COVID-19 Vaccine Safety Technical (VaST) Subgroup

Assessment

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Advisory Committee on Immunization Practices

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COVID-19 Vaccine Safety Technical (VaST) Subgroup

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 Working Group and the ACIP on COVID-19 vaccine safety

VaST Activities

Pre-authorization

Jun-Dec 2020

- 14 meetings to prepare for vaccine safety surveillance in the U.S.

ACIP Recommendations

- Dec 12 – Pfizer/BioNTech
- Dec 14 – 1st dose administered in U.S.
- Dec 19 – Moderna
- Feb 28 – Janssen

Post-authorization

Dec 21-present

- 16 meetings to review vaccine safety data across multiple surveillance systems

VaST review of data on cerebral sinus venous thrombosis (CSVT)

- VaST reviewed data on CVST on April 12
- Data from the Vaccine Adverse Event Reporting System (VAERS) through April 10, 2021
  - 3 cases following Moderna vaccine *without* thrombocytopenia (82.6M doses administered)
  - 0 cases following Pfizer-BioNTech vaccine (94.7M doses administered)
  - 6 cases following J&J vaccine *with* thrombocytopenia (5.9M doses administered)

VaST review of data on cerebral sinus venous thrombosis (CSVT)

- Characteristics of cases* following J&J vaccine similar to those following another COVID-19 adenovirus vector vaccine reported from Europe
  - Thrombosis with thrombocytopenia
  - Elevated D-dimer
  - Antibodies to platelet factor 4 (PF4)

	J&J/Janssen (N=6)	AZ (N=106)
Age group	<50 years	<60 years
Gender	All female	F > M
Race/Ethnicity	White, NH	TBD
Timing of onset	Within 2 weeks	Within 2 weeks

*Denominators needed to evaluate risk

Key Issues

- Rare, but serious adverse event
- Risk factors not yet well understood
- Concern for delayed recognition (new entity → CVST with thrombocytopenia)
- Need for timely management (IVIG, anticoagulation with non-heparin- based therapies)

VaST Discussion – 04/12/2021

- Vaccine safety is paramount
  - Global safety monitoring efforts and VAERS enabled the CDC and FDA to rapidly detect adverse events
- Information about this potential life-threatening adverse event should be promptly provided to clinicians to enhance early recognition and appropriate treatment of persons who develop thrombosis with thrombocytopenia following vaccination

VaST Discussion – 04/12/2021

- Further evaluation of the benefit-risk balance of using J&J/Janssen vaccine in specific subgroups is warranted
  - Other vaccines are currently available for use in the U.S. for prevention of COVID-19
- Timely and transparent communication with healthcare providers and the public is crucial to maintain confidence in the vaccination program

Joint CDC and FDA Statement on Johnson & Johnson COVID-19 Vaccine

The following statement is attributed to Dr. Anne Schuchat, Principal Deputy Director of the CDC and Dr. Peter Marks, director of the FDA's Center for Biologics Evaluation and Research

As of April 12, more than 6.8 million doses of the Johnson & Johnson (Janssen) vaccine have been administered in the U.S. CDC and FDA are reviewing data involving six reported U.S. cases of a rare and severe type of blood clot in individuals after receiving the J&J vaccine. In these cases, a type of blood clot called cerebral venous sinus thrombosis (CVST) was seen in combination with low levels of blood platelets (thrombocytopenia). All six cases occurred among women between the ages of 18 and 48, and symptoms occurred 6 to 13 days after vaccination. Treatment of this specific type of blood clot is different from the treatment that might typically be administered. Usually, an anticoagulant drug called heparin is used to treat blood clots. In this setting, administration of heparin may be dangerous, and alternative treatments need to be given.

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

HAN HEALTH ALERT NETWORK

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Distributed via the CDC Health Alert Network
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VaST Plans

- Enhanced case identification via public health, clinicians, patients, including recent vaccine recipients
  - v-safe, VAERS

VaST Plans

- Signal refinement for CVST with thrombocytopenia
  - Review findings in other vaccine safety surveillance systems
  - Determine risk of developing CVST to inform risk mitigation strategies
- VaST will continue to review all safety data from the U.S. COVID-19 vaccination program
- Update the ACIP COVID-19 vaccines workgroup, ACIP secretariat and ACIP on a regular basis.

VaST Members

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