

COVID-19 Vaccine Safety Technical (VaST) Work Group

Assessment

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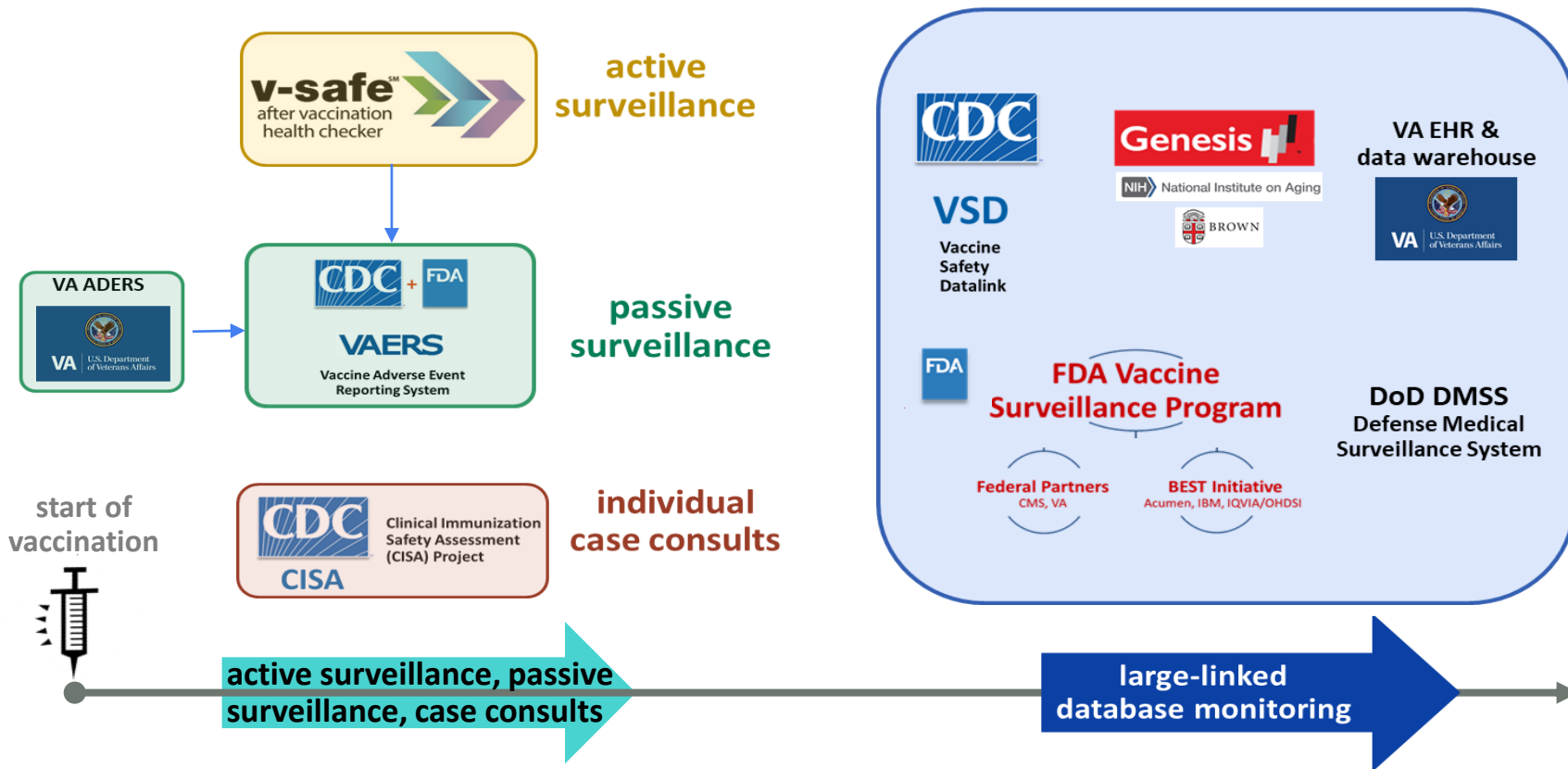
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Advisory Committee on Immunization Practices

June 23, 2021



Vaccine Safety Surveillance in the U.S.



COVID-19 Vaccine Safety Technical (VaST) Work Group

Objectives

- Review, evaluate, and interpret post-authorization/approval COVID-19 vaccine 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 data presentation
- Provide updates to the ACIP COVID-19 Vaccines Work Group and the ACIP on COVID-19 vaccine safety

VaST Activities

Dec 21, 2020 – present:

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

ACIP votes following EUA

Dec 12 Pfizer (16+)
Dec 19 Moderna (18+)

Feb 28 Janssen (18+)

May 12 Pfizer (12-15)

Dec

Jan

Feb

Mar

Apr

May

Jun

VaST assessments at ACIP meetings or website

Jan 27 Anaphylaxis following mRNA vaccines

Mar 1 Anaphylaxis updates; Pregnancy vaccine safety data

Apr 14 CVST following Janssen

Apr 23 TTS updates; Janssen resumed with warning
May 12 TTS updates

May 17 & 24 Myocarditis

Jun 23 Myocarditis updates

VaST Work Group Report – May 17

- Relatively few reports of myocarditis to date occurring:
 - predominantly in adolescents and young adults,
 - more often in males than females,
 - more often following dose 2 than dose 1
 - typically, within one week after vaccination
- Majority of patients appear to have transient symptoms, rapid resolution of laboratory abnormalities, and brief hospitalizations
- Long term follow-up data are limited

VaST Work Group Report – May 24

- Higher number of observed vs. expected myocarditis/pericarditis cases in 16–24-year-olds following dose 2 of mRNA vaccines in VAERS using a 30-day window
- VaST members discussed need for:
 - Continued vaccine safety monitoring through multiple surveillance systems as vaccination rates increase in younger age groups
 - Multi-disciplinary collaboration to provide clinical guidance about early recognition, differential diagnosis, diagnostic testing, and appropriate management of persons who develop myocarditis or pericarditis
 - Long-term follow up of patients to understand clinical course and resolution following both COVID-19 infection and COVID-19 vaccination

Myocarditis and Pericarditis Following mRNA COVID-19 Vaccination

Updated May 27, 2021

[Print](#)

What You Need to Know

- More than 165 million people have received at least one dose of COVID-19 vaccine in the United States, and CDC continues to monitor the safety of COVID-19 vaccines for any health problems that happen after vaccination.
- Since April 2021, there have been increased reports to the Vaccine Adverse Event Reporting System (VAERS) of cases of inflammation of the heart—called myocarditis and pericarditis—happening after mRNA COVID-19 vaccination (Pfizer-BioNTech and Moderna) in the United States.
- These reports are rare, given the number of vaccine doses administered, and have been reported after mRNA COVID-19 vaccination (Pfizer-BioNTech and Moderna), particularly in adolescents and young adults.
- CDC and its partners are actively monitoring these reports, by reviewing data and medical records, to learn more about what happened and to see if there is any relationship to COVID-19 vaccination.
- Most patients who received care responded well to medicine and rest and quickly felt better.

Clinical Considerations: Myocarditis and Pericarditis after Receipt of mRNA COVID-19 Vaccines Among Adolescents and Young Adults

Recommendations for Clinicians

- CDC continues to recommend [COVID-19 vaccination](#) for everyone 12 years of age and older given the greater risk of other serious complications related to COVID-19, such as hospitalization, multisystem inflammatory syndrome in children (MIS-C), or death.
- [Report all cases of myocarditis and pericarditis post COVID-19 vaccination to VAERS](#) [🔗](#) .
- Consider myocarditis and pericarditis in adolescents or young adults with acute chest pain, shortness of breath, or palpitations. In this younger population, coronary events are less likely to be a source of these symptoms.
- Ask about prior COVID-19 vaccination if you identify these symptoms, as well as relevant other medical, travel, and social history.
- For initial evaluation, consider an ECG, troponin level, and inflammatory markers such as C-reactive protein and erythrocyte sedimentation rate. In the setting of normal ECG, troponin, and inflammatory markers, myocarditis or pericarditis are unlikely.
- For suspected cases, consider consultation with cardiology for assistance with cardiac evaluation and management. Evaluation and management may vary depending on the patient age, clinical presentation, potential causes, or practice preference of the provider.
- For follow-up of patients with myocarditis, consult the recommendations from the [American Heart Association and the American College of Cardiology](#) [🔗](#) .

VaST Discussion and Interpretation Regarding Adolescent Vaccination

- v-safe data indicate comparable local and systemic reactogenicity rates among 12–15-year-olds and 16–25-year-olds
- Dizziness and syncope are the most common adverse events reported among 12–15-year-olds in VAERS
- Partnerships and ongoing communication with clinician communities have enhanced vaccine safety efforts through early recognition of potential adverse events, such as myocarditis

VaST Discussion and Interpretation

- Risk of myocarditis/pericarditis following mRNA vaccination in adolescents and young adults aged 12-39 years is notably higher after dose 2 and in males

Myocarditis/pericarditis per million doses administered in VSD and VAERS

| | All (chart confirmed in VSD) | Females (ICD10 in VSD) | Females (crude in VAERS) | Males (ICD10 in VSD) | Males (crude in VAERS) |
|--------|------------------------------|------------------------|--------------------------|----------------------|------------------------|
| Dose 1 | 4.4 | 1.9 | 0.8 - 1.5 | 4.7 | 2.0 - 9.8 |
| Dose 2 | 12.6 | 4.7 | 1.8 - 9.1 | 32.0 | 10.0 - 66.7 |

VaST Discussion and Interpretation

- Data available to date suggest likely association of myocarditis with mRNA vaccination in adolescents and young adults
- Clinical presentation of myocarditis cases following vaccination has been distinct, occurring most often within one week after dose 2, with chest pain as the most common presentation
- Further data are being compiled to understand potential risk factors, optimal management strategies, and long-term outcomes

VaST will continue to

- Review data on myocarditis/pericarditis from available surveillance systems and ongoing safety evaluations
- Review and assess all safety data from surveillance systems and ongoing safety evaluations
- Update the ACIP COVID-19 Vaccines Workgroup, ACIP secretariat and ACIP on a regular basis

VaST Members

VaST Members

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