# COVID-19 Vaccine Safety Technical (VaST) Work Group

## Assessment

Grace M. Lee, MD MPH

VaST ACIP Chair

Advisory Committee on Immunization Practices

May 12, 2021

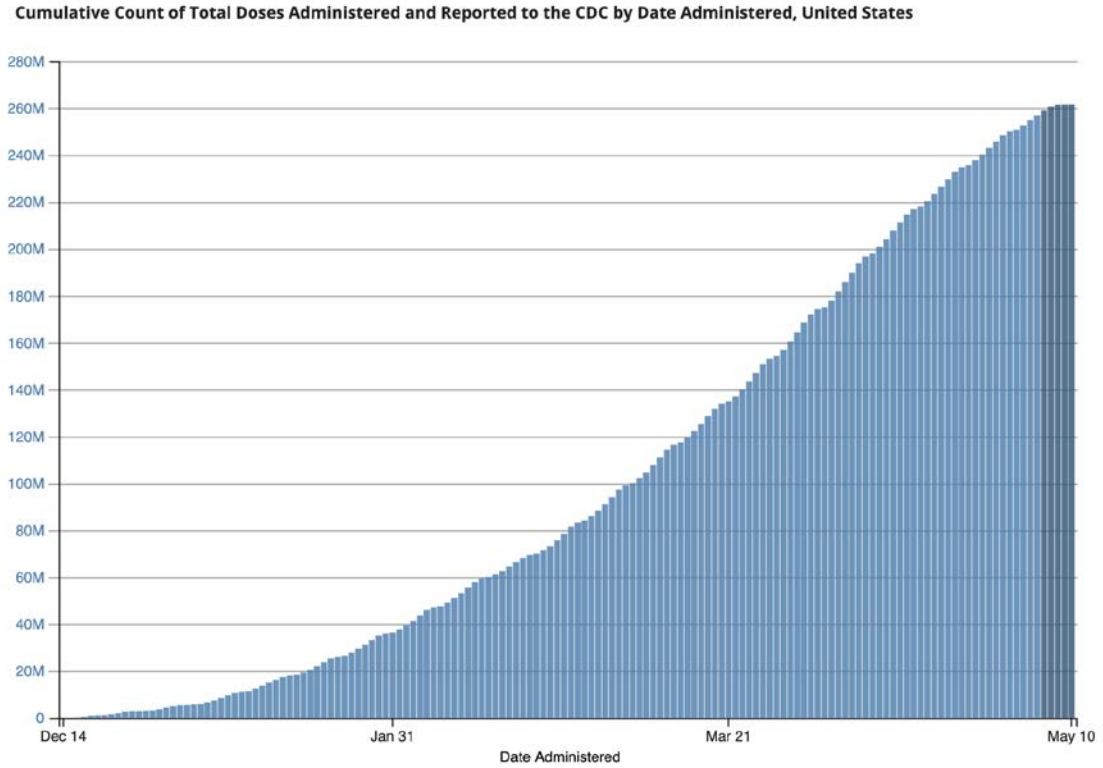
# COVID-19 Vaccine Safety Technical (VaST) Work Group

## Objectives

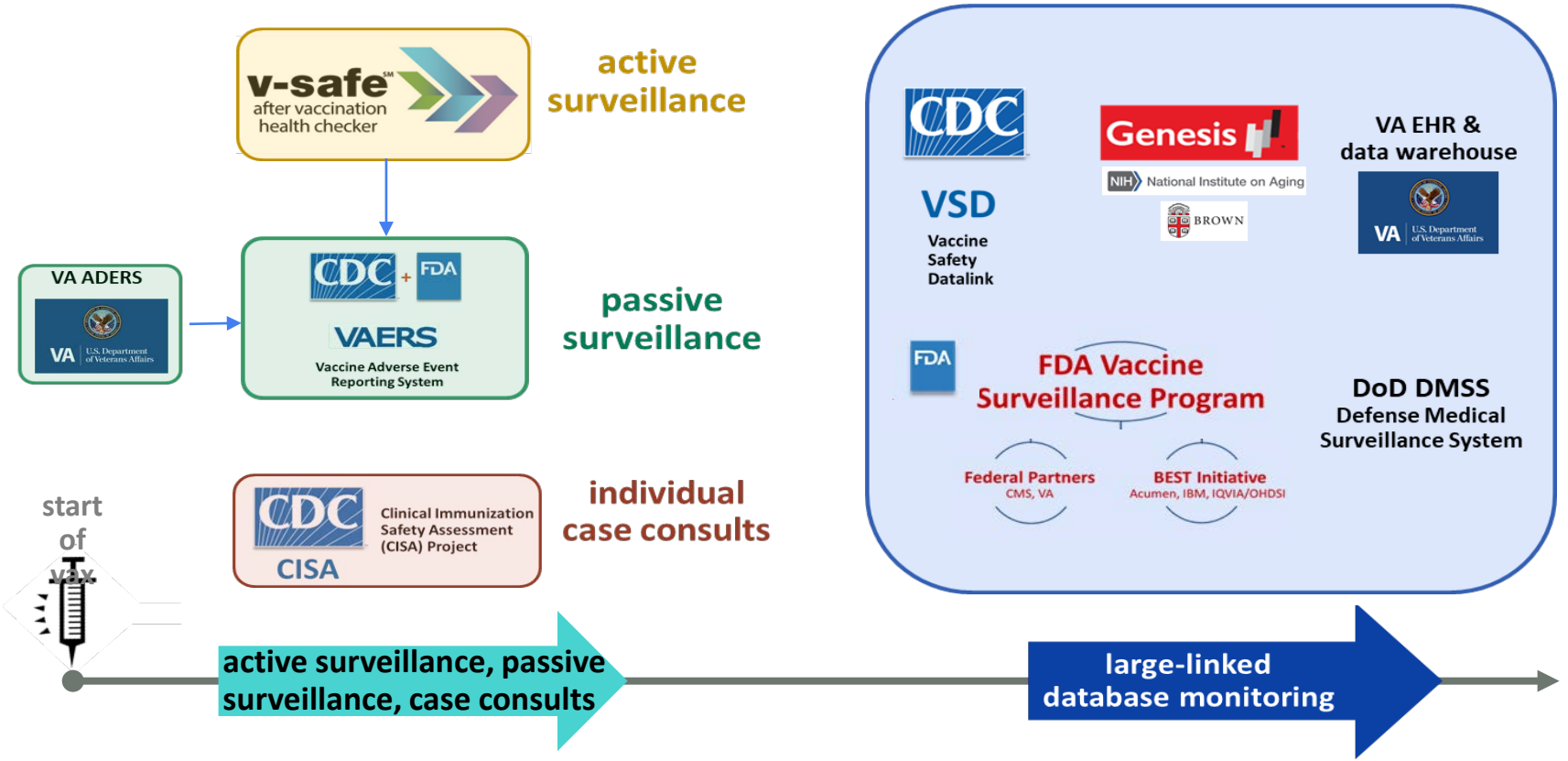
- Review, evaluate, and interpret post-authorization/approval COVID-19 vaccine safety data
- Serve as the central hub for technical subject matter expertise from federal agencies conducting post-authorization/approval safety monitoring
- Advise on analyses, interpretation, and data presentation
- Provide updates to the ACIP COVID-19 Vaccines Work Group and the ACIP on COVID-19 vaccine safety

# U.S. Vaccination Program

- As of May 10
  - 262 million doses administered in the U.S.
    - 140 million Pfizer-BioNTech
    - 113 million Moderna
    - 9 million Janssen
  - 153 million individuals who received ≥1 dose



# Vaccine Safety Monitoring Timeline



# VaST Activities

Dec 21, 2020 – present:

- 20 independent meetings to review vaccine safety data
- 4 joint meetings with COVID-19 Vaccines Work Group focused on safety

# Janssen Vaccine - Thrombosis with Thrombocytopenia Syndrome (TTS)

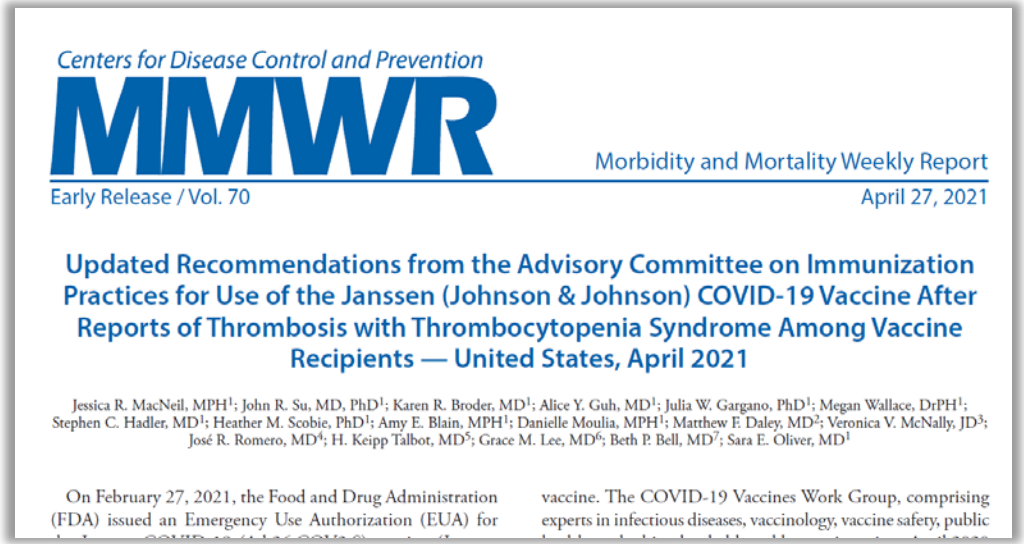
| VaST meeting<br>April 12 | CDC and FDA<br>April 13 | ACIP meeting<br>April 14 |
|---|---|---|
| • CVST with thrombocytopenia identified as a rare, but serious adverse event following Janssen vaccine | • Safety pause of Janssen COVID-19 vaccine<br>• HAN issued to ensure timely recognition and appropriate management | • Review of TTS cases<br>• Request for additional information to support evidence-based decision making |

# VaST Meetings to Review Data on Thrombosis with Thrombocytopenia Syndrome (TTS)

- April 12
- April 19
- April 22

**April 23: ACIP Meeting** ➡

- April 26
- May 3
- May 10



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

# TTS – reviewed at VaST Meetings*

- Enhanced monitoring and refined CDC case ascertainment approach used for TTS cases following Janssen in VAERS
  - Median age 40 years (range 18-59)
  - 28 cases identified - 22 female, 6 male
- Review of data from VSD RCA and VA RCA
  - Broad electronic algorithms implemented to capture potential CVST or TTS events, followed by rapid review of electronic medical records for confirmation
  - No safety signals identified for CVST or TTS following mRNA or Janssen vaccines

Most recently, May 10; data through May 7

# Safety Monitoring of the Janssen (Johnson & Johnson) COVID-19 Vaccine — United States, March–April 2021

David K. Shay, MD[1]; Julianne Gee, MPH[1]; John R. Su, MD, PhD[1]; Tanya R. Myers, PhD[1]; Paige Marquez, MSPH[1]; Ruiling Liu, PhD[1]; Bicheng Zhang, MS[1]; Charles Licata, PhD[1]; Thomas A. Clark, MD[1]; Tom T. Shimabukuro, MD[1]

*On April 30, 2021, this report was posted as an* MMV
*Release on the* MMWR *website (https://www.cdc.gov/n*

On February 27, 2021, the Food and Drug Admin
(FDA) issued an Emergency Use Authorization
for Janssen (Ad.26.COV2.S) COVID-19 vaccine
Biotech, Inc., a Janssen Pharmaceutical company,
& Johnson) (*1*). The Janssen COVID-19 vaccine,
COVID-19 vaccine authorized for use in the Unite
uses a replication-incompetent human adenoviral typ
tor platform* (*2*) and is administered as a single intrar
dose, whereas the first two authorized vaccines use ar

Research

JAMA | Original Investigation

# US Case Reports of Cerebral Venous Sinus Thrombosis With Thrombocytopenia After Ad26.COV2.S Vaccination, March 2 to April 21, 2021

Isaac See, MD; John R. Su, MD, PhD, MPH; Allison Lale, MD, MPH; Emily Jane Woo, MD, MPH; Alice Y. Guh, MD, MPH; Tom T. Shimabukuro, MD, MPH, MBA; Michael B. Streiff, MD; Agam K. Rao, MD; Allison P. Wheeler, MD, MSCI; Suzanne F. Beavers, MD; Anna P. Durbin, MD; Kathryn Edwards, MD; Elaine Miller, RN, MPH; Theresa A. Harrington, MD, MPH&TM; Adamma Mba-Jonas, MD, MPH; Narayan Nair, MD; Duong T. Nguyen, DO; Kawsar R. Talaat, MD; Victor C. Urrutia, MD; Shannon C. Walker, MD; C. Buddy Creech, MD; Thomas A. Clark, MD, MPH; Frank DeStefano, MD, MPH; Karen R. Broder, MD

# Talking to Patients
## about Safety of the Janssen COVID-19 Vaccine

Effective April 23, 2021, CDC and FDA recommend use of the Janssen COVID-19 Vaccine (Johnson & Johnson) resume in the United States.
**The available data show that the vaccine's known and potential benefits outweigh its known and potential risks.**
You can offer the Janssen COVID-19 Vaccine to people 18 years and older who want to get vaccinated against COVID-19.

As a clinician, your answers to patient questions matter. Your strong recommendation can help them make an informed decision and feel confident about getting vaccinated

**If your patient has questions about the safety of the Janssen COVID-19 Vaccine:**

- Discuss the possibility of a **rare but inc** clots with low platelets seen after receip COVID-19 Vaccine.
- To date, most of these reports have beer younger than 50 years old, but there hav men and older women.
- The reporting rate for this event in wom about 7 per 1 million women vaccinatec

## What do I need to know about Johnson & Johnson's Janssen COVID-19 Vaccine (J&J/Janssen) now?

There is a risk of a rare but serious condition involving blood clots and low platelets in people after receiving the J&J/Janssen COVID-19 Vaccine. **This risk is very low.**

**This problem is rare and happened in about 7 per 1 million vaccinated women between 18 and 49 years old.**

For women 50 years and older and men of any age, this problem is even more rare.

This problem has not been linked to the other two COVID-19 vaccines (Pfizer-BioNTech and Moderna).

# VaST Summary

- No confirmed TTS cases following mRNA vaccines
- Risk of TTS following Janssen vaccine highest in females <50 years
- Continue risk mitigation strategies
  - Educate patients about benefits and risks of available vaccines
  - Earlier recognition and timely management of TTS
- VaST will continue to monitor TTS, thromboembolic disease, and thrombocytopenia in all available vaccine safety surveillance systems
- VaST will update the ACIP COVID-19 vaccines workgroup, ACIP secretariat and ACIP on a regular basis

# VaST Members

**VaST Members**
Grace Lee (ACIP)
Robert Hopkins (NVAC)
Matt Daley
Veronica McNally
Keipp Talbot
Kathy Edwards
Lisa Jackson
Jennifer Nelson
Laura Riley
Robert Schechter
Patricia Whitley-Williams

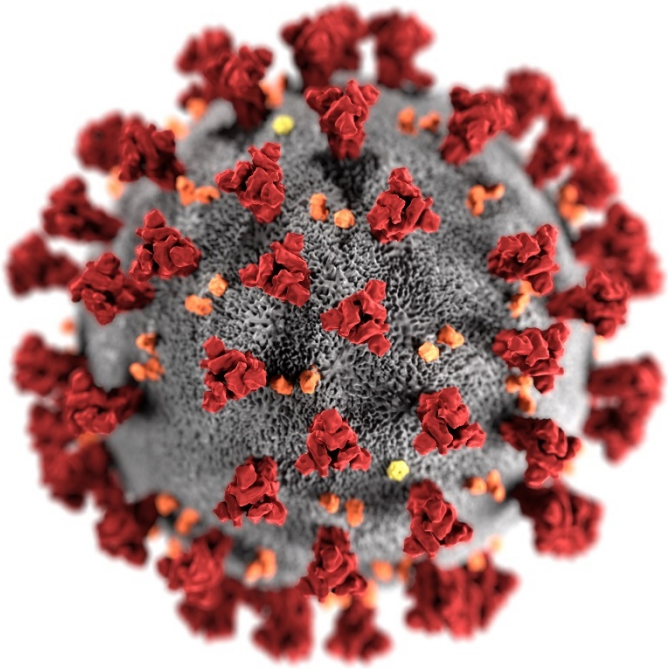
**CDC Co-Leads**
Lauri Markowitz
Melinda Wharton

**Ex Officio and Liaison Representatives**
Tatiana Beresnev (NIH)
Karen Farizo; Hui Lee Wong (FDA)
Judith Steinberg (OIDP)
Jeffrey Kelman (CMS)
Matthew Clark (IHS)
Mary Rubin (HRSA)
Fran Cunningham (VA)
Limone Collins (DoD)

**Administrative Support**
Jared Woo

COVID 19
CORONAVIRUS DISEASE

# TTS Updates:
# Work Group Interpretation



Sara Oliver MD, MSPH
ACIP Meeting
May 12, 2021

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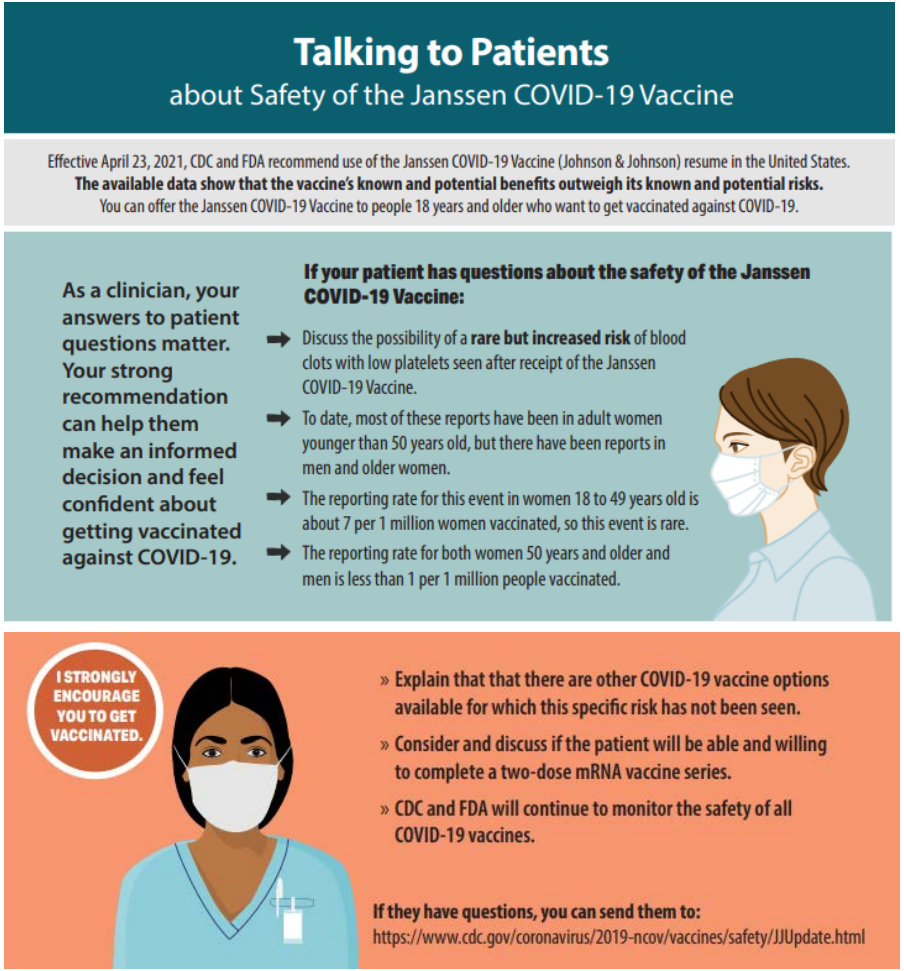
"ACIP reaffirmed its interim recommendations for use of the Janssen COVID-19 vaccine in all persons aged ≥18 years under FDA's EUA, which now includes a **warning** that **rare clotting events** might occur after vaccination, primarily among **women aged 18-49 years**.

**Patient and provider education** about the risk for TTS with the Janssen COVID-19 vaccine, especially among women aged <50 years, as well as the **availability of alternative COVID-19 vaccines**, is required to guide vaccine decision making and ensure early recognition and clinical management of TTS."




https://www.cdc.gov/mmwr/volumes/70/wr/mm7017e4.htm?s_cid=mm7017e4_w
https://www.cdc.gov/vaccines/covid-19/downloads/talking-patients-Janssen-COVID-19-Vaccine-safety.pdf

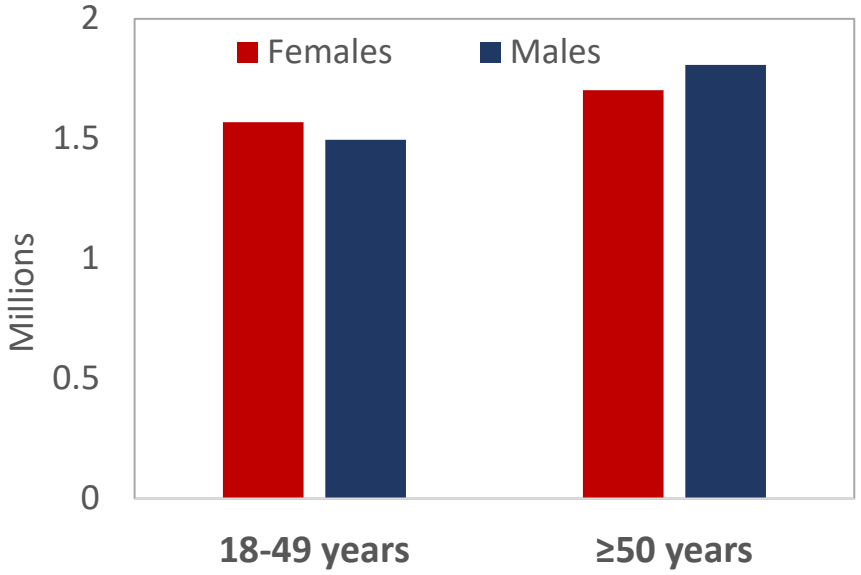
# Janssen COVID-19 vaccine administration:

## Before and after the safety pause

- **1,209,404** doses of the Janssen COVID-19 vaccine administered after the safety pause

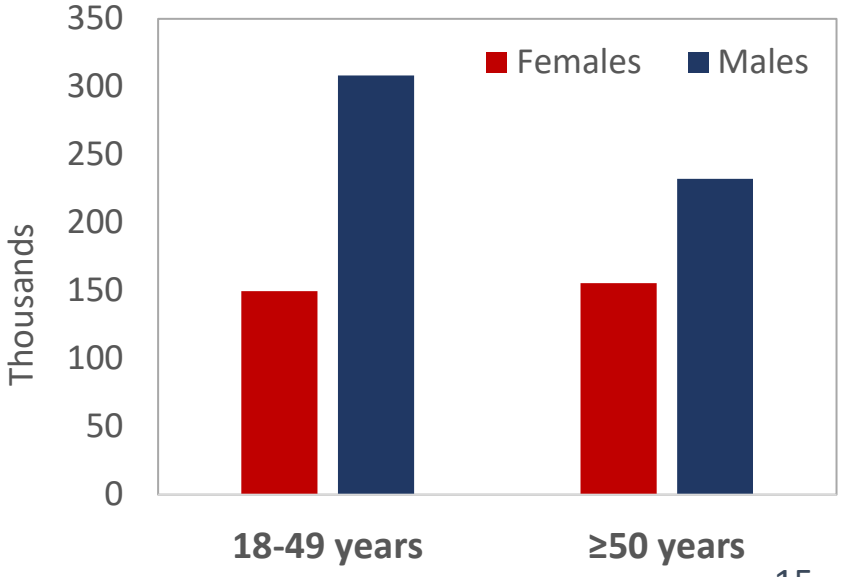
**Before the Safety Pause***

(Before April 13, 2021)




**After the Safety Pause***

(April 13–May 11, 2021)

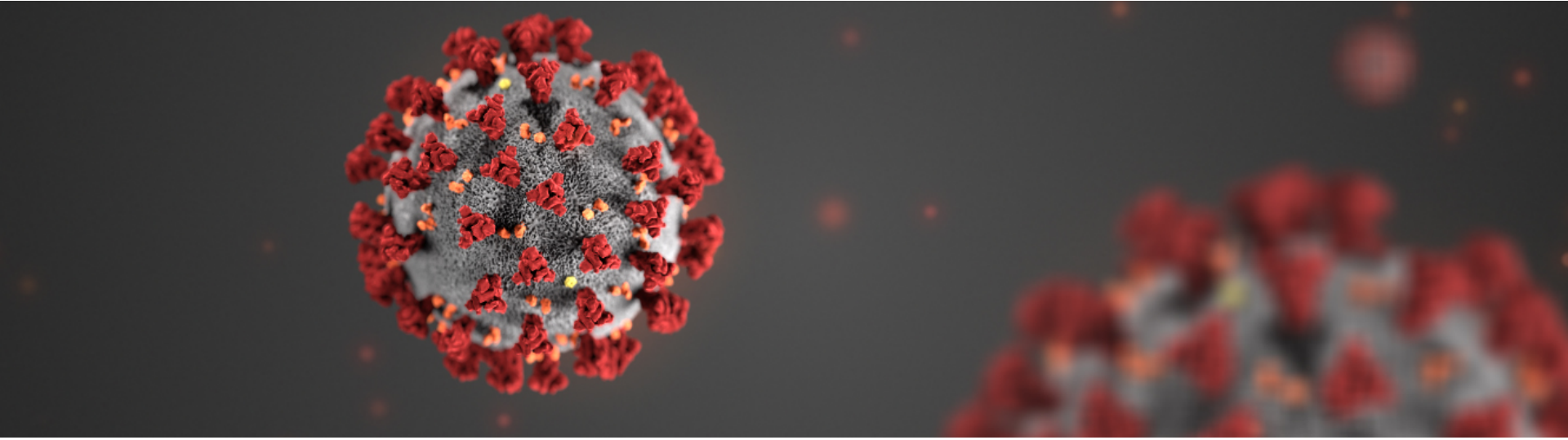



***Does not include administration records from Texas, or records without a valid age or sex**

**CDC | Data as of: May 11, 2021 6:00am ET**

# Janssen COVID-19 vaccine:
## Risk/benefit analysis

- The **Risk/benefit analysis** was updated with the updated incidence of TTS and reviewed by the COVID-19 vaccines Work Group
- The Work Group's interpretation is that the **benefits** still outweighed the **risks** at this time, and no updates to vaccine policy are needed at this time
  - The Work Group will continue to review TTS updates and the Risk/benefit analysis
- If/when the Work Group's assessment is that updates to recommendations for use of the Janssen COVID-19 vaccine should be considered, the Risk/benefit analysis will be presented to ACIP again, along with updated **policy considerations**



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.

# Janssen COVID-19 vaccine administration:

## Before and after the safety pause

| | Pre Pause (Before April 13, 2021) | | | | | | Post Pause (April 23, 2021 - May 11, 2021) | | | | | |
|---|---|---|---|---|---|---|---|---|---|---|---|---|
| | Female | | | Male | | | Female | | | Male | | |
| | n | % | | n | % | | n | % | | n | % | |
| **18-29 years old** | 488,795 | 15% | | 464,502 | 14% | | 50,420 | 17% | | 112,525 | 21% | |
| **30-39 years old** | 521,914 | 16% | | 476,125 | 14% | | 46,497 | 15% | | 97,630 | 18% | |
| **40-49 years old** | 558,793 | 17% | | 554,773 | 17% | | 52,723 | 17% | | 98,091 | 18% | |
| **50-64 years old** | 1,155,482 | 35% | | 1,153,702 | 35% | | 97,652 | 32% | | 163,970 | 30% | |
| **64+ years old** | 547,140 | 17% | | 653,789 | 20% | | 57,998 | 19% | | 68,255 | 13% | |
| **Total** | 3,272,124 | | | 3,302,891 | | | 305,290 | | | 540,471 | | |