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

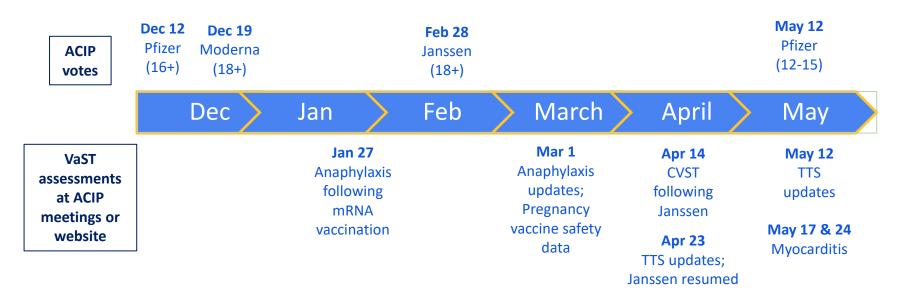
VaST continues to review COVID-19 vaccination safety data from passive and active surveillance systems

- U.S. safety monitoring systems including Vaccine Adverse Events
 Reporting System (VAERS), Vaccine Safety Datalink (VSD), FDA BEST
 System,¹ 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

VaST activities

December 21, 2020 – present

41 independent meetings to review vaccine safety data 11 joint meetings with COVID-19 Vaccines Work Group focused on safety



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

Oct 21 **Aug 13** Nov 2 **Nov 19 Aug 30** Sept 22 Moderna Additional mRNA Pfizer Pfizer BLA **Boosters** Pfizer 3rd dose **ACIP** vaccine doses for (5-11)(18+)(16+)3rd dose Janssen votes immunocompromised 2nd dose June July Sept Oct Nov Aug **July 22 Aug 30** Sept 22 Oct 21 **Nov 19 Jun 23 VaST GBS** Safety **Myocarditis** Pfizer Moderna Boosters assessments following overview 3rd dose 3rd dose (18+)updates at ACIP Janssen Janssen meetings or 2nd dose website

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

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