COVID-19 Vaccine Safety Technical (VaST) Subgroup

Discussion and Interpretation

Grace M. Lee, MD MPH

VaST Co-Chair

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

Centers for Disease Control and Prevention
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
coronavirus disease 2019 (COVI
ated deaths have been reported i
term sequalae of COVID-19 ov

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

As of January 20, 2021, a tota
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

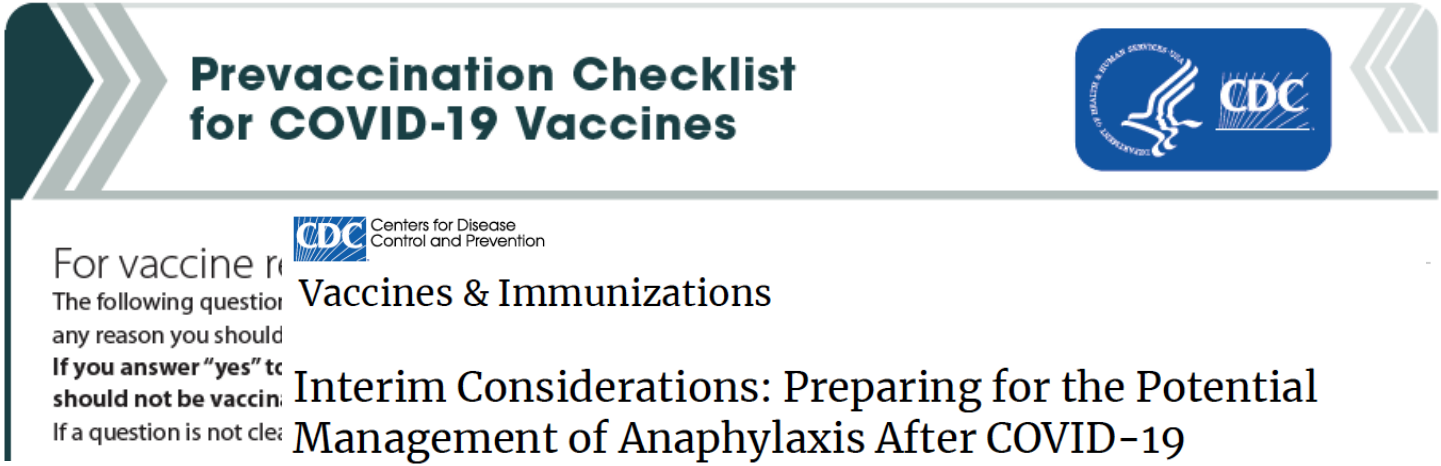
Tom Shimabukuro, MD, MPH, MBA; Narayan Nair, MD

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

Centers for Disease Control and Prevention

Vaccines & Immunizations

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
appropriate medical treatment for severe al
anaphylactic reaction occurs following admi

Appropriate medical treatment
acute anaphylactic reaction oc

Centers for Disease Control and Prevention

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

VaST Members

Co-Chairs

Grace Lee (ACIP)

Robert Hopkins (NVAC)

ACIP Members

Beth Bell

Matt Daley

Veronica McNally

Kiepp Talbot

Expert Consultants

Kathy Edwards

Lisa Jackson

Martin Kulldorff

Laura Riley

Robert Schechter

Patricia Whitley-Williams

CDC Co-Leads

Lauri Markowitz

Melinda Wharton

Ex Officio and Liaison Representatives

Tatiana Beresnev (NIH)

Steven Anderson; Karen Farizo; Richard Forshee; Narayan Nair; Hui Lee Wong (FDA)

Judith Steinberg (OIDP)

Jeffrey Kelman (CMS)

Matthew Clark (IHS)

Mary Rubin (HRSA)

Fran Cunningham (VA)

Limone Collins (DoD)

Administrative Support

Susan Hiers

Jared Woo