

COVID-19 Vaccine Safety Technical (VaST) Work Group

VaST 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 meetings

- December 21, 2020 – present: 57 meetings to review vaccine safety data

VaST assessment – Pfizer-BioNTech COVID-19 vaccine booster dose in 5–11-year-olds

- VaST reviewed the most recent data from three U.S. safety monitoring systems*
 - Safety after the primary vaccination series in 5–11-year-olds
 - Safety after booster doses in 12–15-year-olds (the youngest age group for which boosters were previously authorized)
- 18.1 million doses of Pfizer-BioNTech vaccine administered to children aged 5–11 years in the United States
 - In VAERS, reporting rate for myocarditis among males lower in ages 5–11 vs. 12–15 years
 - In VSD Rapid Cycle Analysis, no statistical safety signals after > 778,000 doses in 5–11-year-olds
- Data do not suggest potential safety concerns regarding a Pfizer-BioNTech COVID-19 vaccine booster dose for 5–11-year-olds, beyond those previously identified in older age groups

VaST assessment – Mortality following COVID-19 vaccination in the United States

- CDC Immunization Safety Office and FDA have standard and systematic methods for following up on all reported deaths following vaccination
- Because of the importance of mortality as a potential adverse event following vaccination, VaST has reviewed mortality data, as available, from several systems
- Population-based studies conducted to date have not identified increased risk of death following COVID-19 vaccination
- Spontaneous reporting to VAERS has not identified any unusual reporting or patterns of causes of death

VaST assessment – Mortality following COVID-19 vaccination in the United States (continued)

- In a cohort of 6.4M COVID-19 vaccinees and 4.6M demographically similar unvaccinated persons, no increased risk of mortality among COVID-19 vaccine recipients¹
- Among >20,000 nursing home residents in 284 facilities, no increase in 7-day mortality following COVID-19 vaccination²
- Among deaths reported to VAERS following COVID-19 vaccination
 - Bayesian data mining identified no signals other than mortality due to COVID-19 disease (vaccine failure) following the Ad26.COVS vaccine (in adults)³
 - No unusual clustering of causes of death associated with U.S. authorized COVID-19 vaccines^{3,4}

¹COVID-19 Vaccination and Non-COVID-19 Mortality Risk - Seven Integrated Health Care Organizations, United States, December 14, 2020-July 31, 2021 [MMWR Morb Mortal Wkly Rep 2021;29;70:1520-4](https://www.cdc.gov/mmwr/morbidity-and-mortality-reports/2021/29-70/1520-4)

²Adverse events following mRNA SARS-CoV-2 vaccination among U.S. nursing home residents. [Vaccine 2021;39:3844-51](https://doi.org/10.1093/vaccine/kzab011).

³Reporting Rates for VAERS Death Reports Following COVID-19 Vaccination, December 14, 2020-November 17, 2021 <https://www.medrxiv.org/content/10.1101/2022.05.05.22274695v1>

⁴Safety of mRNA vaccines administered during the initial 6 months of the US COVID-19 vaccination programme: an observational study of reports to the Vaccine Adverse Event Reporting System and v-safe. Lancet ID 2022 3099(22):00054-8. Epub March 7, 2022. doi: [https://doi.org/10.1016/S1473-3099\(22\)00054-8](https://doi.org/10.1016/S1473-3099(22)00054-8).

VaST plans

- VaST will continue to
 - Review vaccine safety data from multiple U.S. safety systems, in specific age groups, and after primary series and booster doses
 - 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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