COVID-19 Vaccine Safety Technical (VaST) Subgroup

Discussion and Interpretation

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Vaccine Safety Surveillance in the U.S.

- Well-established vaccine safety surveillance systems remain the cornerstone of COVID-19 vaccine safety monitoring in the U.S.
- Novel approaches to surveillance have enriched our understanding of COVID-19 vaccine safety in the early phases of vaccine deployment.
- VaST meets weekly to review all available data and to ensure a coordinated approach across multiple safety surveillance systems.
VaST Discussion and Interpretation

- Consistent with clinical trial data, local and systemic reactions are commonly reported following vaccination in V-SAFE and VAERS.
- During the early phase of the U.S. vaccination program (<3 months)
  - Rely on data reported to VAERS
  - Limitations - numerator only data; descriptive; reporting bias
- During the later phase of the U.S. vaccination program
  - Rely on data from population-based surveillance systems (e.g., VSD, CMS, Genesis) to understand the risk of AESIs following vaccination
  - Numerator and denominator data; comparison groups available
Anaphylaxis following COVID-19 vaccination is being closely monitored – Estimated rates currently range from 2.8 to 5.0 per million doses (using Brighton Collaboration case definition)

In response, CDC has recommended risk mitigation strategies, including:
- Screening for risk prior to vaccination
- Monitoring for symptoms post-vaccination
- Early recognition and management of anaphylaxis on-site

Provider and patient education ongoing by CDC and partners
Allergic Reactions Including Anaphylaxis After Receipt of the First Dose of Pfizer-BioNTech COVID-19 Vaccine

As of January 20, 2021, a total of 17 cases of anaphylaxis were reported to the US Food and Drug Administration (FDA) as of December 11, 2020, the date on which the Pfizer-BioNTech COVID-19 vaccine was authorized for emergency use. These cases were reported as part of the Vaccine Adverse Event Reporting System (VAERS) and were among the first doses administered. Anaphylaxis is a life-threatening allergic reaction that occurs rarely after vaccination, with onset typically within minutes to hours. Following implementation of vaccination, reports of anaphylaxis after the first dose of the Pfizer-BioNTech COVID-19 vaccine emerged. Notifications and reports of suspected severe allergic reactions and anaphylaxis following vaccination were captured in the Vaccine Adverse Event Reporting System (VAERS), the national...
Interim Considerations: Preparing for the Potential Management of Anaphylaxis After COVID-19 Vaccination

Anaphylaxis, an acute and potentially life-threatening reaction, can occur following COVID-19 vaccination. While most people who receive COVID-19 vaccines experience no serious side effects, some may have allergic reactions.

These interim considerations provide information on how to manage anaphylaxis and allergic reactions following COVID-19 vaccination. It is important to note that anaphylaxis is a medical emergency requiring immediate treatment. If you or someone you know experiences symptoms of anaphylaxis, seek medical attention immediately.

Lab Tests to Collect Shortly After Severe Allergic Reaction/Anaphylaxis Following COVID-19 Vaccination

For Healthcare Providers

There are no specific lab tests that can definitively diagnose the cause of a severe allergic reaction (e.g., anaphylaxis) following COVID-19 vaccination. In the United States, two commercially available lab tests can be ordered by healthcare providers and processed through healthcare facilities to better characterize a severe allergic reaction.

This document provides an overview of the timing and procedure for collecting blood samples for these lab tests. These samples should only be collected after medically stabilizing a patient who has experienced a severe allergic reaction.
**VaST Interpretation and Plans**

- Serious AEs following COVID-19 vaccination are being closely monitored
  - Data in the U.S. and Europe suggest that case reports are consistent with all-cause mortality rates, particularly in frail, elderly individuals
- Anticipate additional vaccine safety surveillance systems will begin reporting data as we vaccinate a larger proportion of the U.S. population
- VaST will continue to update the ACIP COVID-19 vaccines workgroup, ACIP secretariat and ACIP on a regular basis
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