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Brigham and Women's Hospital
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Dear Drs. [redacted] and [redacted]:

On behalf of the Clinical Immunization Safety Assessment (CISA) Project, thank you for the opportunity to review the case of your 64-year-old female patient who experienced persistent paresthesias and band-like sensation of chest tightening (at approximately the T-6 dermatome) following receipt of the Pfizer COVID-19 vaccine. CISA was asked to review the case to assess the diagnosis, whether receipt of the Pfizer COVID-19 vaccine might have caused or contributed to the adverse event following immunization (AEFI), and to provide guidance regarding future vaccinations.

As part of our mission under the Centers for Disease Control and Prevention (CDC) contract, CISA is a national research network that provides healthcare providers with expert opinions on adverse events following immunizations. This case was reviewed on March 24, 2021 by the CISA Clinical Consultation Case Review Working Group, which includes vaccine safety experts as well as subject matters experts (SMEs) in infectious diseases, allergy/immunology, and neurology.

The following questions were posed:

1. What is the diagnosis?

2. Did the vaccine cause or contribute to the AEFI?

3. What is CISA guidance regarding future vaccines for this individual?
    a. COVID-19 vaccine?

    b. Routine vaccines?

4. Is any additional testing warranted?

5. When to schedule follow-up?

email

5-24-21 to

CISA vaccine safety and other SMEs reviewed available evidence, including the patient's medical and family history, vaccine safety literature, and Vaccine Adverse Event Reporting Systems (VAERS) search results, and the U.S. Food and Drug Administration's EUA (Emergency Use Authorization) information on the Pfizer COVID-19 vaccine. The SMEs discussed that the patient's paresthesias could be related to or caused by an underlying condition that needed further evaluation. In the setting of elevated tryptase and associated clinical findings, mastocytosis and mast cell activation syndrome are part of the differential diagnosis, as are paraneoplastic syndromes or occult malignancies.

The SMEs assessed whether the adverse event of persistent paresthesias was causally related to the receipt of the Pfizer COVID-19 vaccine using the causality algorithm (see diagram and reference below). The application of the causality algorithm resulted in "Indeterminate," in large part because the diagnosis causing or contributing to the persistent symptoms was uncertain. The SMEs also discussed but could not agree as to whether the vaccine could have triggered or unmasked an underlying disorder. The SMEs agreed, however, that a vaccine could not cause a mast cell disorder, if that is the underlying condition, which needs to be evaluated through further testing. This patient has indicated that she is not interested in receiving a second dose of the Pfizer COVID-19 vaccine, so this topic was not addressed during the consultation.

The following guidance was suggested by the CISA PI's and SMEs:

Continue current antihistamines as prescribed for the next 3-6 months.

Repeat the tryptase. If it remains elevated, suspicion for mastocytosis or mast cell activation syndrome would be higher.

Check for additional mutations (D816V) associated with mastocytosis. Consider checking terminal complement; the 24-hour urine for n-methylhistamine and prostaglandins would be key to understand mast cell activation syndrome if she doesn't have mastocytosis.

Consider bone marrow biopsy to further elucidate cause of elevated tryptase and patient's other symptoms; this would assess for mastocytosis and occult myeloid malignancies.

Consider deep skin tissue biopsy to assess for small fiber neuropathy

Dr. [redacted] might also repeat spine imaging.

Continue to be evaluated by Dr. [redacted] and ultimately to provide a local expert who could coordinate her care.

We hope that we have fully addressed your questions and concerns. Please feel free to contact us if you have any further questions or need to consult us in the future. We have included in the body of the email accompanying this letter, a link to a survey to evaluate the CISA consultation process. An additional patient follow-up survey will be sent in one to two months' time to assess the patient's status.

Surgeon

Sincerely,

[redacted], MD
Sarah H. Sell and Cornelius Professor of Pediatrics Vanderbilt University Medical Center

[redacted], MD, MPH
Associate Professor, Pediatric Infectious Diseases Vanderbilt University Medical Center

Disclaimer:

The findings and conclusions in this report are those of the subject matter experts and do not necessarily represent the official position of the Centers for Disease Control and Prevention. Advice from CDC and CISA experts is meant to assist in decision-making rather than provide direct patient management. Patient management decisions are the responsibility of the treating healthcare provider.