COVID-19 Vaccine Safety Technical (VaST) Subgroup

Discussion and Interpretation

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Advisory Committee on Immunization Practices

January 27, 2021

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

VaST Discussion and Interpretation

- 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

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MMWR
Morbidity and Mortality Weekly Report
Early Release / Vol. 70
January 6, 2021

Allergic Reactions
Pfizer-BioNTech CO

As of January 3, 2021, a tota
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Centers for Disease Control and Prevention
MMWR
Morbidity and Mortality Weekly Report
Early Release / Vol. 70
January 22, 2021

Allergic Reactions Including Anaphylaxis After Receipt of the First Dose c

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coronavirus disease 2019 (COVID-1
deaths had been reported in the Un
cdc.gov/covid-data-tracker/#cases

JAMA Insights | CLINICAL UPDATE

Allergic Reactions Including Anaphylaxis After Receipt of the First Dose of Pfizer-BioNTech COVID-19 Vaccine

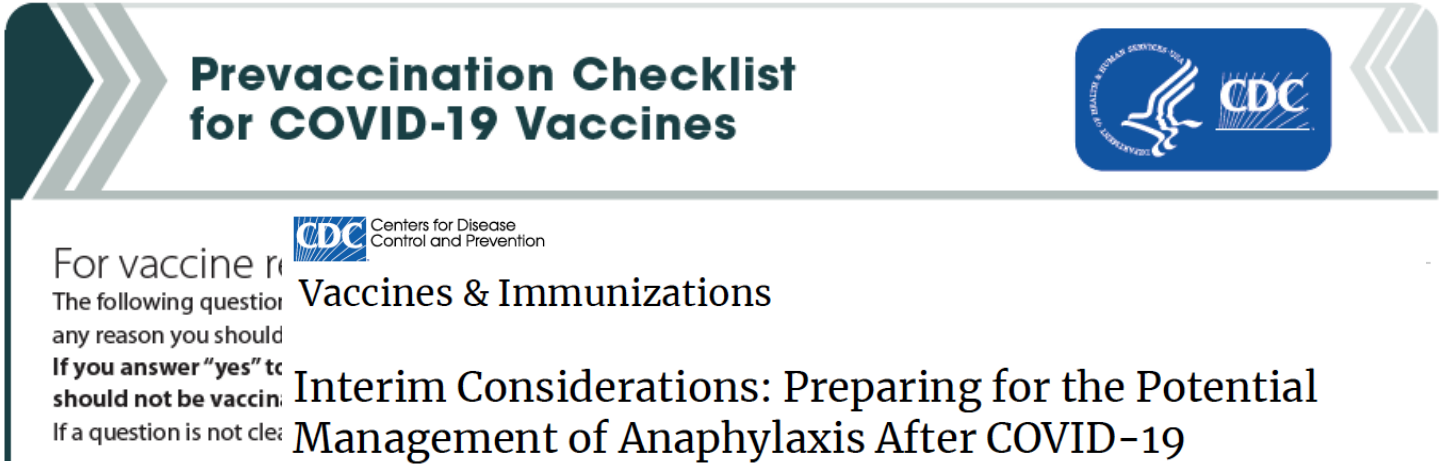
Tom Shimabukuro, MD, MPH, MBA; Narayan Nair, MD

On December 11, 2020, the US Food and Drug Administration (FDA) issued an Emergency Use Authorization (EUA) for the Pfizer-BioNTech coronavirus disease 2019 (COVID-19) vaccine, administered as 2 doses separated by 21 days.[1] Shortly after, the Advisory Committee on Immunization Practices (ACIP) issued an interim recommendation for its use.[2]

Multimedia

Following implementation of vaccination, reports of anaphylaxis after the first dose of the Pfizer-BioNTech COVID-19 vaccine emerged.[3] Anaphylaxis is a life-threatening allergic reaction that occurs rarely after vaccination, with onset typically within minutes to hours.[4]

Notifications and reports of suspected severe allergic reactions and anaphylaxis following vaccination were captured in the Vaccine Adverse Event Reporting System (VAERS), the national



Prevaccination Checklist for COVID-19 Vaccines

For vaccine r
The following questio
any reason you should
If you answer "yes" t
should not be vaccin
If a question is not cle

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Interim Considerations: Preparing for the Potential Management of Anaphylaxis After COVID-19 Vaccination

Anaphylaxis, an acute and potentially life-th
Detailed information on CDC recommendat
can be found in the Clinical Considerations f

These interim considerations provide inforn
following COVID-19 vaccination. Institutiona
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Vaccines & Immunizations

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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