# 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: 59 meetings to review vaccine safety data

# VaST assessment – Review of monitoring data for consideration of Moderna COVID-19 vaccine in children ages 6–17 years

- VaST reviewed
  - Data from U.S. safety monitoring systems* for Pfizer-BioNTech vaccine in 5–17-year-olds
  - Comparative data on safety monitoring for Moderna and Pfizer-BioNTech vaccines in older age groups where comparisons possible

*Vaccine Adverse Event Reporting System (VAERS), v-safe, Vaccine Safety Datalink (VSD), Biologics Effectiveness and Safety (BEST) system

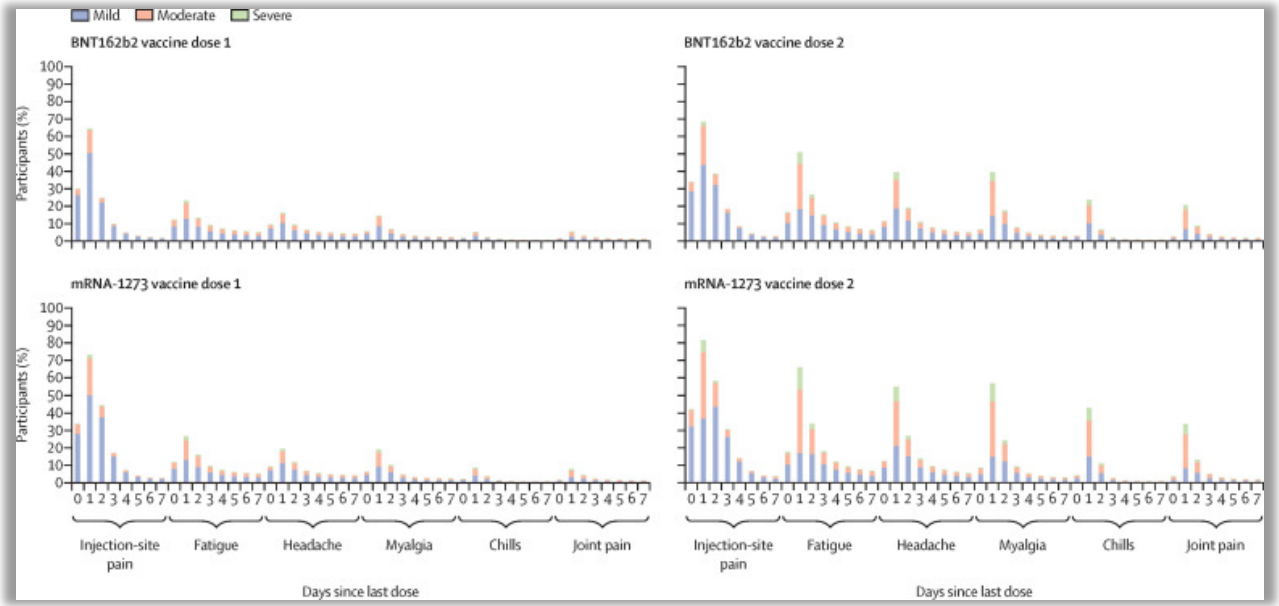
# v-safe - injection site and systemic reactions

- **Among 49,392 v-safe participants ages 5–11 years who received Pfizer-BioNTech COVID-19 vaccination reported to v-safe**
  - Reactions generally mild to moderate; most reported day after vaccination
  - Reactions more frequently reported after dose 2 than dose 1
  - Patterns generally similar to those observed in older age groups

Through April 2022; Shimabukuro, ACIP presentation May 19, 2022:
https://www.cdc.gov/vaccines/acip/meetings/downloads/slides-2022-05-19/03-COVID-Shimabukuro-508.pdf

# v-safe – injection site and systemic reactions

- In age groups (18 years and older) where comparison between the mRNA COVID-19 vaccines possible, injection site and systemic reactions reported more frequently after Moderna than Pfizer-BioNTech COVID-19 vaccination




Rosenblum et al. Lancet ID 2022. https://www.ncbi.nlm.nih.gov/pmc/articles/PMC8901181/

# VAERS and enhanced follow-up: myocarditis following Pfizer-BioNTech vaccination in 5–17-year-olds

- **54.8 million Pfizer-BioNTech doses administered to children ages 5–17 yrs**
  - 27.7 million dose 1, 23.3 million dose 2, 3.8 million 1st booster dose (ages 12–17 years)
- **VAERS: 635 myocarditis case reports that met the CDC case definition**
  - Symptom onset clusters within several days of vaccination, most within 0–7 days
  - Reporting rates generally higher for males than females, especially for age groups 16–17 and 12–15 years; differences by sex in children ages 5–11 years less pronounced
  - Reporting rate of myocarditis in male children ages 5–11 years after dose 2 of the primary series slightly elevated when compared to background incidence; otherwise, reporting rates for both sexes similar to background incidence
- **Enhanced follow-up of myocarditis cases**
  - Most patients reached reported no impact on quality of life, missing school or work
  - Most (80%) healthcare providers indicated patient fully recovered or probably fully recovered

Shimabukuro, ACIP presentation, June 23, 2022

# VSD: Pfizer-BioNTech vaccination in 5–11-year-olds

- ~878,000 children ages 5–11 years in VSD
- 41% had completed the Pfizer-BioNTech vaccine primary series
- No statistical signals in the 21-day risk interval for any outcomes identified

Through April 2022; Shimabukuro, ACIP presentation, May 19, 2022

# VSD: myocarditis/pericarditis days 0-7 post vaccination among 18–39-year-olds, Moderna vs Pfizer vaccination

- Both vaccines associated with increased risk of myocarditis/pericarditis in 0-7 days post-vaccination, particularly after dose 2
- No noticeable differences in level of care and clinical status between cases after Moderna or after Pfizer vaccination; most cases were hospitalized and had stays of one day or less
- Direct head-to-head comparison, in ages where possible, provides evidence that the risk of myocarditis and pericarditis may be higher after Moderna than after Pfizer vaccination

Klein, ACIP presentation Feb 4, 2022: Rapid Cycle Analysis (RCA) to Monitor the Safety of COVID-19 Vaccines in Near Real-Time within the Vaccine Safety Datalink (cdc.gov)

# BEST: Pfizer-BioNTech vaccination in 5–17-year-olds

- 5.4 million Pfizer-BioNTech vaccine doses in children ages 5–17 years
- Statistical signals
  - 5–11-year-olds: none
  - 12-15- and 16–17-year-olds: myocarditis/pericarditis

BEST, Biologics Effectiveness and Safety System (FDA)
Wong, FDA's VRBPAC presentation, June 14, 2022. https://www.fda.gov/media/159224/download

# BEST: myocarditis/pericarditis days 1-7 post vaccination among 18–25-year-olds, Moderna vs Pfizer vaccination

- Large study in several U.S. administrative health plan claims databases of people aged 18–64 years[1]
  - Occurrence of myocarditis/pericarditis after COVID-19 mRNA vaccination rare (411 events per 16.9 M doses of Pfizer-BioNTech and 10.6 M doses of Moderna)
  - 95% CI for the incidence rate ratio comparing brands (Moderna to Pfizer-BioNTech) ranged from 0.80 to 1.94
  - Risk highest in men aged 18–25 years, 1–7 days after dose 2
- Among 18–25-year-old men, elevated rate ratio for Moderna vs Pfizer-BioNTech vaccination, but not statistically significant[2]

BEST, Biologics Effectiveness and Safety System (FDA)

[1]Wong et al, Lancet 2022; [2]Wong, FDA's VRBPAC presentation, June 14, 2022. https://www.fda.gov/media/159224/download

# VaST assessment – Review of U.S. monitoring data for consideration of Moderna COVID-19 vaccine in 6–17-year-olds

| System | Pfizer-BioNTech vaccine in children & adolescents aged 5–17 years |
|---|---|
| **V-safe** | • Patterns of reports for local and systemic reactions similar for all age groups |
| **VAERS** | • Reporting rates for myocarditis exceed background for males ages 5–11-, 12–15-, 16–17 (mainly for dose 2 and booster) and for females 12–15-, 16–17 (dose 2 only) |
| **VSD** | • Risk for myocarditis/pericarditis is elevated; greatest in age groups 16–17 and 12–15 years, generally higher after dose 2 vs dose 1 primary series and in males vs females<br>• No statistical signals for children ages 5–11 years |
| **BEST** | • Risk appears greatest in age groups 16–17 and 12–15 years, generally higher after dose 2 than dose 1<br>• No statistical signals for children ages 5–11 years<br>• Only statistical signals for 12–15- and 16–17-year-olds: myocarditis/pericarditis |

VAERS, Vaccine Adverse Event Reporting System; VSD, Vaccine Safety Datalink; BEST, Biologics Effectiveness and Safety system

# VaST assessment – Review of U.S. monitoring data for consideration of Moderna COVID-19 vaccine in 6–17-year-olds

| System | Comparative data: Moderna vs Pfizer-BioNTech vaccines, same age groups |
|---|---|
| **V-safe** | • Higher frequently of local and systemic reports after Moderna than Pfizer-BioNTech vaccination in persons age 18 years and older |
| **VAERS** | • Slightly higher myocarditis/pericarditis reporting rates for Moderna vs Pfizer-BioNTech vaccination for both males and females in age groups where comparisons possible |
| **VSD** | • In head-to-head analyses in 18–39-year-olds, myocarditis/pericarditis risk higher after Moderna than Pfizer-BioNTech vaccination |
| **BEST** | • In head-to-head analyses in 18-25-year-olds, myocarditis/pericarditis risk higher after Moderna than Pfizer-BioNTech vaccination, but not statistically significant |

VAERS, Vaccine Adverse Event Reporting System; VSD, Vaccine Safety Datalink; BEST, Biologics Effectiveness and Safety system

# VaST assessment

- There is a risk of myocarditis/pericarditis after both mRNA COVID-19 vaccines; most cases had prompt improvement in symptoms; follow-up surveys suggest most fully recover from myocarditis
  - Risk observed in adolescents and adults
  - Potential risk under assessment in children (< age 12 years)
- Continued monitoring and natural history studies needed for myocarditis/pericarditis following mRNA COVID-19 vaccination
  - To understand rates, outcomes, risk factors, and mechanisms
- Monitoring data for Moderna vaccine are available from persons age 18 years and older who received 100 ug dose
  - EUA is for 100 ug dose for 12–17-year-olds, 50 ug dose for 6–11-year-olds
  - Unknown if 50 ug dose will pose lower risk

# 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 COVID-19 Vaccines Work Group and to ACIP at future meetings

# VaST Members

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