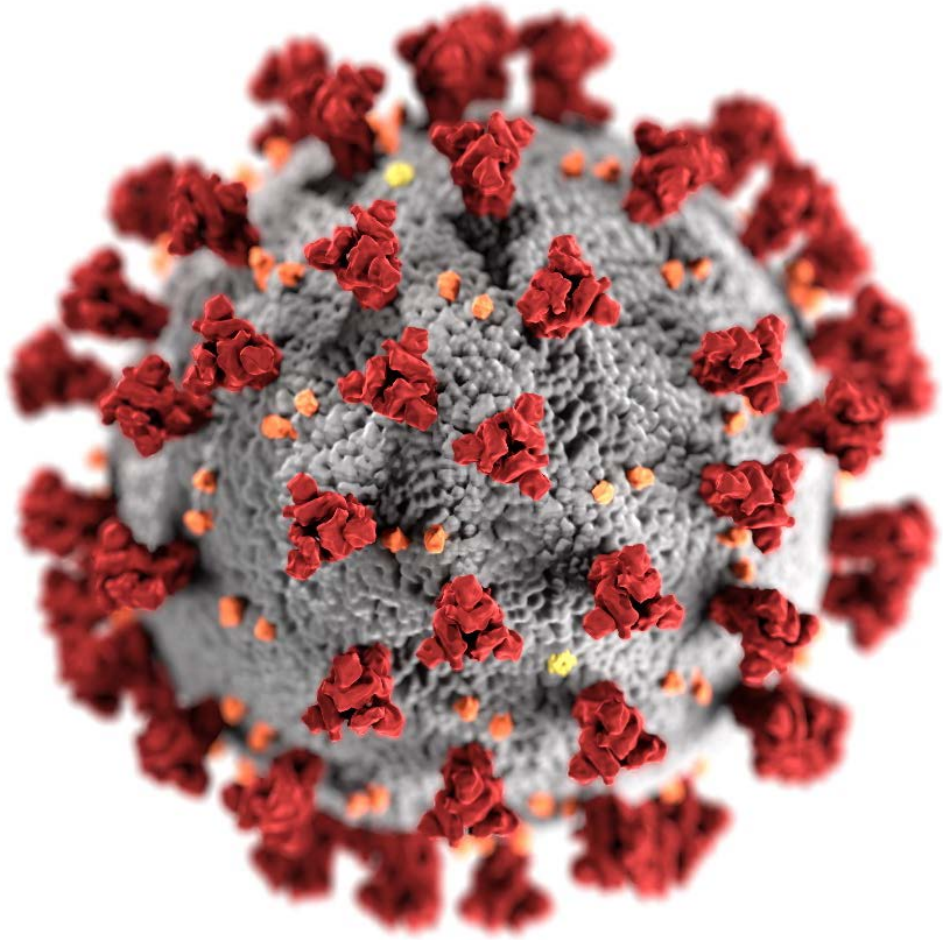
ACIP COVID-19 Vaccines Work Group



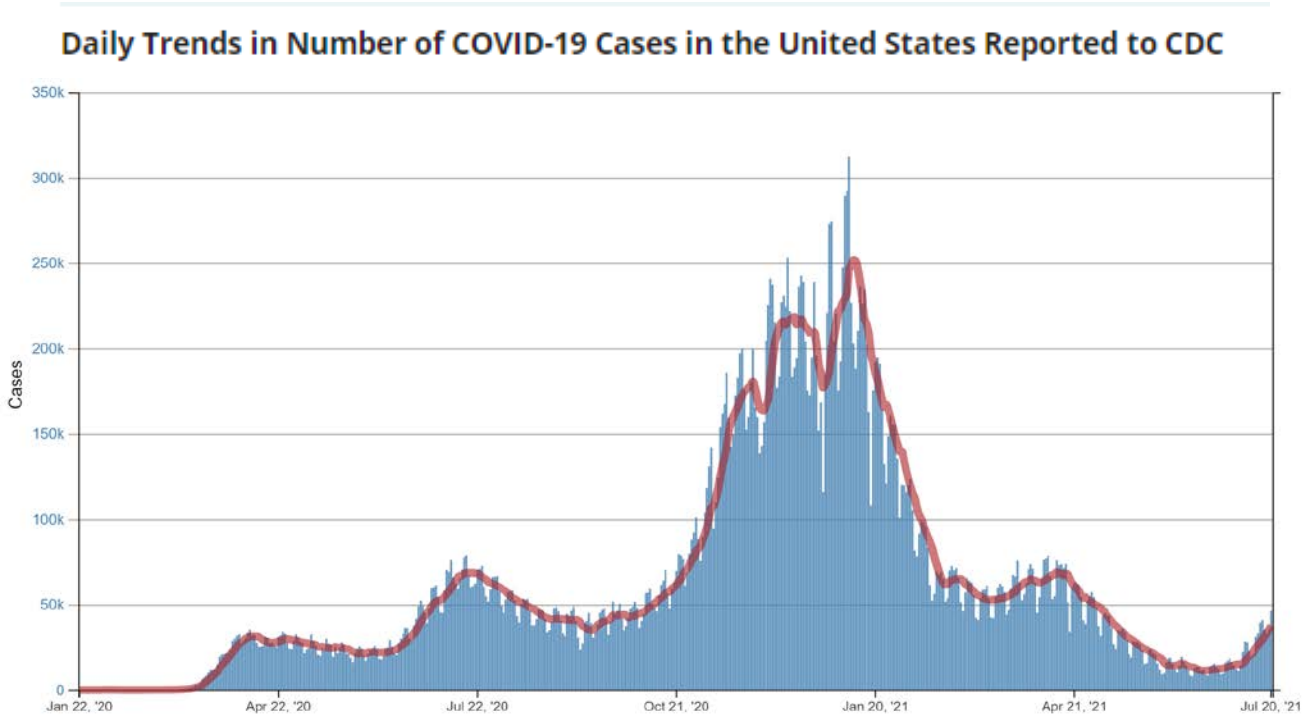
Dr. Matthew F. Daley, Work Group Chair

July 22, 2021

cdc.gov/coronavirus

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

VSD

https://www.cdc.gov/coronavirus/2019-ncov/vaccines/reporting-systems.html

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

CDC + FDA

VAERS

Vaccine Adverse Event Reporting System

http://vaers.hhs.gov

Vaccine Adverse Event Reporting System

VAERS accepts all reports from everyone regardless of the plausibility of the vaccine causing the event or the clinical seriousness of the event

Key strengths:

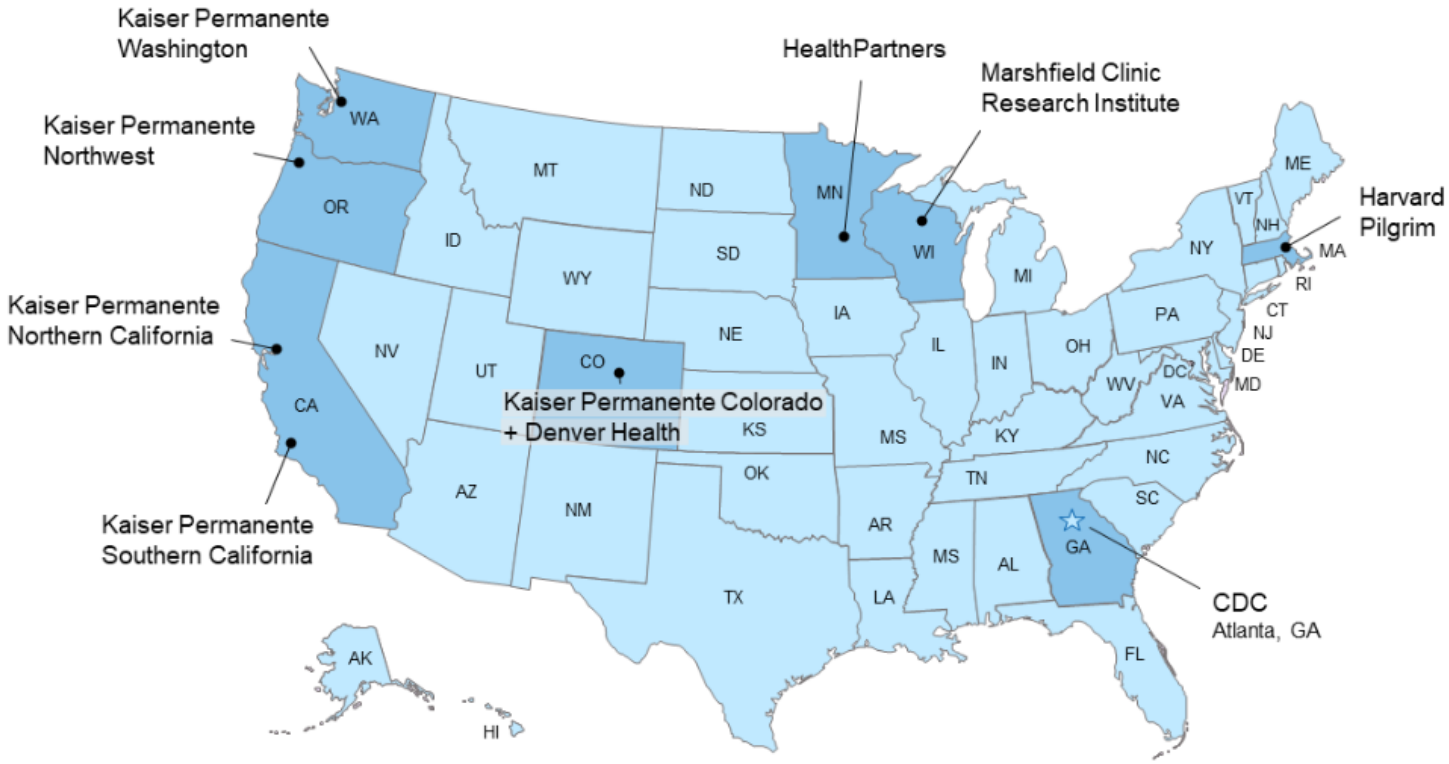
- Rapidly detects potential safety problems
- Can detect rare adverse events
- National in scope

Key limitations:

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

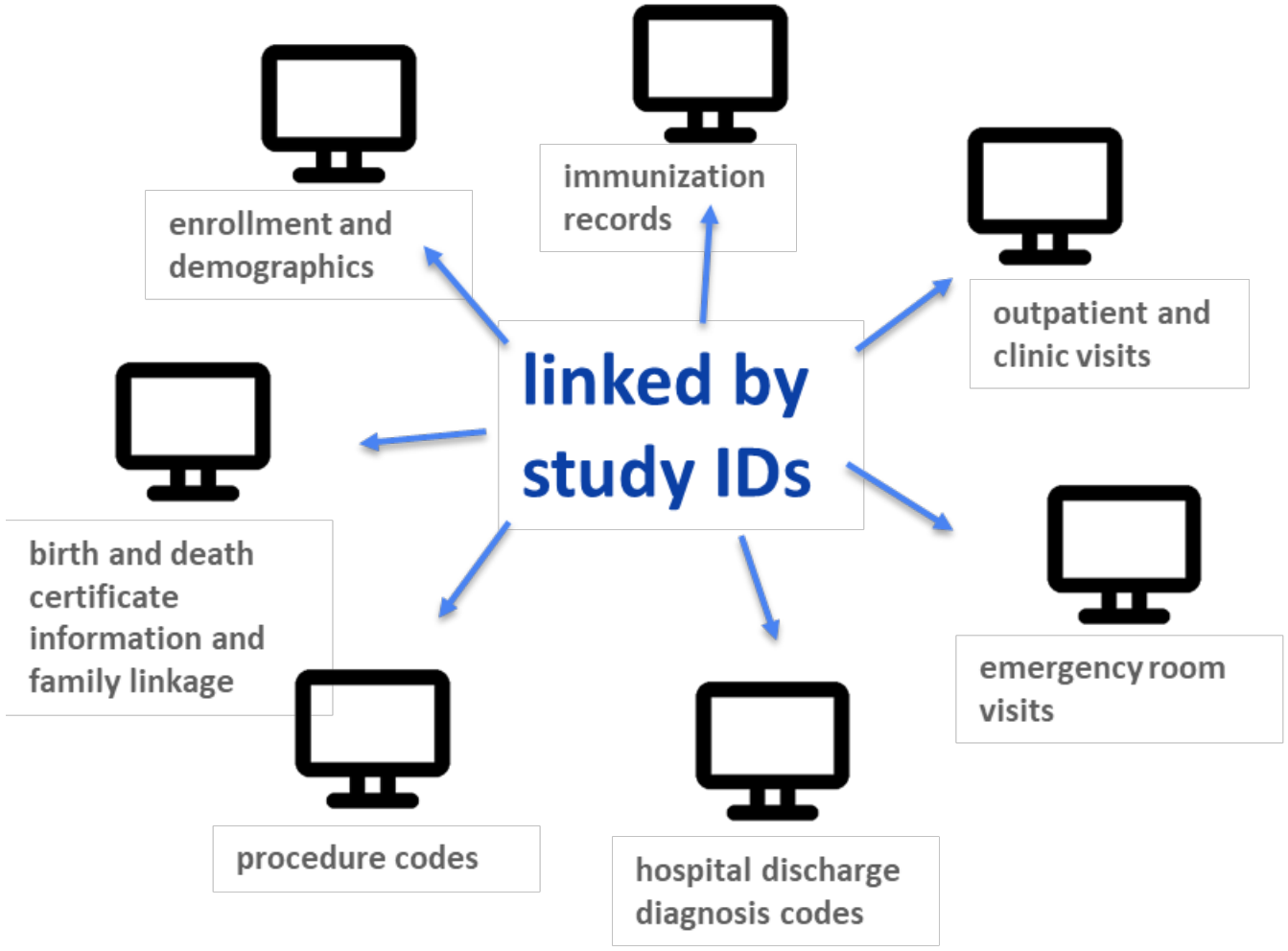
Vaccine Safety Datalink (VSD)

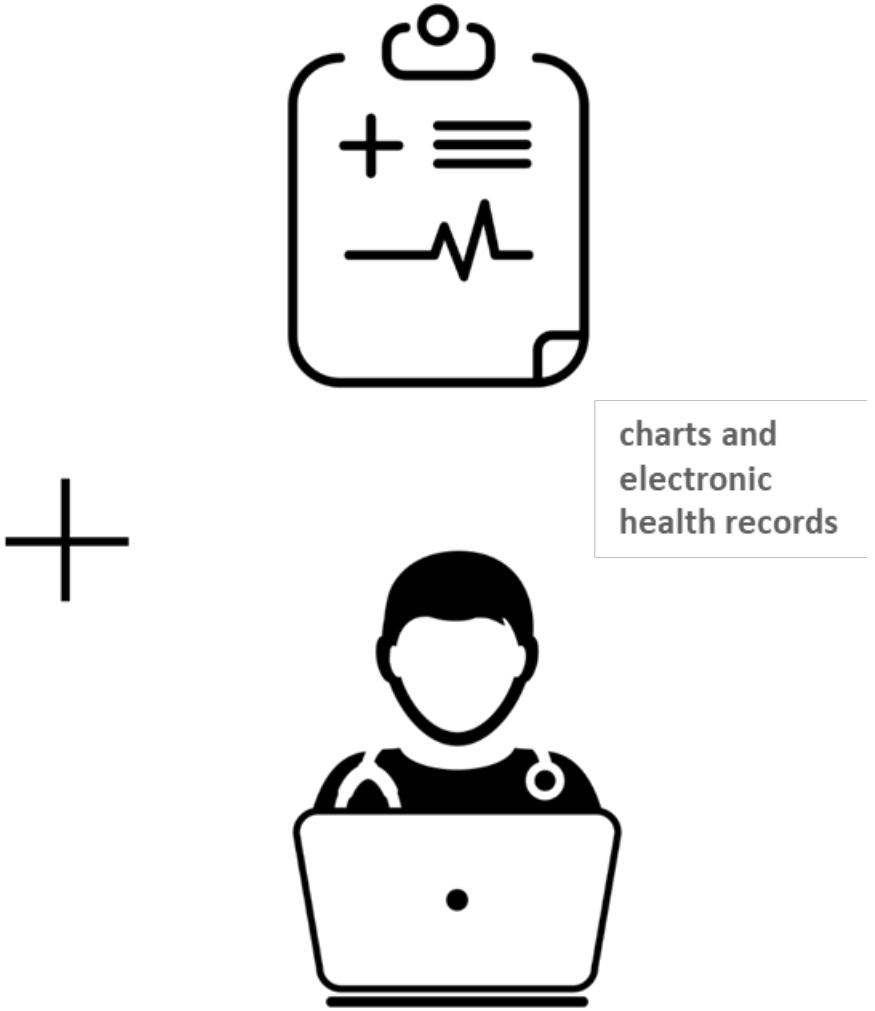
- **9** participating integrated healthcare organizations
- Data on over **12 million** persons per year



https://www.cdc.gov/vaccinesafety/ensuringsafety/monitoring/vsd/index.html

Types of information in VSD

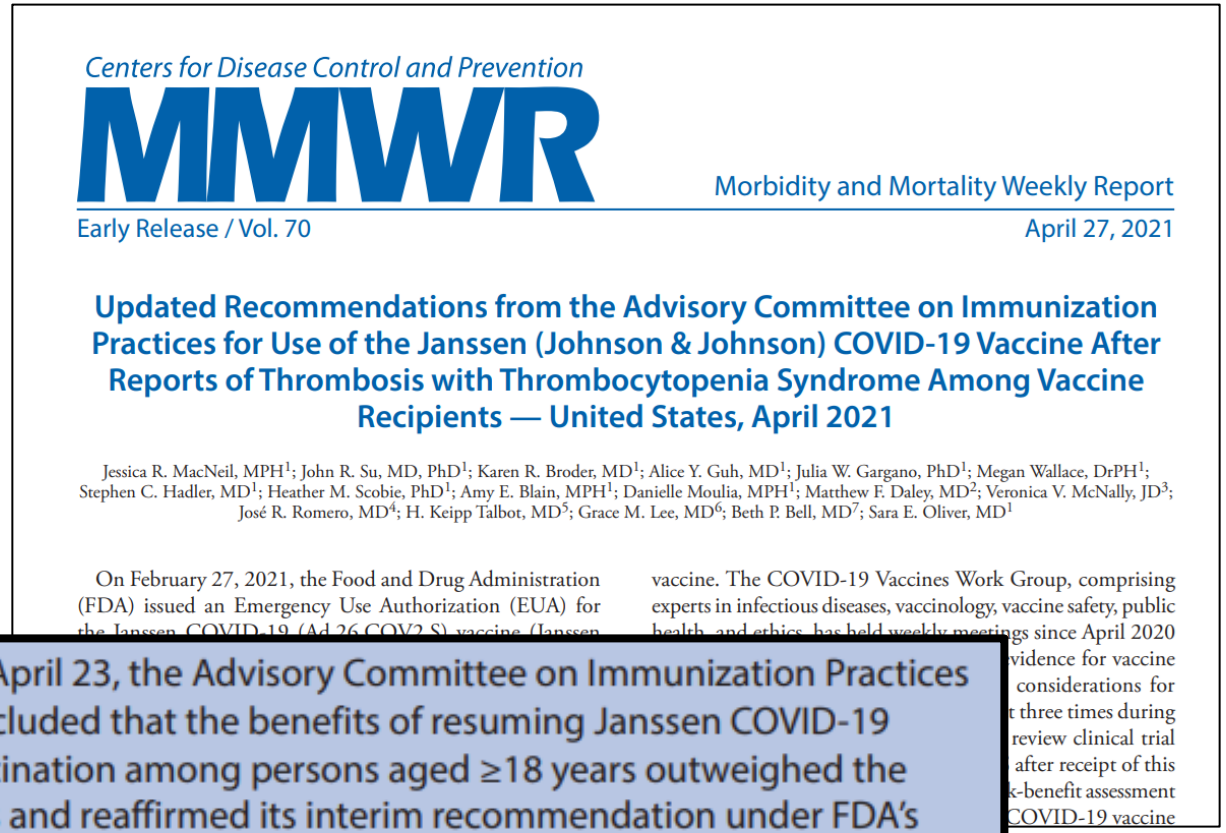




Images created by Wilson Joseph, Megan Mitchell, Ananth, and Iga from the noun project

Rare Serious Adverse Events Detected After COVID-19 Vaccination

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



Centers for Disease Control and Prevention

MMWR

Morbidity and Mortality Weekly Report

Early Release / Vol. 70 April 27, 2021

Updated Recommendations from the Advisory Committee on Immunization Practices for Use of the Janssen (Johnson & Johnson) COVID-19 Vaccine After Reports of Thrombosis with Thrombocytopenia Syndrome Among Vaccine Recipients — United States, April 2021

Jessica R. MacNeil, MPH[1]; John R. Su, MD, PhD[1]; Karen R. Broder, MD[1]; Alice Y. Guh, MD[1]; Julia W. Gargano, PhD[1]; Megan Wallace, DrPH[1]; Stephen C. Hadler, MD[1]; Heather M. Scobie, PhD[1]; Amy E. Blain, MPH[1]; Danielle Moulia, MPH[1]; Matthew F. Daley, MD[2]; Veronica V. McNally, JD[3]; José R. Romero, MD[4]; H. Keipp Talbot, MD[5]; Grace M. Lee, MD[6]; Beth P. Bell, MD[7]; Sara E. Oliver, MD[1]

On February 27, 2021, the Food and Drug Administration (FDA) issued an Emergency Use Authorization (EUA) for

vaccine. The COVID-19 Vaccines Work Group, comprising experts in infectious diseases, vaccinology, vaccine safety, public

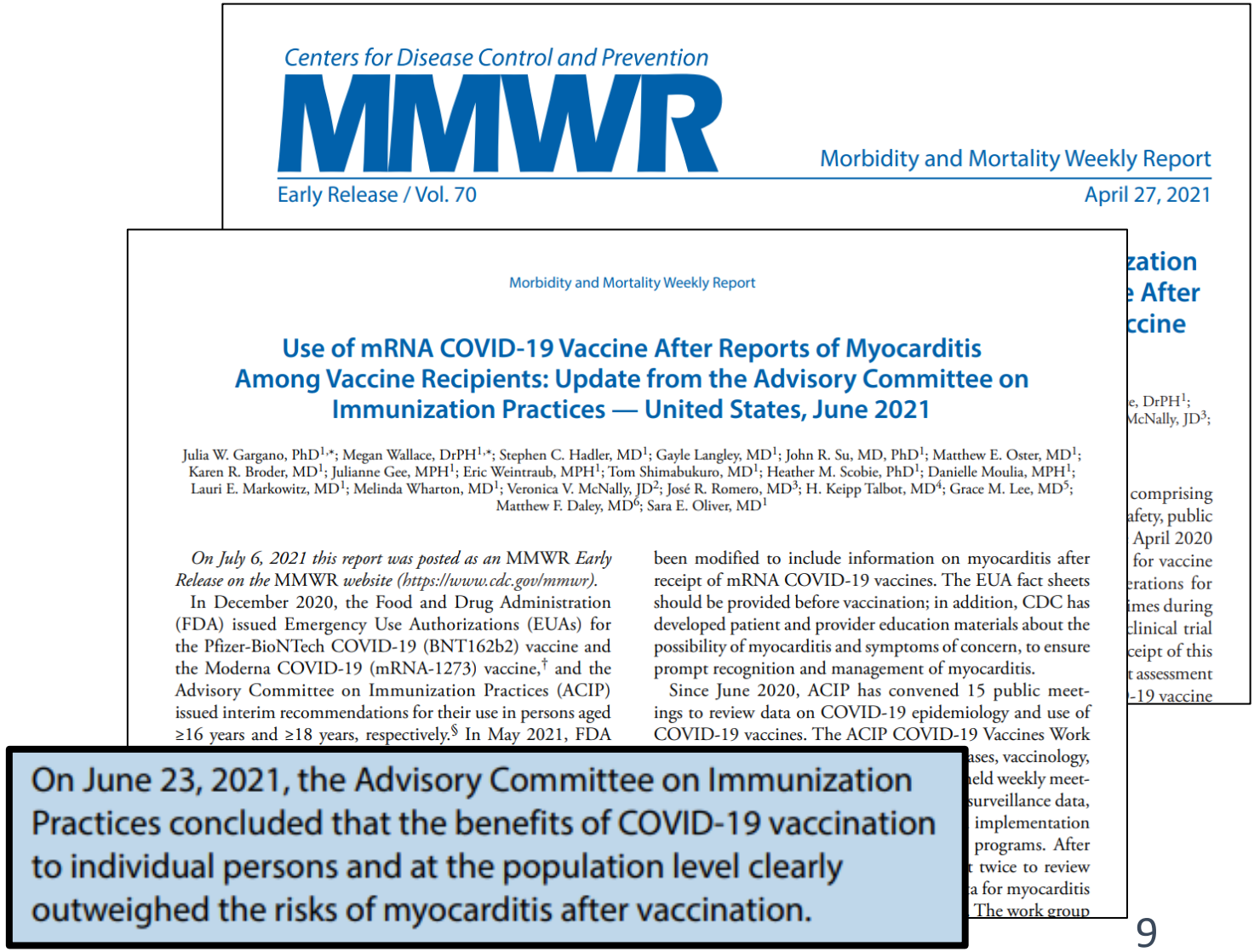
gs since April 2020
vidence for vaccine
considerations for
t three times during
review clinical trial
after receipt of this
k-benefit assessment
COVID-19 vaccine

On April 23, the Advisory Committee on Immunization Practices concluded that the benefits of resuming Janssen COVID-19 vaccination among persons aged ≥18 years outweighed the risks and reaffirmed its interim recommendation under FDA's Emergency Use Authorization, which includes a new warning for rare clotting events among women aged 18–49 years.

https://www.cdc.gov/mmwr/volumes/70/wr/mm7017e4.htm

Rare Serious Adverse Events Detected After COVID-19 Vaccination

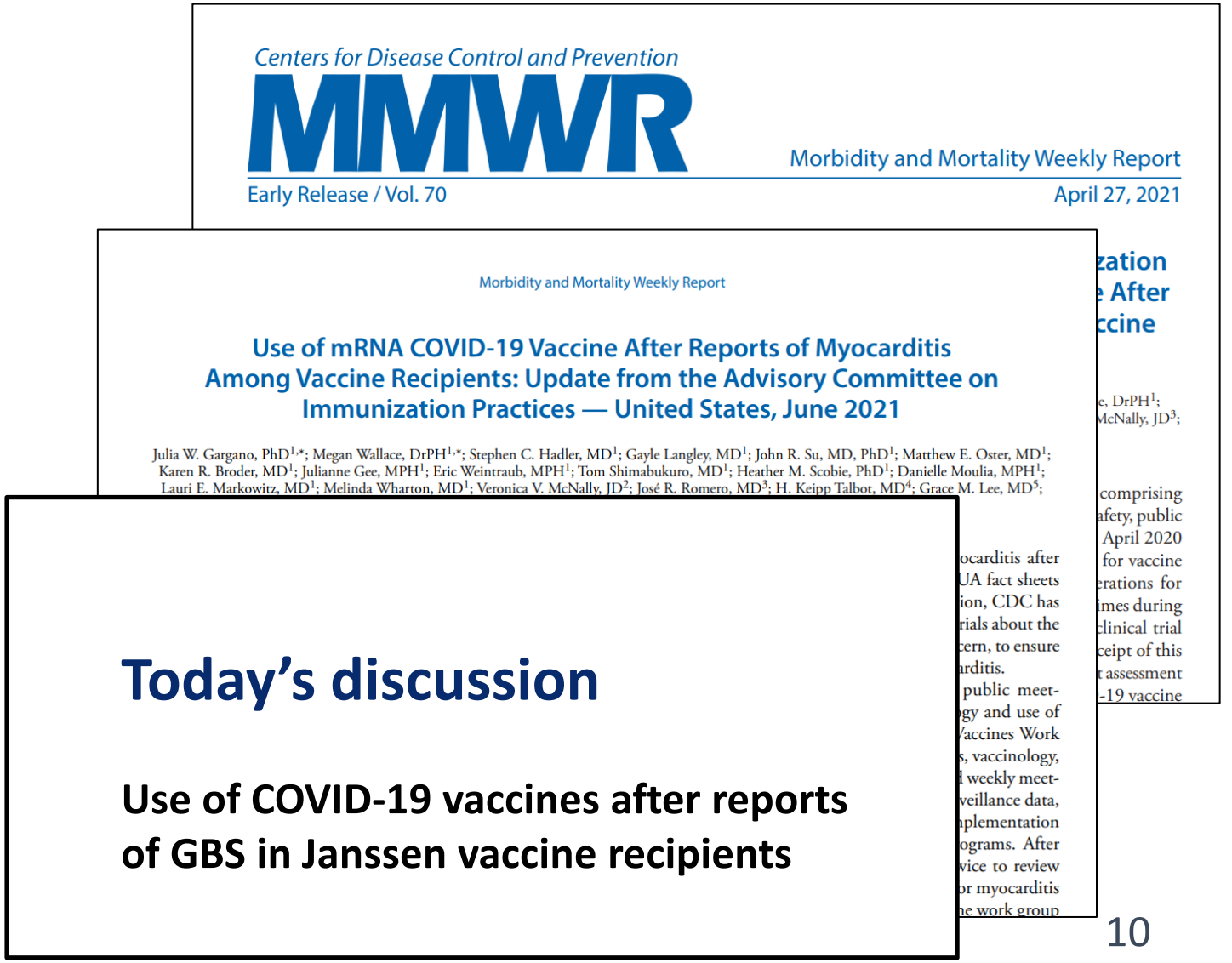
- Thrombosis with thrombocytopenia syndrome (TTS) after Janssen COVID-19 vaccine
- Myocarditis after mRNA COVID-19 vaccines



https://www.cdc.gov/mmwr/volumes/70/wr/mm7017e4.htm
https://www.cdc.gov/mmwr/volumes/70/wr/mm7027e2.htm

Rare Serious Adverse Events Detected After COVID-19 Vaccination

- 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**



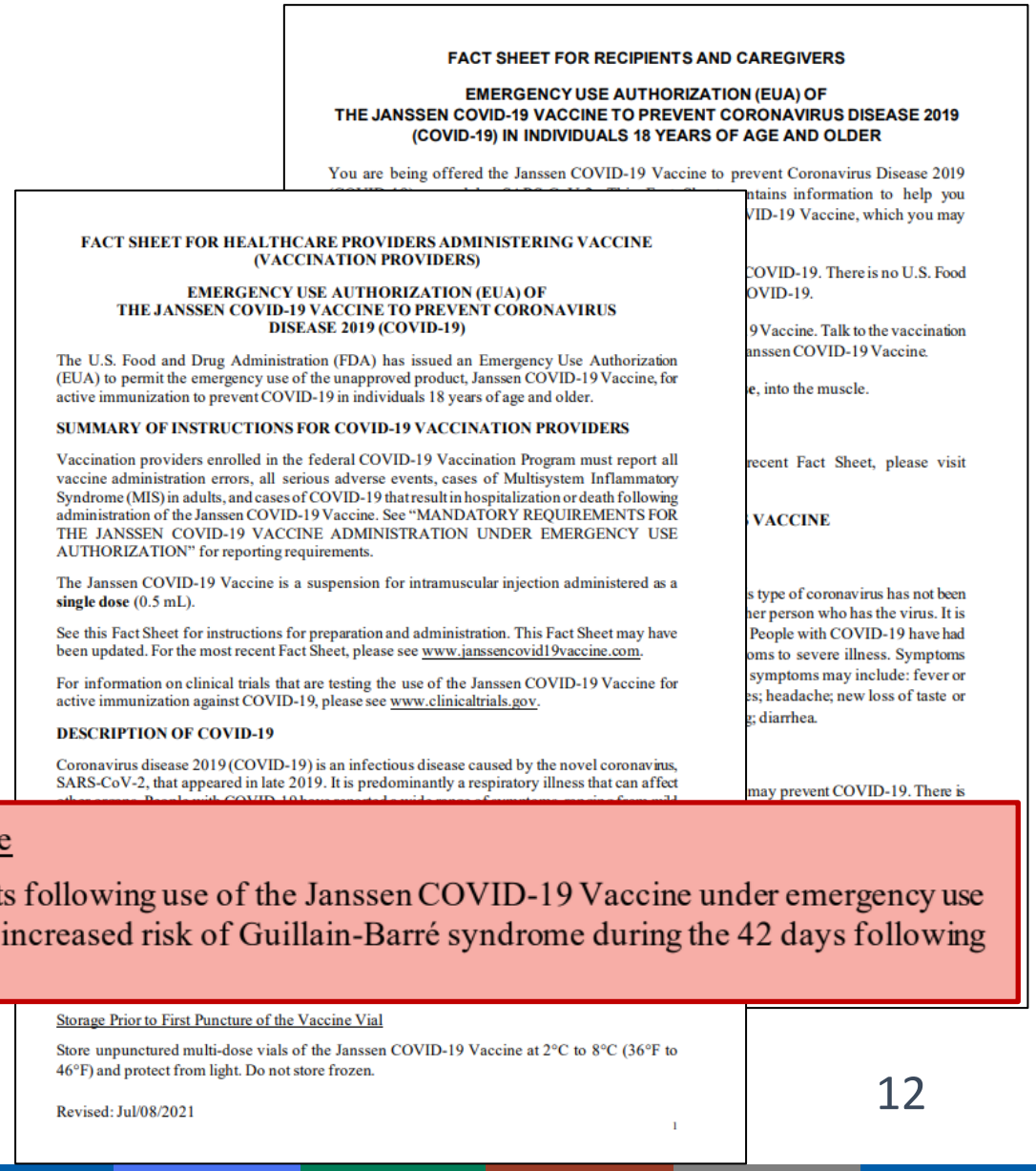
https://www.cdc.gov/mmwr/volumes/70/wr/mm7017e4.htm
https://www.cdc.gov/mmwr/volumes/70/wr/mm7027e2.htm

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

GBS After Janssen COVID-19 Vaccination

- 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



FACT SHEET FOR RECIPIENTS AND CAREGIVERS

EMERGENCY USE AUTHORIZATION (EUA) OF
THE JANSSEN COVID-19 VACCINE TO PREVENT CORONAVIRUS DISEASE 2019
(COVID-19) IN INDIVIDUALS 18 YEARS OF AGE AND OLDER

You are being offered the Janssen COVID-19 Vaccine to prevent Coronavirus Disease 2019

FACT SHEET FOR HEALTHCARE PROVIDERS ADMINISTERING VACCINE
(VACCINATION PROVIDERS)

EMERGENCY USE AUTHORIZATION (EUA) OF
THE JANSSEN COVID-19 VACCINE TO PREVENT CORONAVIRUS
DISEASE 2019 (COVID-19)

The U.S. Food and Drug Administration (FDA) has issued an Emergency Use Authorization (EUA) to permit the emergency use of the unapproved product, Janssen COVID-19 Vaccine, for active immunization to prevent COVID-19 in individuals 18 years of age and older.

SUMMARY OF INSTRUCTIONS FOR COVID-19 VACCINATION PROVIDERS

Vaccination providers enrolled in the federal COVID-19 Vaccination Program must report all vaccine administration errors, all serious adverse events, cases of Multisystem Inflammatory Syndrome (MIS) in adults, and cases of COVID-19 that result in hospitalization or death following administration of the Janssen COVID-19 Vaccine. See "MANDATORY REQUIREMENTS FOR THE JANSSEN COVID-19 VACCINE ADMINISTRATION UNDER EMERGENCY USE AUTHORIZATION" for reporting requirements.

The Janssen COVID-19 Vaccine is a suspension for intramuscular injection administered as a **single dose** (0.5 mL).

See this Fact Sheet for instructions for preparation and administration. This Fact Sheet may have been updated. For the most recent Fact Sheet, please see www.janssencovid19vaccine.com.

For information on clinical trials that are testing the use of the Janssen COVID-19 Vaccine for active immunization against COVID-19, please see www.clinicaltrials.gov.

DESCRIPTION OF COVID-19

Coronavirus disease 2019 (COVID-19) is an infectious disease caused by the novel coronavirus, SARS-CoV-2, that appeared in late 2019. It is predominantly a respiratory illness that can affect

Storage Prior to First Puncture of the Vaccine Vial

Store unpunctured multi-dose vials of the Janssen COVID-19 Vaccine at 2°C to 8°C (36°F to 46°F) and protect from light. Do not store frozen.

Revised: Jul/08/2021

Guillain-Barré Syndrome

Reports of adverse events following use of the Janssen COVID-19 Vaccine under emergency use authorization suggest an increased risk of Guillain-Barré syndrome during the 42 days following vaccination.

https://www.fda.gov/media/146305/download
https://www.fda.gov/media/146304/download

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

DeStefano, F, et al. *Clinical Infectious Diseases* 69.4 (2019): 726-731.
https://www.fda.gov/media/108597/download
Baxter, R, et al. *Clinical infectious diseases* 57.2 (2013): 197-204.

Over 30 Other Prespecified Outcomes Monitored Through Safety Surveillance for COVID-19 Vaccines

Acute disseminated encephalomyelitis	Immune thrombocytopenic purpura
Acute myocardial infarction	Kawasaki disease
Anaphylaxis	Meningitis
Appendicitis	Meningoencephalitis
Acute respiratory distress syndrome	Multiple sclerosis
Arthritis and arthralgia	Multisystem Inflammatory Syndrome
Ataxia	Myelitis
Autoimmune disease	Myocarditis/pericarditis
Bell's palsy	Narcolepsy/cataplexy
Chronic inflammatory demyelinating polyneuropathy	Non-anaphylactic allergic reactions
COVID-19	Optic neuritis
Death	Seizures/convulsions
Disseminated intravascular coagulation	Stroke
Encephalitis	Thrombocytopenia
Encephalomyelitis	Transverse myelitis
Encephalopathy	Vaccination during pregnancy/adverse pregnancy outcomes
	Venous thromboembolism

Over 30 Other Prespecified Outcomes Monitored Through Safety Surveillance for COVID-19 Vaccines

Acute disseminated encephalomyelitis	Immune thrombocytopenic purpura
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Encephalomyelitis	Transverse myelitis
Encephalopathy	Vaccination during pregnancy/adverse pregnancy outcomes
	Venous thromboembolism

No other safety signals detected

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

- Meets weekly

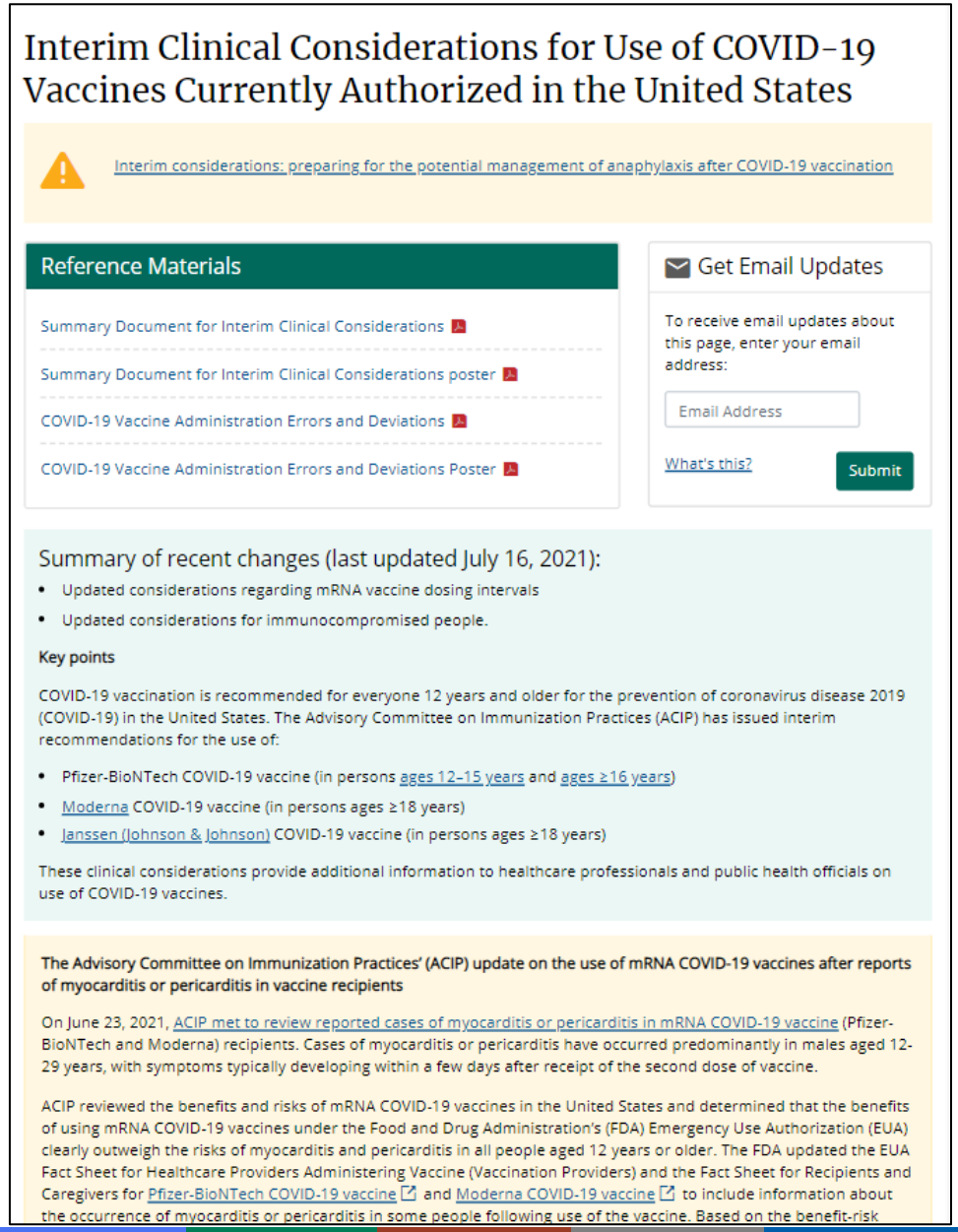
- Topics covered:
  - Review of GBS cases after Janssen COVID-19 vaccination
  - Discussion of benefit-risk balance for COVID-19 vaccines
  - **Review of data and considerations for additional COVID-19 vaccine doses in immunocompromised persons**

Updated CDC Clinical Considerations for Immunocompromised People

Updated July 16, 2021

- 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**

https://www.cdc.gov/vaccines/covid-19/clinical-considerations/covid-19-vaccines-us.html



Interim Clinical Considerations for Use of COVID-19 Vaccines Currently Authorized in the United States

Interim considerations: preparing for the potential management of anaphylaxis after COVID-19 vaccination

Reference Materials

Summary Document for Interim Clinical Considerations

Summary Document for Interim Clinical Considerations poster

COVID-19 Vaccine Administration Errors and Deviations

COVID-19 Vaccine Administration Errors and Deviations Poster

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Summary of recent changes (last updated July 16, 2021):

- Updated considerations regarding mRNA vaccine dosing intervals
- Updated considerations for immunocompromised people.

Key points

COVID-19 vaccination is recommended for everyone 12 years and older for the prevention of coronavirus disease 2019 (COVID-19) in the United States. The Advisory Committee on Immunization Practices (ACIP) has issued interim recommendations for the use of:

- Pfizer-BioNTech COVID-19 vaccine (in persons ages 12–15 years and ages ≥16 years)
- Moderna COVID-19 vaccine (in persons ages ≥18 years)
- Janssen (Johnson & Johnson) COVID-19 vaccine (in persons ages ≥18 years)

These clinical considerations provide additional information to healthcare professionals and public health officials on use of COVID-19 vaccines.

The Advisory Committee on Immunization Practices' (ACIP) update on the use of mRNA COVID-19 vaccines after reports of myocarditis or pericarditis in vaccine recipients

On June 23, 2021, ACIP met to review reported cases of myocarditis or pericarditis in mRNA COVID-19 vaccine (Pfizer-BioNTech and Moderna) recipients. Cases of myocarditis or pericarditis have occurred predominantly in males aged 12-29 years, with symptoms typically developing within a few days after receipt of the second dose of vaccine.

ACIP reviewed the benefits and risks of mRNA COVID-19 vaccines in the United States and determined that the benefits of using mRNA COVID-19 vaccines under the Food and Drug Administration's (FDA) Emergency Use Authorization (EUA) clearly outweigh the risks of myocarditis and pericarditis in all people aged 12 years or older. The FDA updated the EUA Fact Sheet for Healthcare Providers Administering Vaccine (Vaccination Providers) and the Fact Sheet for Recipients and Caregivers for Pfizer-BioNTech COVID-19 vaccine and Moderna COVID-19 vaccine to include information about the occurrence of myocarditis or pericarditis in some people following use of the vaccine. Based on the benefit-risk

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

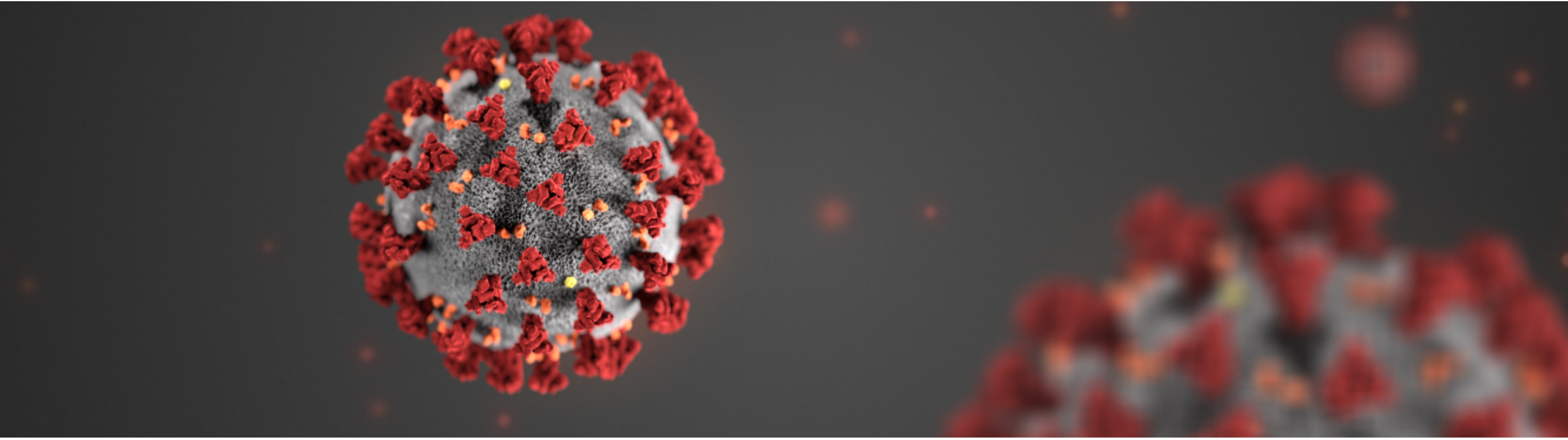
- NACCHO: Matt Zahn (primary), Jeff Duchin (alternate)
- NACI: Matthew Tunis (primary), Kelsey Young (alternate)
- NFID: Bill Schaffner (primary), Marla Dalton (alternate)
- NMA: Oliver Brooks
- SHEA: Marci Drees

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



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.