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BU Boston University School of Medicine

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March 31, 2021

Lauren Fontana, DO
Infectious Diseases and Internal Medicine
University of Minnesota
420 Delaware Street SE Mayo D-416
Minneapolis, MN 55455

Dear Dr. Fontana:

On behalf of the Clinical Immunization Safety Office (CISA) Project, thank you for the opportunity to review the case of your 49-year-old female patient who was diagnosed with MIS-A following receipt of 2 doses of the Pfizer COVID-19 vaccine. CISA was asked to review the case to assess whether receipt of Pfizer COVID-19 vaccine might have caused or contributed to the adverse event following immunization (AEFI), and to provide guidance regarding future vaccinations, if needed.

CISA is a national research network that provides healthcare providers with expert opinions on adverse events following immunizations as part of the mission of the Centers for Disease Control and Prevention (CDC). This case was reviewed on March 10, 2021 by the CISA Clinical Consultation Case Review Working Group, which includes vaccine safety experts as well as subject matters experts (SME) in neurology, infectious diseases, and allergy/immunology.

The following questions were posed:

1. Is the diagnosis correct?
2. Did the vaccine(s) cause or contribute to the AEFI?
3. What is CISA guidance regarding future vaccines for this patient?
    a. Different formulation?
    b. Vaccine spacing?
4. Is any additional testing warranted?
5. When to schedule follow-up?

CISA vaccine safety and other SMEs reviewed available evidence, including the patient's medical and family history, vaccine safety literature, Vaccine Adverse Event Reporting Systems (VAERS) search results, and package insert information on the Pfizer COVID-19 vaccine. We agreed that the patient met the CDC internal case definition for MIS-A.

Assessment of whether the diagnosis was causally related to the receipt of the Pfizer COVID-19 vaccine was made using the causality algorithm (see diagram and reference below). The SMEs noted that no cases of MIS-A have been associated solely with COVID vaccine (that we know of); all patients to date had some evidence of prior COVID infection. Your patient, too, had evidence of natural disease from SARS CoV-2 infection as documented by a positive nucleocapsid protein antibody on 2/16/21. We are therefore unable to conclude that vaccine caused this case of MIS-A and are unable at this time to assess whether the vaccine may have contributed to this condition. Continued surveillance of similar cases will be important to be able to learn more about this in the future.

The SMEs agreed that currently, the patient does not need another dose of COVID 19 vaccine as she has already received 2 doses. However, if a booster dose should become standard of care, we will need to await further data to help inform that decision at that time.

It is recommended that the patient receive all routine vaccines as necessary and indicated.

No further testing is indicated at this time. However, there is a patient serum sample in storage. The team would recommend hanging on to that sample, as there might be additional testing opportunities in the future that would be helpful for this patient.

The team recommended follow up as needed post discharge.

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 a link to a survey to evaluate the CISA consultation process in the body of the email accompanying this letter. An additional patient follow-up survey will be sent within the next six months to assess whether the patient has received additional vaccines and how she tolerated them.

Thank you for contacting CISA; we wish your patient a continued recovery.

Sincerely,

Elizabeth D. Barnett, MD
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Section Chief, Pediatric Infectious Diseases
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Review of Case Reports of Adverse Events Following Immunizations
Causality Algorithm
Causality Work Group of CISA