COVID-19 Vaccine Safety Technical (VaST) Work Group

Safety assessment of booster doses

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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
start of vax

active surveillance, passive surveillance, case consults

active surveillance

passive surveillance

individual case consults

large-linked database monitoring

safety monitoring timeline
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VAERS, Vaccine Adverse Event Reporting System; VSD, Vaccine Safety Data Link
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