COVID-19 Vaccine Safety Technical (VaST) Work Group

VaST assessment

H. Keipp Talbot, MD MPH (VaST Chair)
Robert H. Hopkins, Jr., MD (NVAC Chair)

Advisory Committee on Immunization Practices
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COVID-19 Vaccine Safety Technical (VaST) Work Group

Objectives

- Review, evaluate, and interpret post-authorization/approval COVID-19 vaccination 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 presentation of vaccine safety data
- Provide updates to the ACIP COVID-19 Vaccines Work Group and the entire ACIP on COVID-19 vaccine safety

VaST meetings

- December 21, 2020 – present: 57 meetings to review vaccine safety data
VaST assessment – Pfizer-BioNTech COVID-19 vaccine booster dose in 5–11-year-olds

- VaST reviewed the most recent data from three U.S. safety monitoring systems*
  - Safety after the primary vaccination series in 5–11-year-olds
  - Safety after booster doses in 12–15-year-olds (the youngest age group for which boosters were previously authorized)

- 18.1 million doses of Pfizer-BioNTech vaccine administered to children aged 5–11 years in the United States
  - In VAERS, reporting rate for myocarditis among males lower in ages 5–11 vs. 12–15 years
  - In VSD Rapid Cycle Analysis, no statistical safety signals after > 778,000 doses in 5–11-year-olds

- Data do not suggest potential safety concerns regarding a Pfizer-BioNTech COVID-19 vaccine booster dose for 5–11-year-olds, beyond those previously identified in older age groups

*Vaccine Adverse Event Reporting System, v-safe, Vaccine Safety Datalink
VaST assessment – Mortality following COVID-19 vaccination in the United States

- CDC Immunization Safety Office and FDA have standard and systematic methods for following up on all reported deaths following vaccination
- Because of the importance of mortality as a potential adverse event following vaccination, VaST has reviewed mortality data, as available, from several systems
- Population-based studies conducted to date have not identified increased risk of death following COVID-19 vaccination
- Spontaneous reporting to VAERS has not identified any unusual reporting or patterns of causes of death
VaST assessment – Mortality following COVID-19 vaccination in the United States (continued)

- In a cohort of 6.4M COVID-19 vaccinees and 4.6M demographically similar unvaccinated persons, no increased risk of mortality among COVID-19 vaccine recipients

- Among >20,000 nursing home residents in 284 facilities, no increase in 7-day mortality following COVID-19 vaccination

- Among deaths reported to VAERS following COVID-19 vaccination
  - Bayesian data mining identified no signals other than mortality due to COVID-19 disease (vaccine failure) following the Ad26.COV2.S vaccine (in adults)
  - No unusual clustering of causes of death associated with U.S. authorized COVID-19 vaccines

3 Reporting Rates for VAERS Death Reports Following COVID-19 Vaccination, December 14, 2020-November 17, 2021. https://www.medrxiv.org/content/10.1101/2022.05.05.22274695v1
VaST plans

- VaST will continue to
  - Review vaccine safety data from multiple U.S. safety systems, in specific age groups, and after primary series and booster doses
  - Collaborate with global vaccine safety colleagues on key issues
  - Provide updates to the ACIP Work Group and ACIP at future meetings
VaST Members

**VaST Members**
- Keipp Talbot (ACIP)
- Robert Hopkins (NVAC)
- Matt Daley
- Grace Lee
- Veronica McNally
- Kathy Edwards
- Lisa Jackson
- Jennifer Nelson
- 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)
- Valerie Marshall (OIDP)
- Jeffrey Kelman (CMS)
- Matthew Clark (IHS)
- Mary Rubin (HRSA)
- Fran Cunningham (VA)
- Limone Collins (DoD)

**Administrative Support**
- Jared Woo