

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

## Assessment

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Advisory Committee on Immunization Practices

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

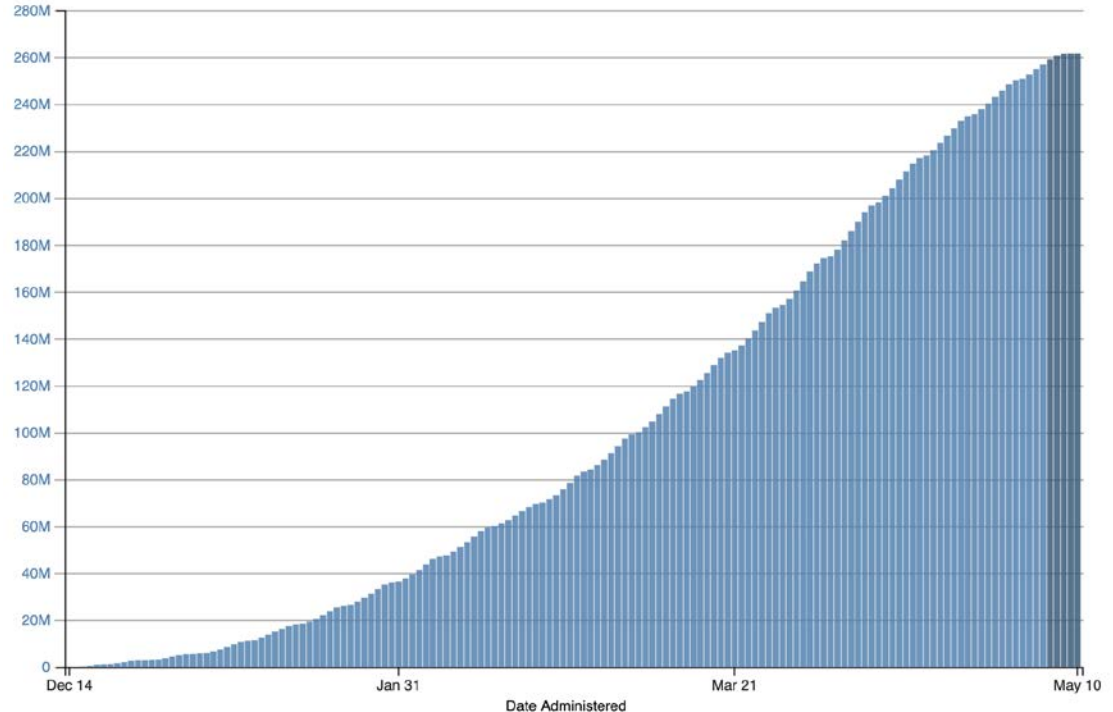
## Objectives

- 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

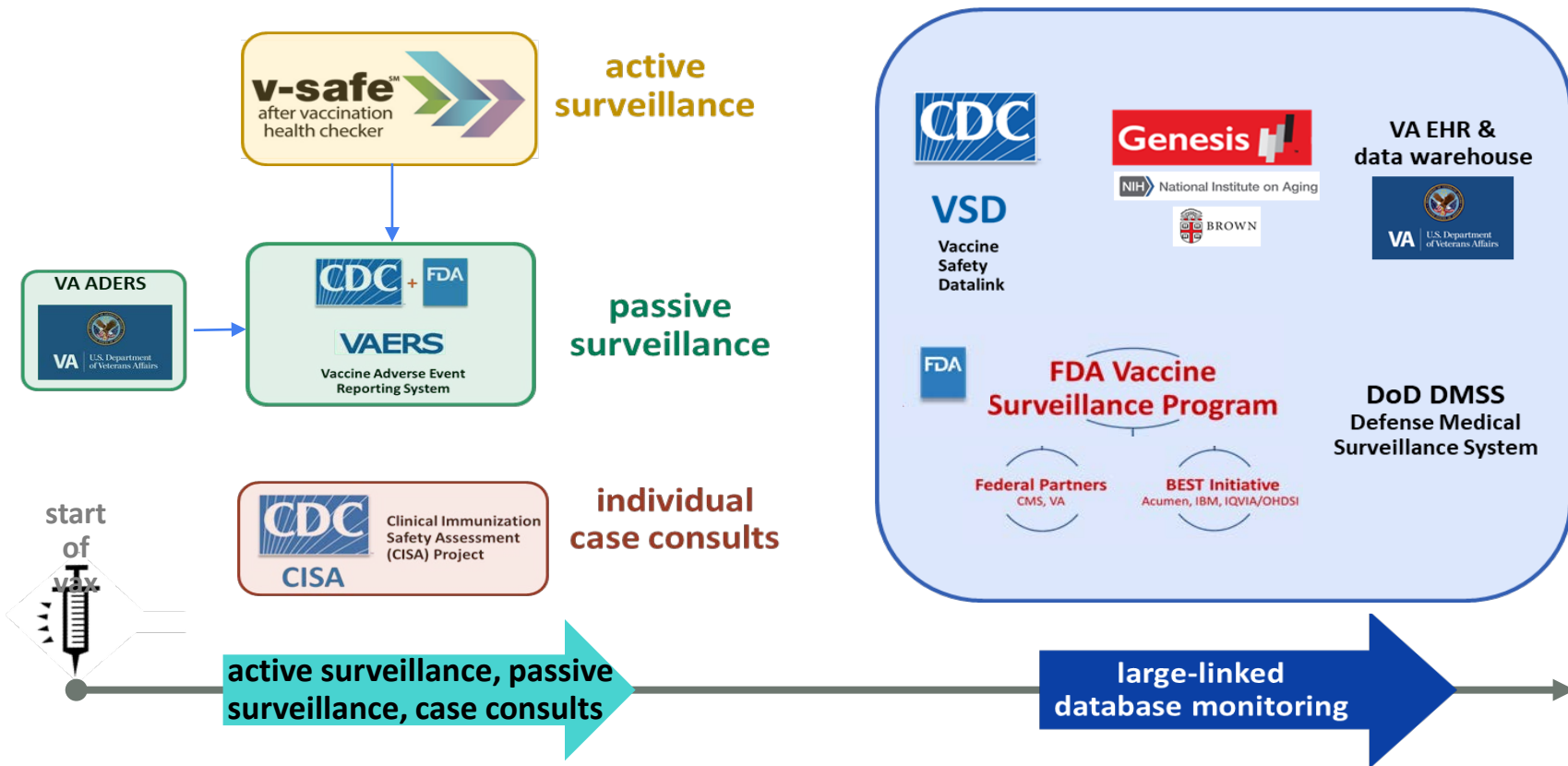
# U.S. Vaccination Program

- 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  $\geq 1$  dose

Cumulative Count of Total Doses Administered and Reported to the CDC by Date Administered, United States



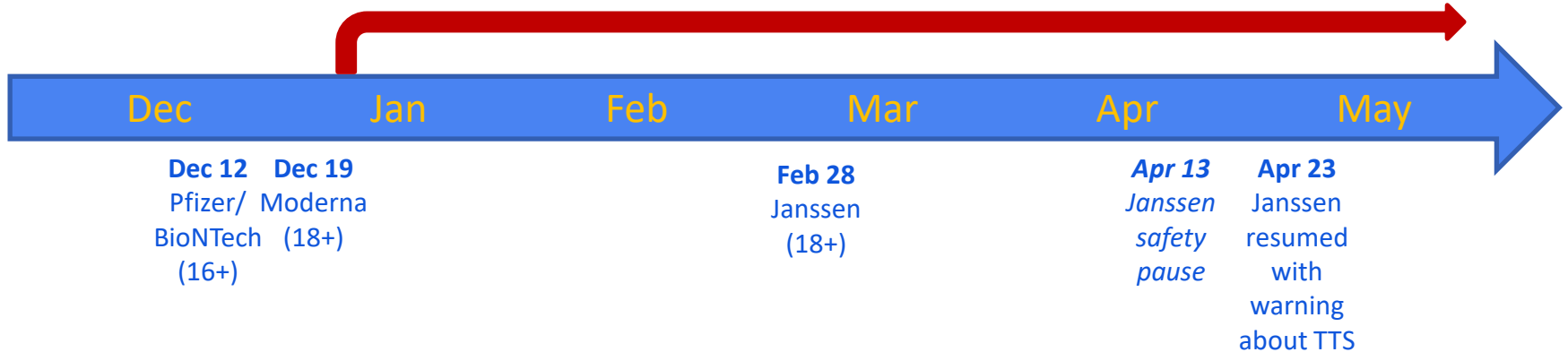
# Vaccine Safety Monitoring Timeline



# 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 April 12

- CVST with thrombocytopenia identified as a rare, but serious adverse event following Janssen vaccine

## CDC and FDA April 13

- Safety pause of Janssen COVID-19 vaccine
- HAN issued to ensure timely recognition and appropriate management

## ACIP meeting April 14

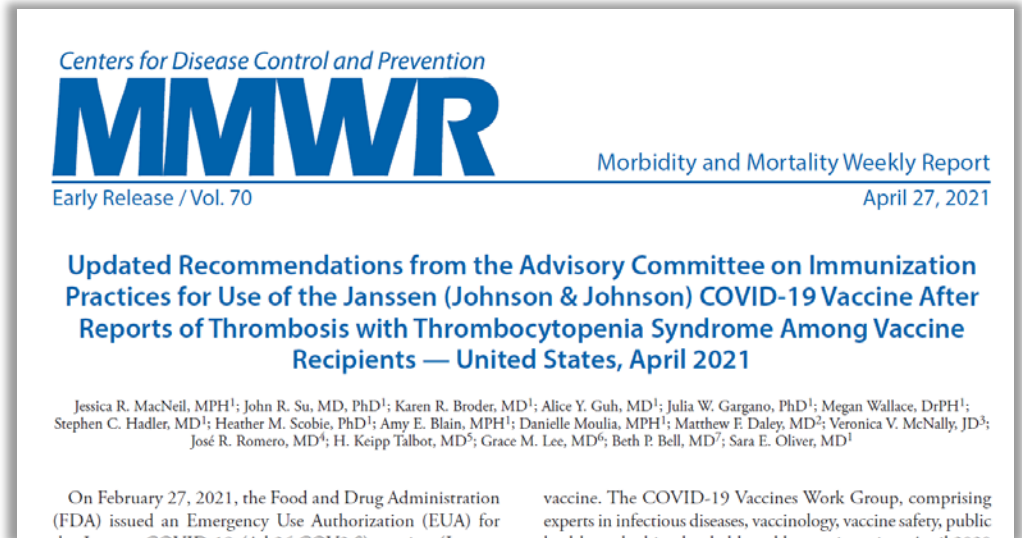
- Review of TTS cases
- Request for additional information to support evidence-based decision making

# 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



## 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



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

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

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

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

### Research

### JAMA | Original Investigation

## US Case Reports of Cerebral Venous Sinus Thrombosis With Thrombocytopenia After Ad26.COVS.2.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 increased risk of blood clots with low platelets seen after receiving the J&J/Janssen COVID-19 Vaccine.
- ➔ To date, most of these reports have been in women younger than 50 years old, but there have been reports in men and older women.
- ➔ The reporting rate for this event in women is about 7 per 1 million women vaccinated.

## 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

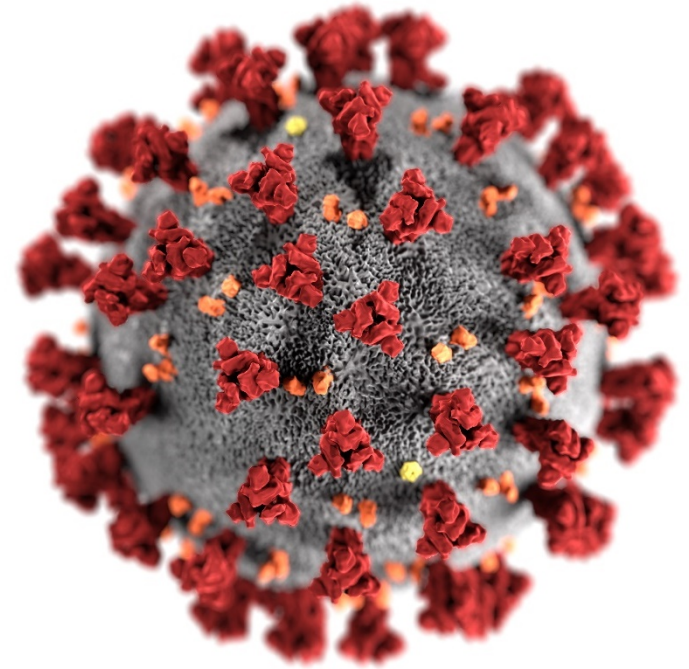
## Ex Officio and Liaison Representatives

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

# TTS Updates: Work Group Interpretation



Sara Oliver MD, MSPH  
ACIP Meeting  
May 12, 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<sup>1</sup>; John R. Su, MD, PhD<sup>1</sup>; Karen R. Broder, MD<sup>1</sup>; Alice Y. Guh, MD<sup>1</sup>; Julia W. Gargano, PhD<sup>1</sup>; Megan Wallace, DrPH<sup>1</sup>; Stephen C. Hadler, MD<sup>1</sup>; Heather M. Scobie, PhD<sup>1</sup>; Amy E. Blain, MPH<sup>1</sup>; Danielle Moulia, MPH<sup>1</sup>; Matthew F. Daley, MD<sup>2</sup>; Veronica V. McNally, JD<sup>3</sup>; José R. Romero, MD<sup>4</sup>; H. Keipp Talbot, MD<sup>5</sup>; Grace M. Lee, MD<sup>6</sup>; Beth P. Bell, MD<sup>7</sup>; Sara E. Oliver, MD<sup>1</sup>

“ACIP reaffirmed its interim recommendations for use of the Janssen COVID-19 vaccine in all persons aged  $\geq 18$  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/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>

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

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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 against COVID-19.

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

- ➔ Discuss the possibility of a **rare but increased risk** of blood clots with low platelets seen after receipt of the Janssen COVID-19 Vaccine.
- ➔ To date, most of these reports have been in adult women younger than 50 years old, but there have been reports in men and older women.
- ➔ The reporting rate for this event in women 18 to 49 years old is about 7 per 1 million women vaccinated, so this event is rare.
- ➔ The reporting rate for both women 50 years and older and men is less than 1 per 1 million people vaccinated.



I STRONGLY ENCOURAGE YOU TO GET VACCINATED.



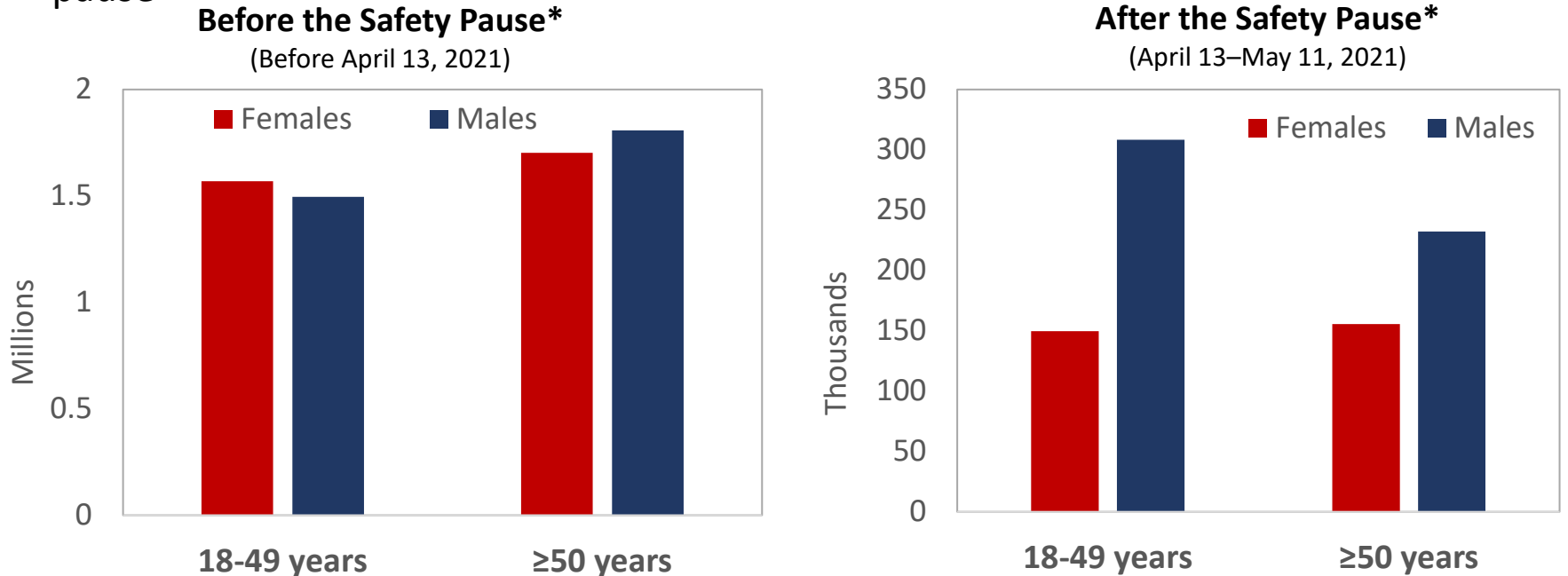
- » Explain that there are other COVID-19 vaccine options available for which this specific risk has not been seen.
- » Consider and discuss if the patient will be able and willing to complete a two-dose mRNA vaccine series.
- » CDC and FDA will continue to monitor the safety of all COVID-19 vaccines.

If they have questions, you can send them to:

<https://www.cdc.gov/coronavirus/2019-ncov/vaccines/safety/JJUpdate.html>

# 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



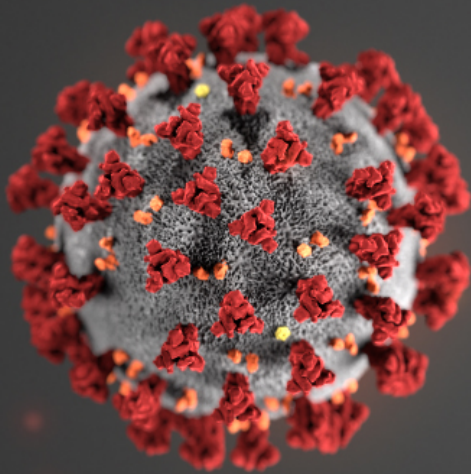
\*Does not include administration records from Texas, or records without a valid age or sex  
CDC | Data as of: May 11, 2021 6:00am ET

# 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](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.



# 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	%
<b>18-29 years old</b>	488,795	15%	464,502	14%	50,420	17%	112,525	21%
<b>30-39 years old</b>	521,914	16%	476,125	14%	46,497	15%	97,630	18%
<b>40-49 years old</b>	558,793	17%	554,773	17%	52,723	17%	98,091	18%
<b>50-64 years old</b>	1,155,482	35%	1,153,702	35%	97,652	32%	163,970	30%
<b>64+ years old</b>	547,140	17%	653,789	20%	57,998	19%	68,255	13%
<b>Total</b>	3,272,124		3,302,891		305,290		540,471	