

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

VaST Discussion and Interpretation

- 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
 - Most common reason for CISA consultation
 - 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

Centers for Disease Control and Prevention

MMWR

Morbidity and Mortality Weekly Report

Early Release / Vol. 70

February 19, 2021

**First Month of COVID-19 Vaccine Safety Monitoring — United States,
December 14, 2020–January 13, 2021**

Clinical Review & Education

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

ACT NOW!



WEAR A MASK



STAY 6 FEET APART



AVOID CROWDS

Ensuring COVID-19 Vaccine Safety in the US

Updated Feb. 15, 2021 Languages Print

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 intense safety monitoring in U.S. history.



COVID-19 Vaccine Reporting Systems

Updated Feb. 12, 2021 Languages Print

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 systems to ensure that COVID-19 vaccines are safe.

COVID-19 Vaccine Safety Surveillance

Share Tweet LinkedIn Email Print

February 9, 2021

The Center for Biologics Evaluation and Research (CBER) at the FDA is monitoring the safety of authorized COVID-19 vaccines through both passive and active safety surveillance systems. CBER is doing so in collaboration with the Centers for Disease Control and Prevention (CDC), the Center for Medicare and Medicaid Services (CMS), the Department of Veterans Affairs (VA), and other academic and large non-government healthcare data systems. In addition, CBER participates actively in ongoing international

Content current as of:
02/09/2021

Regulated Product(s)
Biologics
Vaccines

Topic(s)
Safety - Issues, Errors, and

Selected Adverse Events Reported after COVID-19 Vaccination

Updated Feb. 25, 2021 Languages Print

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.

Is the Vaccine Safe?

<https://www.cdc.gov/coronavirus/2019-ncov/vaccines/safety.html>

<https://www.fda.gov/vaccines-blood-biologics/safety-availability-biologics/covid-19-vaccine-safety-surveillance>

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