COVID-19 Vaccine Safety Technical (VaST) Subgroup

Discussion and Interpretation

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VaST Co-Chairs

Advisory Committee on Immunization Practices

March 1, 2021

Vaccine Safety Surveillance in the United States

- Well-established vaccine safety surveillance systems remain the cornerstone for monitoring the safety of approved COVID-19 vaccines in the United States
- Enhanced approaches to surveillance have enriched our understanding of COVID-19 vaccine safety in the early phases of vaccine deployment
- VaST continues to meet weekly to review all available data and to ensure a coordinated approach across multiple safety surveillance systems

VaST Discussion and Interpretation

- Local and systemic reactions continue to be most commonly reported following vaccination in v-safe, VAERS and VA-ADERS
- Anaphylaxis reporting rate ranges from 2.5 to 4.7 cases per million doses administered
  - Most common reason for CISA consultation
  - Allergy/immunology specialists provide expert input on clinical considerations

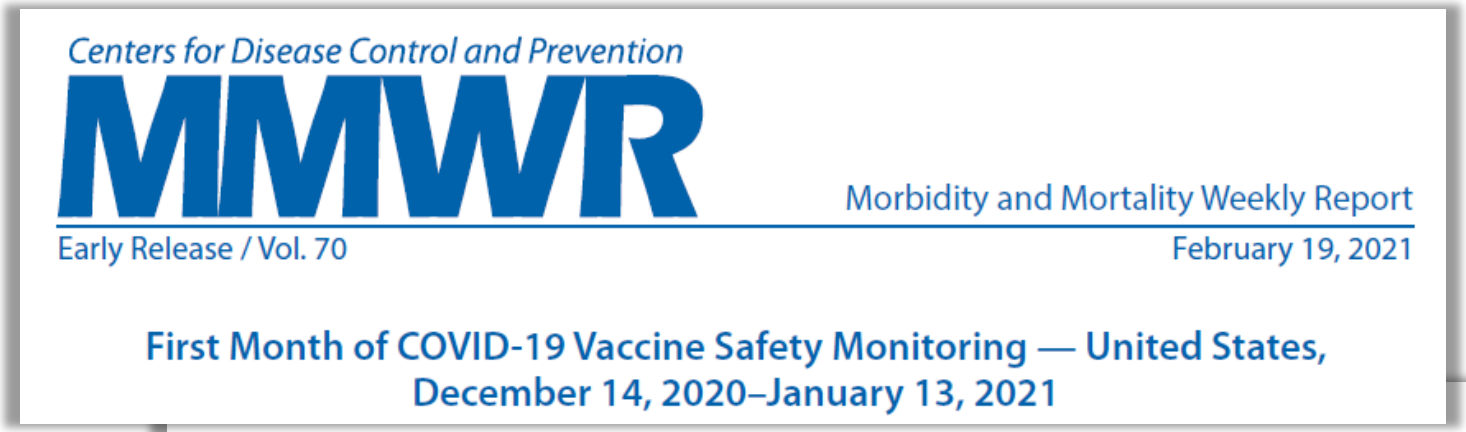
VaST Discussion and Interpretation

- VSD Rapid Cycle Analysis
  - Multiple methods for surveillance are being used, depending on phase of the vaccination program
  - Pre-specified outcomes are actively monitored
  - No statistical signals detected to date
- CMS Rapid Cycle Analysis
  - Descriptive analyses reviewed; sequential analyses to begin soon

VaST Discussion and Interpretation

- A large number of pregnant women have chosen to receive COVID-19 vaccines in the United States
- A novel pregnancy registry in v-safe was established to monitor pregnancy and birth outcomes
  - Similar to non-pregnant adults, pregnant women commonly report local and systemic reactogenicity (e.g. pain, fatigue, headache)
  - Pregnancy and birth outcomes following COVID-19 vaccination appear similar to rates reported in the literature

Vaccine Safety Updates



Centers for Disease Control and Prevention

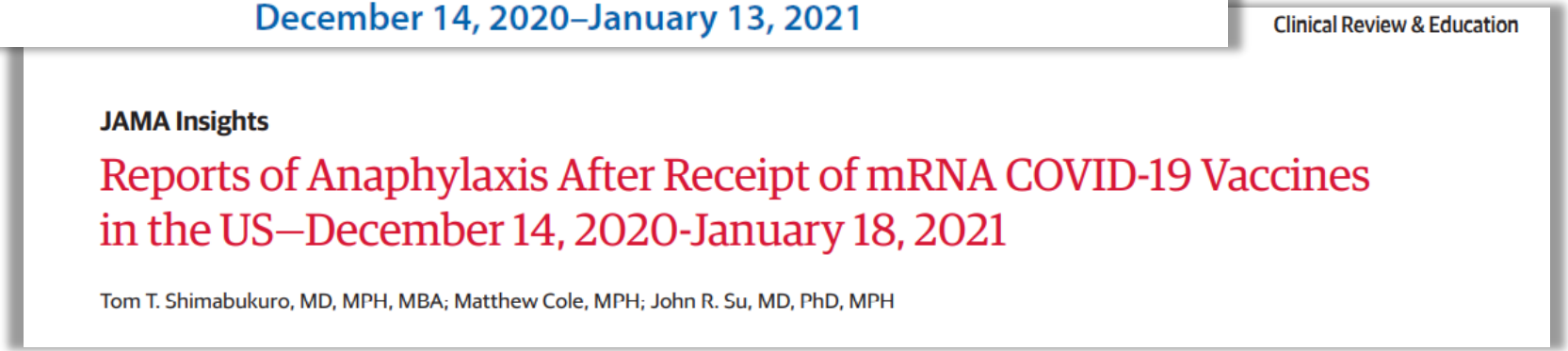
MMWR

Morbidity and Mortality Weekly Report

Early Release / Vol. 70

February 19, 2021

First Month of COVID-19 Vaccine Safety Monitoring — United States, December 14, 2020–January 13, 2021

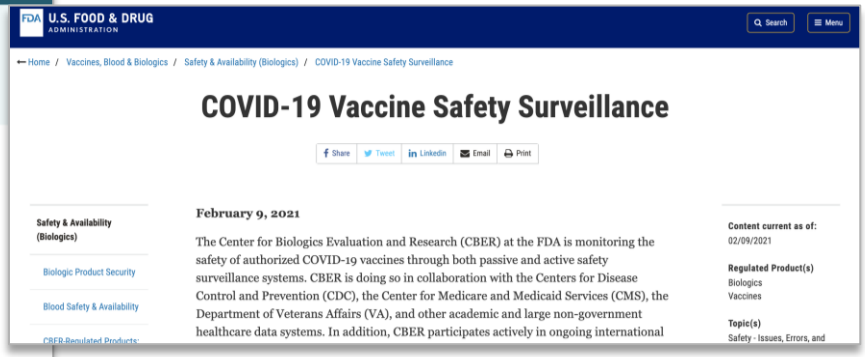


Clinical Review & Education

JAMA Insights

Reports of Anaphylaxis After Receipt of mRNA COVID-19 Vaccines in the US—December 14, 2020-January 18, 2021

Tom T. Shimabukuro, MD, MPH, MBA; Matthew Cole, MPH; John R. Su, MD, PhD, MPH



https://www.cdc.gov/coronavirus/2019-ncov/vaccines/safety.html

https://www.fda.gov/vaccines-blood-biologics/safety-availability-biologics/covid-19-vaccine-safety-surveillance

VaST Plans

- Statistical signals should be expected in a robust monitoring program
  - Timely investigations will be conducted once signals are identified
  - Only 1 in 10 statistical signals have been *true associations*
- Maternal vaccine safety data from multiple sources will be regularly reviewed in collaboration with pregnancy experts
- Future vaccine safety surveillance activities will include the newly approved Janssen COVID-19 vaccine
- VaST will continue to update the ACIP COVID-19 vaccines workgroup, ACIP secretariat and ACIP on a regular basis

VaST Members

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