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

- **v-safe™** after vaccination health checker
- **VA ADERS**
- **CDC + FDA**
- **VAERS** Vaccine Adverse Event Reporting System
- **active surveillance**
- **passive surveillance**
- **individual case consults**
- **active surveillance, passive surveillance, case consults**
- **large-linked database monitoring**
- **VSD** Vaccine Safety Datalink
- **FDA Vaccine Surveillance Program**
- **Federal Partners**
  - CMS, VA
- **BEST Initiative**
  - Acumen, IBM, IQVIA/OHDSI
- **VA EHR & data warehouse**
- **DoD DMSS** Defense Medical Surveillance System
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

Dec 12
Pfizer/ BioNTech (16+)

Dec 19
Moderna (18+)

Feb 28
Janssen (18+)

Apr 13
Janssen safety pause

Apr 23
Janssen resumed with warning about TTS

Feb
Mar
Apr
May
## Janssen Vaccine - Thrombosis with Thrombocytopenia Syndrome (TTS)

<table>
<thead>
<tr>
<th>Event</th>
<th>Date</th>
<th>Summary</th>
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<tbody>
<tr>
<td>VaST meeting</td>
<td>April 12</td>
<td>CVST with thrombocytopenia identified as a rare, but serious adverse event following Janssen vaccine</td>
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<tr>
<td>CDC and FDA</td>
<td>April 13</td>
<td>Safety pause of Janssen COVID-19 vaccine; HAN issued to ensure timely recognition and appropriate management</td>
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<tr>
<td>ACiP meeting</td>
<td>April 14</td>
<td>Review of TTS cases; Request for additional information to support evidence-based decision making</td>
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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

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, MD1; Julianne Gee, MPH1; John R. Su, MD, PhD1; Tanya R. Myers, PhD1; Paige Marquez, MSPH1; Ruiling Liu, PhD1; Bicheng Zhang, MS1; Charles Licata, PhD1; Thomas A. Clark, MD1; Tom T. Shimabukuro, MD1

On April 30, 2021, this report was posted as an MMWR 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 (Ad26.COV2.S) COVID-19 vaccine Biotech, Inc., a Janssen Pharmaceutical company, & Johnson) (1). The Janssen COVID-19 vaccine, t COVID-19 vaccine authorized for use in the Unite uses a replication-incompetent human adenoviral typpor platform* (2) and is administered as a single intrat dose, whereas the first two authorized vaccines use ar

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; Kawzar 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 receipt of the Janssen COVID-19 Vaccine.

→ To date, most of these reports have been in younger individuals, younger than 50 years old, but there have also 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; John R. Su, MD, PhD; Karen R. Broder, MD; Alice Y. Gah, MD; Julia W. Gargacco, PhD; Megan Wallace, DVM; Stephen C. Hadler, MD; Heather M. Scoble, PhD; Amy E. Blain, MPH; Danielle Mosulli, MPH; Matthew E. Dakey, MD; Veronica V. McNally, JD; Josef R. Romero, MD; H. Keppel Talbott, MD; Grace M. Lee, MD; Beth P. Bell, MD; Sara E. Oliver, MD

“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.”
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**.
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

<table>
<thead>
<tr>
<th>Age Group</th>
<th>Pre Pause (Before April 13, 2021)</th>
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<th>Post Pause (April 23, 2021 - May 11, 2021)</th>
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<tbody>
<tr>
<td></td>
<td>Female n</td>
<td>%</td>
<td>Male n</td>
<td>%</td>
</tr>
<tr>
<td>18-29 years old</td>
<td>488,795</td>
<td>15%</td>
<td>464,502</td>
<td>14%</td>
</tr>
<tr>
<td>30-39 years old</td>
<td>521,914</td>
<td>16%</td>
<td>476,125</td>
<td>14%</td>
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<tr>
<td>40-49 years old</td>
<td>558,793</td>
<td>17%</td>
<td>554,773</td>
<td>17%</td>
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<tr>
<td>50-64 years old</td>
<td>1,155,482</td>
<td>35%</td>
<td>1,153,702</td>
<td>35%</td>
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<tr>
<td>64+ years old</td>
<td>547,140</td>
<td>17%</td>
<td>653,789</td>
<td>20%</td>
</tr>
<tr>
<td>Total</td>
<td>3,272,124</td>
<td></td>
<td>3,302,891</td>
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