

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

## Safety Assessment

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

## Objectives

- Review, evaluate, and interpret post-authorization/approval COVID-19 vaccination 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 presentation of vaccine safety data
- Provide updates to the ACIP COVID-19 Vaccines Work Group and the entire ACIP on COVID-19 vaccine safety

## VaST meetings

- December 21, 2020 – present: 45 meetings to review vaccine safety data

# VaST meeting - April 12, 2021

## First review of Central Venous Sinus Thrombosis (CVST) with thrombocytopenia

- 6 cases of CVST with thrombocytopenia identified as rare but serious adverse event following Janssen COVID-19 vaccine
- Risk factors for CVST with thrombocytopenia not well understood
- Timely and transparent communication with healthcare providers and the public is crucial to maintain confidence in the COVID-19 vaccination program

# HAN Communication

## April 13, 2021

Cases of Cerebral Venous Sinus Thrombosis with Thrombocytopenia after Receipt of the Johnson & Johnson COVID-19 Vaccine



- Recommendations for Clinicians: diagnosis and treatment
  - Evaluate patients with a screening PF4 enzyme-linked immunosorbent (ELISA) assay as would be performed for autoimmune HIT. Consultation with a hematologist is strongly recommended.
  - Do not treat with heparin, unless HIT testing is negative
- Recommendations for Public Health: case reporting through VAERS
  - Encourage healthcare providers and the public to report all serious and life-threatening adverse events and deaths following receipt of COVID-19 vaccines to VAERS
- Recommendations for the Public: clinical signs and symptoms to monitor
  - Contact healthcare provider, or seek medical care if you develop severe headache, abdominal pain, leg pain, or shortness of breath within three weeks after vaccination with the J&J COVID-19 vaccine

# ACIP meetings – April 14 and 23, 2021

## April 14

- Reviewed cases of CVST with thrombocytopenia after COVID-19 vaccination
- Discussed need for additional information to support evidence-based decision making, including
  - Age and gender-specific risk estimates
  - Evaluation of the benefit-risk balance of using Janssen vaccine in specific subgroups

# ACIP meetings – April 14 and 23, 2021

## April 23

- Risk of TTS appears to be highest in females <50 years
  - 15 cases reported; rare but serious condition
  - Other risk factors for TTS not well established yet
- Risk mitigation strategies
  - Minimize exposure in high-risk populations
  - Increase awareness & ensure timely diagnosis and management of TTS
  - Educate patients about benefits and risks of available vaccines
- VaST will continue to monitor TTS, other 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

# Talking to Patients

about Safety of the Janssen COVID-19 Vaccine

Effective April 23, 2021, CDC and FDA have updated their guidance on the J&J COVID-19 vaccine. **The available data show that the risk of thrombosis with thrombocytopenia syndrome (TTS) is very low.** You can offer the Janssen COVID-19 vaccine to patients who are 18 years of age and older.

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.

## 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 COVID-19 Vaccine. **This risk is very low.**

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

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).



Centers for Disease Control and Prevention

# MMWR

Morbidity and Mortality Weekly Report

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### 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

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On February 27, 2021, the Food and Drug Administration (FDA) issued an Emergency Use Authorization (EUA) for the Janssen COVID-19 (J&J COVID-19) vaccine.

The COVID-19 Vaccines Work Group, comprising experts in infectious diseases, vaccinology, vaccine safety, public health, and clinical research, has reviewed the available data on the J&J COVID-19 vaccine. The COVID-19 Vaccines Work Group, comprising experts in infectious diseases, vaccinology, vaccine safety, public health, and clinical research, has reviewed the available data on the J&J COVID-19 vaccine.

# Ongoing VaST review of TTS and Janssen COVID-19 vaccination, May through December 2021

- VaST meetings
  - Regular updates on TTS data from VAERS, VSD and other safety systems
- VaST assessments of Janssen J&J COVID-19 vaccination safety represented to ACIP\*
  - May 12 (focus on TTS) and July 22 (focus on GBS)

TTS, thrombosis with thrombocytopenia syndrome; GBS, Guillain-Barré syndrome

[\\*https://www.cdc.gov/vaccines/acip/work-groups-vast/index.html](https://www.cdc.gov/vaccines/acip/work-groups-vast/index.html)



## VaST assessment – December 6, 2021

- Through August 2021, 54 TTS cases and 9 deaths reported following Janssen COVID-19 vaccination in the United States
- The TTS case reporting rate following Janssen COVID 19 vaccination is higher than previous estimates in men as well as women, and in wider age range
- Follow-up investigations have provided more evidence for relationship between Janssen COVID-19 vaccination and TTS and associated severe outcomes
- VaST recognizes the public health benefits of the Janssen COVID-19 vaccine; however, the additional TTS cases and reported deaths are concerning
- VaST felt that the new data on TTS risk need to be put into context of a benefit-risk assessment, and should be presented to the ACIP COVID-19 Vaccines Work Group and to ACIP

# VaST Members

## VaST Members

Keipp Talbot (ACIP)  
Robert Hopkins (NVAC)  
Matt Daley  
Grace Lee  
Veronica McNally  
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)  
Valerie Marshall (OIDP)  
Jeffrey Kelman (CMS)  
Matthew Clark (IHS)  
Mary Rubin (HRSA)  
Fran Cunningham (VA)  
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## Administrative Support

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