COVID-19 Vaccine Safety Technical (VaST) Work Group

Safety Assessment

H. Keipp Talbot, MD MPH (VaST Chair)
Robert H. Hopkins, Jr., MD (NVAC Chair)

Advisory Committee on Immunization Practices
December 16, 2021
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
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

- 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

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

As a clinician, you may be receiving questions from your patients about the vaccine. This is normal, and your strong recommendations can help them make an informed decision and feel confident about getting vaccinated.

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 million vaccinated women between 18 and 49 years of age. For women 50 years and older and men of any age, this risk is even more rare.

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

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; John R. Su, MD, PhD; Karen R. Broder, MD; Alice Y. Gub, MD; Julia W. Gargano, PhD; Megan Wallace, DrPH; Stephen C. Hadler, MD; Heather M. Sobic, PhD; Amy E. Blain, MPH; Danielle Moula, MPH; Matthew E. Daley, MD; Veronica V. McNally, JD; José R. Romero, MD; H. Keipp Talbot, MD; Grace M. Lee, MD; Beth B. Bell, MD; Sara E. Oliver, MD

On February 27, 2021, the Food and Drug Administration (FDA) issued an Emergency Use Authorization (EUA) for the COVID-19 vaccine. The COVID-19 Vaccines Work Group, comprising experts in infectious diseases, vaccinology, vaccine safety, public health, and hematologic medicine, met to discuss this emerging issue. After reviewing the clinical data and evidence, the ACIP voted to recommend use of the J&J/Janssen vaccine, with the following recommendations:

1. Use the J&J/Janssen COVID-19 vaccine only in adults 18 years of age and older.
2. Use the J&J/Janssen COVID-19 vaccine only in women younger than 50 years of age at this time.
3. Use the J&J/Janssen COVID-19 vaccine for individuals younger than 50 years of age if: (a) the individual specifically requests the J&J/Janssen COVID-19 vaccine; (b) the individual understands the risk for the rare and serious condition involving blood clots and low platelets; (c) the individual has discussed this condition with the provider; and (d) the provider determines the benefits of vaccination outweigh the risks.
4. Use the J&J/Janssen COVID-19 vaccine for individuals 50 years of age and older if: (a) the individual specifically requests the J&J/Janssen COVID-19 vaccine; (b) the individual understands the risk for the rare and serious condition involving blood clots and low platelets; and (c) the provider determines the benefits of vaccination outweigh the risks.

Additional guidance for clinicians and patients is available on the CDC website.
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
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

**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)
- Limone Collins (DoD)

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

**Administrative Support**
- Jared Woo