COVID-19 Vaccine Safety Technical (VaST) Subgroup

Introduction

Grace M. Lee, MD MPH
VaST Co-Chair

Advisory Committee on Immunization Practices
January 27, 2021
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
COVID-19 Vaccine Safety Technical (VaST) Subgroup

- Ensure independence, transparency, and public accountability
- Composition
  - Co-chairs: Grace Lee (ACIP) and Bob Hopkins (NVAC)
  - Members: ACIP and NVAC representation independent expert consultants
  - 2 CDC co-leads
  - 8 ACIP ex officio members (FDA, NIH, OIDP, CMS, HRSA, IHS) and liaisons (VA, DoD)
## VaST Activities

### Pre-authorization

<table>
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<th>Jun – Oct 2020</th>
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<td>• 10 meetings to prepare for vaccine safety surveillance</td>
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<th>Nov – mid Dec 2020</th>
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<tr>
<td>• Transition to Vaccine Safety Data Review Group</td>
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<td>• 4 meetings to review methods for vaccine safety monitoring and to finalize VaST procedures</td>
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### ACIP Recommendations

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<th>Dec 12</th>
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<td>• ACIP vote for Pfizer/BioNTech</td>
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<th>Dec 14</th>
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<td>• 1st dose administered on in the U.S.</td>
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<th>Dec 19</th>
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<td>• ACIP vote for Moderna</td>
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### Post-authorization

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<th>Dec 21</th>
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<td>• First call to review safety data, one week after the start of vaccine administration in the U.S.</td>
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<th>Dec 21 – present</th>
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<tr>
<td>• 6 meetings to date to review post-authorization data</td>
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Safety Monitoring Timeline

1. Start of Vax
2. Active Surveillance, Passive Surveillance, Case Consults
3. Large-Linked Database Monitoring

Active Surveillance
- v-safe (after vaccination health checker)
- VA ADERS (VA Vaccine Adverse Event Reporting System)
- CDC + FDA
- VAERS (Vaccine Adverse Event Reporting System)
- CISA (Clinical Immunization Safety Assessment (CISA) Project)

Passive Surveillance

Individual Case Consults

Federal Partners
- CMS, VA
- BEST Initiative
- PRISM

Best Initiative
- Acumen, IBM, IQVIA/CHOSI
- Harvard Pilgrim Healthcare Institute

DoD DMSS
- Defense Medical Surveillance System

VA EHR & Data Warehouse
- National Institute on Aging
- Brown University
- US Department of Veterans Affairs

CDC
- Vaccine Safety Datalink

FDA
- Vaccine Surveillance Program
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
Outline of Today’s Session

- COVID-19 vaccine safety update
- 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
Kiepp 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)
Steven Anderson; Karen Farizo; Richard Forshee; Narayan Nair; 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