

# COVID-19 Vaccine Safety Technical (VaST) Work Group

## Safety Assessment

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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 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,<sup>1</sup> 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

**ACIP  
votes**

**Dec 12**  
Pfizer  
(16+)

**Dec 19**  
Moderna  
(18+)

**Feb 28**  
Janssen  
(18+)

**May 12**  
Pfizer  
(12-15)

Dec

Jan

Feb

March

April

May

**VaST  
assessments  
at ACIP  
meetings or  
website**

**Jan 27**  
Anaphylaxis  
following  
mRNA  
vaccination

**Mar 1**  
Anaphylaxis  
updates;  
Pregnancy  
vaccine safety  
data

**Apr 14**  
CVST  
following  
Janssen

**Apr 23**  
TTS updates;  
Janssen resumed

**May 12**  
TTS  
updates

**May 17 & 24**  
Myocarditis

# 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

**ACIP  
votes**



**Aug 13**  
 Additional mRNA  
 vaccine doses for  
 immunocompromised

**Aug 30**  
 Pfizer BLA  
 (16+)

**Sept 22**  
 Pfizer  
 3<sup>rd</sup> dose

**Oct 21**  
 Moderna  
 3<sup>rd</sup> dose  
 Janssen  
 2<sup>nd</sup> dose

**Nov 2**  
 Pfizer  
 (5-11)

**Nov 19**  
 Boosters  
 (18+)

**VaST  
assessments  
at ACIP  
meetings or  
website**

**Jun 23**  
 Myocarditis  
 updates

**July 22**  
 GBS  
 following  
 Janssen

**Aug 30**  
 Safety  
 overview

**Sept 22**  
 Pfizer  
 3<sup>rd</sup> dose

**Oct 21**  
 Moderna  
 3<sup>rd</sup> dose  
 Janssen  
 2<sup>nd</sup> dose

**Nov 19**  
 Boosters  
 (18+)

# 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 3<sup>rd</sup> 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 ( $\geq 93\%$ ) were non-serious
- Almost half (46%) of VAERS reports were among persons aged  $\geq 65$  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: 3<sup>rd</sup> dose Pfizer-BioNTech COVID-19 vaccination, Israel Ministry of Health\*

- In Israel, booster doses of Pfizer-BioNTech vaccine were phased in, first for persons  $\geq 60$  years and, since the end of August 2021, everyone  $\geq 12$  years of age eligible for 3<sup>rd</sup> dose
- $\sim 3.9$  M 3<sup>rd</sup> doses administered to persons  $\geq 12$  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<sup>†</sup>
- Rates of myocarditis lower than after dose 2<sup>‡</sup>

\*Updated from: <https://www.fda.gov/media/153086/download>

<sup>†</sup> Passive surveillance

<sup>‡</sup> 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 (50 $\mu$ g) than the primary series dose (100 $\mu$ g)
- 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

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