COVID-19 Vaccine Safety Technical (VaST) Work Group

Safety Assessment

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Advisory Committee on Immunization Practices
November 19, 2021
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 continues to review COVID-19 vaccination safety data from passive and active surveillance systems

- U.S. safety monitoring systems including Vaccine Adverse Events Reporting System (VAERS), Vaccine Safety Datalink (VSD), FDA BEST System, Department of Veterans Affairs (VA), Indian Health Service (IHS), Department of Defense (DoD)
- Israeli and Canadian data, Global Advisory Committee on Vaccine Safety
- Special evaluations underway; myocarditis case follow-up

December 21, 2020 – present
41 independent meetings to review vaccine safety data
11 joint meetings with COVID-19 Vaccines Work Group focused on safety

**ACIP votes**
- **Dec 12**: Pfizer (16+)
- **Dec 19**: Moderna (18+)
- **Feb 28**: Janssen (18+)
- **May 12**: Pfizer (12-15)

**VaST assessments at ACIP meetings or website**
- **Dec**: Jan 27
  - Anaphylaxis following mRNA vaccination
- **Jan**: Mar 1
  - Anaphylaxis updates; Pregnancy vaccine safety data
- **Feb**: Apr 14
  - CVST following Janssen
- **March**: Apr 23
  - TTS updates; Janssen resumed
- **April**: May 12
  - TTS updates
- **May**: May 17 & 24
  - Myocarditis

CVST, cerebral venous sinus thrombosis; TTS, thrombosis with thrombocytopenia syndrome; GBS, Guillain-Barré syndrome
**VaST activities**

**December 21, 2020 – present (continued)**
41 independent meetings to review vaccine safety data
11 joint meetings with COVID-19 Vaccines Work Group focused on safety

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**ACIP votes**
- Aug 13: Additional mRNA vaccine doses for immunocompromised
- Aug 30: Pfizer BLA (16+)
- Sept 22: Pfizer 3rd dose
- Oct 21: Moderna 3rd dose Janssen 2nd dose
- Nov 2: Pfizer (5-11)
- Nov 19: Boosters (18+)

**VaST assessments at ACIP meetings or website**
- June 23: Myocarditis updates
- July 22: GBS following Janssen
- Aug 30: Safety overview
- Sept 22: Pfizer 3rd dose
- Oct 21: Moderna 3rd dose Janssen 2nd dose
- Nov 19: Boosters (18+)

CVST, cerebral venous sinus thrombosis; TTS, thrombosis with thrombocytopenia syndrome; GBS, Guillain-Barré syndrome
Safety data regarding COVID-19 booster dose vaccination reviewed by VaST

- When VaST reviewed U.S. data for the September 22 ACIP vote on booster doses, data available for 3rd doses were mainly for those provided under recommendation for persons with immunocompromising conditions.

- More booster vaccination safety data now available from:
  - VAERS
  - v-safe
  - Israel Ministry of Health data
Safety data: COVID-19 booster vaccination, VAERS

- 25.9 million mRNA and 334,000 Janssen vaccine booster doses administered*
- Among 11,904 VAERS reports, most (≥93%) were non-serious
- Almost half (46%) of VAERS reports were among persons aged ≥65 years
- Most frequently reported non-serious AEs were similar to AEs reported after earlier doses of COVID-19 vaccine
- 54 preliminary reports of myocarditis – all after mRNA vaccination
  - 12 verified reports that met CDC case definition; 38 pending investigation
  - Age distribution reflects booster dose recommendations

* Among reports of persons known to be 18+ years of age, who received dose 3 of Pfizer-BioNTech vaccine during Sept 22 through Nov 15, 2021, dose 3 of Moderna vaccine during Oct 20 through Nov 15, 2021, or dose 2 Janssen during Oct 20 through Nov 15, 2021; received as of Nov 15, 2021.
Safety data: COVID-19 booster vaccination, v-safe

- Safety data after booster doses recorded by 725,917 v-safe participants*
  - Most reported a primary mRNA vaccine series followed by booster from the same manufacturer

- For Pfizer-BioNTech and Moderna vaccination, local and systemic reactions and health impacts were reported less frequently following a booster dose than following dose 2 of the primary series

- Moderna booster appears to be more reactogenic than Pfizer-BioNTech booster, regardless of the type mRNA vaccine given previously

*Data as of Nov 14, 2021. Includes participants who completed at least one survey in the first week after booster dose (administered beginning Sept 22, 2021, for Pfizer-BioNTech and Oct 20, 2021, for Moderna and Janssen).
Safety data: 3rd dose Pfizer-BioNTech COVID-19 vaccination, Israel Ministry of Health*

- In Israel, booster doses of Pfizer-BioNTech vaccine were phased in, first for persons ≥60 years and, since the end of August 2021, everyone ≥12 years of age eligible for 3rd dose
- ~3.9 M 3rd doses administered to persons ≥12 years (through November 15)
- Rates of reported systemic, local, neurologic, allergic, and other reactions were lower after dose 3 than after either dose 1 or 2†
- Rates of myocarditis lower than after dose 2‡

*Updated from: https://www.fda.gov/media/153086/download
† Passive surveillance
‡ Proactive surveillance
VaST assessment
COVID-19 booster vaccination safety data

- Data regarding booster doses to date are reassuring; reactogenicity and AESI are similar to or lower than those seen after the primary series
- Myocarditis risk after a Pfizer booster dose appears lower than after dose 2
- Limited data available to assess myocarditis risk after a Moderna booster dose
  - Moderna booster dose is a lower dose (50μg) than the primary series dose (100μg)
- Deaths reported to VAERS after a primary series or a booster dose do not suggest any concerning patterns and reporting rates are below background rates
- 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)
- David Kim (OIDP)
- Jeffrey Kelman (CMS)
- Matthew Clark (IHS)
- Mary Rubin (HRSA)
- Fran Cunningham (VA)
- Limone Collins (DoD)

**Administrative Support**
- Jared Woo