

COVID-19 Vaccine Safety Technical (VaST) Work Group

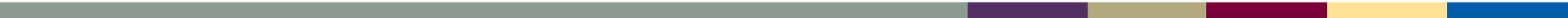
Safety assessment of booster doses

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: 55 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 review & assessment of booster dose safety data

VaST reviews	Assessment presented to ACIP
September 13, 2021 – v-safe and Israeli data	September 22, 2021
October 18, 2021 – v-safe and VAERS	October 21, 2021
November 8, 2021 – v-safe and VAERS	November 19, 2021
December 6, 2021 – v-safe and VAERS December 13, 2021 – Israeli data	January 4, 2022 (12–15-year-olds)
March 28, 2022 – VSD and VAERS April 11, 2022 – Department of Veteran’s Affairs April 18, 2022 – VSD, VAERS, v-safe	April 20, 2022

Safety of first mRNA COVID-19 booster dose

- **v-safe**
 - Age ≥ 18 years: injection site, systemic reactions less frequent following booster than following primary dose 2
 - Age 12–17 years: frequency of reactions equal or slightly higher following booster than following primary dose 2
- **Vaccine Adverse Event Reporting System (VAERS)**
 - Myocarditis rates highest among males ages 12–29 years
 - Rates higher than background, lower than after primary dose 2
 - Pericarditis reported similarly by sex and age group
 - Low case counts complicate estimation of rates

Safety of first mRNA COVID-19 booster dose (continued)

- **Vaccine Safety Datalink (VSD) rapid cycle analysis**
 - Only safety signal: myocarditis/pericarditis in the 21 days after a 1st booster dose
 - Myocarditis/pericarditis differed by age group
 - 12–39 years: mostly myocarditis/myopericarditis, onset < 7 days after vaccination; rate per million 1st booster doses not higher than after primary series dose 2
 - ≥ 40 years: mostly pericarditis, onset up to 3 weeks after vaccination
- **Department of Veteran’s Affairs (VA) rapid cycle analysis**
 - No safety signals observed for mRNA booster dose in a 21-day window.
 - Chart review confirmed 15 of 40 myocarditis/pericarditis reports after booster dose
 - 10 pericarditis, 5 myocarditis
 - 14 of 15 in persons age ≥ 40 years

VaST assessment

COVID-19 vaccine first booster dose safety data to inform second dose booster vaccination

- VaST has provided assessments on booster dose safety at 4 ACIP meetings
- Today's assessment included data from VSD as well as v-safe, VAERS, VA
- Reactogenicity is similar to or lower than that seen after the primary series
- Myocarditis risk appears lower than after a primary series dose 2
- Further work and analyses are needed to understand pericarditis risk
- While data do not suggest safety concerns beyond those previously identified, VaST will carefully monitor data on myocarditis and pericarditis after booster doses

VaST plans

COVID-19 vaccine booster dose safety data

- VaST will continue to
 - Review further safety regarding booster doses as data become available
 - 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