

COVID-19 Vaccine Safety Technical (VaST) Subgroup

Introduction

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VaST Co-Chairs

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

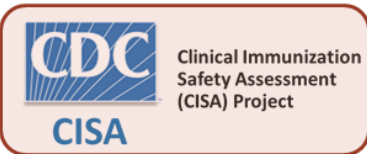
- 10 meetings to review vaccine safety data



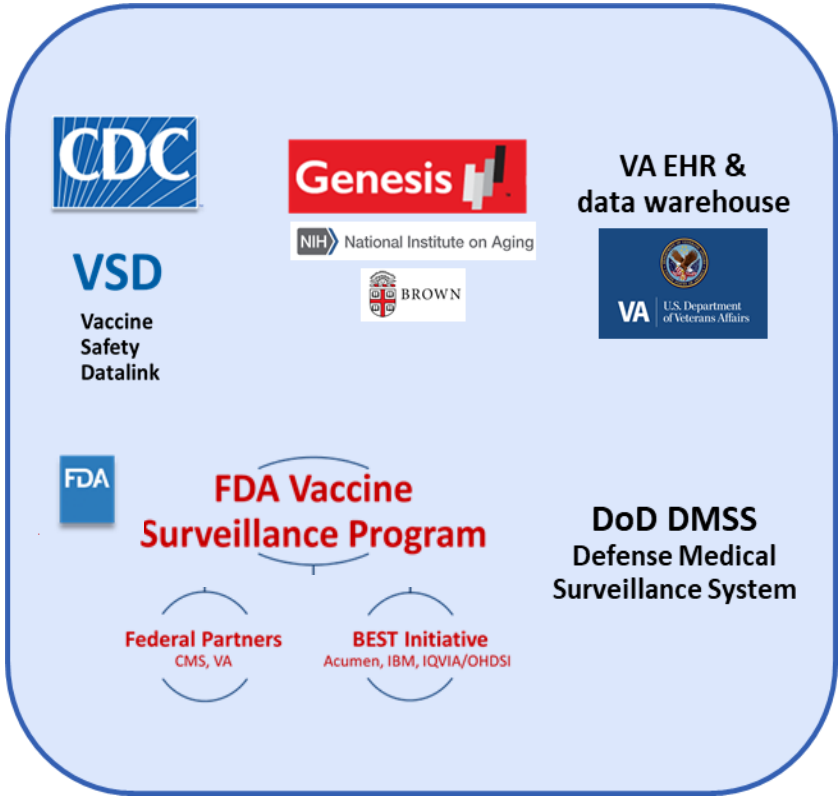
**active
surveillance**



**passive
surveillance**



**individual
case consults**



**active surveillance, passive
surveillance, case consults**

**large-linked
database monitoring**

safety monitoring timeline



VaST Procedures

- *Data* – Weekly review of available data on vaccine administration and adverse events of special interest (AESI)
- *Shared learning* – All members, federal partners, and subject matter experts are present for presentation of data
- *Independence* – VaST members discuss findings independently
- *Reports* – Summary and interpretation of aggregate data provided to the ACIP Secretariat on a regular basis

VaST Topics Covered

- Reviewed routine data from VAERS, v-safe, VA ADERS, VSD and CMS
- Reviewed special topics including
 - Background rates for AESI
 - Maternal immunization
 - Thrombocytopenia
 - Multisystem Inflammatory Syndrome (MIS)
 - Vaccination of persons with prior infection
- Initiated monthly sessions with additional experts to review data on vaccine safety in pregnancy

Outline of Today's Session

- COVID-19 vaccine safety update
 - Maternal immunization
- COVID-19 Vaccine Safety Technical (VaST) Subgroup discussion and interpretation

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

Acknowledgments

- CISA
 - Karen Broder
- FDA
 - Rich Forshee
 - Steve Anderson
 - Narayan Nair
- Genesis
 - Barbara Bardenheier
- VAERS
 - John Su
- v-safe
 - Tanya Myers
 - Shin Kim
- VSD
 - Nicola Klein
 - Ned Lewis
 - Eric Weintraub
 - Michael McNeil
- Vaccine in pregnancy
 - Richard Beigi
 - Brenna Hughes
 - Denise Jamieson
 - Dana Meaney Delman
 - Titilope Oduyebo
 - Lakshmi Panagiotakopoulos
- CDC Vaccine Evaluation Unit
 - Tom Shimabukuro
 - Julianne Gee
 - David Shay
 - Tom Clark
 - Stacey Martin
- Other CDC and ISO
 - Frank Destefano
 - Rita Helfand
 - Jessica MacNeil