COVID-19 Vaccine Safety Technical (VaST) Subgroup

Discussion and Interpretation

Grace M. Lee, MD MPH & Robert Hopkins, MD
VaST Co-Chairs

Advisory Committee on Immunization Practices
March 1, 2021
Vaccine Safety Surveillance in the United States

- Well-established vaccine safety surveillance systems remain the cornerstone for monitoring the safety of approved COVID-19 vaccines in the United States
- Enhanced approaches to surveillance have enriched our understanding of COVID-19 vaccine safety in the early phases of vaccine deployment
- VaST continues to meet weekly to review all available data and to ensure a coordinated approach across multiple safety surveillance systems
Local and systemic reactions continue to be most commonly reported following vaccination in v-safe, VAERS and VA-ADERS.

Anaphylaxis reporting rate ranges from 2.5 to 4.7 cases per million doses administered. The most common reason for CISA consultation includes:
- Allergy/immunology specialists provide expert input on clinical considerations.
VaST Discussion and Interpretation

- **VSD Rapid Cycle Analysis**
  - Multiple methods for surveillance are being used, depending on phase of the vaccination program
  - Pre-specified outcomes are actively monitored
  - No statistical signals detected to date

- **CMS Rapid Cycle Analysis**
  - Descriptive analyses reviewed; sequential analyses to begin soon
VaST Discussion and Interpretation

- A large number of pregnant women have chosen to receive COVID-19 vaccines in the United States.
- A novel pregnancy registry in v-safe was established to monitor pregnancy and birth outcomes.
  - Similar to non-pregnant adults, pregnant women commonly report local and systemic reactogenicity (e.g. pain, fatigue, headache).
  - Pregnancy and birth outcomes following COVID-19 vaccination appear similar to rates reported in the literature.
Vaccine Safety Updates


JAMA Insights

Reports of Anaphylaxis After Receipt of mRNA COVID-19 Vaccines in the US—December 14, 2020-January 18, 2021

Tom T. Shimabukuro, MD, MPH, MBA, Matthew Cole, MPH, John R. Su, MD, PhD, MPH
Ensuring COVID-19 Vaccine Safety in the US

Updated Feb. 15, 2021

Vaccine Safety and Monitoring

- COVID-19 vaccines are safe and effective.
- Millions of people in the United States have received COVID-19 vaccines under the most intensive safety monitoring in U.S. history.

COVID-19 Vaccine Reporting Systems

Updated Feb. 12, 2021

COVID-19 vaccines are safe and effective. Millions of people in the United States have received COVID-19 vaccines, and these vaccines have undergone the most intensive safety monitoring in U.S. history. This monitoring includes using both established and new safety vaccines are safe.

Selected Adverse Events Reported after COVID-19 Vaccination

Updated Feb. 25, 2021

Safety of COVID-19 Vaccines

Results from monitoring efforts are reassuring. Some people have no side effects. Many people have reported only mild side effects after COVID-19 vaccination.


VaST Plans

- Statistical signals should be expected in a robust monitoring program
  - Timely investigations will be conducted once signals are identified
  - Only 1 in 10 statistical signals have been true associations
- Maternal vaccine safety data from multiple sources will be regularly reviewed in collaboration with pregnancy experts
- Future vaccine safety surveillance activities will include the newly approved Janssen COVID-19 vaccine
- VaST will continue to update the ACIP COVID-19 vaccines workgroup, ACIP secretariat and ACIP on a regular basis
VaST Members

**Co-Chairs**
Grace Lee (ACIP)
Robert Hopkins (NVAC)

**ACIP Members**
Beth Bell
Matt Daley
Veronica McNally
Keipp Talbot

**Expert Consultants**
Kathy Edwards
Lisa Jackson
Martin Kulldorff
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**
Susan Hiers
Jared Woo