(b)(3):42 U.S.C. §242m(d) ; (b)(5) ; (b)(6)

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(b)(3):42 U.S.C. §242m(d) ; (b)(5) ; (b)(6)

(b)(3):42 U.S.C. §242m(d), (b)(6)

March 31, 2022

(b)(3):42 U.S.C. §242m(d), (b)(6)

On behalf of the Clinical Immunization Safety Office (CISA) Project, thank you for the opportunity to review the case of your (b)(3):42 U.S.C. (b)(3) patient who was diagnosed with (b)(3):42 (b)(3):42 U.S.C. following receipt of two doses of the Moderna COVID-19 mRNA vaccine. CISA was asked to review the case to assess whether the diagnosis was correct, if receipt of the Moderna COVID-19 mRNA 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 clinical research network that provides healthcare providers with expert opinions on adverse events following immunizations. This case was reviewed on March 9, 2022 by the CISA Clinical Consultation Case Review Working Group, which includes vaccine safety experts, as well as subject matter experts (SME) in (b)(3):42 U.S.C. §242m(d), (b)(6)

The following questions were posed:

1. Is the diagnosis correct?
2. Did the vaccine cause or contribute to the AEFI?
3. What is CISA guidance regarding future COVID-19 vaccines for this patient?
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, and Vaccine Adverse Event Reporting Systems (VAERS) search results, and package insert information on the Moderna COVID-19 mRNA vaccine.

The SMEs agreed that (b)(3):42 U.S.C. §242m(d), was the diagnosis and assessed whether the diagnosis was causally related to the receipt of the Moderna COVID-19 vaccine using the causality algorithm (see diagram and reference below).[1] On our call, the application of the causality algorithm resulted in "Indeterminate" because there was not definitive evidence for another cause. Although the temporal association between the patient's e (b)(3):42 U.S.C. §242m(d), (b)(3):42 U.S.C. nd (b)(3) (b)(3):42 U.S.C. §242m(d), was discussed as plausible evidence for another cause.

Upon further review of the published literature after the consultation, CISA SMEs identified additional references supporting the assessment that (b)(3):42 U.S.C. §242m(d), could cause these symptoms. We have attached two additional references supporting the assessment that (b)(3):42

(b)(3):42 U.S.C. §242m(d), (b)(6)

(b)(3):42 can cause [redacted][2,3] The CISA (b)(3):42 SME commented that upon further consideration of the case, he has become more convinced that (b)(3):42 U.S.C. §242m(d), secondary to (b)(3):42 U.S.C. is the cause of the patient's symptoms. We have reassessed the causality of this case using the CISA causality algorithm (attached below) and have determined this adverse event as "Inconsistent with causal association."

In addition, the SMEs agreed that the patient should receive future vaccination with a COVID-19 booster vaccine. It was felt the patient's risk for serious illness and (b)(3):42 events with COVID-19 disease outweighed the potential risks of the vaccine. Current CDC recommendations do not contraindicate a booster mRNA vaccine for this patient.[4] If the patient prefers vaccination with a non-mRNA vaccine, one CISA SME noted that the protein-based Novavax vaccine is currently under review for Emergency Use Authorization by the FDA and, if approved for future use, may be appropriate since (b)(is currently (b)(3):42 U.S.C. §242m(d), (b)(6).

Regarding the question of additional testing, the CISA (b)(3):42 SME on the call opined that additional testing would be dependent on the course of the patient's illness. If the patient continues to improve on daily (b)(3):42 the CISA (b)(3):42 SME did not think additional diagnostic workup would be warranted. However, he did note that this guidance is dependent on whether the (b)(3):42 U.S.C. §242m(d), (b)(6) were normal and that the interpretation of these was done by a (b)(3):42 U.S.C. with expertise in this area. He would also suggest continuing to follow the patient's (b)(3):42 level over time.

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 within the next three months to assess whether the patient has received additional vaccines and how (b)(3):42 tolerated them.

Sincerely,

Disclaimer:

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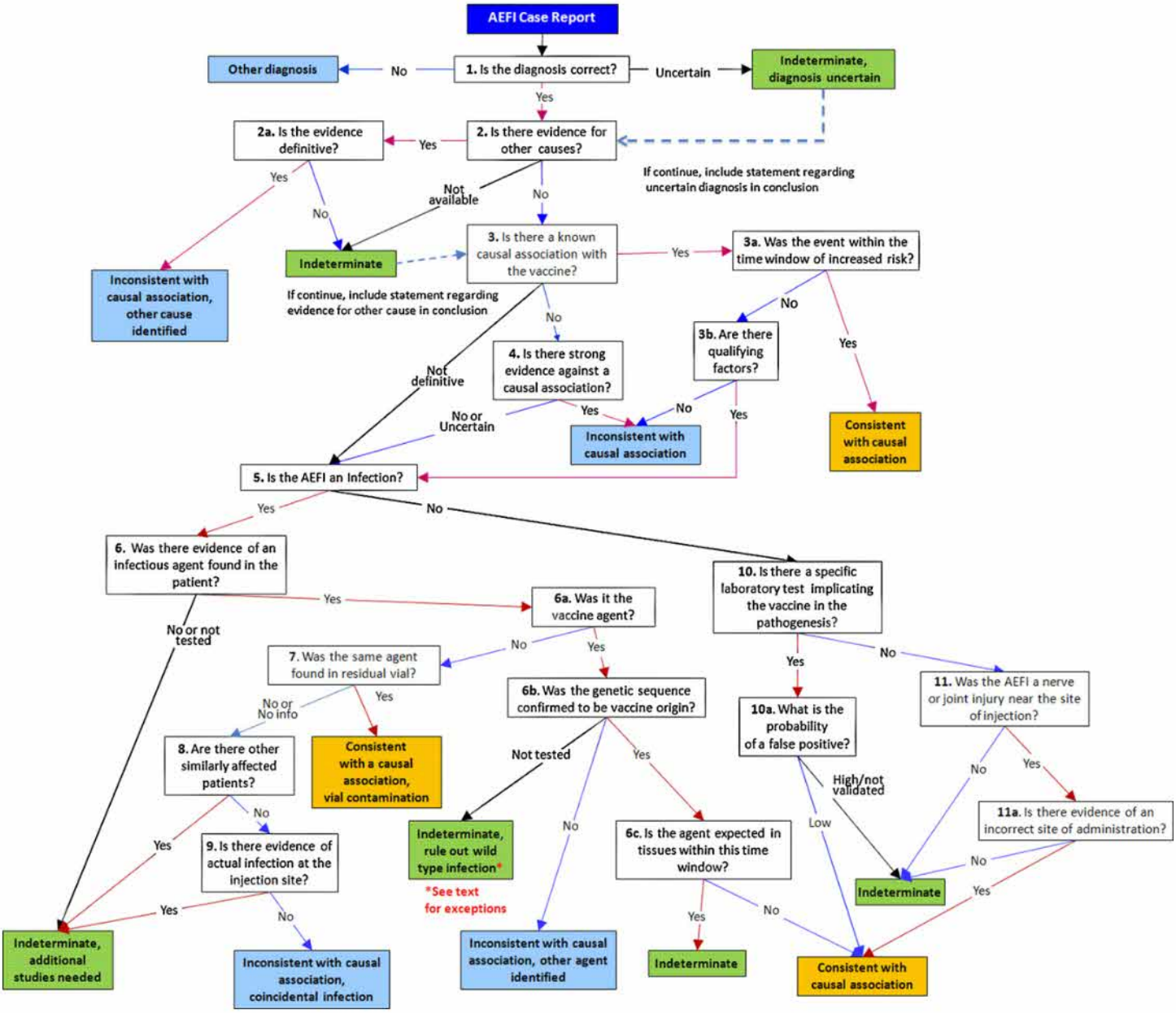
References

1. Halsey NA, Edwards KM, et al, Causality Working Group of the Clinical Immunization Safety Assessment network, Vaccine. 2012 Aug 24;30(39):5791-8. Epub 2012 Apr 14.
2.
3. (b)(3):42 U.S.C. §242m(d); (b)(6)
4. Centers for Disease Control and Prevention. (2022). Interim Clinical Considerations for Use of COVID-19 Vaccines | CDC



(b)(3):42 U.S.C. §242m(d), (b)(6)

May 23, 2022

(b)(3):42 U.S.C. §242m(d), (b)(6)

On behalf of the Clinical Immunization Safety Assessment (CISA) Project, thank you for the opportunity to review the case of your (b)(3):42 U.S.C. (b)(3):42 patient who has (b)(3):42 U.S.C. §242m(d), (b)(6) (b)(3):42 following receipt of the first dose of Pfizer COVID-19 vaccine on April 5, 2021. CISA was asked to review the case to assess whether the diagnosis was correct (or what the diagnosis might be in this case), if receipt of the Pfizer COVID-19 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 (AEFI). This case was reviewed on April 11, 2022 by the CISA Clinical Consultation Case Review Working Group, which includes vaccine safety experts, as well as subject matters experts (SME) in (b)(3):42 U.S.C. §242m(d), (b)(6)

The following questions were posed:

1. What is the diagnosis?
2. Did the vaccine(s) cause or contribute to the AEFI?
3. What is CISA guidance regarding future vaccines for this patient?
    a. COVID vaccines?
    b. Routine vaccines?
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, and Vaccine Adverse Event Reporting Systems (VAERS) search results, and package insert information on the Pfizer COVID-19 vaccine.

A full review of the patient's history and current condition was presented to the team. A discussion of the differential diagnosis of the patient's initial symptoms (b)(3):42 U.S.C. ensued. It was felt that these symptoms could possibly have been a non-severe immediate event, however the presentation was not consistent with an (b)(3):42 U.S.C. §242m(d); (b)(6)

There was further discussion regarding the patient's persistent symptoms. Multiple conditions were considered based on (b)(3):42 U.S.C. §242m(d); (b)(6) (b)(3):42 U.S.C. §242m(d); (definition included in link), and (b)(3):42 U.S.C. (definition included in link). Although (b)(3) had (b)(3):42 U.S.C. §242m(d); (b)(6) (b)(3): symptoms predated this diagnosis by 5 months and (b)(3):42 presentation is not consistent with established criteria for (b)(3):42 U.S.C. §242m(d); (b)(6) (b)(3):42 U.S.C. §242m(d); (b)(6) conditions were also discussed. At this time, the patient does not meet criteria for (b)(3):42 U.S.C. §242m(d); (b)(6) which may be seen in association with the (b)(3):42 U.S.C. §242m(d); (b)(6) (b)(3):4 had a normal (b)(3):42 U.S.C. §242m(d); (b)(6) that did not reveal an underlying diagnosis or (b)(3):42 (b)(3):42 U.S.C. Upon review of your patient's autoantibody results, it was felt that (b)(3):42 may have a propensity for (b)(3):42 U.S.C. §242m(d); especially since (b)(3):42 U.S.C. §242m(d); (b)(6) prior to the COVID-19 vaccination. Review of all (b)(testing indicates that (b)(3):42 may have an (b)(3):42 U.S.C. §242m(d); but does not have a recognizable (b)(3):42 U.S.C. §242m(d); now, especially with the lack of abnormalities on exam or imaging studies. A discussion ensued about whether this could theoretically be an (b)(3):42 (b)(3):42 process, however the (b)(3):42 U.S.C. §242m(d); (b)(6) SME did not feel the vaccine would be related given the chronicity of the symptoms.

Following the presentations of the literature review, VAERS data and discussion, and the current CDC-recommended guidance for COVID-19 vaccination, the majority of the SMEs agreed that the patient does not have a definitive diagnosis, nor a syndrome that has been associated with the mRNA COVID-19 vaccines (i.e., anaphylaxis or myocarditis).

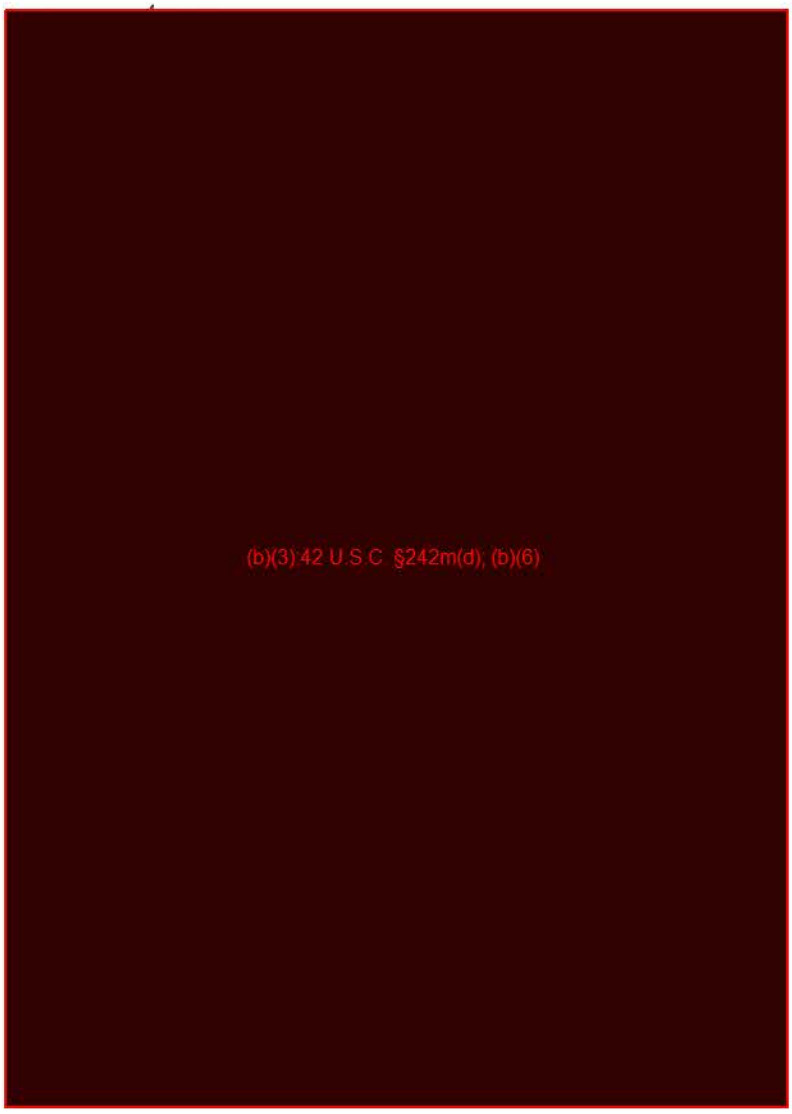
To consider if the vaccine caused or contributed to the AEFI, the team went through the CISA causality algorithm (see diagram and reference below) in two different ways which resulted in either an 'indeterminate' or 'inconsistent' determination. Upon further discussion with all participants, the majority of SMEs agreed with 'indeterminate' because of a lack of strong evidence against a causal association.

The majority of SMEs agreed that the patient should receive future vaccination with COVID-19 vaccine to complet (b)(3):42 primary series. This would be especially important in light of the current surge in circulating Omicron variants. One SME opined that it would be unlikely that the patient has protective immunity to COVID-19, and if (b)(gets COVID-19 again, it could worsen (b)(3):42 clinical condition. Guidance was also provided to administer routine non-COVID-19 vaccines as indicated. The experts agreed that the patient has no known contraindications to receiving other vaccines.

This was considered a very perplexing case, with significant concern for the patient's symptoms, quality of life, and lack of improvement over time, no matter what the cause. Continued work-up was advised since the patient's continued condition is not understood. Suggestions included trending of

(b)(3):42 U.S.C. §242m(d), along with further evaluation by (b)(3):42 U.S.C. §242m(d); (b)(6) (b)(3):42

We hope that we have fully addressed your questions and concerns. We also extend best wishes to your patient for a full recovery. 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 via email within the next two months to assess whether the patient has received additional vaccines and how (b)(3):42 olerated them. We would greatly appreciate your contributions to these surveys.



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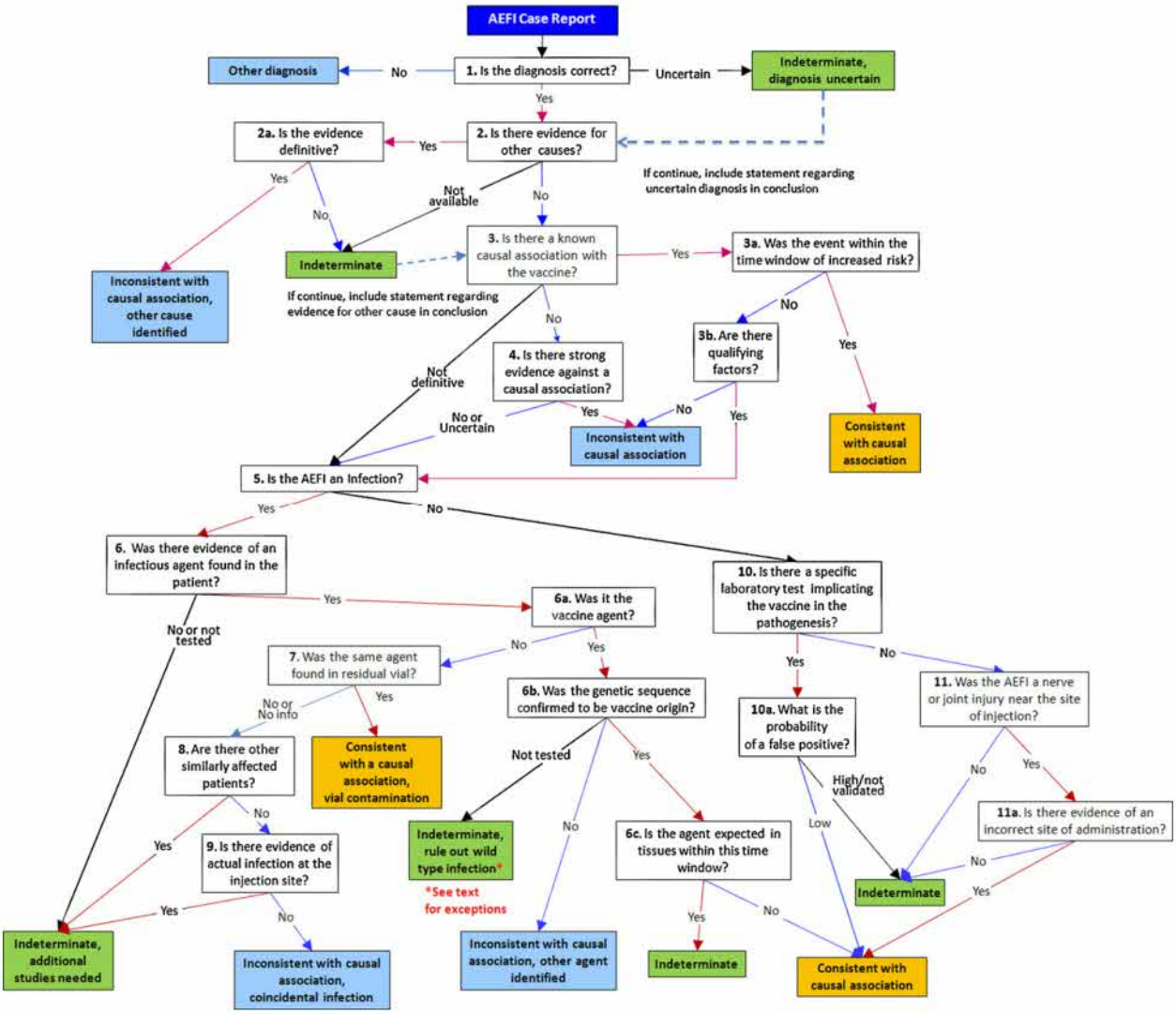

Halsey NA, Edwards KM, et al, Causality Working Group of the Clinical Immunization Safety Assessment network, *Vaccine*. 2012 Aug 24;30(39):5791-8. Epub 2012 Apr 14.

(b)(3):42 U.S.C. §242m(d), (b)(6)

May 23, 2022

(b)(3):42 U.S.C. §242m(d), (b)(6)

On behalf of the Clinical Immunization Safety Assessment (CISA) Project, thank you for the opportunity to review the case of your (b)(3):42 (b)(3) patient who experienced (b)(3):42 U.S.C. §242m(d), (b)(6) following the receipt of the second dose of the Moderna COVID-19 mRNA vaccine, and who had a b (b)(3):42 (b)(3):42 U.S.C. §242m(d), (b)(6) CISA was asked to review the case to assess whether the diagnosis was correct, if receipt of the Moderna COVID-19 mRNA 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 April 26, 2022 by the CISA Clinical Consultation Case Review Working Group, which includes vaccine safety experts, as well as subject matters experts (SME) in (b)(3):42 (b)(6) as well as by experts from the CDC Immunization Safety Office.

The following questions were posed:

1. Did the vaccine contribute to his symptoms?
2. Are there specific characteristics associated with the development of (b)(3):42 U.S.C. §242m(d), (b)(6) following covid-19 vaccination?
3. What is the present CDC guidance for future COVID-19 vaccines?
4. What is CISA guidance regarding future vaccines for this patient?
    a. COVID-19 vaccine?
    b. Routine vaccines?
5. Is any additional testing warranted?
6. When to schedule follow-up?

Together we reviewed available evidence, including the patient's medical history, vaccine safety literature, and Vaccine Adverse Event Reporting Systems (VAERS) search results, and the FDA emergency use authorization information on the Moderna COVID-19 vaccine.

The causality algorithm (see diagram and reference below) was applied using the symptom (b)(3):42 U.S.C. (b)(3):42 U.S.C. §242m(d), (b)(6) (b)(3):42 U.S.C. §242m(d)). Experts discussed whether this patient's AEFI was causally related to the receipt of the Moderna COVID-19 mRNA vaccine. The application of the causality algorithm resulted in "Indeterminate" because the diagnosis is uncertain, and, while there is some evidence to support other causes, that is not definitive either. There is also not a definitive known association between the vaccine and the AEFI. The positive (b)(3):42 U.S.C. §242m(d), (b)(6) and one that is difficult to interpret because it is more frequently a false positive result than other tests.

More importantly, the FDA EUA and CDC Interim Clinical Considerations for Use of COVID-19 Vaccines lists the contraindications and precautions for COVID-19 vaccination. Based on the guidance in that document, your patient does not have a contraindication to receipt of the booster dose of the COVID-19 vaccine. In addition, the SMEs on the call strongly felt that the risk of COVID-19 infection was higher than the potential risk from another dose of vaccine, and that (b)(should receive a booster dose of vaccine. We are aware that since the call, the patient has recently had COVID-19 infection; many CISA SMEs would recommend waiting at least 90 days from the date of infection to receipt of the booster.

The CISA SMEs favored avoiding the Johnson and Johnson vaccine because of the increased (b)(3):42 U.S.C. §242m(d); (b)(6)

(b)(3):42 U.S.C. §242m(d); (b)(6)

Regarding routine vaccinations, CISA agreed that no contraindications exist, and this patient can receive other vaccines according to need/schedule.

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 within the next few months to assess whether the patient has received the second dose, additional vaccines and how (b)(3):42 tolerated them.

Sincerely,

(b)(3):42 U.S.C. §242m(d); (b)(6)

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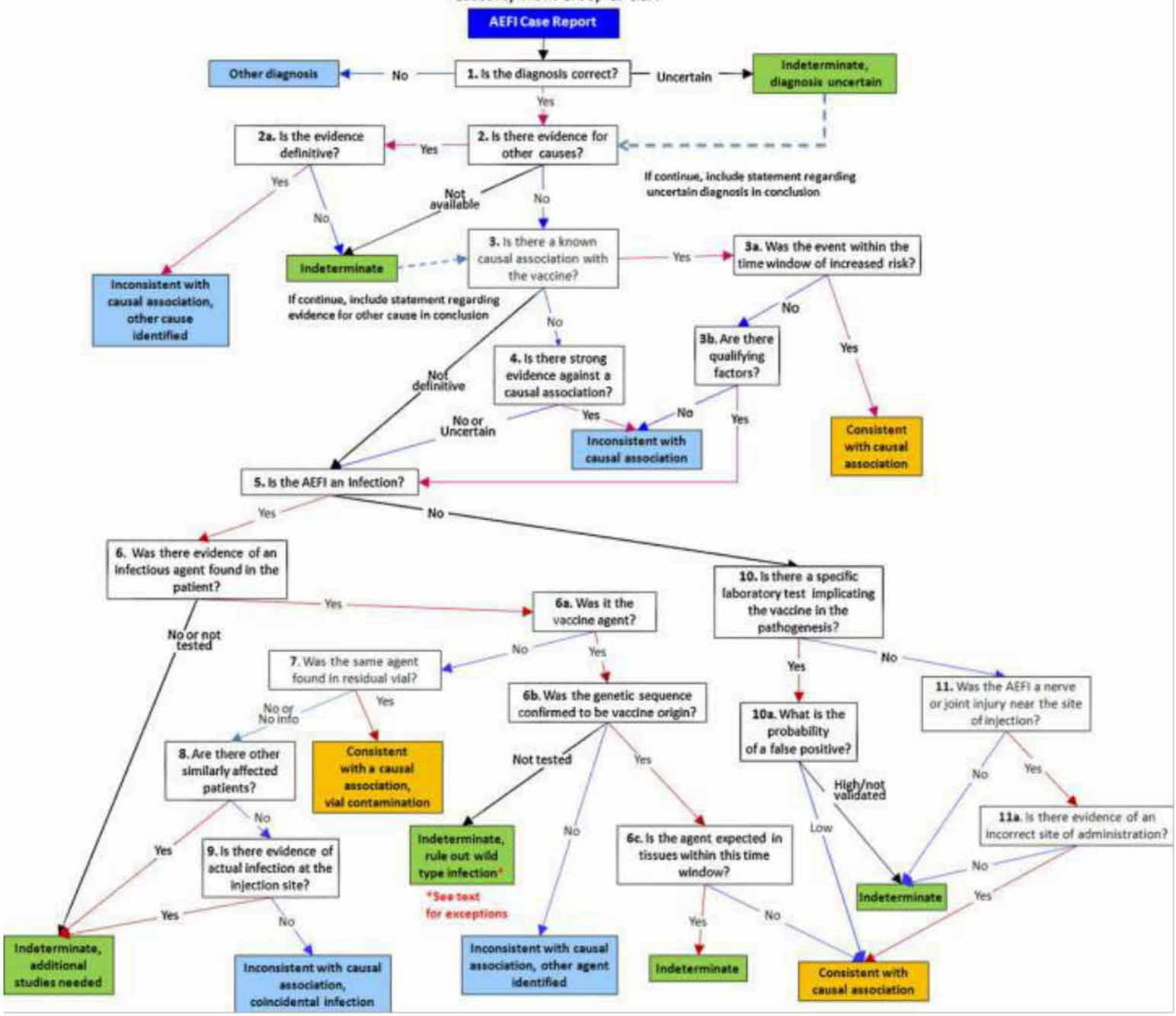
References

1. Halsey NA, Edwards KM, et al, Causality Working Group of the Clinical Immunization Safety Assessment network, *Vaccine*. 2012 Aug 24;30(39):5791-8. Epub 2012 Apr 14.

Review of Case Reports of Adverse Events Following Immunizations

February 28, 2012

Causality Work Group of CISA



(b)(3):42 U.S.C. §242m(d); (b)(6)

May 31, 2022

(b)(3):42 U.S.C. §242m(d); (b)(6)

On behalf of the Clinical Immunization Safety Assessment (CISA) Project, thank you for the opportunity to review the case of your (b)(3):42 U.S.C. (b)(3): patient who experienced (b)(3):42 U.S.C. §242m(d); (b)(6) following receipt of the fourth dose of the (b)(3):42 U.S.C. DTaP vaccine. CISA was asked to review the case to assess whether the diagnosis of a (b)(3):42 U.S.C. §242m(d), (b)(6) was correct, if receipt of the (b)(3):42 U.S.C. DTaP 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 May 3, 2022 by the CISA Clinical Consultation Case Review Working Group, which includes vaccine safety experts, as well as subject matter experts (SME) in (b)(3):42 U.S.C. §242m(d); (b)(6) (b)(3):42 U.S.C. §242m(d); (b)(6)

The following questions were posed:

1. Is the diagnosis correct?
2. Did the vaccine cause or contribute to the AEFI?
3. What is the present CDC guidance for future vaccines?
4. What is CISA guidance regarding future vaccines for this patient?
    a. DTaP Vaccine?
    b. Routine Vaccinations
5. Is any additional testing warranted?
6. 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 System (VAERS) search results, and package insert information on the (b)(3):42 DTaP vaccine.

Following a detailed review, the SMEs determined that the patient's presentation did not support a diagnosis of (b)(3):42 Both (b)(3):42 SMEs agreed that the patient's symptoms were most consistent with (b)(3) associated with the administration of the (b)(3):42 U.S.C. DTaP vaccine and not a (b)(3):42 U.S.C. problem. Application of the Causality Algorithm (see diagram and reference below) using HHE resulted in "Other Diagnosis." When the CISA Causality Algorithm was applied using (b)(3):42 U.S.C. §242m(d); (b)(6) the CISA experts' opinion was that there likely was a causal relationship

(b)(3):42 U.S.C. §242m(d); (b)(6)

with (b)(3) from the injection procedure, but not to the components of the vaccine. In addition, we also reviewed the current CDC recommendations for DTaP vaccine and clarified that there is no contraindication or precaution for (b)(3):42 U.S.C. §242m(d); (b)(6)

The SMEs agreed that the patient should receive future doses of the DTaP vaccine as well as other routine vaccines, and noted the patient should receive catch-up HiB and PCV13 vaccines as soon as possible (CDC's Catch-up Immunization Schedule). An expert proposed the administration of these two vaccines at separate visits if it would make the (b)(3):42 U.S.C more comfortable but added that this alternative schedule is not necessary. The group discussed how the patient's primary care providers are in the best position to help allay (b)(3):42 concerns about vaccination and reduce vaccine hesitancy.

Given that pain with the injection procedure was believed to contribute to this patient's presentation, we would like to provide some additional resources you may find helpful. The Advisory Committee on Immunization Practices (ACIP) General Best Practice Guidelines on Immunization includes a chapter on Vaccine Administration Guidelines. The section *Methods for Alleviating Discomfort and Pain Associated with Vaccination* suggests that comfort measures, such as cooling of the injection site(s), topical analgesia and others, may be beneficial. Although evidence does not support use of antipyretics before or at the time of vaccination, they can be useful for treating fever and local discomfort that may follow vaccination.

No additional testing was suggested given the patient's complete recovery. However, the (b)(3):42 U.S.C SMEs mentioned additional testing for (b)(3):42 U.S.C. §242m(d); (b)(6) if the patient experiences future episodes of (b)(3):42

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 within the next three months to assess the status of the patient.

Sincerely,

(b)(3):42 U.S.C. §242m(d); (b)(6)

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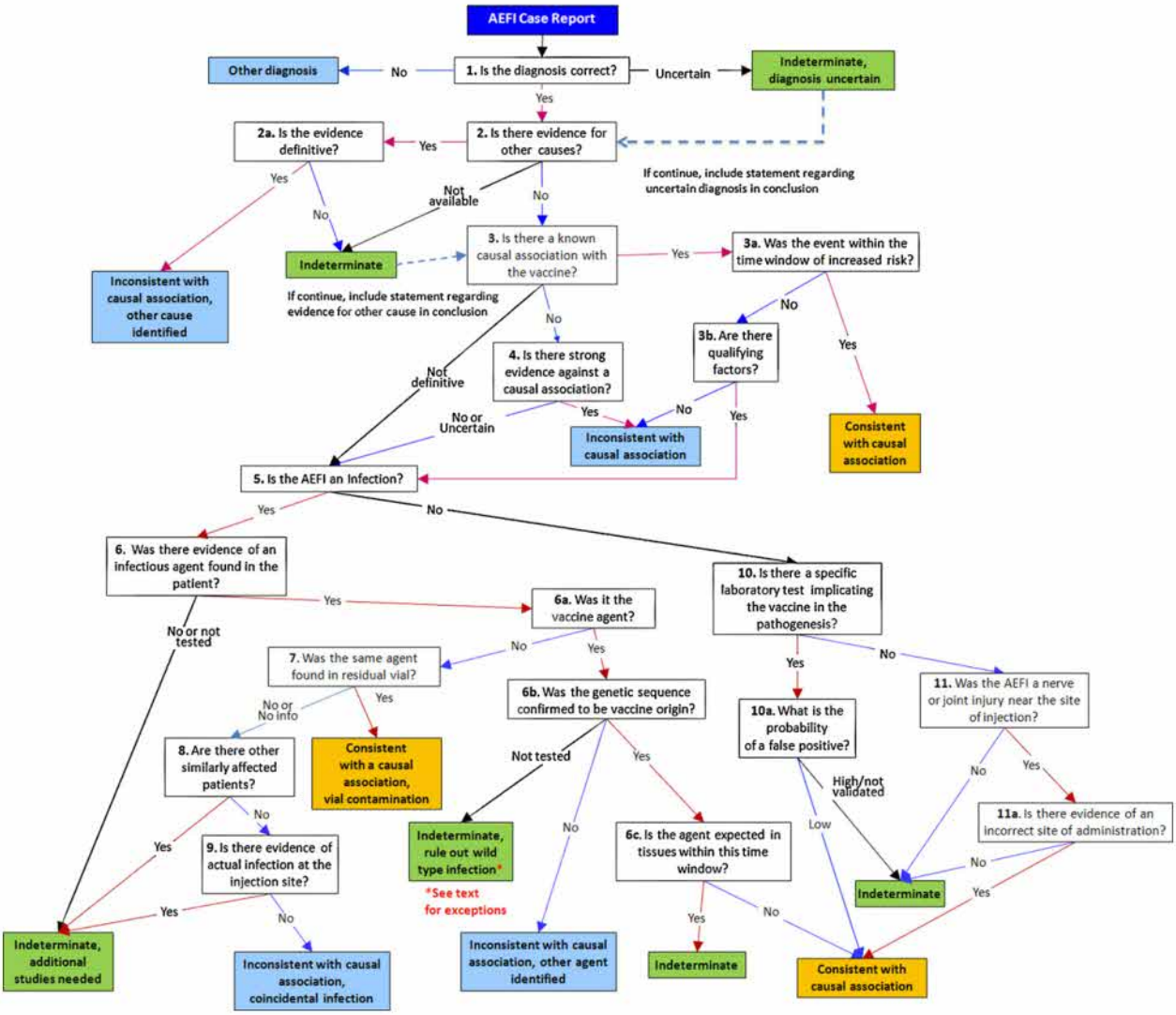


Halsey NA, Edwards KM, et al, Causality Working Group of the Clinical Immunization Safety Assessment network, *Vaccine*. 2012 Aug 24;30(39):5791-8. Epub 2012 Apr 1

(b)(3):42 U.S.C. §242m(d), (b)(6)

July 13, 2022

(b)(3):42 U.S.C. §242m(d), (b)(6)

On behalf of the Clinical Immunization Safety Assessment (CISA) Project, thank you for the opportunity to review the case of your (b)(3):42 (b)(3) patient who experienced symptoms consistent with a (b)(3):42 U.S.C. following the receipt of the 2nd dose of the Pfizer COVID-19 mRNA vaccine. CISA was asked to review the case to assess whether the diagnosis was correct, if receipt of the Pfizer COVID-19 mRNA 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 June 27, 2022 by the CISA Clinical Consultation Case Review Working Group, which includes vaccine safety experts, as well as subject matter experts (SME) in (b)(3):42 U.S.C. §242m(d), (b)(6)

The following questions were posed:

1. What is the diagnosis?
2. Did the vaccine(s) cause or contribute to the AEFI?
3. What is CISA guidance regarding future COVID-19 vaccines for this patient?
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 System (VAERS) search results, and package insert information on the Pfizer COVID-19 mRNA vaccine.

The SMEs agreed that there is no definitive diagnosis for this patient's case. The differential diagnoses include; (b)(3):42 U.S.C. §242m(d), (b)(6)
(b)(3):42 U.S.C. §242m(d), (b)(6) The CISA causality algorithm was applied using (b)(3):42 U.S.C. §242m(d), (b)(6) as the diagnosis. The application of the causality algorithm resulted in an "Indeterminate" classification because there is no definitive evidence for other causes. Even though the causality algorithm result was indeterminate, many SMEs agreed that it was unlikely that this (b)(3):42 U.S.C. was

(b)(3):42 U.S.C. §242m(d), (b)(6)

causally related to the receipt of COVID-19 vaccine. Several experts thought that (b)(3):42 U.S.C. presentation was more likely to be due to (b)(3):42 U.S.C. rather than vaccine.

In addition, the SMEs suggested that the patient should proceed with future doses of COVID-19 vaccine as per the CDC's recommended schedule (Interim Clinical Considerations for Use of COVID-19 Vaccines | CDC).

The SMEs did not think any additional testing was warranted for this patient's case. However, repeat (b)(3):42 of the (b)(3):42 could be considered in the future to assess the evolution of the patient's (b)(3):42 U.S.C. which may help clarify the diagnosis.

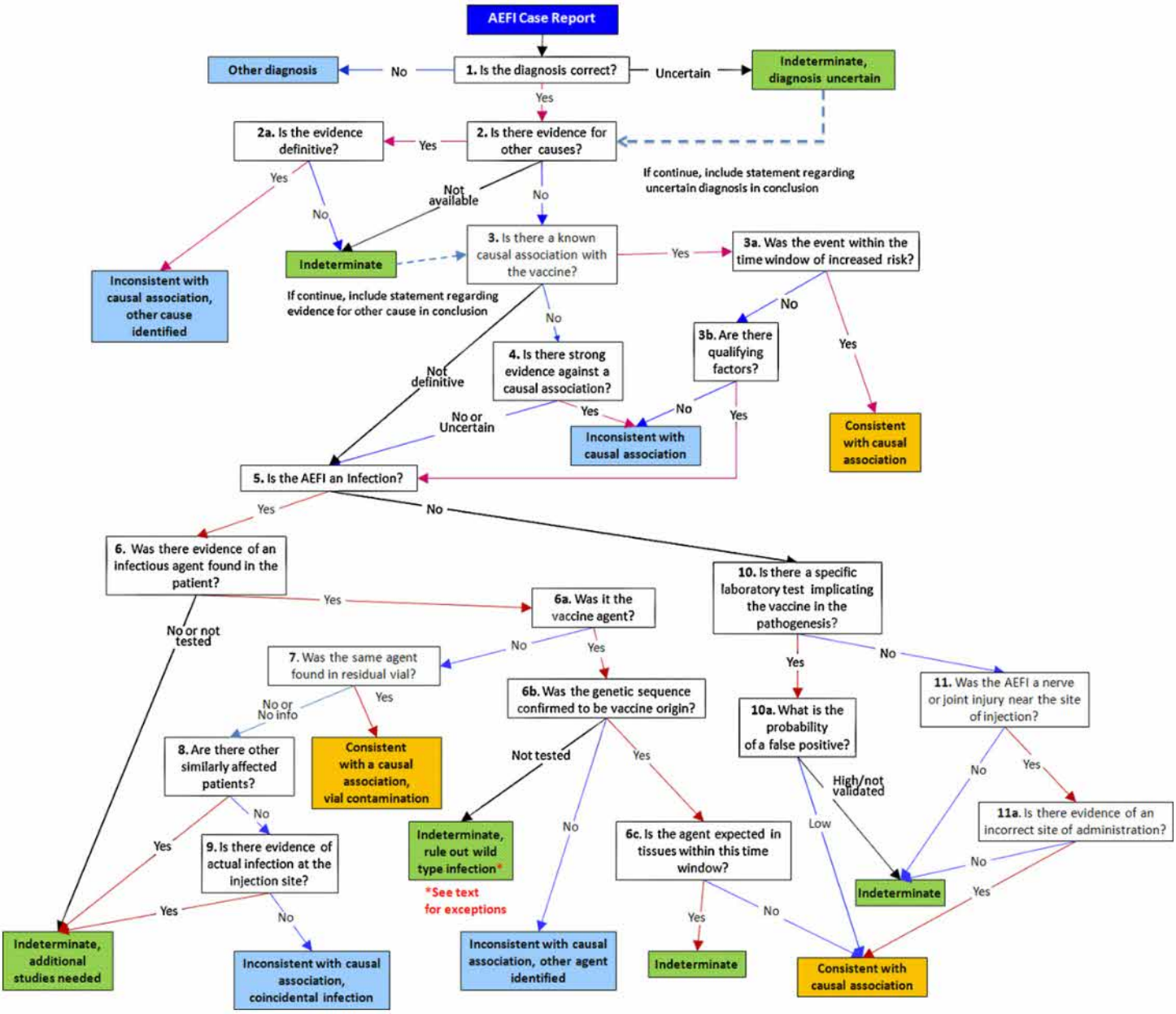
We hope that we have fully addressed your questions and concerns. Please feel free to contact us if you have any further questions or need to consult us in the future. We have included, in the body of the email accompanying this letter, a link to a survey to evaluate the CISA consultation process. An additional patient follow-up survey will be sent within the next 3 months to assess whether the patient has received additional vaccines and how (b)(3):42 tolerated them.

Sincerely,

(b)(3):42 U.S.C. §242m(d); (b)(6)

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.



Halsey NA, Edwards KM, et al, Causality Working Group of the Clinical Immunization Safety Assessment network, *Vaccine*. 2012 Aug 24;30(39):5791-8. Epub 2012 Apr 14.

(b)(6)

September 1, 2022

(b)(6)

On behalf of the Clinical Immunization Safety Assessment (CISA) Project, we thank you for the opportunity to review the case of your (b)(6) (b)(6) patient who was diagnosed with (b)(6) (b)(6) following the first dose of Pfizer COVID-19 vaccine. CISA was asked to review the diagnosis, assess if receipt of the Pfizer COVID-19 vaccine might have caused or contributed to the adverse event following immunization (AEFI) and provide guidance regarding future COVID-19 vaccination.

As part of our mission under the Centers for Disease Control and Prevention (CDC), CISA is a national research network that provides healthcare providers with expert opinions on adverse events following immunizations. This case was reviewed on July 13th, 2022, by the CISA COVID Vaccine (COVIDvax) Clinical Consult Case Review Working Group, which includes vaccine safety experts, as well as subject matter experts in (b)(6) (b)(6)

We reviewed the available medical records, pertinent vaccine safety literature, as well as CDC's integrated surveillance for (b)(6) n persons who have received COVID-19 vaccine. We discussed all of this information with the CISA subject matter experts (SMEs) during our initial call. We also readdressed questions during a follow-up discussion on August 24th, 2022. We have summarized our findings and guidance below.

The following questions were posed and the answers are presented in bold italics:

1. What is the diagnosis? ***The patient showed clinical symptoms, laboratory results, and imaging findings consistent with the definition of*** (b)(6) (b)(6)
2. Did the vaccine cause or contribute to the AEFI? ***Indeterminate/Inconsistent with a causal***

[redacted]

association, other cause identified. A majority of CISA SMEs agreed with the assessment of 'Indeterminate', however 2 SMEs felt the result should be 'Inconsistent with a causal association, other cause identified' with that other cause being SARS-CoV-2 infection.

3. What is CISA guidance regarding future vaccines for this patient?
   - COVID-19 vaccine? ***CISA SMEs agreed that this patient should not receive an additional COVID-19 vaccine at the time of the call, consistent with the CDC interim clinical considerations for COVID-19 vaccine (last updated August 22,2022). At the time of the consult about 4 months had elapsed since the patient was first diagnosed with [redacted] The experts suggest reassessing the risk and benefits of the COVID-19 vaccination when [redacted] is fully recovered and consulting the CDC interim clinical considerations for COVID-19 vaccine for the available COVID-19 vaccine products including, potentially, vaccines updated for SARS -CoV-2 variants. CISA could be re-consulted if that would be useful.***
   - Routine vaccines? ***Proceed as usual following the general precaution to defer vaccination in the event of moderate or severe acute illness with or without fever.***
4. Is any additional testing warranted? ***CISA SMEs did not have any additional testing suggestions beyond the follow-up assessments planned by the clinical care team.***
5. When to schedule follow-up? ***The patient could be reassessed later this year in the context of the COVID-19 community prevalence and the patient's [redacted] resolution. Follow-up to reconsider the question of a second dose of the COVID-19 vaccine could be scheduled once the patient has fully clinically recovered from [redacted] CISA could be re-consulted if that would be useful.***

Please see appended below the CISA Vaccine Adverse Event Causality Algorithm[1], and bibliography that might be of use to you in the future[2-14].

We hope that this review will be helpful in the management of your patient. 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 to you in approximately one to two months to assess whether the patient has received additional vaccines and how [redacted] tolerated them.

Sincerely,

[redacted]

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(b)(3):42 U.S.C. §242m(d), (b)(6)

References

1. Halsey NA, Edwards KM, Dekker CL, et al. Algorithm to assess causality after individual adverse events following immunizations. Vaccine 2012;30:5791-8.
2. (b)(3):42 U.S.C. §242m(d), (b)(6)
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10. (b)(3):42 U.S.C. §242m(d), (b)(6)
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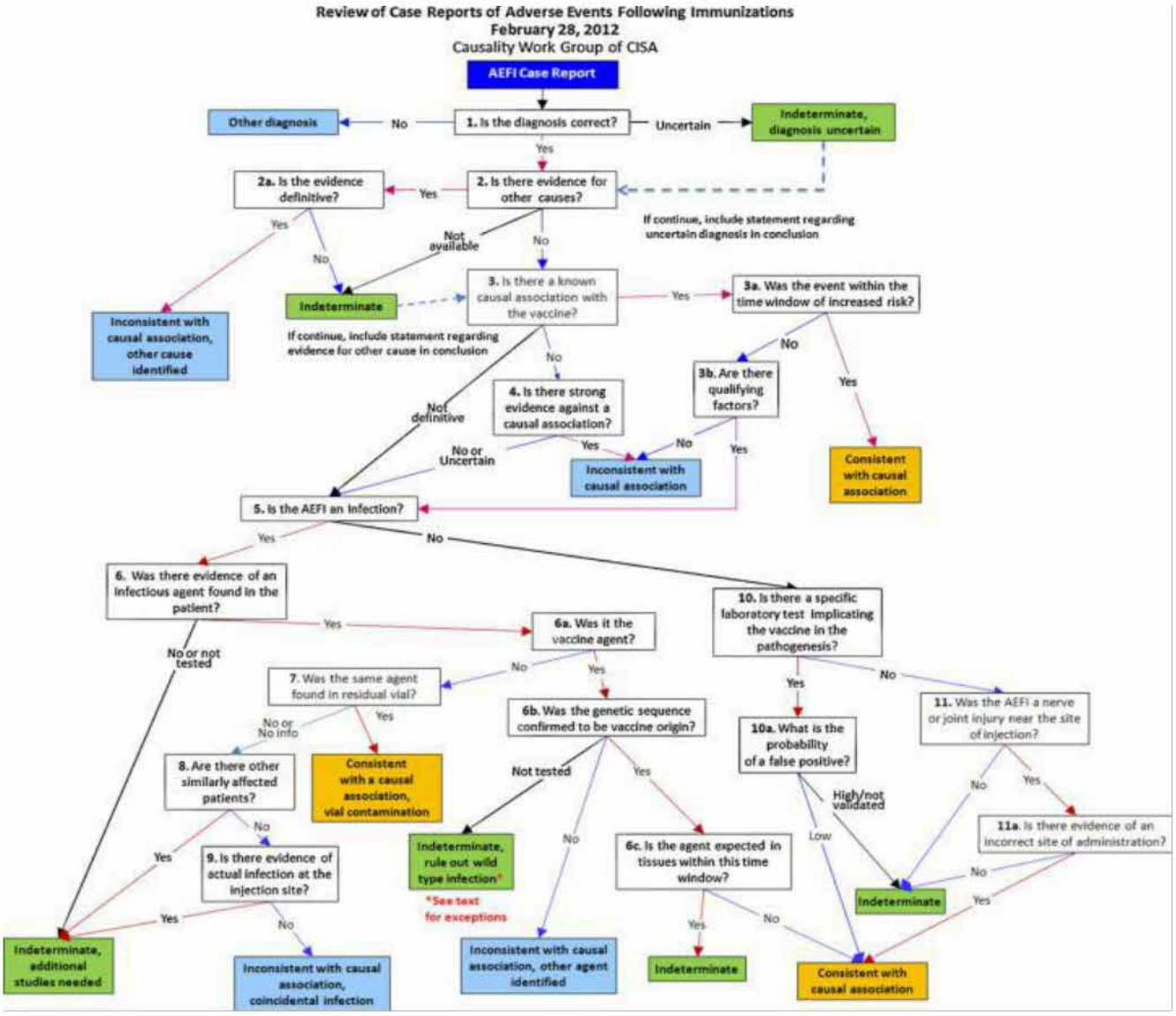
12.

(b)(3):42 U.S.C. §242m(d), (b)(6)

13. (b)(3):42 U.S.C. §242m(d), (b)(6)

14. Hachmann NP, Miller J, Collier AR, Ventura JD, Yu J, Rowe M, Bondzie EA, Powers O, Surve N, Hall K, Barouch DH. Neutralization escape by SARS-CoV-2 Omicron subvariants BA. 2.12. 1, BA. 4, and BA. 5. New England Journal of Medicine 2022;387(1):86-8.

(b)(3) 42 U.S.C. §242m(d), (b)(6)



(b)(3):42 U.S.C. §242m(d); (b)(6)

November 11, 2022

(b)(3):42 U.S.C. §242m(d); (b)(6)

On behalf of the Clinical Immunization Safety Office (CISA) Project, thank you for the opportunity to review the case of your (b)(3):42 U.S.C. (b)(3): patient who was diagnosed with (b)(3):42 U.S.C. following receipt of dose #1 of the Moderna COVID-19 mRNA vaccine. CISA was asked to review the case to assess whether the diagnosis was correct, if receipt of the Moderna 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 October 3, 2022 by the CISA Clinical Consultation Case Review Working Group, which includes vaccine safety experts, as well as subject matters experts (SME) in (b)(3):42 U.S.C. §242m(d); (b)(6) a (b)(3):42 U.S.C. §242m(d); (b)(6).

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 patient?
    a. COVID-19 vaccine?
    b. Routine vaccines?
4. Is any additional testing warranted?
5. When to schedule follow-up?

CISA vaccine safety and other SMEs reviewed the 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 Moderna COVID-19 mRNA vaccine.

The SMEs agreed that (b)(3):42 U.S.C. §242m(d); (b)(6) was the correct diagnosis and assessed whether the diagnosis was causally related to the receipt of the Moderna COVID-19 mRNA vaccine using the causality algorithm (see diagram and reference below). The application of the causality algorithm resulted in indeterminate because there was evidence for other causes, but that evidence was not considered definitive.

(b)(3):42 U.S.C. §242m(d); (b)(6)

In addition, all the SMEs who commented agreed that the patient should receive future COVID-19 vaccines and routine vaccines. One SME suggested that future COVID-19 vaccines not be co-administered with routine vaccines and suggested a spacing of two weeks. This SME reasoned that if there is concern for an adverse event following a vaccine then it is better to isolate the variable each time.

No additional testing was recommended.

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. In a few months, a patient follow-up survey will be sent to assess whether the patient has received additional vaccines and how (b)(3): 42 olerated them.

Sincerely,

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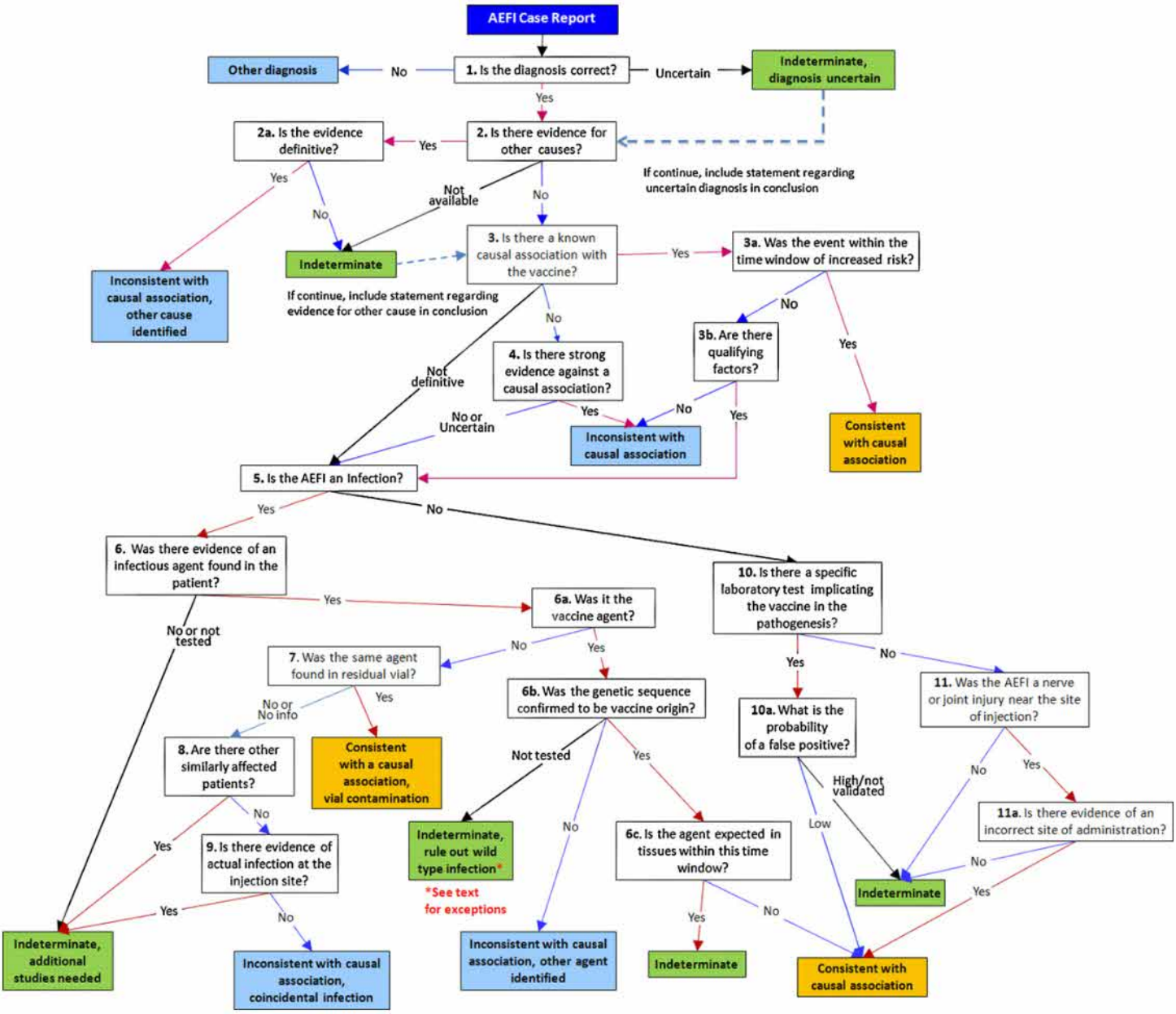

Halsey NA, Edwards KM, et al, Causality Working Group of the Clinical Immunization Safety Assessment network, *Vaccine*. 2012 Aug 24;30(39):5791-8. Epub 2012 Apr 14.

(b)(3):42 U.S.C. §242m(d), (b)(6)

January 14, 2021

(b)(3):42 U.S.C. §242m(d), (b)(6)

On behalf of the Clinical Immunization Safety Office (CISA) Project, thank you for the opportunity to review the case of your (b)(3):42 (b)(3):42 patient who was diagnosed with (b)(3):42 U.S.C. following receipt of the Pfizer-BioNTech COVID-19 Vaccine. CISA was asked to review the case to assess whether the diagnosis was correct, if receipt of 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 Friday, December 18, 2020 by the CISA Clinical Consultation Case Review Working Group, which includes vaccine safety experts, as well as subject matters experts (SME) in (b)(3):42 U.S.C. §242m(d), (b)(6)

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 child?
    a. COVID-19 vaccine?
    b. Routine vaccines?
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, and package insert information on the Pfizer-BioNTech COVID-19 Vaccine.

The SMEs agreed that (b)(3):42 U.S.C. was the correct diagnosis and met the Brighton Collaboration case definition with a Level 2 of diagnostic certainty. The SMEs assessed whether the diagnosis was causally related to the receipt of the Pfizer-BioNTech COVID-19 Vaccine using the causality algorithm (see diagram and reference below). The application of the causality algorithm resulted in Consistent with Causal Association because an (b)(3):42 U.S.C. §242m(d), is a known possible adverse event following immunization.

In addition, the SMEs agreed that the patient should not receive a second dose of COVID-19 vaccine. Regarding other routine vaccines, CISA SMEs provided guidance that the patient

(b)(3):42 U.S.C. §242m(d), (b)(6)

should follow-up with an (b)(3):42 to determine which vaccines (non-COVID) can safely be given.

The CISA SMEs address the question of whether additional testing is warranted for this patient. CISA would encourage this patient to follow-up with (b)(3): 42 healthcare provider to have (b)(3): 42 (b)(3):42 evaluated, specifically (b)(3):42 U.S.C. §242m(d), (b)(6) (b)(3):42 U.S.C. Additionally, CISA would encourage this patient to follow-up with an (b)(3):42 that can properly evaluate (b)(for (b)(3):42 U.S.C. §242m(d), (b)(6) CISA SMEs discussed that there is a possibility this patient might have an (b)(3):42 U.S.C. §242m(d), (b)(6) (b)(3):42 but currently there is no test validated for clinical use that can confirm this.

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 two months' time to assess the patient's status and results of follow-up.

Sincerely,

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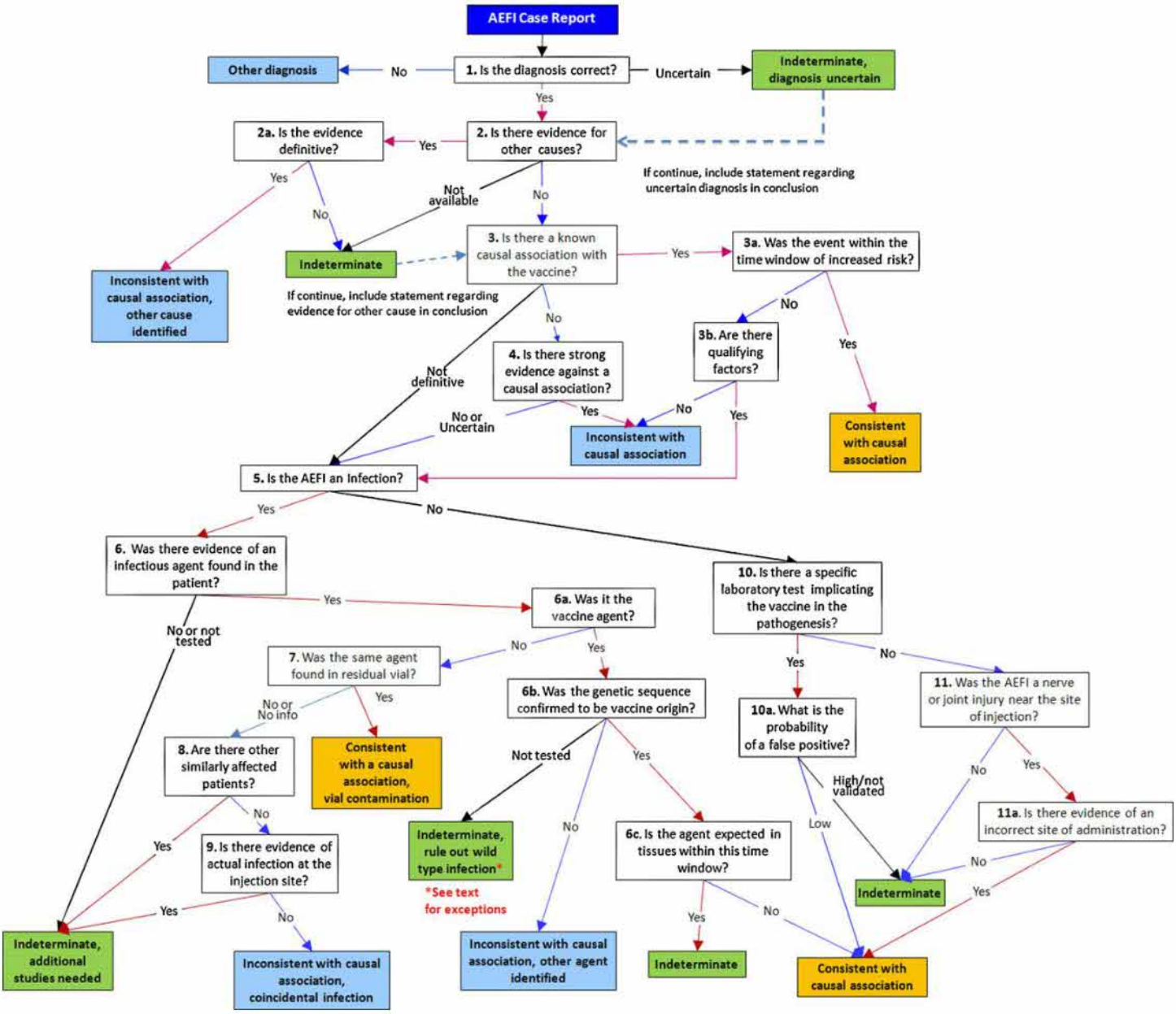

Halsey NA, Edwards KM, et al, Causality Working Group of the Clinical Immunization Safety Assessment network, *Vaccine*. 2012 Aug 24;30(39):5791-8. Epub 2012 Apr 14.

[redacted]

January 14, 2021

[redacted]

On behalf of the Clinical Immunization Safety Office (CISA) Project, thank you for the opportunity to review the case of your [redacted] patient who was diagnosed with [redacted] following receipt of the Pfizer-BioNTech COVID-19 Vaccine. CISA was asked to review the case to assess whether the diagnosis was correct, if receipt of 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 Friday, December 18, 2020 by the CISA Clinical Consultation Case Review Working Group, which includes vaccine safety experts, as well as subject matters experts (SME) in [redacted]

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 child?
    a. COVID-19 vaccine?
    b. Routine vaccines?
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, and package insert information on the Pfizer-BioNTech COVID-19 Vaccine.

The SMEs agreed that this patient did not meet the Brighton Collaboration criteria (referenced) for [redacted] diagnosis but agreed that [redacted] were the correct diagnoses. The SMEs assessed whether these diagnoses were causally related to the receipt of the Pfizer-BioNTech COVID-19 Vaccine using the causality algorithm (see diagram and reference below). The application of the causality algorithm resulted in Consistent with Causal Association because the patient's adverse events following immunization are known possible AEFIs.

[redacted]

In addition, the SMEs agreed that the patient should not receive a second dose of COVID-19 vaccine. A CISA (b)(3):42 on the call reasoned that this (b)(3):42 might have been a (b)(3):42 (b)(3):42 U.S.C. §242m(d); (b)(6), and if the patient has (b)(3):42 U.S.C. §242m(d); (b)(6) (b)(3):42, (b)(3):42 U.S.C. §242m(d); (b)(6) In this patient's case, it is possible (b)(could have a more (b)(3):42 U.S.C. with the second dose. Regarding other routine vaccines, CISA SMEs provided guidance that the patient should follow-up with an (b)(3):42 to determine which vaccines can safely be given.

The CISA SMEs address the question of whether additional testing is warranted for this patient and agreed that this patient should follow-up with an (b)(3):42 experienced with (b)(3):42 U.S.C. §242m(d); (b)(6) (b)(3):42 U.S.C. §242m(d); (b)(6)

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 two months' time to assess the patient's status and results of follow-up.

Sincerely,

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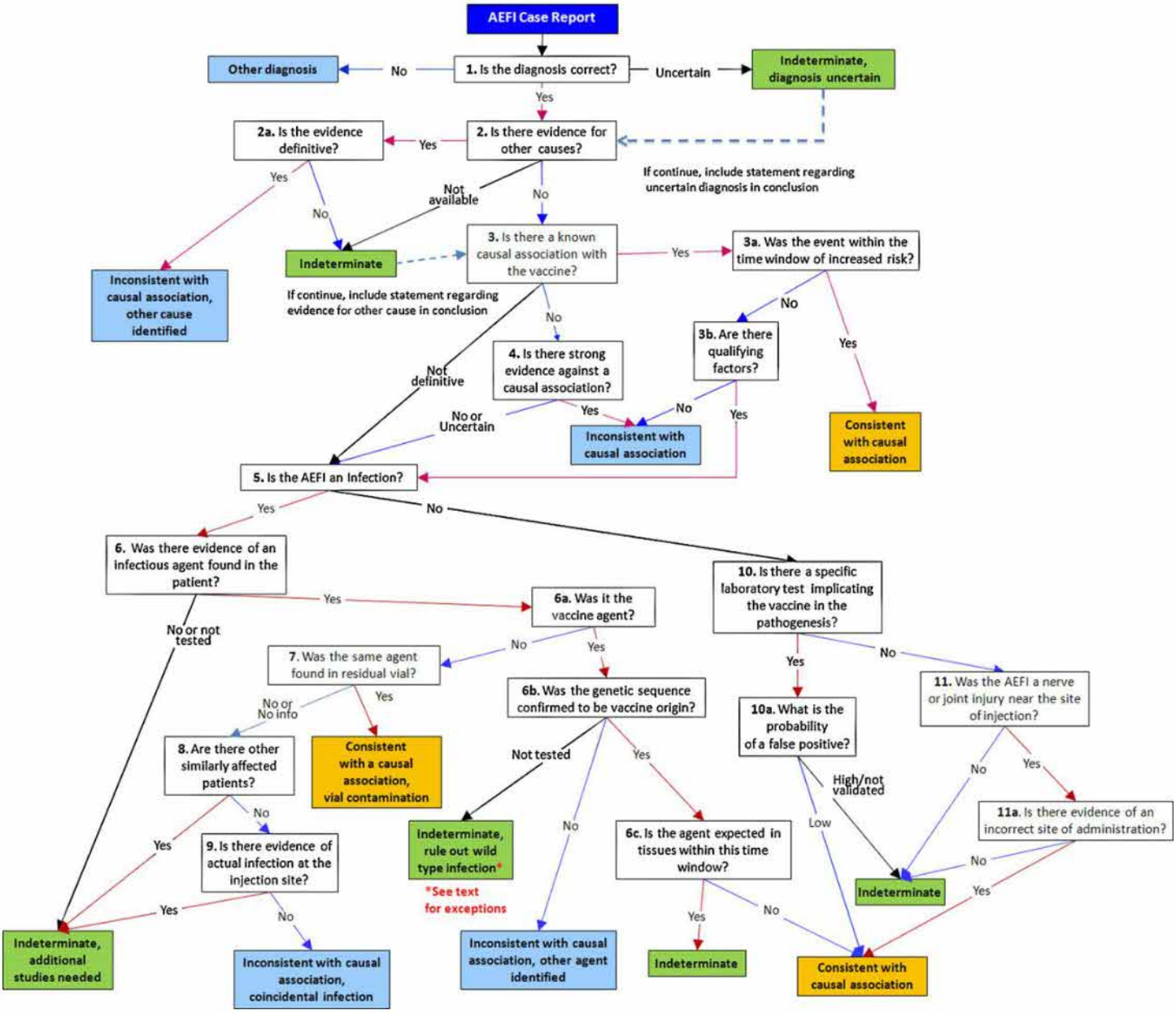
References

1. Halsey NA, Edwards KM, et al, Causality Working Group of the Clinical Immunization Safety Assessment network, *Vaccine*. 2012 Aug 24;30(39):5791-8. Epub 2012 Apr 14.
2. (b)(3);42 U.S.C. §242m(d); (b)(6)



(b)(3):42 U.S.C. §242m(d), (b)(6)

January 12,2020

(b)(3):42 U.S.C. §242m(d), (b)(6)

On behalf of the Clinical Immunization Safety Office (CISA) Project, thank you for the opportunity to review the case of your (b)(3):42 U.S.C. §242m(d), (b)(6) (b)(3):42 patient who was diagnosed with (b)(3):42 U.S.C. following receipt of the Pfizer-BioNTech COVID-19 vaccine. CISA was asked to review the case to assess whether the diagnosis was correct, if receipt of the Pfizer-BioNTech 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 December 29, 2020 by the CISA Clinical Consultation Case Review Working Group, which includes vaccine safety experts, as well as subject matters experts (SME) in (b)(3):42 U.S.C. §242m(d), (b)(6)

The following questions were posed:

1. Is the diagnosis correct?
2. Did the vaccine cause or contribute to the AEFI?
3. What is CISA guidance regarding future vaccines for this child?
    a. COVID-19 vaccine?
    b. Routine vaccines?
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, and package insert information on Pfizer-BioNTech COVID-19 vaccine.

The SMEs agreed that (b)(3):42 U.S.C. §242m(d), (b)(6) was the correct diagnosis, and this case met the Brighton Collaboration case definition (referenced below) with a Level 1 of diagnostic certainty. The SMEs assessed whether the diagnosis was causally related to the receipt of Pfizer-BioNTech COVID-19 vaccine using the causality algorithm (see diagram and reference below). The application of the causality algorithm resulted in "Consistent with Causal Association" because (b)(3):42 U.S.C. is known possible adverse event following immunization.

(b)(3):42 U.S.C. §242m(d), (b)(6)

The SMEs agreed that the patient should not receive dose #2 of the COVID-19 vaccine. Regarding other routine vaccines, CISA SMEs provided guidance that the patient should follow-up with an (b)(3):42 to determine which vaccines can safely be given.

Additionally, CISA SMEs discussed whether additional testing is warranted for this patient and agreed the patient should follow up with an (b)(3):42 that can properly evaluate (b)(3) for (b)(3):42 (b)(3):42 U.S.C. §242m(d), (b)(6). CISA SMEs discussed there is a possibility this patient might have (b)(3):42 U.S.C. §242m(d), (b)(6), but there is no test currently available and validated for clinical use that can confirm this. A (b)(3):42 U.S.C. and (b)(3):42 U.S.C. §242m(d), (b)(6) were also suggested to be collected on this patient as part of the future (b)(3):42 evaluation.

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 and result of (b)(3): follow-up wit (b)(3):42 U.S.C. §242m(d); (b)(6)

Sincerely,

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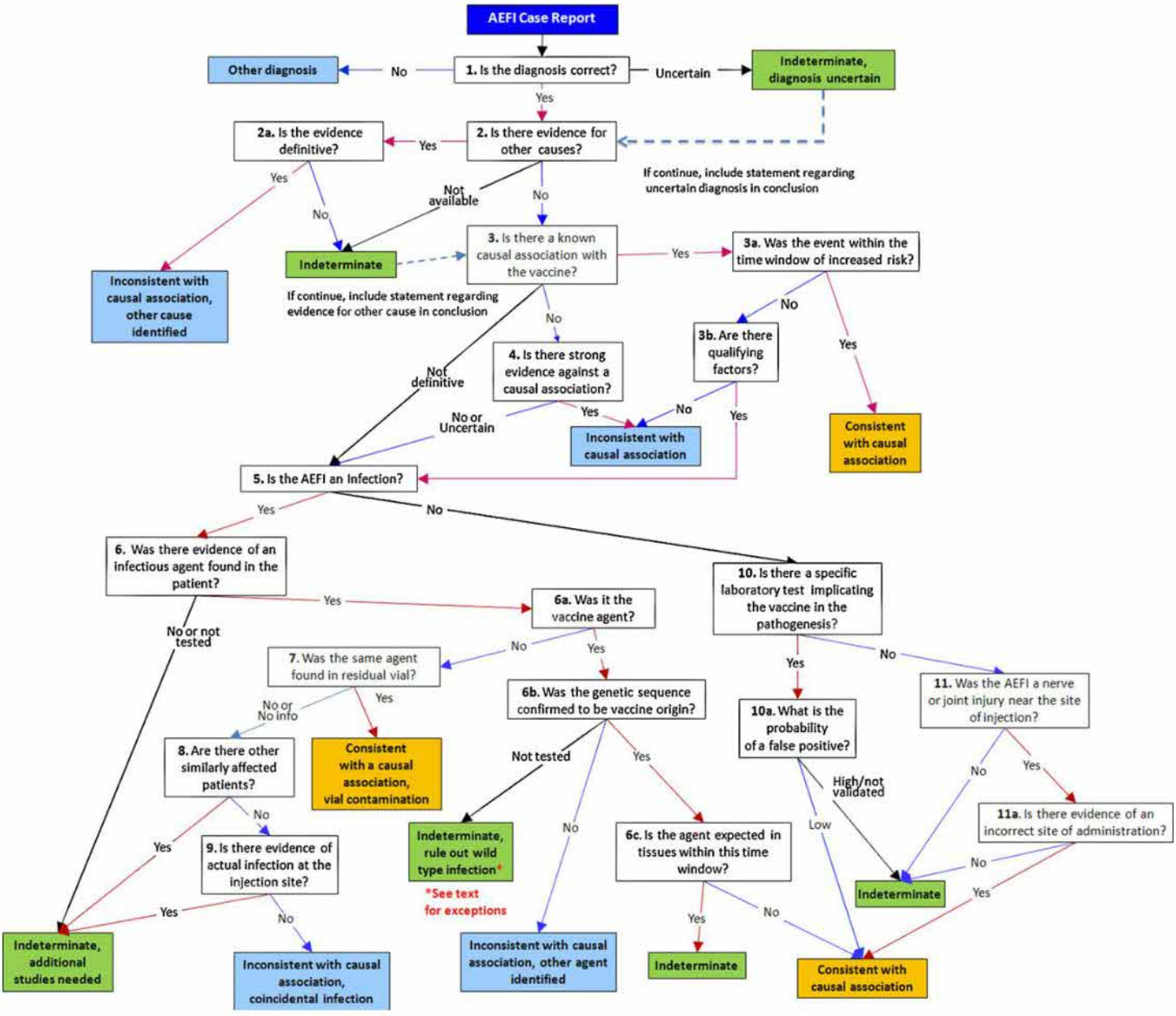
References

1. Halsey NA, Edwards KM, et al, Causality Working Group of the Clinical Immunization Safety Assessment network, *Vaccine*. 2012 Aug 24;30(39):5791-8. Epub 2012 Apr 14.
2. [redacted] (b)(3) 42 U.S.C. §242m(d); (b)(6)



(b)(3):42 U.S.C. §242m(d); (b)(6)

January 12,2020

(b)(3):42 U.S.C. §242m(d); (b)(6)

On behalf of the Clinical Immunization Safety Office (CISA) Project, thank you for the opportunity to review the case of your (b)(3):42 U.S.C. §242m(d); (b)(6) (b)(3):42 patient who was diagnosed with (b)(3):42 U.S.C following receipt of the Pfizer-BioNTech COVID-19 vaccine. CISA was asked to review the case to assess whether the diagnosis was correct, if receipt of the Pfizer-BioNTech 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 December 29, 2020 by the CISA Clinical Consultation Case Review Working Group, which includes vaccine safety experts, as well as subject matters experts (SME) in (b)(3):42 U.S.C. §242m(d); (b)(6)

The following questions were posed:

1. Is the diagnosis correct?
2. Did the vaccine cause or contribute to the AEFI?
3. What is CISA guidance regarding future vaccines for this child?
    a. COVID-19 vaccine?
    b. Routine vaccines?
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, and package insert information on Pfizer-BioNTech COVID-19 vaccine.

The SMEs agreed that (b)(3):42 U.S.C. §242m(d); (b)(6) was the correct diagnosis, and this case met the Brighton Collaboration case definition (referenced) with a Level 2 of diagnostic certainty. The SMEs assessed whether the diagnosis was causally related to the receipt of Pfizer-BioNTech COVID-19 vaccine using the causality algorithm (see diagram and reference below). The application of the causality algorithm resulted in "Consistent with Causal Association" because (b)(3):42 U.S.C. is known possible adverse event following immunization.

(b)(3):42 U.S.C. §242m(d); (b)(6)

The SMEs agreed that the patient should not receive dose #2 of the COVID-19 vaccine. Regarding other routine vaccines, CISA SMEs provided guidance that the patient should follow-up with an (b)(3):42 U.S.C. to determine which vaccines can safely be given.

Additionally, CISA SMEs discussed whether additional testing is warranted for this patient and agreed the patient should follow up with an (b)(3):42 U.S.C. that can properly evaluate (b)(3):42 or (b)(3):42 U.S.C. §242m(d); (b)(6) CISA SMEs discussed there is a possibility this patient might have (b)(3):42 U.S.C. §242m(d); (b)(6) but there is no test currently available and validated for clinical use that can confirm this. A (b)(3):42 U.S.C and (b)(3):42 (b)(3):42 U.S.C. were also suggested to have collected on this patient. It was noted that the (b)(6) (b)(6) level is important and might inform a fundamental predisposition to (b)(3):42 U.S.C whether (b)(3):42 U.S.C. §242m(d); (b)(6)

(b)(3):42 U.S.C. §242m(d); (b)(6)

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 within one to two months' time to assess the patient's condition and result of (b)(3): follow-up with allergy.

Sincerely,

(b)(3):42 U.S.C. §242m(d); (b)(6)

Disclaimer:

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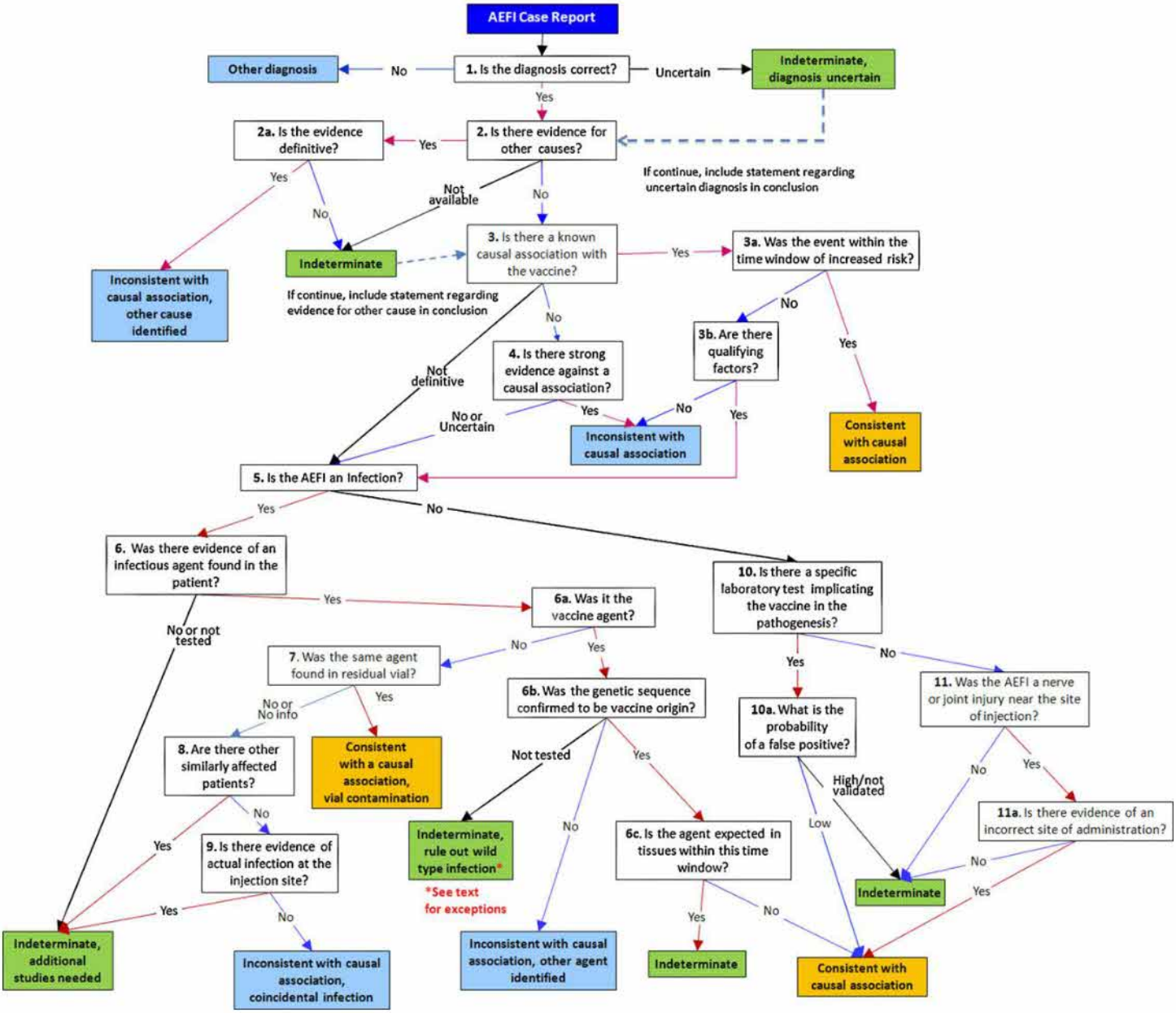
References

1. Halsey NA, Edwards KM, et al, Causality Working Group of the Clinical Immunization Safety Assessment network, *Vaccine*. 2012 Aug 24;30(39):5791-8. Epub 2012 Apr 14.
2. (b)(3):42 U.S.C. §242m(d), (b)(6)



(b)(3):42 U.S.C. §242m(d), (b)(6)

January 22, 2021

(b)(3):42 U.S.C. §242m(d), (b)(6)

On behalf of the Clinical Immunization Safety Office (CISA) Project, thank you for the opportunity to review the case of your (b)(3):42 (b)(3):42 patient who was diagnosed with (b)(3):42 U.S.C. following receipt of the Pfizer-BioNTech COVID-19 vaccine. CISA was asked to review the case to assess whether the diagnosis was correct, if receipt of the Pfizer-BioNTech 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 December 30, 2020 by the CISA Clinical Consultation Case Review Working Group, which includes vaccine safety experts, as well as subject matters experts (SME) in (b)(3):42 U.S.C. §242m(d), (b)(6)

The following questions were posed:

1. Is the diagnosis correct?
2. Did the vaccine cause or contribute to the AEFI?
3. What is CISA guidance regarding future vaccines for this patient?
    a. COVID-19 vaccine?
    b. Routine vaccines?
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, and package insert information on the Pfizer-BioNTech COVID-19 vaccine.

The SMEs agreed tha (b)(3):42 U.S.C. §242m(d), (b)(6) was the correct diagnosis and that this case met the Brighton Collaboration case definition (referenced below) with a Level 2 of diagnostic certainty. The SMEs assessed whether the diagnosis was causally related to the receipt of the Pfizer-BioNTech COVID-19 vaccine using the causality algorithm (see diagram and reference below). The application of the causality algorithm resulted in "Consistent with Causal Association" because this patient's (b)(3):42 is a known possible AEFI with this vaccine.

(b)(3):42 U.S.C. §242m(d), (b)(6)

The SMEs agreed that the patient should not receive dose #2 of the Pfizer-BioNTech vaccine. Regarding other routine vaccines, CISA SMEs provided guidance that the patient should follow-up with an (b)(3):42 to determine which vaccines can safely be given.

Additionally, CISA SMEs discussed whether additional testing is warranted for this patient and agreed the patient should follow up with an (b)(3):42 that can properly evaluate (b)(3): 42 for (b)(3):4 (b)(3):42 U.S.C. §242m(d), (b)(6) CISA SMEs discussed there is a possibility this patient might have (b)(3):42 U.S.C. §242m(d), (b)(6) but there is no test currently available and validated for clinical use that can confirm this. An (b)(3):42 on the call suggested that given this patient's history of (b)(3):42 U.S.C. §242m(d), (b)(6) should be collected.

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 and result of (b)(3): follow-up with (b)(3):42 U.S.C.

Sincerely,

(b)(3):42 U.S.C. §242m(d), (b)(6)

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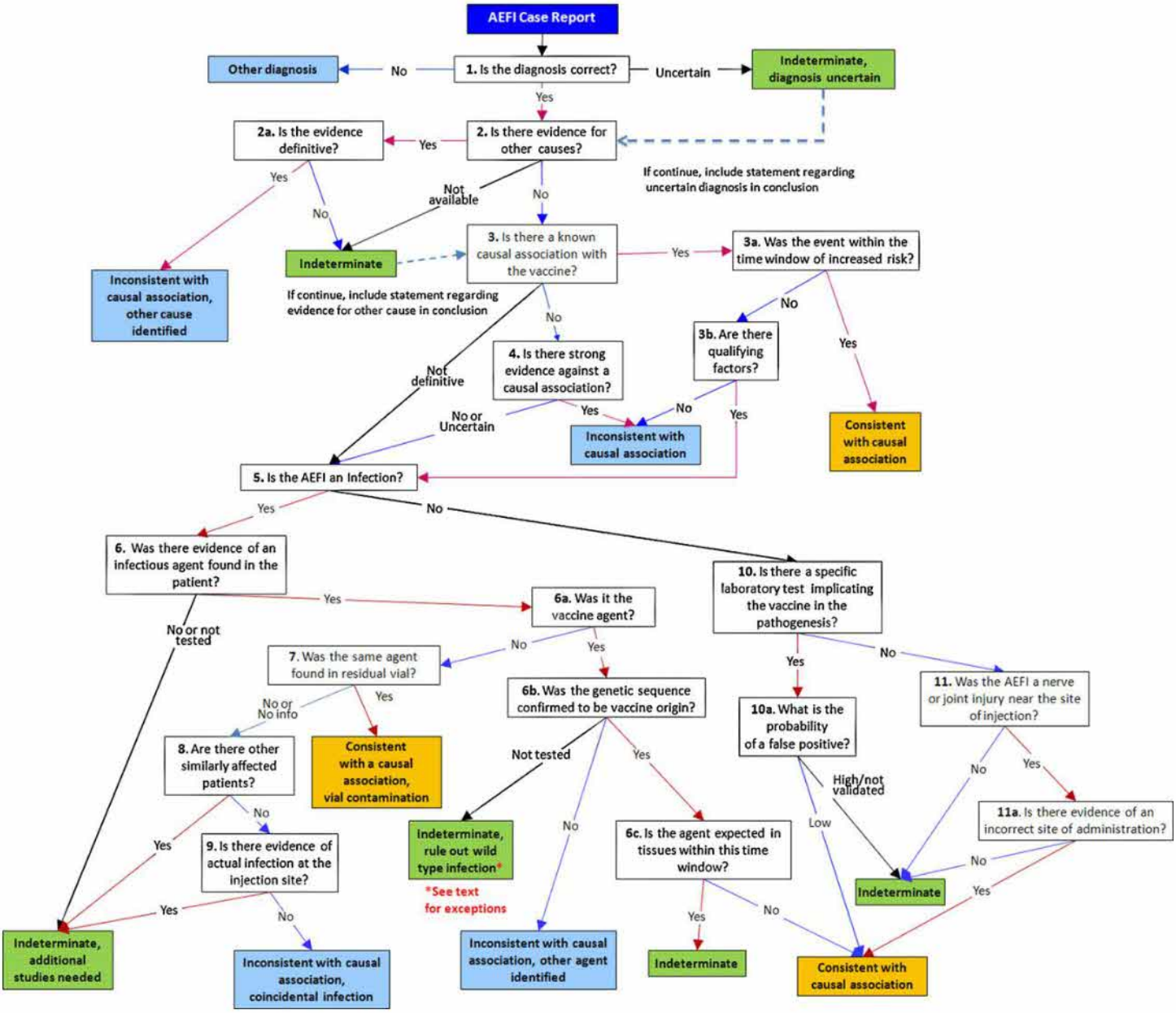
References

1. Halsey NA, Edwards KM, et al, Causality Working Group of the Clinical Immunization Safety Assessment network, *Vaccine*. 2012 Aug 24;30(39):5791-8. Epub 2012 Apr 14.
2. [redacted]
3. (b)(3) 42 U.S.C. §242m(d), (b)(6)



(b)(3):42 U.S.C. §242m(d), (b)(6)

January 22, 2021

(b)(3):42 U.S.C. §242m(d), (b)(6)

On behalf of the Clinical Immunization Safety Office (CISA) Project, thank you for the opportunity to review the case of your (b)(3):42 U.S.C. (b)(3):42 patient who was diagnosed with an (b)(3):42 U.S.C. §242m(d), (b)(6) following receipt of the Pfizer-BioNTech COVID-19 vaccine. CISA was asked to review the case to assess whether the diagnosis was correct, if receipt of the Pfizer-BioNTech 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 December 30, 2020 by the CISA Clinical Consultation Case Review Working Group, which includes vaccine safety experts, as well as subject matters experts (SME) in i (b)(3):42 U.S.C. §242m(d), (b)(6)

The following questions were posed:

1. Is the diagnosis correct?
2. Did the vaccine cause or contribute to the AEFI?
3. What is CISA guidance regarding future vaccines for this patient?
    a. COVID-19 vaccine?
    b. Routine vaccines?
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, and package insert information on the Pfizer-BioNTech COVID-19 vaccine.

The SMEs agreed that the patient's symptoms were indicative of an (b)(3):42 U.S.C. §242m(d), (b)(6) but her symptoms did not meet the Brighton Collaboration criteria for (b)(3):42 U.S.C. The SMEs assessed whether the diagnosis was causally related to the receipt of the Pfizer-BioNTech COVID-19 vaccine using the causality algorithm (see diagram and reference below). The application of the causality algorithm resulted in "Consistent with Causal Association" because this patient's (b)(3):42 is a known possible AEFI with this vaccine.

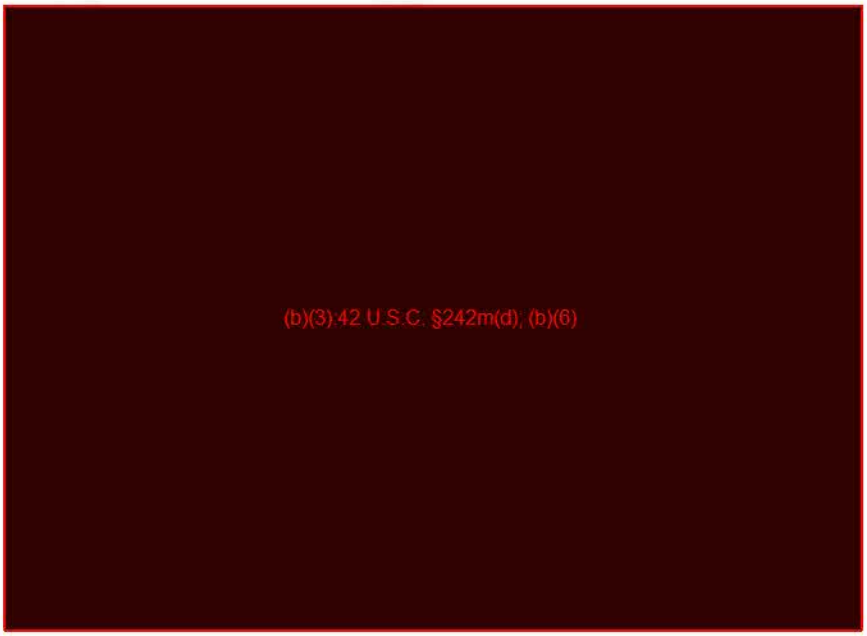
(b)(3):42 U.S.C. §242m(d), (b)(6)

The SMEs agreed that the patient should not receive dose #2 of the Pfizer-BioNTech vaccine. Regarding other routine vaccines, CISA SMEs provided guidance that the patient should follow-up with an (b)(3):42 to determine which vaccines can safely be given.

Additionally, CISA SMEs discussed whether additional testing is warranted for this patient and agreed the patient should follow up with an (b)(3):42 that can properly evaluat (b)(3): 42 for (b)(3):42 (b)(3):42 U.S.C. §242m(d); (b)(6) CISA SMEs discussed there is a possibility this patient might have (b)(3):42 U.S.C. §242m(d); (b)(6) but there is no test currently available and validated for clinical use that can confirm this. CISA did not offer strong guidance for this patient to have a (b)(3):42 U.S.C. done, but it was noted that it would not be wrong to do.

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 and result of (b)(3): 42 follow-up with (b)(3):42 U.S.C. §242m(d); (b)(6)

Sincerely,



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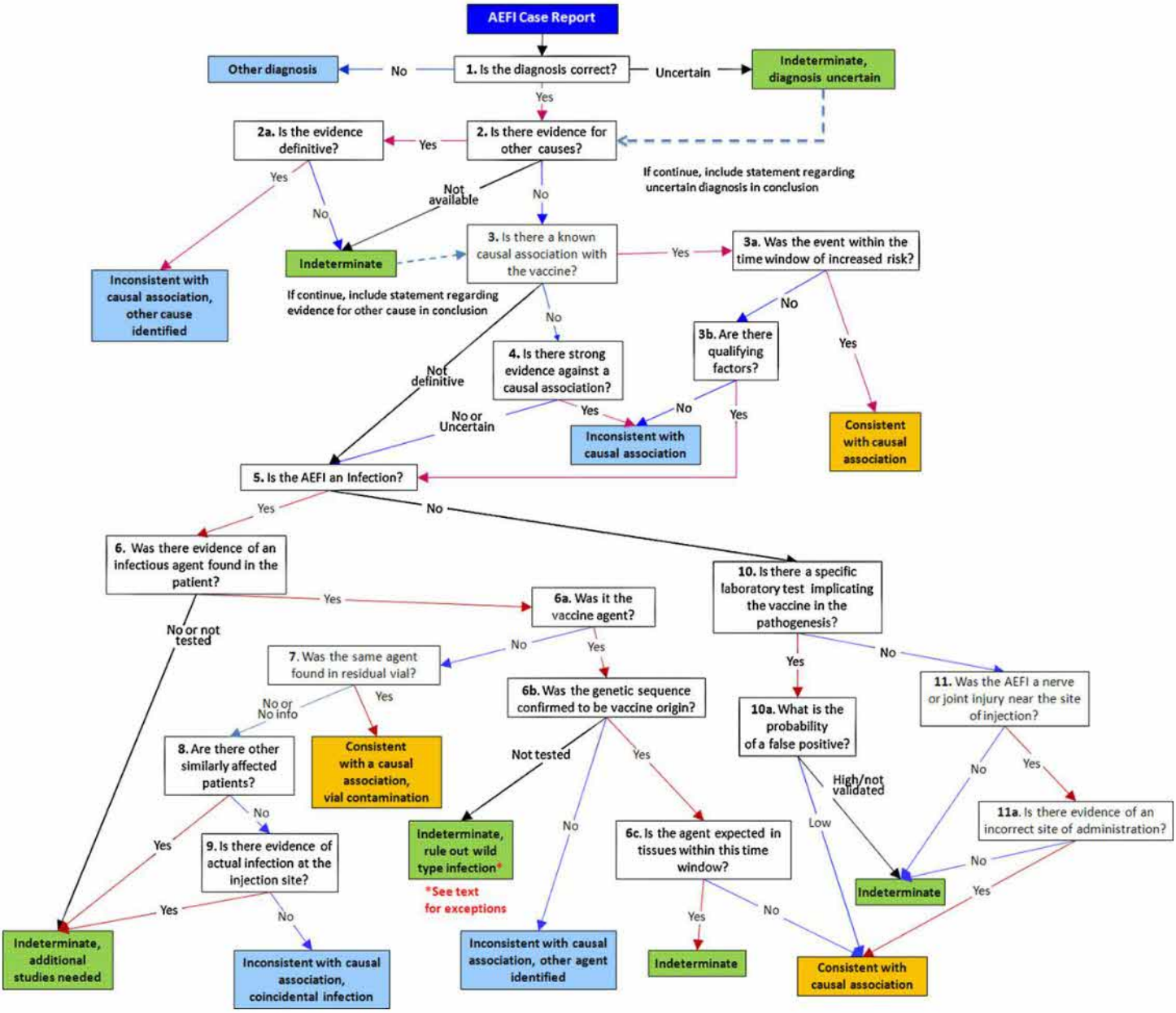
References

1. Halsey NA, Edwards KM, et al, Causality Working Group of the Clinical Immunization Safety Assessment network, *Vaccine*. 2012 Aug 24;30(39):5791-8. Epub 2012 Apr 14.
2. [redacted]
3. (b)(3) 42 U.S.C. §242m(d), (b)(6)



(b)(3):42 U.S.C. §242m(d), (b)(6)

February 23, 2021

(b)(3):42 U.S.C. §242m(d), (b)(6)

On behalf of the Clinical Immunization Safety Office (CISA) Project, thank you for the opportunity to review the case of your (b)(3):42 U.S.C. (b)(3):42 patient who was diagnosed with (b)(3):42 U.S.C. (b)(3):42 U.S.C. §242m(d), (b)(6) following recent COVID-19 illness and receipt of the Pfizer/BioNTech mRNA COVID-19 vaccine. CISA was asked to review the case to assess whether the diagnosis was correct, if receipt of Pfizer/BioNTech 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 January 13, 2021 by the CISA Clinical Consultation Case Review Working Group, which includes vaccine safety experts, as well as subject matters experts (SME) in (b)(3):42 U.S.C. §242m(d), (b)(6)

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, and Vaccine Adverse Event Reporting Systems (VAERS) search results, and package insert information on the Pfizer/BioNTech vaccine.

The SMEs agreed that (b)(3):4 was the correct diagnosis using the CDC working definition. When using the Brighton Collaboration definition (see link below), the case was less clear, given the history of illness prior to vaccination, which the definition was not developed to consider. The determination of whether the vaccine played a role in this patient developing (b)(3):42 was a complicated one, because the (b)(3):42 U.S.C. (b)(3):42 U.S.C. alone could have triggered the (b)(3):42, and it is unclear what, if any role the vaccine played. We usually utilize the causality assessment tool to help determine the role that the vaccine might play in the adverse event (see reference below), however, the tool was not developed to assess questions of disease enhancement.

When polled the SMEs agreed that the patient should not receive future vaccinations with a COVID-19 vaccine, due to the significant serious symptoms (b)(3) experienced after dose #1. In addition, recent data suggests that the immune responses in those with (b)(3),42 U.S.C. §242m(d), (b)(6) is excellent after one dose of vaccine (see references below).

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. We would appreciate your response to this survey.

Sincerely,

(b)(3),42 U.S.C. §242m(d), (b)(6)

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References

1. Halsey NA, Edwards KM, et al, Causality Working Group of the Clinical Immunization Safety Assessment network, *Vaccine*. 2012 Aug 24;30(39):5791-8. Epub 2012 Apr 14.
2.
3.
4.

(b)(3),42 U.S.C. §242m(d), (b)(6)

(b)(3):42 U.S.C. §242m(d), (b)(6)

February 10, 2021

(b)(3):42 U.S.C. §242m(d), (b)(6)

On behalf of the Clinical Immunization Safety Office (CISA) Project, thank you for the opportunity to review the case of your (b)(3):42 U.S.C. (b)(3) patient who was diagnosed with (b)(3):42 (b)(3):4 following receipt of the Pfizer-BioNTech COVID-19 mRNA vaccine. CISA was asked to review the case to assess whether the diagnosis was correct, if receipt of Pfizer mRNA 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 January 20, 2021 by the CISA Clinical Consultation Case Review Working Group, which includes vaccine safety experts, as well as subject matters experts (SME) in (b)(3):42 U.S.C. §242m(d), (b)(6) (b)(3):42 U.S.C. §242m(d), (b)(6)

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. COVID-19 vaccine?
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, and Vaccine Adverse Event Reporting Systems (VAERS) search results, and package insert information on the Pfizer-BioNTech COVID-19 mRNA vaccine.

The SMEs agreed that (b)(3):42 U.S.C. was the correct diagnosis and that this case met the criteria for a Brighton Collaboration Level 1 of diagnostic certainty. CISA SMEs assessed whether the diagnosis was causally related to the receipt of the Pfizer-BioNTech COVID-19 mRNA vaccine using the causality algorithm (see diagram and reference below). The application of the causality algorithm resulted in an assessment of "indeterminate" because of a lack of current evidence to support a causal link between the diagnosis and COVID-19 mRNA vaccines.

(b)(3):42 U.S.C. §242m(d), (b)(6)

In addition, the SMEs agreed that the patient should receive dose two of the Pfizer-BioNTech COVID-19 mRNA vaccine after the [redacted] associated with [redacted] are mostly resolved. The Working Group did not recommend any further testing or clinical follow up.

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 within the next two months to assess whether the patient has received additional vaccines and how [redacted] olerated them.

Sincerely,

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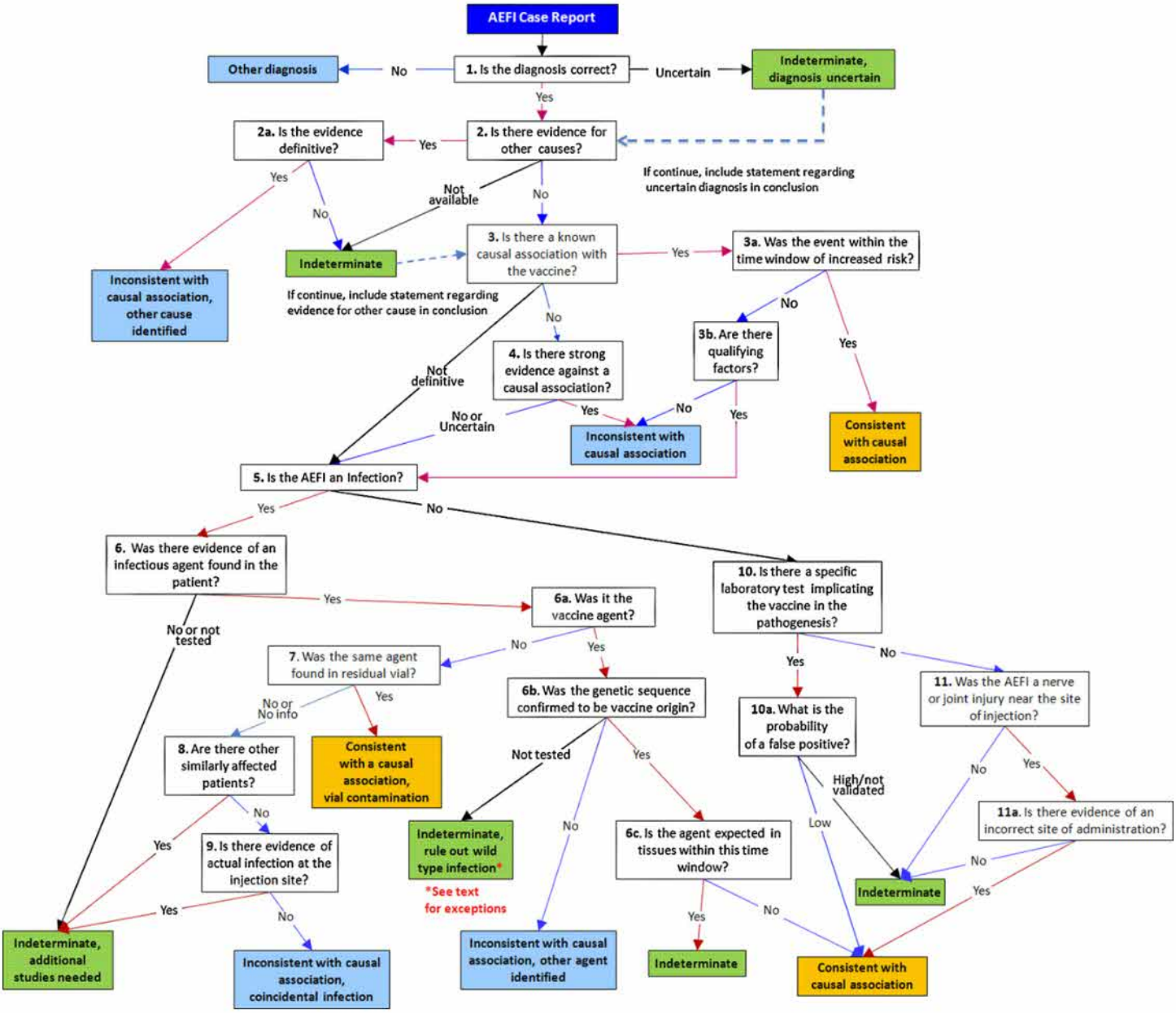
References

1. (b)(3) 42 U.S.C. §242m(d); (b)(6)

2. Algorithm to assess causality after individual adverse events following immunizations. *Vaccine*. 2012 Aug 24;30(39):5791-8. doi: 10.1016/j.vaccine.2012.04.005. Epub 2012 Apr 14.



(b)(3):42 U.S.C. §242m(d), (b)(6)

February 10, 2021

(b)(3):42 U.S.C. §242m(d), (b)(6)

On behalf of the Clinical Immunization Safety Office (CISA) Project, thank you for the opportunity to review the case of your (b)(3):42 U.S.C. §242m(d) (b)(3):42 patient who was diagnosed with (b)(3):42 (b)(3):4 following receipt of the Pfizer-BioNTech COVID-19 mRNA vaccine. CISA was asked to review the case to assess whether the diagnosis was correct, if receipt of Pfizer mRNA 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 January 20, 2021 by the CISA Clinical Consultation Case Review Working Group, which includes vaccine safety experts, as well as subject matters experts (SME) in (b)(3):42 U.S.C. §242m(d), (b)(6) (b)(3):42 U.S.C. §242m(d), (b)(6)

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. COVID-19 vaccine?
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, and Vaccine Adverse Event Reporting Systems (VAERS) search results, and package insert information on the Pfizer-BioNTech COVID-19 mRNA vaccine.

The SMEs agreed that (b)(3):42 U.S.C. §242m(d), (b)(6) was the correct diagnosis and that this case met criteria for a Brighton Collaboration Level 3 of diagnostic certainty. CISA SMEs assessed whether the diagnosis was causally related to the receipt of the Pfizer-BioNTech COVID-19 mRNA vaccine using the causality algorithm (see diagram and reference below). The application of the causality algorithm resulted in an assessment of "indeterminate". This assessment was made due to the patient's (b)(3):42 U.S.C. being a possible cause of the diagnosis of (b)(3):42 U.S.C. but this evidence

(b)(3):42 U.S.C. §242m(d), (b)(6)

for another cause is not definite (see algorithm below). Further, current evidence does not support a causal link between the diagnosis and COVID-19 mRNA vaccines.

In addition, the SMEs agreed that the patient should receive dose two of the Pfizer-BioNTech COVID-19 mRNA vaccine after the [redacted] associated with [redacted] are mostly resolved. The Working Group did not recommend any further testing or clinical follow up.

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 within the next two months to assess whether the patient has received additional vaccines and how [redacted] tolerated them.

Sincerely,

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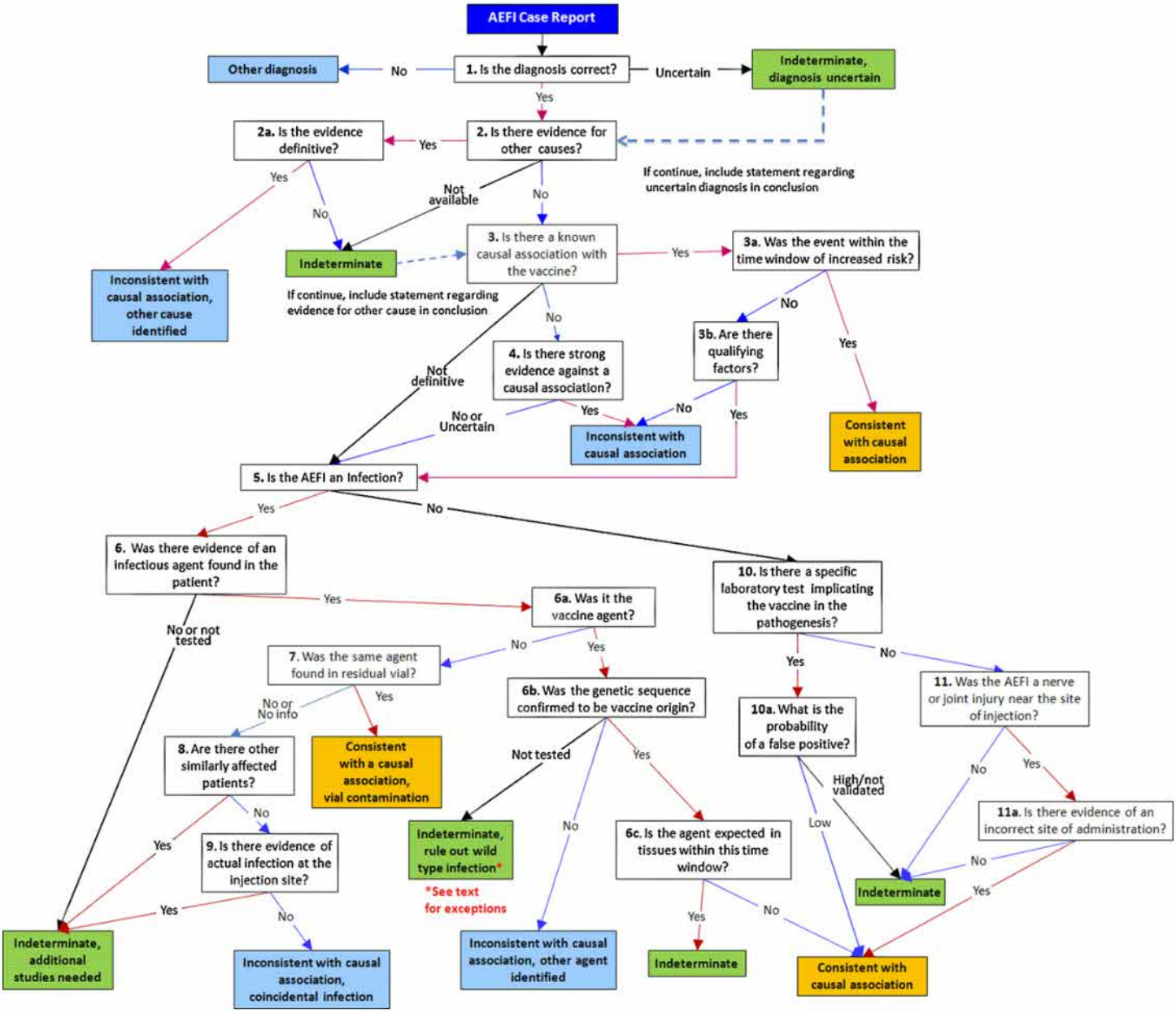
References

1. (b)(3):42 U.S.C. §242m(d); (b)(6)

2. Algorithm to assess causality after individual adverse events following immunizations. *Vaccine*. 2012 Aug 24;30(39):5791-8. doi: 10.1016/j.vaccine.2012.04.005. Epub 2012 Apr 14.



(b)(3):42 U.S.C. §242m(d), (b)(6)

February 10, 2021

(b)(3):42 U.S.C. §242m(d), (b)(6)

On behalf of the Clinical Immunization Safety Office (CISA) Project, thank you for the opportunity to review the case of your (b)(3):42 U.S.C. §242m(d), (b)(6) (b)(3):42 patient who was diagnosed with (b)(3):42 U.S.C. (b)(3):4 following receipt of the Pfizer-BioNTech COVID-19 mRNA vaccine. CISA was asked to review the case to assess whether the diagnosis was correct, if receipt of Pfizer mRNA 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 January 20, 2021 by the CISA Clinical Consultation Case Review Working Group, which includes vaccine safety experts, as well as subject matters experts (SME) in (b)(3):42 U.S.C. §242m(d), (b)(6) (b)(3):42 U.S.C. §242m(d), (b)(6)

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. COVID-19 vaccine?
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, and Vaccine Adverse Event Reporting Systems (VAERS) search results, and package insert information on the Pfizer-BioNTech COVID-19 mRNA vaccine.

The SMEs agreed tha (b)(3):42 U.S.C. §242m(d), (b)(6) was the correct diagnosis and that this case met the criteria for a Brighton Collaboration Level 3 of diagnostic certainty. CISA SMEs assessed whether the diagnosis was causally related to the receipt of the Pfizer-BioNTech COVID-19 mRNA vaccine using the causality algorithm (see diagram and reference below). The application of the causality algorithm resulted in an assessment of "indeterminate." This assessment was made due to the patient's (b)(3):42 U.S.C. being a possible cause of the diagnosis of (b)(3):42 U.S.C. but this evidence

(b)(3):42 U.S.C. §242m(d), (b)(6)

for another cause is not definite (see algorithm below). Further, current evidence does not support a causal link between the diagnosis and COVID-19 mRNA vaccines.

In addition, the SMEs agreed that the patient should receive dose two of the Pfizer-BioNTech COVID-19 mRNA vaccine after the (b)(3):42 U.S.C associated with (b)(3):42 U.S.C §242m(d), (b)(6) are mostly resolved. The Working Group did not recommend any further testing or clinical follow up.

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 within the next six months to assess whether the patient has received additional vaccines and how (b)(3):42 U.S.C. §242m(d), (b)(6) erated them.

Sincerely,

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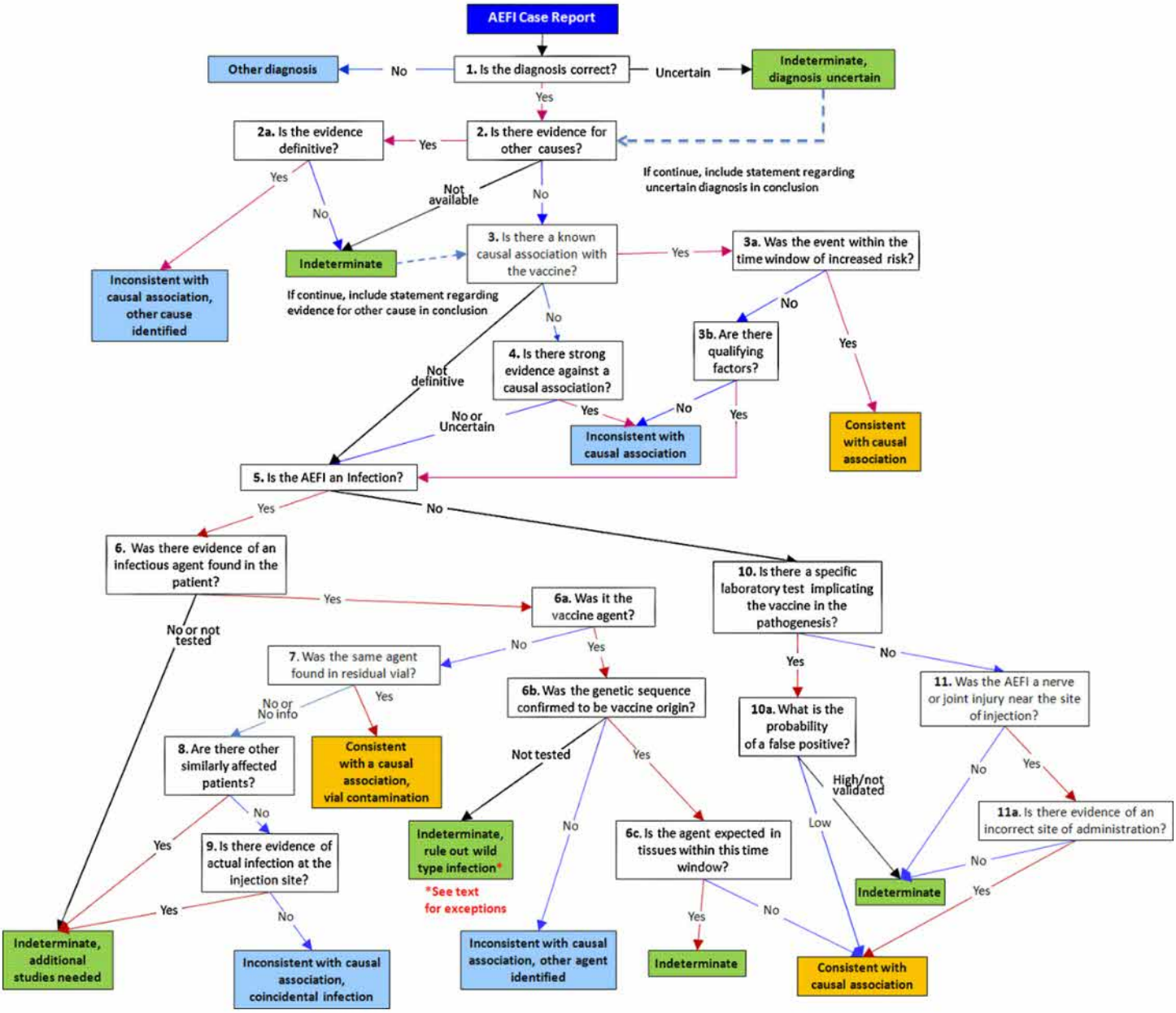
References

1. (b)(3):42 U.S.C. §242m(d); (b)(6)

2. Algorithm to assess causality after individual adverse events following immunizations. *Vaccine*. 2012 Aug 24;30(39):5791-8. doi: 10.1016/j.vaccine.2012.04.005. Epub 2012 Apr 14.



(b)(3) 42 U.S.C. §242m(d), (b)(6)

February 10, 2021

(b)(3) 42 U.S.C. §242m(d), (b)(6)

On behalf of the Clinical Immunization Safety Office (CISA) Project, thank you for the opportunity to review the case of your (b)(3) 42 U.S.C. (b)(3) 42 patient who was diagnosed with (b)(3) 42 U.S.C. (b)(3) 4 following receipt of the Pfizer-BioNTech COVID-19 mRNA vaccine. CISA was asked to review the case to assess whether the diagnosis was correct, if receipt of Pfizer mRNA 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 January 20, 2021 by the CISA Clinical Consultation Case Review Working Group, which includes vaccine safety experts, as well as subject matters experts (SME) in (b)(3) 42 U.S.C. §242m(d), (b)(6) (b)(3) 42 U.S.C. §242m(d), (b)(6)

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. COVID-19 vaccine?
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, and Vaccine Adverse Event Reporting Systems (VAERS) search results, and package insert information on the Pfizer-BioNTech COVID-19 mRNA vaccine.

The SMEs agreed that (b)(3) 42 U.S.C. §242m(d); (b)(6) was the correct diagnosis and that this case met the criteria for a Brighton Collaboration Level 3 of diagnostic certainty. CISA SMEs assessed whether the diagnosis was causally related to the receipt of the Pfizer-BioNTech COVID-19 mRNA vaccine using the causality algorithm (see diagram and reference below).

The application of the causality algorithm resulted in an assessment of

(b)(3) 42 U.S.C. §242m(d), (b)(6)

"indeterminate". This assessment was made due to the patient's (b)(3):42 U.S.C being a possible cause of the diagnosis of (b)(3):42 U.S.C, but this evidence for another cause is not definite (see algorithm below). Further, current evidence does not support a causal link between the diagnosis and COVID-19 mRNA vaccines.

In addition, the SMEs agreed that the patient should receive dose two of the Pfizer-BioNTech COVID-19 mRNA vaccine after the (b)(3):42 U.S.C associated with (b)(3):42 U.S.C §242m(d); (b)(6) are mostly resolved. The Working Group did not recommend any further testing or clinical follow up.
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 within the next six months to assess whether the patient has received additional vaccines and how (b)(3):42 olerated them.

Sincerely,

Disclaimer:
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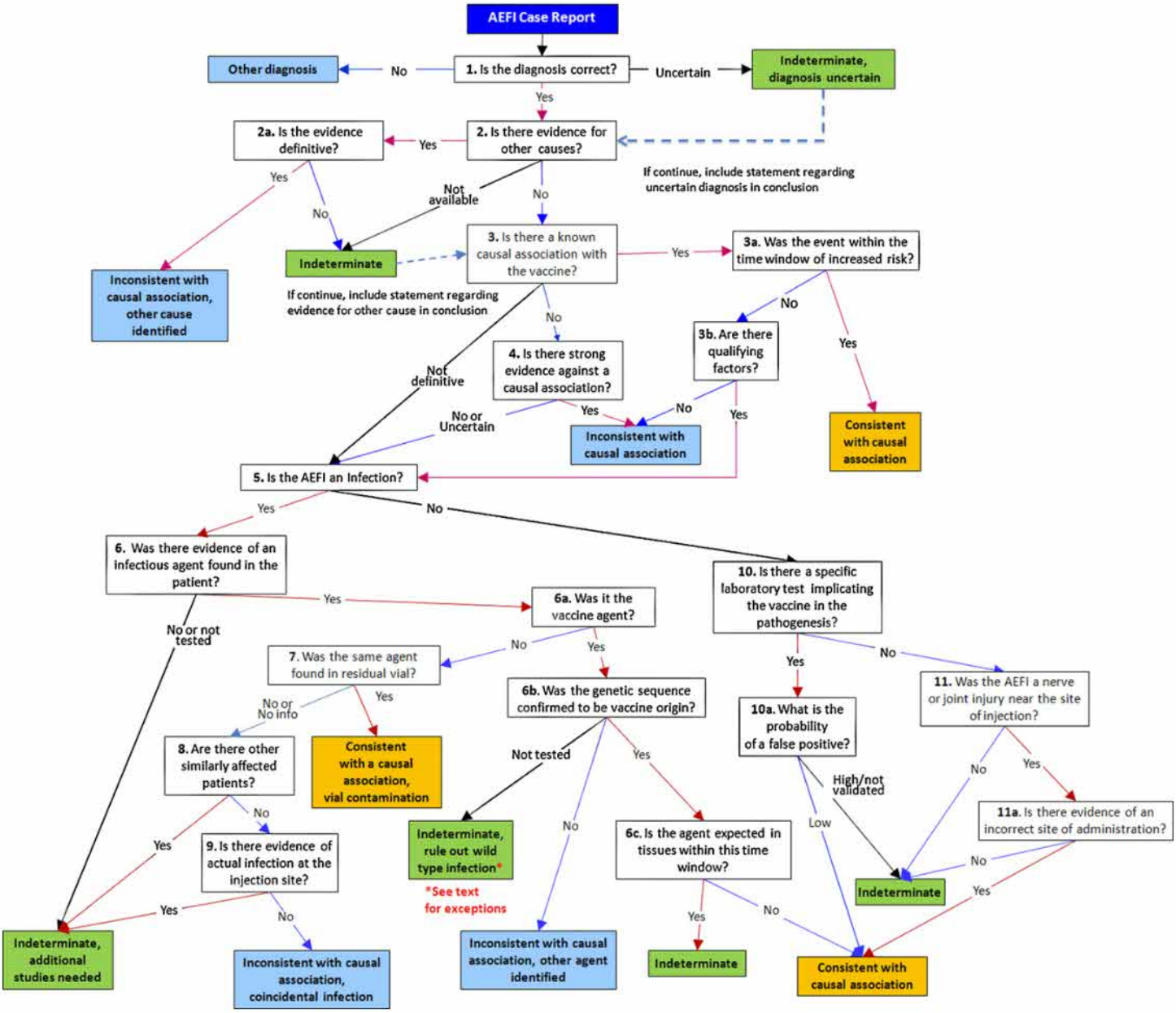
References

1. (b)(3) 42 U.S.C. §242m(d); (b)(6)

2. Algorithm to assess causality after individual adverse events following immunizations. *Vaccine*. 2012 Aug 24;30(39):5791-8. doi: 10.1016/j.vaccine.2012.04.005. Epub 2012 Apr 14.



(b)(3):42 U.S.C. §242m(d), (b)(6)

March 17, 2021

(b)(3):42 U.S.C. §242m(d), (b)(6)

On behalf of the Clinical Immunization Safety Office (CISA) Project, thank you for the opportunity to review the case of your (b)(3):42 U.S.C. (b)(3) patient who was diagnosed with (b)(3):42 following receipt of the Moderna COVID-19 vaccine. CISA was asked to review the case to assess whether the diagnosis was correct, if receipt of Moderna 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 January 28.2021, by the CISA Clinical Consultation Case Review Working Group, which includes vaccine safety experts, as well as subject matters experts (SME) in (b)(3):42 U.S.C. §242m(d), (b)(6)

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, and Vaccine Adverse Event Reporting Systems (VAERS) search results, and package insert information on the Moderna COVID-19 vaccine.

The SMEs agreed that the diagnosis of (b)(3):42 U.S.C. §242m(d) was UNCERTAIN.

The patient did not have objective signs of (b)(3):42 It was assessed whether the diagnosis was causally related to the receipt of the Moderna COVID-19 Vaccine using the causality algorithm (see diagram and reference below). The application of the causality algorithm resulted in a designation of INDETERMINATE because the diagnosis is uncertain. The patient did not meet the Brighton Criteria for (b)(3):42 .

In addition, the SMEs agreed that the patient should not receive future vaccinations(s) with a COVID-19 vaccine. The SMEs agreed that the patient should have follow up with an (b)(3):42 U.S.C. for further evaluation and testing.

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 within the next six months to assess whether the patient has received additional vaccines and how (b)(3): 42 U.S.C. tolerated them.

Sincerely,

Disclaimer:

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(b)(3):42 U.S.C. §242m(d), (b)(6)

March 18, 2021

(b)(3):42 U.S.C. §242m(d), (b)(6)

On behalf of the Clinical Immunization Safety Office (CISA) Project, thank you for the opportunity to review the case of your (b)(3):42 (b)(3):42 U.S.C. §242m(d), patient who developed (b)(3):42 after a presumed COVID-19 illness. CISA was asked to review the case to assess whether the diagnosis was correct, and to provide guidance as to whether receipt of the COVID-19 vaccine might exacerbate (b)((b)(3):42 U.S.C.

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 February 3, 2021 by the CISA Clinical Consultation Case Review Working Group, which includes vaccine safety experts, as well as subject matters experts (SME) in (b)(3):42 U.S.C. §242m(d), (b)(6)

The following questions were posed:

1. Is the diagnosis correct?
2. What are the recommendations for future SARS-CoV-2 vaccination?
    a. Is there added risk for (b)(3):42 U.S.C. §242m(d), (b)(6) ?
    b. Should (b)(3 receive the vaccine?
    c. When should (b)(be vaccinated?
    d. Is there a specific SARS-CoV-2 vaccine (b)(should get or avoid?
3. Is any additional testing warranted?
4. 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, and Vaccine Adverse Event Reporting Systems (VAERS) search results, and FDA emergency use authorization information on the mRNA COVID-19 vaccine.

There was a long discussion as to whethe (b)(3):4 (b)(3):42 was due to (b)(3):42 U.S.C. §242m(d), infection, since, while (b)(3): symptoms were consistent with (b)(3):42 (b)(3) didn't have laboratory confirmation. It is also unknown if there is any increased risk in those with p (b)(3):42 U.S.C. §242m(d), (b)(6) in receipt of the COVID-19 vaccine. The SMEs suggested that given the lack of data around this question, the information should be given to the patient and to allow for shared decision making based on the risks and benefits of vaccination vs. not vaccinating. In general, they would recommend vaccinating, with (b)(3):42 U.S.C. to ensure no abnormalities. As to the question of whether there is further risk of (b)(3):42 U.S.C. §242m(d), , while there is the theoretical potential, there has been no data to date to support this. While unlikely, in this patient's family, there seems to be a risk of (b)(3):42 U.S.C. that would warrant close monitoring, and the question of familial (b)(3):42 U.S.C. should be considered. At the time of

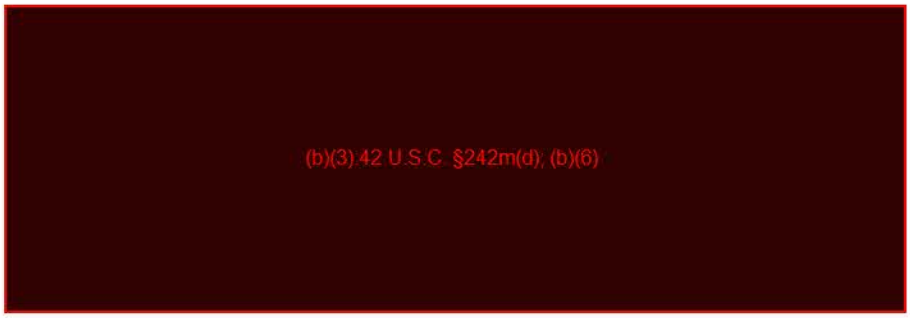
the discussion, there were only the mRNA vaccines available, but we do not believe that there is enough information to recommend one kind of vaccine vs. another. They recommended NO pretreatment with (b)(3):42 U.S.C. §242m(d), (b)(6) before vaccination so as to not blunt the (b)(3):42 U.S.C. however if (b)(3):42 develops symptoms, quick treatment would be warranted. The SMEs did recommend getting a (b)(3):4

(b)(3):42 U.S.C. §242m(d), (b)(6)

With regard to routine vaccinations, (b)(can receive any other vaccine once (b)(3):42 has recovered or (b)(3 condition is improving. The ACIP General Best Practices considers a moderate or severe acute illness to be a precaution for vaccination: https://www.cdc.gov/vaccines/hcp/acip-recs/general-recs/contraindications.html

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 within the next six months to assess whether the patient has received additional vaccines and how (b)(3):42 tolerated them.

Sincerely,



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(b)(3):42 U.S.C. §242m(d), (b)(6)

March 9, 2021

(b)(3):42 U.S.C. §242m(d), (b)(6)

On behalf of the Clinical Immunization Safety Office (CISA) Project, thank you for the opportunity to review the case of your (b)(3):42 U.S.C. (b)(3)' patient who was diagnosed with (b)(6) following receipt of the Moderna COVID-19 vaccine. CISA was asked to review the case to assess whether the diagnosis was correct, if receipt of the Moderna 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 February 17, 2021 by the CISA Clinical Consultation Case Review Working Group, which includes vaccine safety experts, as well as subject matters experts (SME) in (b)(3):42 U.S.C. §242m(d), (b)(6) (b)(3):42 U.S.C. §242m(d).

The following questions were posed:

1. Is the diagnosis correct?
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?

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 package insert information on the Moderna COVID-19 vaccine.

The SMEs assessed that the diagnosis of the patient's (b)(3):42 U.S.C. §242m(d), (b)(6) may have represented a variant of (b)(3):42 U.S.C. §242m(d), (b)(6); however, included among the differential diagnoses for this patient's clinical presentation and course of illness are (b)(3):42 U.S.C. or a (b)(3):42 U.S.C. §242m(d), (b)(6) Additional (b)(3):42 U.S.C. §242m(d), (b)(6) would have been helpful to exclude these other diagnoses; however, we understand that the community

(b)(3):42 U.S.C. §242m(d), (b)(6)

hospital where your patient was hospitalized lacks (b)(3) 42 U S C capability. The SMEs assessed whether the diagnosis of (b)(3) 42 was causally related to the receipt of the Moderna COVID-19 vaccine using the causality algorithm (see diagram and reference below). The application of the causality algorithm resulted in "indeterminate", in part because the diagnosis of (b)(3) 42 was not definitive.

The SMEs agreed that there is no contraindication to this patient receiving dose #2 of the Moderna COVID-19 vaccine and other routine vaccines.

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.

Sincerely,

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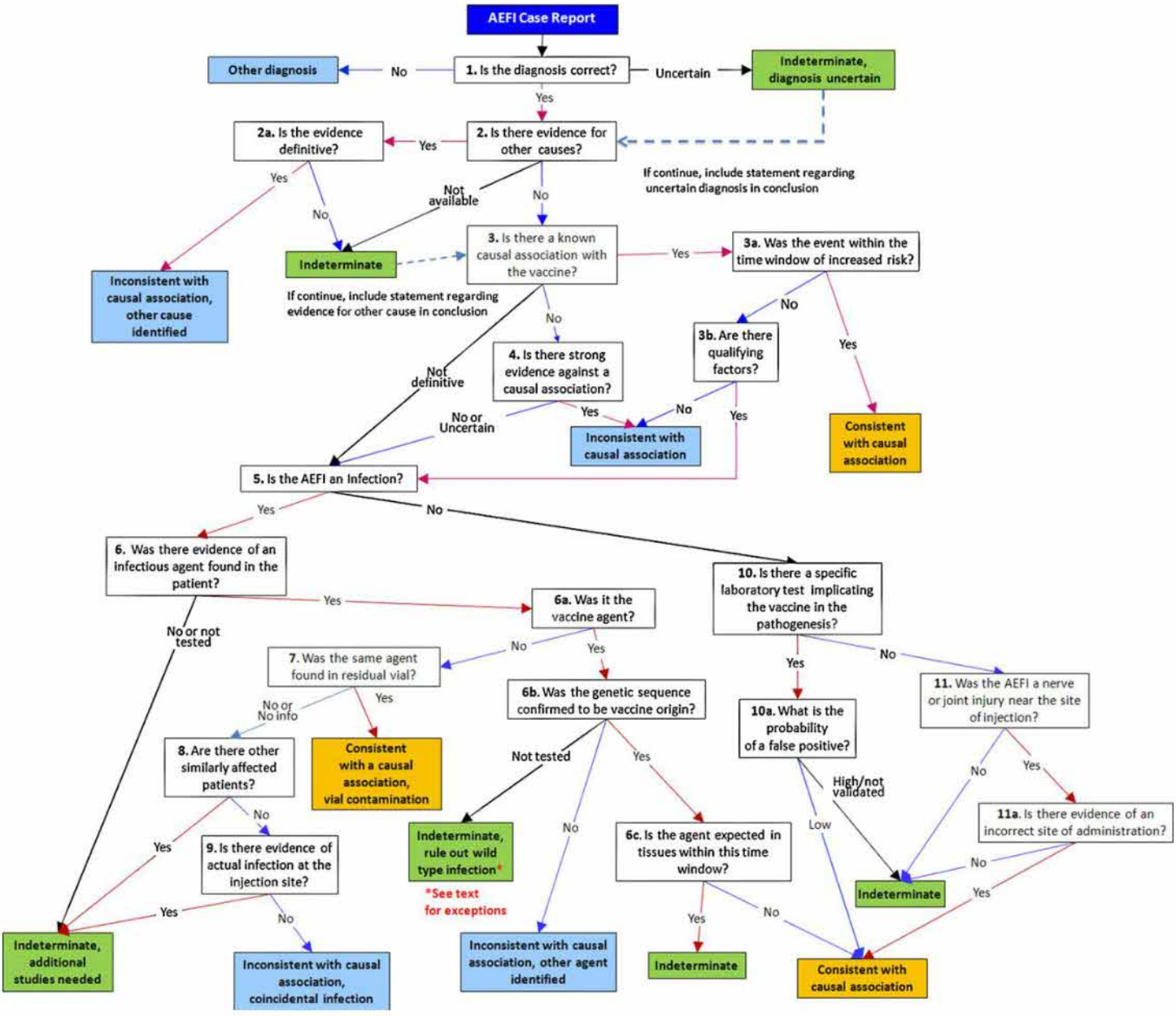
References

1. Halsey NA, Edwards KM, et al, Causality Working Group of the Clinical Immunization Safety Assessment network, *Vaccine*. 2012 Aug 24;30(39):5791-8. Epub 2012 Apr 14.
2. (b)(3) 42 U.S.C §242m(d), (b)(6)



(b)(3):42 U.S.C. §242m(d), (b)(6)

March 31, 2021

(b)(3):42 U.S.C. §242m(d), (b)(6)

On behalf of the Clinical Immunization Safety Office (CISA) Project, thank you for the opportunity to review the case of your (b)(3):42 U.S.C. (b)(3) patient who was diagnosed with (b)(3):42 U.S.C. §242m(d), (b)(6) (b)(3):42 following receipt of the first dose of Pfizer COVID-19 vaccine. CISA was asked to review the case to assess whether the diagnosis was correct, if receipt of the 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 February 17, 2021 by the CISA Clinical Consultation Case Review Working Group, which includes vaccine safety experts, as well as subject matters experts (SME) in (b)(3):42 U.S.C. §242m(d), (b)(6)

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. COVID-19 Vaccine dose 2?
    b. Routine vaccines?
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, and Vaccine Adverse Event Reporting Systems (VAERS) search results, and the FDA emergency use authorization information on the Pfizer COVID-19 vaccine.

The SMEs agreed that (b)(3):42 was the correct diagnosis and assessed whether the diagnosis was causally related to the receipt Pfizer mRNA COVID-19 vaccine using the causality algorithm (see diagram and reference below). The application of the causality algorithm resulted in **Indeterminate** because while there is no known causal association between the vaccine and (b)(3) there is not strong evidence of there was no clear evidence of another cause of the (b)(3) although it is possible that (b)(3):42 U.S.C. §242m(d) may have been the cause, and there is not strong evidence against a causal association.

The SMEs did suggest that if possible, blood be sent to a reference lab (e.g. B (b)(3):42 U.S.C. §242m(d), (b)(6) (b)(3):42 U.S.C. §242m(d), (b)(6) . They can look for evidence of (b)(3):42 U.S.C. §242m(d), (b)(6) including

against the medications that (b)(3) is taking. In addition, the SMEs agreed that if possible, it would be good to test the patient for previous COVID-19 infection by looking for anti-nucleocapsid antibodies. There is increasing evidence that in those with previous infection, one dose of vaccine is likely sufficient for protection.

Given (b)(receipt of IVIG, we would not give a second dose in any case for 3 months, as we are not sure what the level of anti-SARS-CoV-2 antibodies are in IVIG. We also recommend waiting until (b)(3 (b)(3) completely resolves, and then reassessing (b)(3 need for a second dose 3 months after (b)(illness.

In regards to routine vaccinations (b)(can receive any other vaccine according to need/schedule with the exception that a measles containing vaccine should not be given for 8-11 months after receipt of the IVIG.

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 within the next six months to assess whether the patient has received additional vaccines and how (b)(tolerated them.

Sincerely,

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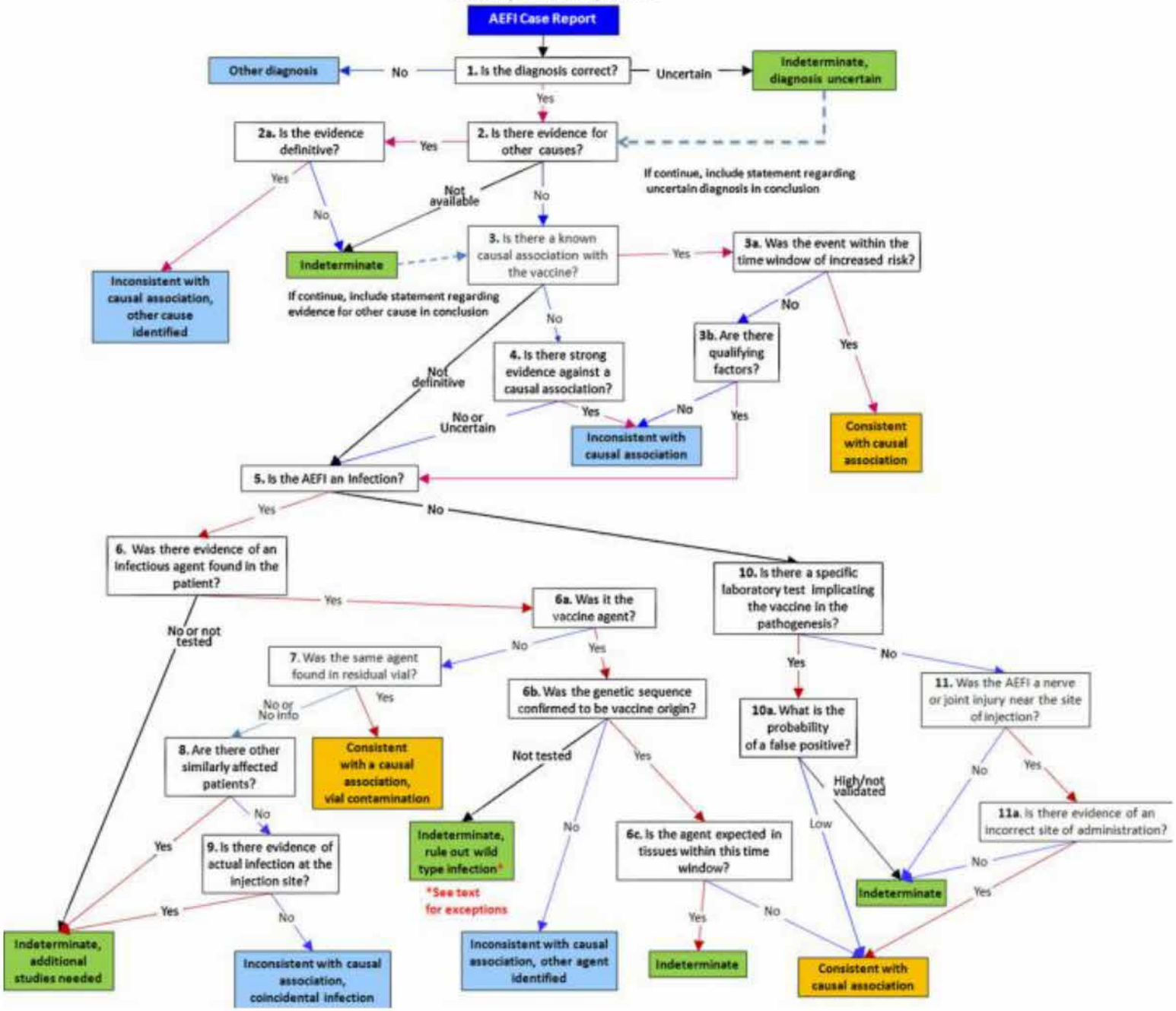
References

1. Halsey NA, Edwards KM, et al, Causality Working Group of the Clinical Immunization Safety Assessment network, *Vaccine*. 2012 Aug 24;30(39):5791-8. Epub 2012 Apr 14.

Review of Case Reports of Adverse Events Following Immunizations
February 28, 2012
Causality Work Group of CISA



(b)(3):42 U.S.C. §242m(d) ; (b)(5) ; (b)(6)

(b)(3):42 U.S.C. §242m(d) ; (b)(5) ; (b)(6)

(b)(5)

(b)(3):42 U.S.C. §242m(d); (b)(6)

March 18, 2021

(b)(3):42 U.S.C. §242m(d); (b)(6)

On behalf of the Clinical Immunization Safety Office (CISA) Project, thank you for the opportunity to review the case of your (b)(3):42 U.S.C. (b)(3):42 and patient who was diagnosed with (b)(3):42 U.S.C following receipt of the first dose of Pfizer COVID-19 vaccine. CISA was asked to review the case to assess whether the diagnosis was correct, if receipt of the 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 4, 2021 by the CISA Clinical Consultation Case Review Working Group, which includes vaccine safety experts, as well as subject matters experts (SME) in (b)(3):42 U.S.C. §242m(d); (b)(6)

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. Further COVID-19 vaccination?
    b. Routine vaccines?
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, and Vaccine Adverse Event Reporting Systems (VAERS) search results, and FDA emergency use authorization information on the Pfizer COVID-19 vaccine.

There was a long discussion as to whether (b)(3):42 U.S.C. §242m(d); (b)(6) was the correct diagnosis. While (b)(3) symptoms didn't meet the strict Brighton criteria (Reference below), in further discussion with our SME, it was assessed that (b)(3) likely had a (b)(3):42 U.S.C. §242m(d); (b)(6) CISA then assessed whether the diagnosis was causally related to the receipt Pfizer mRNA COVID-19 vaccine using the causality algorithm (see diagram and reference below). The application of the causality algorithm resulted in **Indeterminant** because while there is no known causal association between the vaccine and (b)(3) there was no evidence of another cause for (b)(3) symptoms, and there is not strong evidence against a causal association.

In regard to (b)(second dose of an mRNA vaccine, the SME felt that (b)(has a reasonable level of protection for now from (b)(first dose of vaccine, and that (b)(3):42 would need to just take appropriate precautions (b)(3):42 U.S.C. §242m(d), We recommend that (b)(3): wait one or two months to see if there is additional information, and also until (b)(3):4 is fully recovered from (b)(illness.

The only other test that we would recommend is a repeat (b)(3):42 U.S.C. we appreciate the exam by the (b)(3):42 U.S.C. §242m(d), but would recommend a thorough exam by a (b)(3):42 U.S.C.
In regard to routine vaccinations, (b)(3) :42 can receive any other vaccine once (b)(3):4 is fully recovered.

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 within the next six months to assess whether the patient has received additional vaccines and how (b)(3) tolerated them.

Sincerely,

(b)(3):42 U.S.C. §242m(d), (b)(6)

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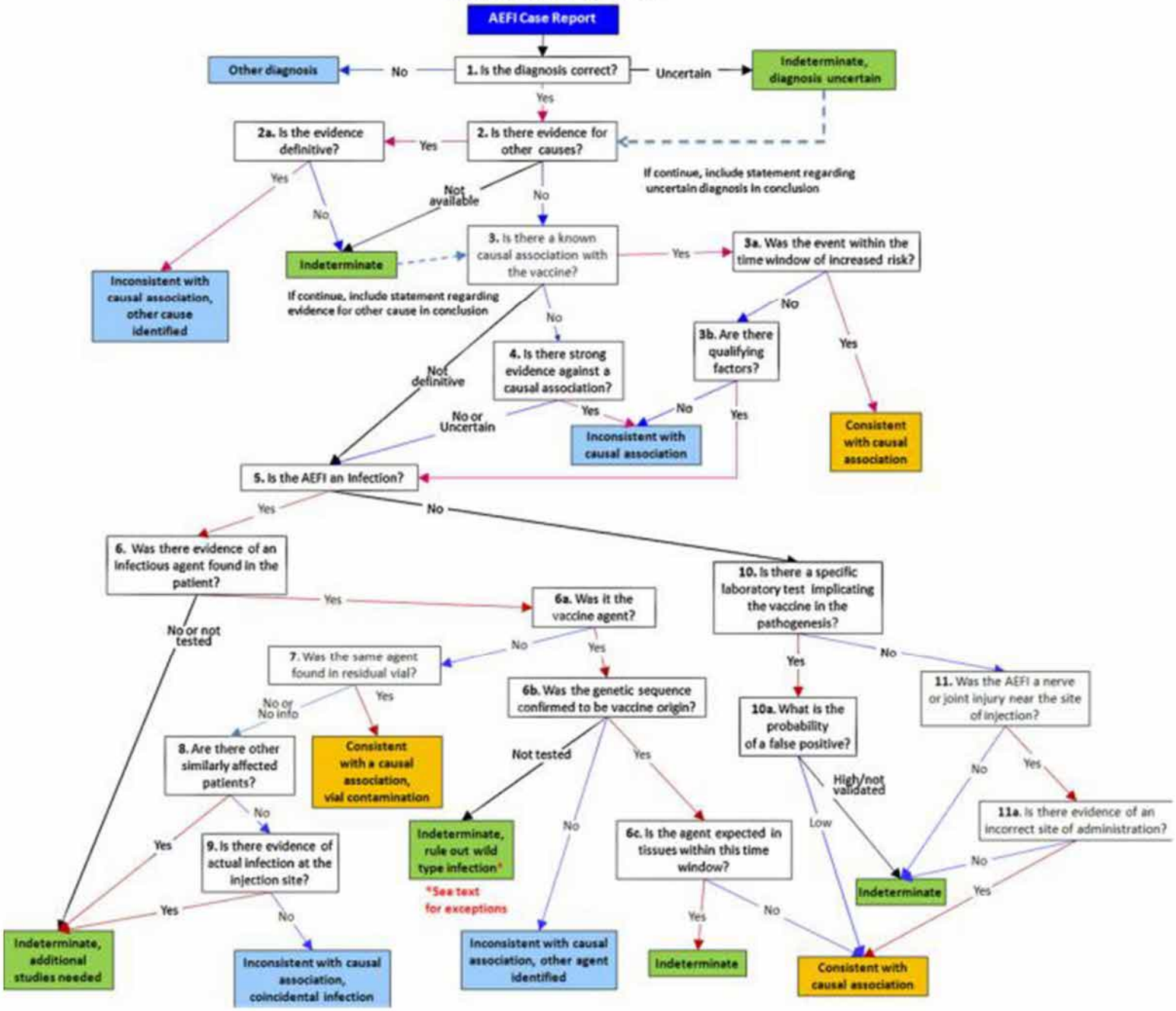
References

1. Halsey NA, Edwards KM, et al, Causality Working Group of the Clinical Immunization Safety Assessment network, *Vaccine*. 2012 Aug 24;30(39):5791-8. Epub 2012 Apr 14.
2. (b)(3):42 U.S.C. §242m(d), (b)(6)

Review of Case Reports of Adverse Events Following Immunizations
February 28, 2012
Causality Work Group of CISA



(b)(3):42 U.S.C. §242m(d); (b)(6)

May 24, 2021

(b)(3):42 U.S.C. §242m(d); (b)(6)

On behalf of the Clinical Immunization Safety Office (CISA) Project, thank you for the opportunity to review the case of your (b)(3):42 (b)(3):42 patient who developed e (b)(3):42 U.S.C. §242m(d); (b)(6) and (b)(3):42 U.S.C. §242m(d); (b)(6) approximately 8 hours after receiving (b)(first dose of Moderna COVID-19 vaccine on February 7, 2020, and was found to have a (b)(3):42 U.S.C. §242m(d); (b)(6) (b)(6). CISA was asked to provide guidance as to whether the patient should receive the second dose of the Moderna COVID-19 vaccine.

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 10, 2021 by the CISA Clinical Consultation Case Review Working Group, which includes vaccine safety experts, as well as subject matters experts (SME) in (b)(3):42 U.S.C. §242m(d); (b)(6)

The following questions were posed:

1. Is the diagnosis correct?
2. Did the vaccine cause or contribute to the AEFI?
3. What are the recommendations for future vaccines?
    a. Should (b)(3 receive the vaccine?
    b. When should (b)(3 be vaccinated?
    c. Is there a specific SARS-CoV-2 vaccine (b)(3 should get or avoid?
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, literature on myocardial infarction and vaccines, and FDA emergency use authorization information on the mRNA COVID-19 vaccines. Results from Vaccine Adverse Event Reporting Systems (VAERS) data mining and Vaccine Safety Datalink (VSD) analysis on a (b)(3):42 U.S.C. §242m(d); (b)(6) were also reviewed.

The SMEs agreed that (b)(3):42 was the correct diagnosis, and that the patient's symptoms and lab work were consistent with (b)(3):42 The SMEs assessed whether the diagnosis was causally related to the receipt of the Moderna COVID-19 vaccine using the causality algorithm (see diagram and reference below). The application of the causality algorithm resulted in "Indeterminate", due to the limited data available. Although currently there are no safety concerns or signals for (b)(3):42 at this time, more data are needed to conclude that (b)(is <u>not</u> associated with the Moderna COVID-19 vaccine.
CDC's Interim Clinical Considerations for Use of COVID-19 vaccines https://www.cdc.gov/vaccines/covid-19/info-by-product/clinical-considerations.html does not consider (b)(3) :42 as a contraindication or

precaution to COVID-19 vaccine, but does not specifically address the situation of a person who had an (b) after dose 1 mRNA vaccine. ACIP General Best Practices recommends that the presence of a moderate or severe acute illness with or without a fever is a precaution to administration of all vaccines (https://www.cdc.gov/vaccines/hcp/acip-recs/general-recs/contraindications.html.

CISA experts provided opinions regarding future COVID-19 vaccination for this patient. The SMEs agreed that the patient should not receive dose #2 of the Moderna COVID-19 vaccine at this time. Some experts suggested to delay administering dose #2 of the Moderna COVID-19 vaccine for approximately 2-3 months to collect additional safety data *and allow the patient more time to recover from the* (b)(3 The SMEs discussed potentially administering the Johnson & Johnson vaccine instead of administering the second Moderna COVID-19 vaccine, as the Johnson & Johnson vaccine is considered to be less reactogenic but noted the caveat that there is no data on the reactogenicity or use of the Johnson & Johnson vaccine after an mRNA COVID-19 vaccine. Use of mixed schedules is not routinely recommended in CDC guidance, which states: "…every effort should be made to determine which vaccine product was received as the first dose to ensure completion of the vaccine series with the same product."

After a temporary pause, the CDC and the U.S. Food and Drug Administration (FDA) lifted the pause on April 23, 2021, and recommended resumption of use of J&J/Janssen's COVID-19 vaccine in the United States. The Janssen (J&J) COVID-19 vaccine is a replication-incompetent adenoviral vector (human [Ad26.COV2.S] for J&J) that encodes the spike glycoprotein of SARS-CoV-2, the virus that causes COVID-19. At the time of writing this guidance letter, the Janssen (J&J) COVID-19 vaccine is the only non-mRNA COVID-19 vaccine available for use for your patient.

Health care providers administering the Janssen vaccine and vaccine recipients or caregivers should review the Janssen COVID-19 Vaccine Fact Sheet for Healthcare Providers Administering Vaccine (Vaccination Providers) and Fact Sheet for Recipients and Caregivers, which have been revised to include information about the risk of this (b)(3):42 U.S.C. §242m(d); (b)(6) which has occurred in a very small number of people who have received the Janssen COVID-19 Vaccine.

SMEs agreed that a future check-in meeting in 2-3 months would be beneficial to discuss these options and determine the next steps.

Additionally, CISA SMEs discussed whether additional testing is warranted for this patient and agreed that a (b)(3):42 U.S.C. to differentiate between (b)(3):42 U.S.C. §242m(d); (b)(6) could be beneficial.

With regards to routine vaccinations (b)(3): 42 can receive any other vaccine once (b)(3): 42 has recovered or (b)(3):4 condition is improving. As noted above the ACIP General Best Practices considers a moderate or severe acute illness to be a precaution for vaccination: https://www.cdc.gov/vaccines/hcp/acip-recs/general-recs/contraindications.html

We hope that we have fully addressed your questions and concerns. Please feel free to contact us if you have any further questions. 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 within the next six months to assess whether the patient has received additional vaccines and how (b)(3): 42 tolerated them.

Sincerely,

Disclaimer:
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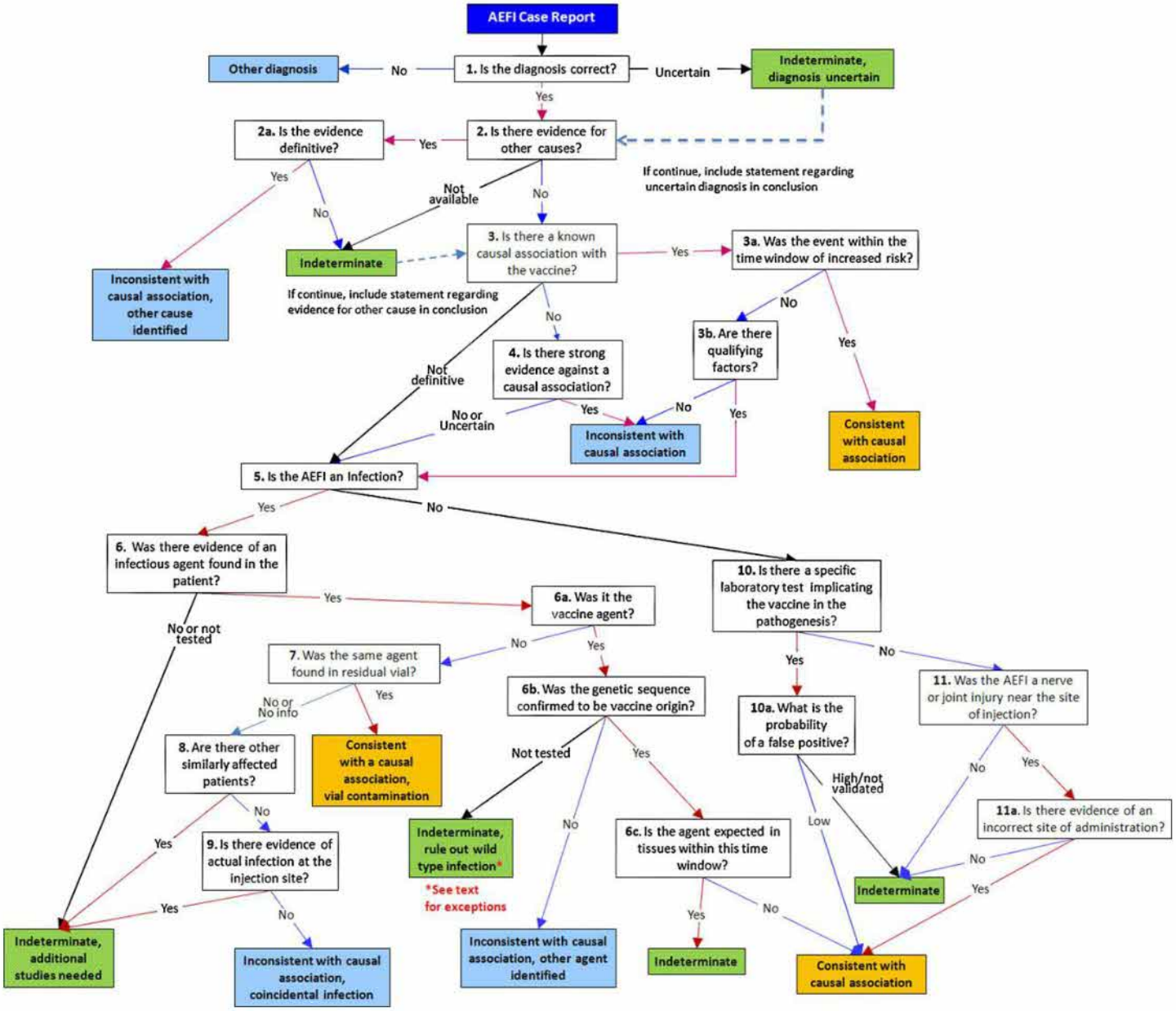
References

(b)(3):42 U.S.C. §242m(d), (b)(6)

4. Baden LR, El Sahly HM, Essink B, Kotloff K, Frey S, Novak R, et al. Efficacy and Safety of the mRNA-1273 SARS-CoV-2 Vaccine. N Engl J Med. 2021;384(5):403-16.

(b)(3):42 U.S.C. §242m(d), (b)(6)



(b)(3):42 U.S.C. §242m(d); (b)(6)

March 31, 2021

(b)(3):42 U.S.C. §242m(d); (b)(6)

On behalf of the Clinical Immunization Safety Office (CISA) Project, thank you for the opportunity to review the case of your (b)(3):42 U.S.C. (b)(3):42 patient who was diagnosed with (b)(3):4 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 (b)(3):42 U.S.C. §242m(d); (b)(6)

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 (b)(3):42

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 (b)(3):42 have been associated solely with COVID vaccine (that we know of); all patients to date had some evidence of (b)(3):42 U.S.C. §242m(d); (b)(6) Your patient, too, had (b)(3):42 U.S.C. §242m(d); (b)(6) as documented by a (b)(3):42 U.S.C. §242m(d); (b)(6) (b)(3):42 U.S.C. §242m(d); (b)(6). We are therefore unable to conclude that vaccine caused this case of (b)(3):4 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 (b)(3) 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 [redacted]. 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 (b)(3) tolerated them.

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

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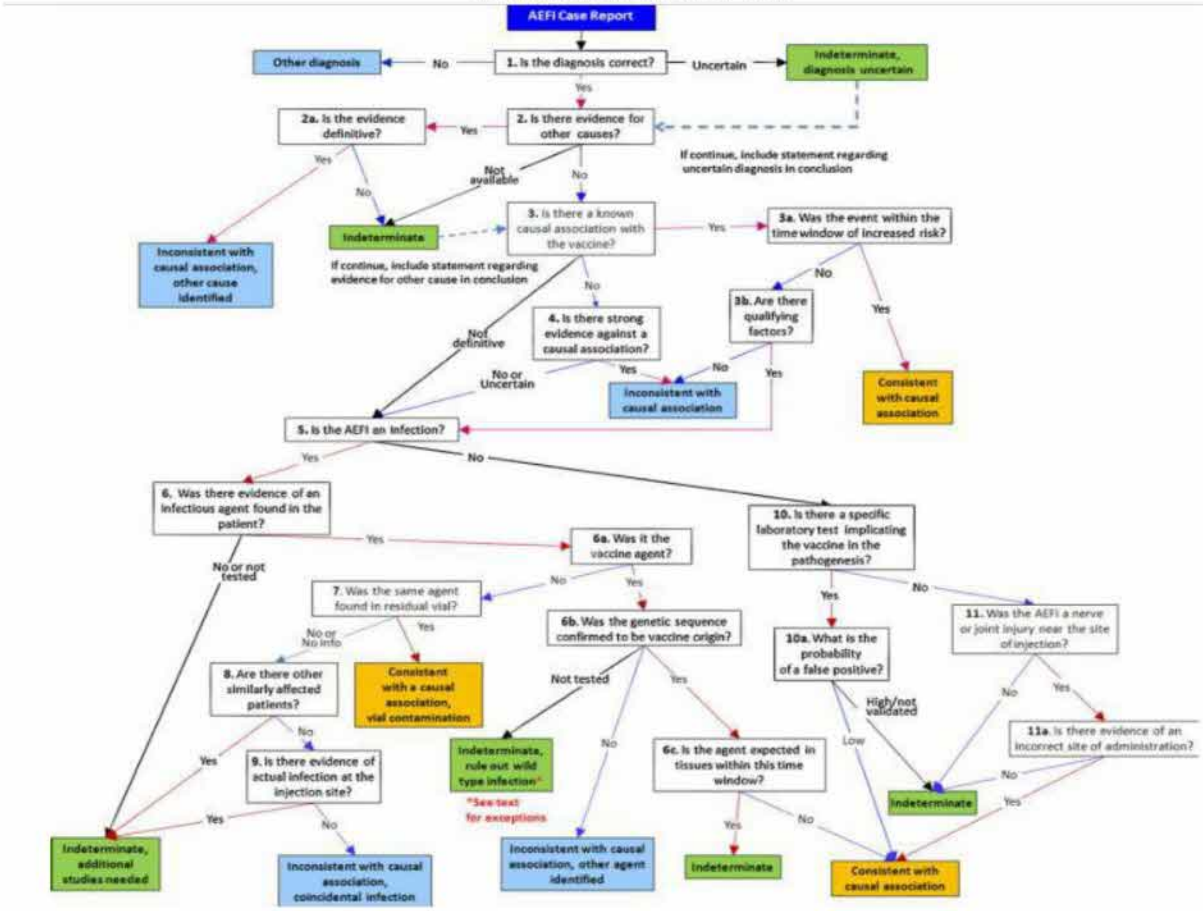
Review of Case Reports of Adverse Events Following Immunizations
Causality Algorithm
Causality Work Group of CISA



(b)(3):42 U.S.C. §242m(d); (b)(6)

May 4, 2021

(b)(3):42 U.S.C. §242m(d); (b)(6)

On behalf of the Clinical Immunization Safety Office (CISA) Project, thank you for the opportunity to review the case of your (b)(3):42 U.S.C. (b)(3) patient who experienced (b)(3):42 U.S.C. §242m(d), (b)(6) (b)(3):42 U.S.C. following the receipt of the first dose of the Pfizer COVID-19 mRNA vaccine. CISA was asked to review the case to assess whether the diagnosis was correct, if receipt of the Pfizer COVID-19 mRNA 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 15, 2021 by the CISA Clinical Consultation Case Review Working Group, which includes vaccine safety experts, as well as subject matters experts (SME) in (b)(3):42 (b)(3):42 U.S.C. §242m(d); (b)(6)

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. COVID-19 vaccine?
    b. Routine vaccines?
4. Is any additional testing warranted?
5. When to schedule follow-up?

Additional specific questions:

1. If (b) is exposed to someone with COVID-19, what are (b) risks?
2. Concern re: variants?
3. What are potential risks for recurrent (b)(3):42 U.S.C. §242m(d); (b)(6) if given a second mRNA vaccine or adenovirus vectored vaccine?

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 FDA emergency use authorization information on the Pfizer COVID-19 vaccine.

While the majority of SMEs agreed that a diagnosis of (b)(3):42 U.S.C. was the likely diagnosis, there was some uncertainty and the (b)(3):42 U.S.C. SMEs on the call deliberated between a diagnosis of (b)(3):42 U.S.C. §242m(d); (b)(6) and a (b)(3):42 U.S.C. The (b)(3):42 SMEs in support of a (b)(3):42 U.S.C. §242m(d); (b)(6) diagnosis provided the rationale that despite hard evidence and data to support the diagnosis the clinical story is more consistent with the condition. Support for a diagnosis of a (b)(3):42 U.S.C. §242m(d); (b)(6) included that this diagnosis is just as

possible as a (b)(3):42 U.S.C and no inciting event is necessary to precipitate the condition.

Despite the slight diagnostic uncertainty, the causality algorithm (see diagram and reference below) was applied using a diagnosis of (b)(3):42 U.S.C to assess whether this patient's AEFI was causally related to the receipt of the Pfizer COVID-19 mRNA vaccine. The application of the causality algorithm resulted in "Indeterminate" because the diagnosis is uncertain, there is no evidence to support other causes, and there is not a definitive known association between the vaccine and AEFI.

In addition, the SMEs had varied guidance regarding a future COVID-19 vaccine which is outlined below. The SMEs unanimously agreed that the decision to receive another COVID-19 vaccine should be a shared decision between the patient and provider.

Various SMEs on the call noted they would probably advise against a second dose of the Pfizer COVID-19 mRNA vaccine. A (b)(3):42 SME from (b)(3):42 U.S.C. §242m(d), (b)(6), shared his personal belief that for the person with the right immunologic makeup, the vaccine could be an initial inciting injury that causes an (b)(3):42 U.S.C. §242m(d), (b)(6). (b)(3):42 added that there is literature describing antecedent events like this with (b)(3):42 U.S.C. §242m(d), (b)(6) patients, but there is not enough overwhelming evidence to support an association. Many SMEs on the call noted they would opt to receive a dose of the J&J vaccine in this patient's situation even though there are not any data to support this decision. Support for this guidance included that it would avoid the lipid envelope and the mRNA presentation of the antigen to this patient. Additional support included that reports have noted the J&J vaccine to be less inflammatory and less reactive than the mRNA vaccines. (b)(3):42 U.S.C. stated that he would add to the conversation that single-dose efficacy has impressed him, especially in preventing severe disease and complications.

Regarding routine vaccinations, CISA agreed that no contraindications exist, and this patient can receive other vaccines according to need/schedule.

In addition, the CISA SMEs agreed that no additional testing is warranted for this patient.

The SMEs addressed that with one dose (b)(3):42 protection for the short term is probably 80-90%, but there is not data to inform long-term protection with one dose. Regarding concern for variants of COVID-19, there is laboratory evidence of variants requiring a higher antibody titer to be neutralized, but ultimately, it is hard to say.

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 within the next six months to assess whether the patient has received additional vaccines and how (b)(3):42 tolerated them.

Sincerely,

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(b)(3):42 U.S.C. §242m(d), (b)(6)

May 4, 2021

(b)(3):42 U.S.C. §242m(d), (b)(6)

On behalf of the Clinical Immunization Safety Assessment (CISA) Project, I would like to thank you for the opportunity to review the case of your patient who experienced a (b)(3):42 U.S.C. §242m(d), (b)(3):42 following receipt of dose 1 of the Moderna COVID-19 mRNA vaccine. CISA was asked to review this case to assess whether the diagnosis of (b)(3):42 U.S.C. §242m(d), (b)(6) was correct, if receipt of the 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 April 5, 2021 by the CISA Clinical Consult Case Review Working Group, which includes vaccine safety experts, as well as subject matter experts (SME) in i (b)(3):42 U.S.C. §242m(d), (b)(6)

The following questions were posed:

- Is the diagnosis correct?
- Did the vaccine cause or contribute to the AEFI?
- What are the recommendations for future vaccines?
    - COVID-19 vaccine?
    - Routine vaccines?
- Is any additional testing warranted?
- 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, (b)(3):42 U.S.C. §242m(d), (b)(6) reaction literature.

(b)(3):42 U.S.C. §242m(d), (b)(6)

The SMEs agreed that (b)(3):42 U.S.C. §242m(d), (b)(6) was the correct diagnosis. The SMEs assessed whether the diagnosis was causally related to the receipt of the Moderna COVID-19 vaccine using the causality algorithm (see diagram and reference below). The application of the causality algorithm resulted in "Indeterminate," as the SMEs agreed that the diagnosis was correct and failed to identify any other causes for the (b)(3):42 U.S.C. §242m(d), (b)(6) However, there is no known causal association with (b)(3):42 U.S.C. §242m(d), (b)(6) and the vaccine and no strong evidence against a casual association with the vaccine, resulting in a causality determination of "Indeterminate."

The SMEs agreed that the patient should not receive dose #2 of either of the available mRNA vaccines. However, it would be reasonable to consider future mRNA vaccines in consultation with an (b)(3):42 The SMEs discussed the possibility of the patient receiving a dose of the Johnson & Johnson's Janssen (J&J/Janssen) COVID-19 vaccine based on shared decision-making with the patient, referring provider, and primary care physician. After a temporary pause, the CDC and the U.S. Food and Drug Administration (FDA) lifted the pause on April 23, 2021, and recommended resumption of use of J&J/Janssen's COVID-19 vaccine in the United States. The Janssen (J&J) COVID-19 vaccine is a replication-incompetent adenoviral vector (human [Ad26.COV2.S] for J&J) that encodes the spike glycoprotein of SARS-CoV-2, the virus that causes COVID-19. At the time of writing this guidance letter, the Janssen (J&J) COVID-19 vaccine is the only non-mRNA COVID-19 vaccine available for use for your patient.

Health care providers administering the Janssen vaccine and vaccine recipients or caregivers should review the Janssen COVID-19 Vaccine Fact Sheet for Healthcare Providers Administering Vaccine (Vaccination Providers) and Fact Sheet for Recipients and Caregivers, which have been revised to include information about the risk of this syndrome, which has occurred in a very small number of people who have received the Janssen COVID-19 Vaccine.

Regarding routine vaccines, CISA SMEs advised that the patient continue to receive immunizations according to the usual Advisory Committee on Immunization Practices (ACIP) recommendations. They agreed that no additional testing is required.

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 months' time to assess the patient's status and the result of (b)(3):42 follow-up.

Guidance regarding COVID-19 vaccines is frequently being updated, and we suggest that you check the following sites for the most updated guidance regarding CDC and ACIP guidance for COVID-19 vaccines:

[redacted]

- For updated information on COVID-19 vaccines that have received a recommendation from the Advisory Committee on Immunization Practices, please see: https://www.cdc.gov/vaccines/hcp/acip-recs/vacc-specific/covid-19.html

- For the most up-to-date information, CDC will continue to post information online at: https://www.cdc.gov/coronavirus/2019-ncov/index.html

Sincerely,

[redacted]

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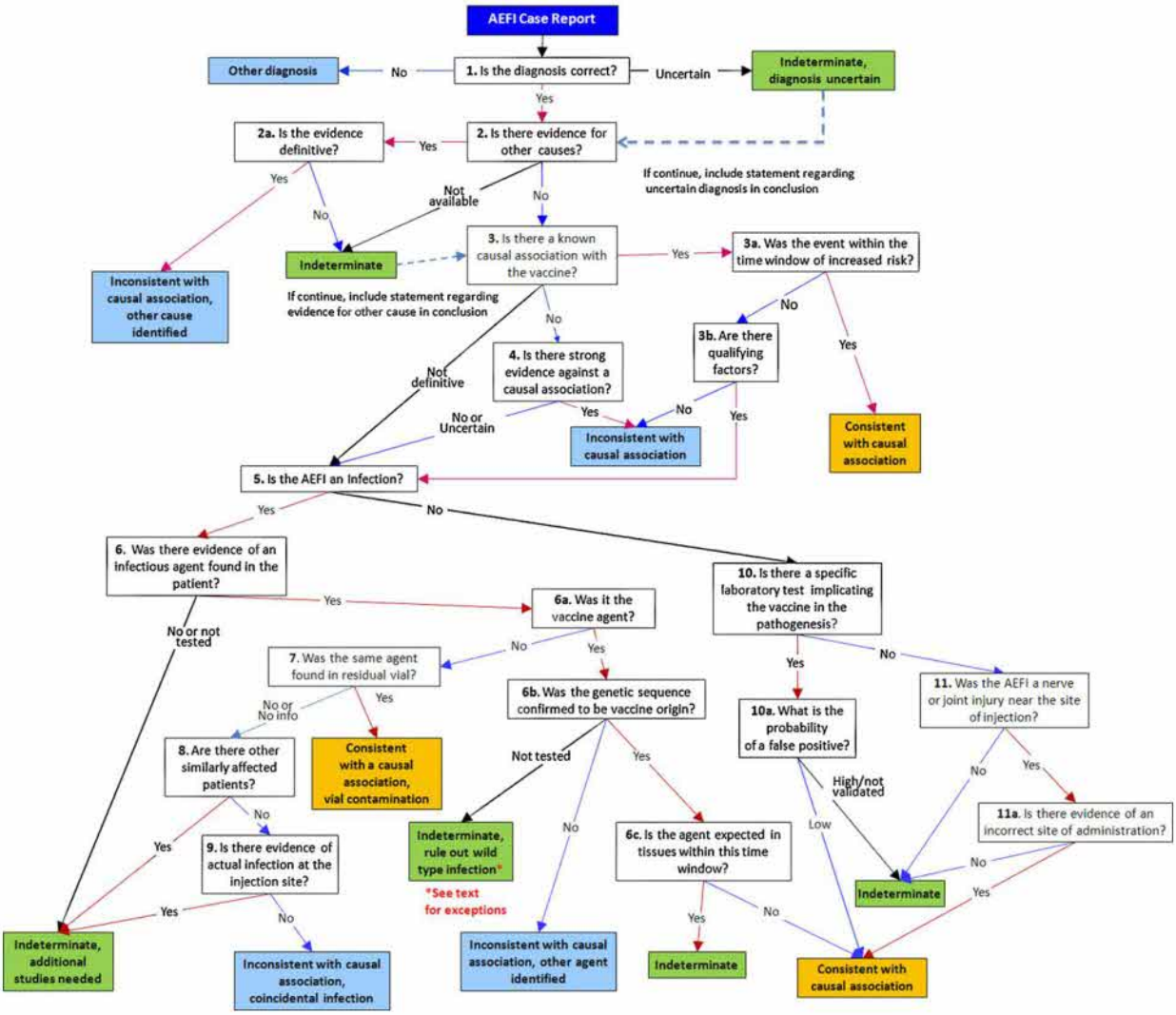
(b)(3):42 U.S.C. §242m(d); (b)(6)

References

1. Halsey NA, Edwards KM, et al, Causality Working Group of the Clinical Immunization Safety Assessment network, *Vaccine*. 2012 Aug24;30(39):5791-8. Epub 2012 Apr 14.

Additional Resources:

- Fact Sheet for Healthcare Providers Administering Vaccine
- Fact Sheet for Recipients and Caregivers
- CDC Health Alert for Health Care Providers
- Johnson & Johnson Granting EUA Amendment (April 23, 2021)



(b)(3):42 U.S.C. §242m(d); (b)(6)

June 4, 2021

(b)(3):42 U.S.C. §242m(d), (b)(6)

On behalf of the Clinical Immunization Safety Office (CISA) Project, thank you for the opportunity to review the case of your (b)(3):42 (b)(3):42 patient who was symptoms of (b)(3):42 U.S.C. following receipt of the first dose of the Moderna COVID-19 vaccine. CISA was asked to review the case to assess whether the diagnosis was correct, if receipt of the COVID-19 vaccine might have caused or contributed to the adverse event following immunization (AEFI), and to provide guidance regarding future vaccinations. We regret any inconvenience caused by our delay in sending this letter. Our letters have been delayed by substantial increases in requests for vaccine safety reviews and consultations.

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 April 6, 2021 by the CISA Clinical Consultation Case Review Working Group, which includes vaccine safety experts, as well as subject matters experts (SME) in (b)(3):42 U.S.C. §242m(d), (b)(6)

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. Further COVID-19 vaccination?
    b. Routine vaccines?
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, and Vaccine Adverse Event Reporting Systems (VAERS) search results, and FDA emergency use authorization information on both the Pfizer and Moderna COVID-19 vaccines. The (b)(3):42 SMEs on the call agreed that there was no clear diagnosis for the patient, as (b)(3) symptoms did not fit any clear category an(b)(3): 42 did not have any objective findings. However, there is no known causal association, or clear biologic pathway for a vaccine to cause (b)(3): 42 ymptoms.

Without a diagnosis it is difficult to determine a causal relationship between the vaccine and the symptoms. When we used the causality algorithm developed by Neal Halsey and colleagues (diagram and reference below), we ended up with an outcome of "Indeterminate" as to whether the vaccine contributed to the adverse event.

The FDA EUA and CDC Interim Clinical Considerations for Use of COVID-19 Vaccines

(https://www.cdc.gov/vaccines/covid-19/info-by-product/clinical-considerations.html) lists the contraindications and precautions for COVID-19 vaccination. Based on the guidance in that document, your patient does not have a contraindication to receipt of the second dose of the COVID-19 vaccine and would fall into the Green category. (b)(3) :42 has since notified me that (b)(3) :42 has received the second dose and has tolerated it well, with no additional (b)(3) 42 U.S.C.

We hope that we have fully addressed your questions and concerns. We have included in the body of the email accompanying this letter, a link to a survey to evaluate the CISA consultation process.

Sincerely,

(b)(3) 42 U.S.C. §242m(d), (b)(6)

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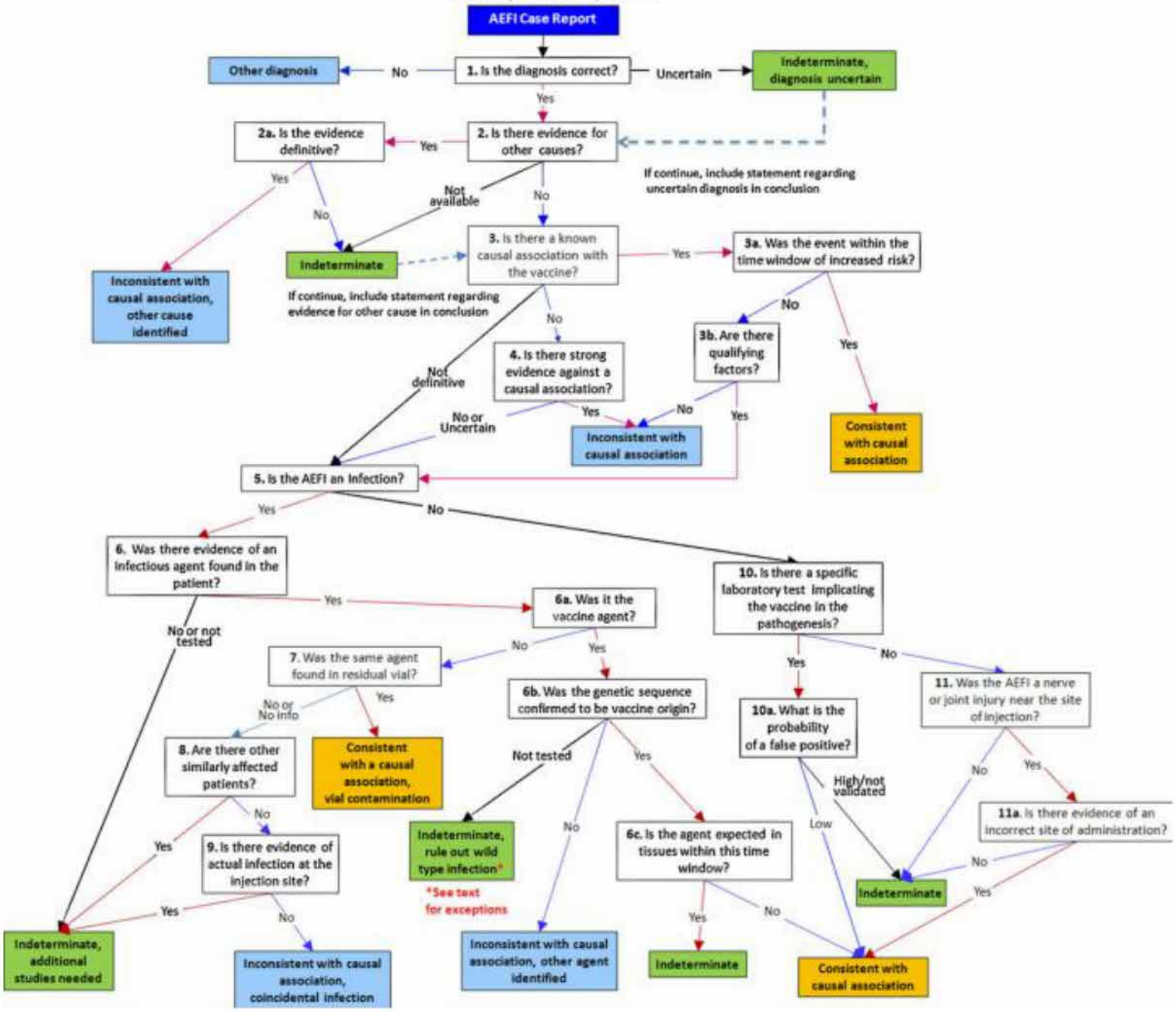
References

1. Halsey NA, Edwards KM, et al, Causality Working Group of the Clinical Immunization Safety Assessment network, *Vaccine*. 2012 Aug 24;30(39):5791-8. Epub 2012 Apr 14.

Review of Case Reports of Adverse Events Following Immunizations
February 28, 2012
Causality Work Group of CISA



(b)(3):42 U.S.C. §242m(d); (b)(6)

May 25, 2021

(b)(3):42 U.S.C. §242m(d); (b)(6)

On behalf of the Clinical Immunization Safety Assessment (CISA) Project, I would like to thank you for the opportunity to review the case of your patient who experienced (b)(3):42 and (b)(3):42 U.S.C following receipt of dose 2 of the Moderna COVID-19 mRNA vaccine. CISA was asked to review this case to assess whether the diagnosis of (b)(3):42 U.S.C. §242m(d); (b)(6) (b)(3):42 was correct, if receipt of the 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 April 12, 2021 by the CISA Clinical COVID-19 vaccine (COVIDvax) Consultation Case Review Working Group, which includes vaccine safety experts, as well as subject matter experts (SME) in (b)(3):42 U.S.C. §242m(d); (b)(3):42 U.S.C. §242m(d); (b)(6)

The following questions were posed:

- Is the diagnosis correct?
- Did the vaccine cause or contribute to the AEFI?
- What are the recommendations for future vaccines?
    - COVID-19 vaccine?
    - Routine vaccines?
- Is any additional testing warranted?
- 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, and (b)(3):42 U.S.C. symptom and (b)(3):42 U.S.C. §242m(d); (b)(6) (b)(3):42 U.S.C. literature.

The SMEs agreed that '(b)(3):42 U.S.C. §242m(d); (b)(6)' was not the correct diagnosis because it merely described the patient's symptoms rather than the disease. They agreed that the correct diagnosis was most likely (b)(3):42 U.S.C. §242m(d); (b)(6) (b)(3):42 This assessment was made based on lack of objective findings despite thorough evaluations. The SMEs assessed whether the diagnosis was causally related to the receipt of the Moderna COVID-19 mRNA vaccine using the causality algorithm (see diagram and reference

(b)(3):42 U.S.C. §242m(d); (b)(6)

below). The application of the causality algorithm resulted in "Inconsistent with causal association", because there is no known causal association with the vaccine.

The SMEs recommended that the patient could receive mRNA COVID-19 vaccines in the future if, for example, a booster dose were recommended. However, since (b)(3): 42 has received both doses of the vaccine, this is purely hypothetical for now. Regarding other routine vaccines, CISA SMEs advised that the patient continue to receive immunizations according to the usual Advisory Committee on Immunization Practices (ACIP) recommendations.

Additionally, CISA SMEs discussed whether additional testing is warranted for this patient and agreed that further (b)(3):42 U.S.C testing is not necessary or recommended. However, the SMEs agreed that an anti-nucleocapsid antibody test would be helpful to assess for past COVID-19 infection.

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 months' time to assess the patient's status and results of the anti-nucleocapsid antibody test and the (b)(3):42 U.S.C. §242m(d); (b)(6)

Guidance regarding COVID-19 vaccines is frequently being updated, and we suggest that you check the following sites for the most updated guidance regarding CDC and ACIP guidance for COVID-19 vaccines:

- For updated information on COVID-19 vaccines that have received a recommendation from the Advisory Committee on Immunization Practices, please see: https://www.cdc.gov/vaccines/hcp/acip-recs/vacc-specific/covid-19.html
- For the most up-to-date information, CDC will continue to post information online at: https://www.cdc.gov/coronavirus/2019-ncov/index.html

Sincerely,

(b)(3):42 U.S.C. §242m(d); (b)(6)

(b)(3) 42 U.S.C. §242m(d), (b)(6)

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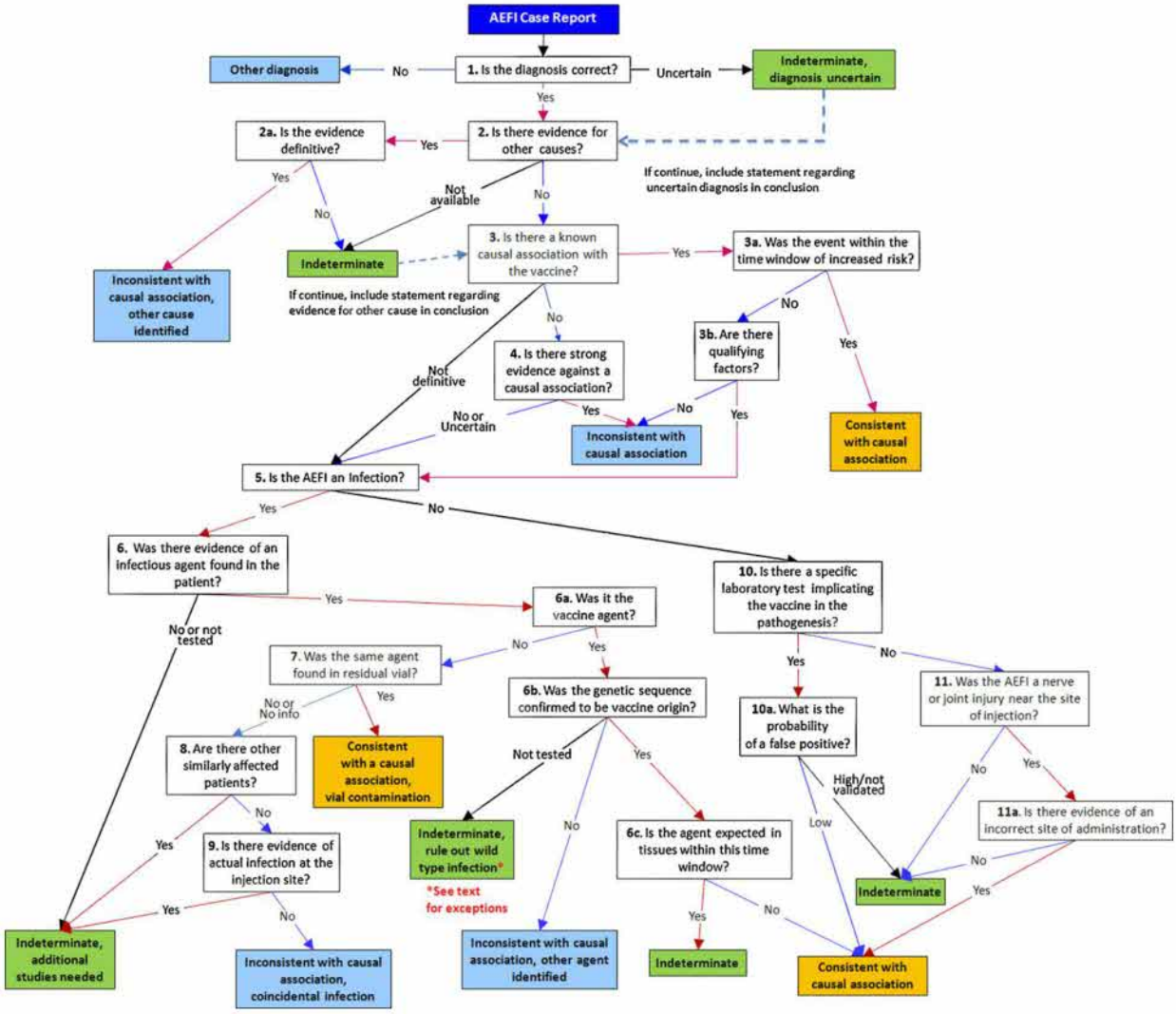
(b)(3):42 U.S.C. §242m(d), (b)(6)

References

1. Halsey NA, Edwards KM, et al, Causality Working Group of the Clinical Immunization Safety Assessment network, *Vaccine*. 2012 Aug24;30(39):5791-8. Epub 2012 Apr 14.



(b)(3):42 U.S.C. §242m(d) ; (b)(5) ; (b)(6)

(b)(3):42 U.S.C. §242m(d) ; (b)(5) ; (b)(6)

(b)(3):42 U.S.C. §242m(d) ; (b)(5) ; (b)(6)

(b)(3):42 U.S.C. §242m(d), (b)(6)

May 17, 2021

(b)(3):42 U.S.C. §242m(d), (b)(6)

On behalf of the Clinical Immunization Safety Assessment (CISA) Project, I would like to thank you for the opportunity to review the case of your patient with (b)(3):42 (b)(3):42 U.S.C. who experienced (b)(3):42 U.S.C. following receipt of the second dose of the Pfizer-BioNTech COVID-19 mRNA vaccine. CISA was asked to review this case to assess whether the diagnosis of (b)(3):42 U.S.C. was correct, if receipt of the 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 April 14, 2021 by the CISA Clinical Consult Case Review Working Group, which includes vaccine safety experts, as well as subject matter experts (SME) in (b)(3):42 U.S.C. §242m(d), (b)(6)

The following questions were posed:

- Is the diagnosis correct?
- Did the vaccine cause or contribute to the AEFI?
- What are the recommendations for future vaccines?
    - COVID-19 vaccine?
    - Routine vaccines?
- Is any additional testing warranted?
- When to schedule follow-up?

CISA vaccine safety and other SMEs reviewed the available evidence, including the patient's medical and family history, vaccine safety literature, and reports of (b)(3):42 U.S.C after COVID-19 vaccination.

The SMEs agreed that (b)(3):42 U.S.C was the correct diagnosis. The SMEs assessed whether the diagnosis was causally related to the receipt of the Pfizer-BioNTech COVID-19 mRNA vaccine using the causality algorithm (see diagram and reference below). The application of the causality algorithm resulted in "Indeterminate", as there was no strong evidence found in the literature to definitively say whether or not there was a causal relationship between the adverse

[redacted]

event and the vaccine and no vaccine safety surveillance signal for [redacted]

The CISA SMEs decided that, at this time, they could not make a recommendation concerning whether or not the patient could receive mRNA COVID-19 vaccines in the future if, for example, a booster dose was recommended. They discussed their hesitancy to give the patient a future COVID-19 vaccine due to the concern for [redacted] but agreed that they could revisit the conversation if a future booster dose is required and there is more information available in the literature. Regarding other routine vaccines, CISA SMEs advised that the patient continue to receive immunizations according to the usual Advisory Committee on Immunization Practices (ACIP) recommendations. Additionally, CISA SMEs discussed whether additional testing is warranted for this patient, and agreed that further testing is not necessary or recommended at this time.

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 month's time to assess the patient's status.

Guidance regarding COVID-19 vaccines is frequently being updated, and we suggest that you check the following sites for the most updated guidance regarding CDC and ACIP guidance for COVID-19 vaccines:

- For updated information on COVID-19 vaccines that have received a recommendation from the Advisory Committee on Immunization Practices, please see: https://www.cdc.gov/vaccines/hcp/acip-recs/vacc-specific/covid-19.html

- For the most up-to-date information, CDC will continue to post information online at: https://www.cdc.gov/coronavirus/2019-ncov/index.html

Sincerely,

[redacted]

(b)(3) 42 U.S.C. §242m(d); (b)(6)

Disclaimer:

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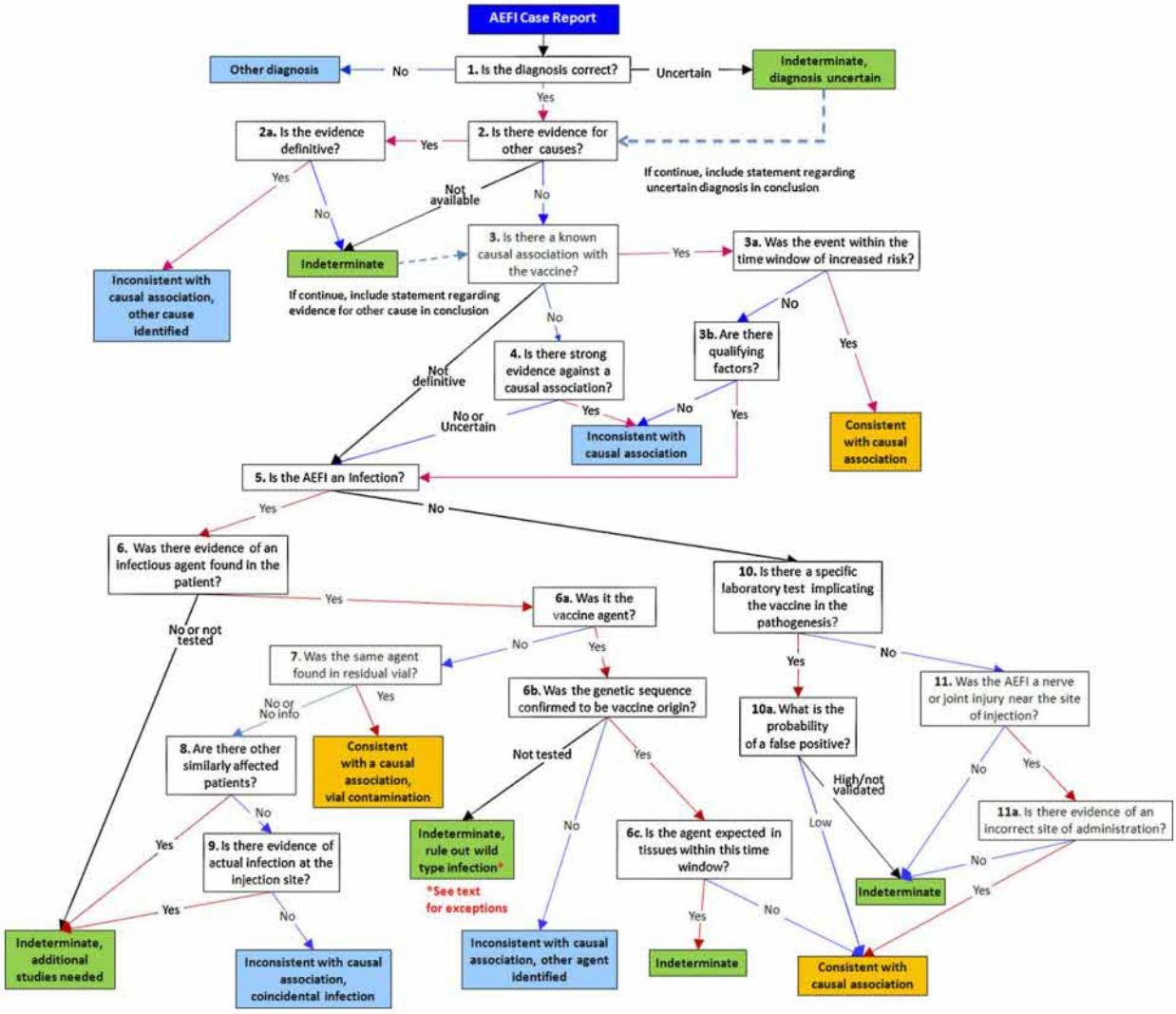
(b)(3):42 U.S.C. §242m(d); (b)(6)

References

1. Halsey NA, Edwards KM, et al, Causality Working Group of the Clinical Immunization Safety Assessment network, *Vaccine*. 2012 Aug24;30(39):5791-8. Epub 2012 Apr 14.



(b)(3):42 U.S.C. §242m(d), (b)(6)

May 6, 2021

(b)(3):42 U.S.C. §242m(d), (b)(6)

On behalf of the Clinical Immunization Safety Office (CISA) Project, thank you for the opportunity to review the case of your (b)(3):42 (b)(3):42 patient who developed a (b)(3):42 U.S.C. §242m(d), (b)(6) after receipt of the 23-Valent Pneumococcal Polysaccharide Vaccine (PPSV23) in November 2020. CISA was asked to review the case to assess whether the diagnosis was correct, and to provide guidance regarding COVID-19 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 April 22, 2021 as a mini-consultation with myself and Dr. Theresa Harrington of the CDC. We also discussed this case with other members of the CISA Clinical Consultation Case Review Working Group, which includes vaccine safety experts, as well as subject matters experts (SME) in infectious diseases and (b)(3):42 U.S.C. §242m(d);

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 COVID-19 vaccines for this patient?
    a. COVID-19 vaccine?
    b. Routine vaccines?
4. Is any additional testing warranted?
5. When to schedule follow-up?

With you on the call, we reviewed available evidence, including the patient's medical history, vaccine safety literature, and Vaccine Adverse Event Reporting Systems (VAERS) search results, the FDA package insert for the PPSV23, and information from the Emergency Use Authorization (EUA) materials on the mRNA vaccines.

We discussed that reports of serious (b)(3):42 U.S.C. §242m(d), (b)(6) have been reported in case reports after the PPSV23, as well in reports to the VAERS published in 2016 (reference below). Based on this, using the causality algorithm developed by Neal Halsey and colleagues (diagram and reference below), it was determined that your patient's symptoms after receiving the PPSV23 were Consistent with a causal association between the vaccine and (b)(3):42 symptoms. However, the symptoms are likely limited to the PPSV23, and should not affect any subsequent vaccines (b)(3):4 gets.

The FDA EUA and CDC Interim Clinical Considerations for Use of COVID-19 Vaccines (https://www.cdc.gov/vaccines/covid-19/info-by-product/clinical-considerations.html) lists the contraindications and precautions for COVID-19 vaccination. Based on the guidance in that document, your patient does not have a contraindication to receipt of the COVID-19 vaccine, and would fall into the Green category.

We also thought that it was important for your patient to receive (b)(3):42 U.S other routine vaccinations as

indicated. It is unknown whether (b)(3):42 will have a similar (b)(3):42 U.S.C. §242m(d) after another dose of PPSV23, however, since (b)(3):42 is not due for another pneumococcal vaccine until (b)(3):4 is (b), it is unlikely that (b)(3) will have the same robust response after such a long time has elapsed.

In terms of additional testing, we recommended checking a SARS-CoV-2 anti-nucleocapsid antibody test prior to vaccination. This test will inform you as to whether or not the patient has had previous SARS-CoV-2 infection. If (b)(3):42 has, (b)(3):42 might have somewhat more robust side effects to the vaccine, but it would still be recommended. The testing is just for the purpose of providing you and the patient with more information.

We hope that we have fully addressed your questions and concerns. Please update us when your patient receives a COVID-19 vaccine and let us know how (b)(3):42 does. 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. We would appreciate your response to this survey.

Sincerely,

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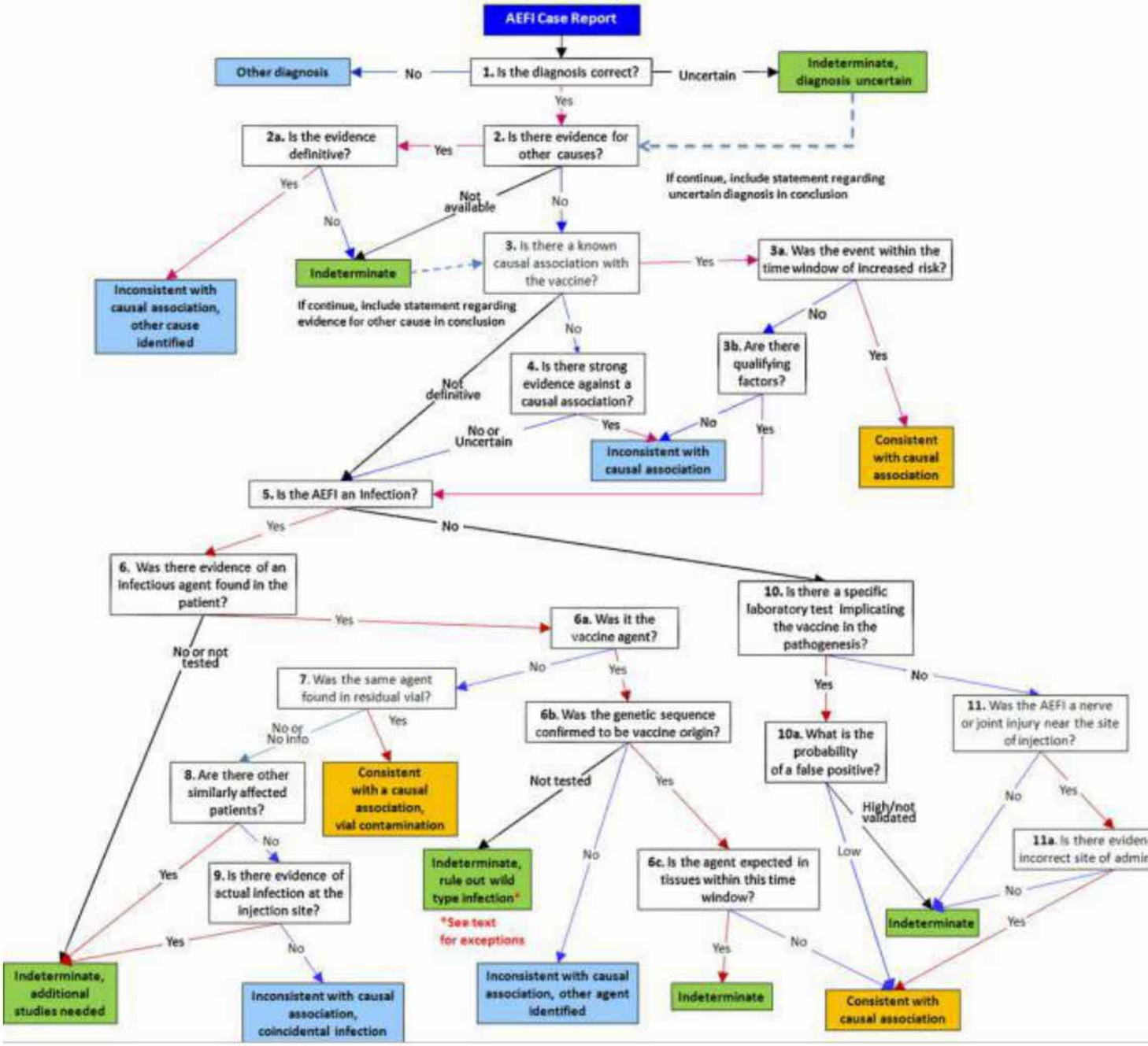
References

1. Miller, ER, Moro, PL, et al, Post-licensure safety surveillance of 23-valent pneumococcal polysaccharide vaccine in the Vaccine Adverse Event Reporting System (VAERS), 1990-2013. Vaccine. 2016 Apr 15; 34(25):2841-2846. DOI: 10.1016/j.vaccine.2016.04.021 PMID: 27087150.
2. Halsey NA, Edwards KM, et al, Causality Working Group of the Clinical Immunization Safety Assessment network, *Vaccine*. 2012 Aug 24;30(39):5791-8. Epub 2012 Apr 14.

Review of Case Reports of Adverse Events Following Immunizations
February 28, 2012
Causality Work Group of CISA



(b)(3):42 U.S.C. §242m(d); (b)(6)

June 3, 2021

(b)(3):42 U.S.C. §242m(d); (b)(6)

On behalf of the Clinical Immunization Safety Office (CISA) Project, thank you for the opportunity to review the case of your (b)(3):42 (b)(3):42 patient who developed (b)(3):42 U.S.C. approximately one day after receiving dose 2 of the Moderna COVID-19 vaccine on February 25, 2021. CISA was asked to provide guidance as to whether the administration of the Moderna COVID-19 vaccine was a direct causation of the patient's (b)(3):42 U.S.C.

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 April 28, 2021 by the CISA Clinical Consultation Case Review Working Group, which includes vaccine safety experts, as well as subject matters experts (SMEs) in (b)(3):42 U.S.C. §242m(d); (b)(6)

The following questions were posed:

1. Is the diagnosis correct?
2. Did the vaccine cause or contribute to the AEFI?
3. What are the recommendations for future vaccines?
    a. Routine vaccines
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, literature on (b)(3):42 U.S.C. and vaccines, and FDA emergency use authorization information on the mRNA COVID-19 vaccines. Results from Vaccine Adverse Event Reporting Systems (VAERS) data mining and Vaccine Safety Datalink (VSD) analysis on (b)(3):42 U.S.C. were also reviewed.

The SMEs agreed that the patient's symptoms and lab work were consistent with (b)(3):42 U.S.C. The SMEs assessed whether the diagnosis was causally related to the receipt of the Moderna COVID-19 vaccine using the causality algorithm (see diagram and reference below). The application of the causality algorithm resulted in "Indeterminate for causation, but likely as contributing", due to the limited data available. Although currently there are no safety concerns or signals for (b)(3):42 U.S.C. at this time, more data are needed to conclude that (b)(3):42 U.S.C. is not directly associated with the Moderna COVID-19 vaccine. However, the SMEs agreed that a causal relationship between the Moderna COVID vaccine and (b)(3):42 U.S.C. is biologically plausible, based off the reactogenicity of the vaccine.
CDC's Interim Clinical Considerations for Use of COVID-19 vaccines https://www.cdc.gov/vaccines/covid-19/info-by-product/clinical-considerations.html does not consider (b)(3):42 U.S.C. as a contraindication or precaution to COVID-19 vaccine. ACIP General Best Practices recommends that the presence of a moderate or severe acute illness with or without a fever is a precaution to administration of all vaccines

(b)(3):42 U.S.C. §242m(d), (b)(6)

(https://www.cdc.gov/vaccines/hcp/acip-recs/general-recs/contraindications.html.

CISA experts provided opinions regarding (b)(3):42 U.S.C. §242m(d), at the time of administering the COVID vaccine. The SMEs agreed that (b)(3):42 U.S.C. §242m(d), due to presumed (b)(3):42 U.S.C. §242m(d), is unnecessary at the time when administering the COVID vaccine. However, the CISA experts did agree that increasing (b)(3):42 U.S.C. for patients who had a significant reaction to dose 1 of an mRNA vaccine would be recommended.

Additionally, CISA SMEs discussed whether it would be beneficial to routinely test for COVID-19 antibody response for patients who had used (b)(3):42 for their symptoms. The SMEs agreed that serologic testing was not recommended, as CDC guidance states that antibody testing is not recommended to assess immunity: https://www.cdc.gov/coronavirus/2019-ncov/lab/resources/antibody-tests-guidelines.html

We hope that we have fully addressed your questions and concerns. Please feel free to contact us if you have any further questions. 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 within the next six months to assess whether the patient has received additional vaccines and how (b)(3):42 tolerated them.

Sincerely,

(b)(3):42 U.S.C. §242m(d), (b)(6)

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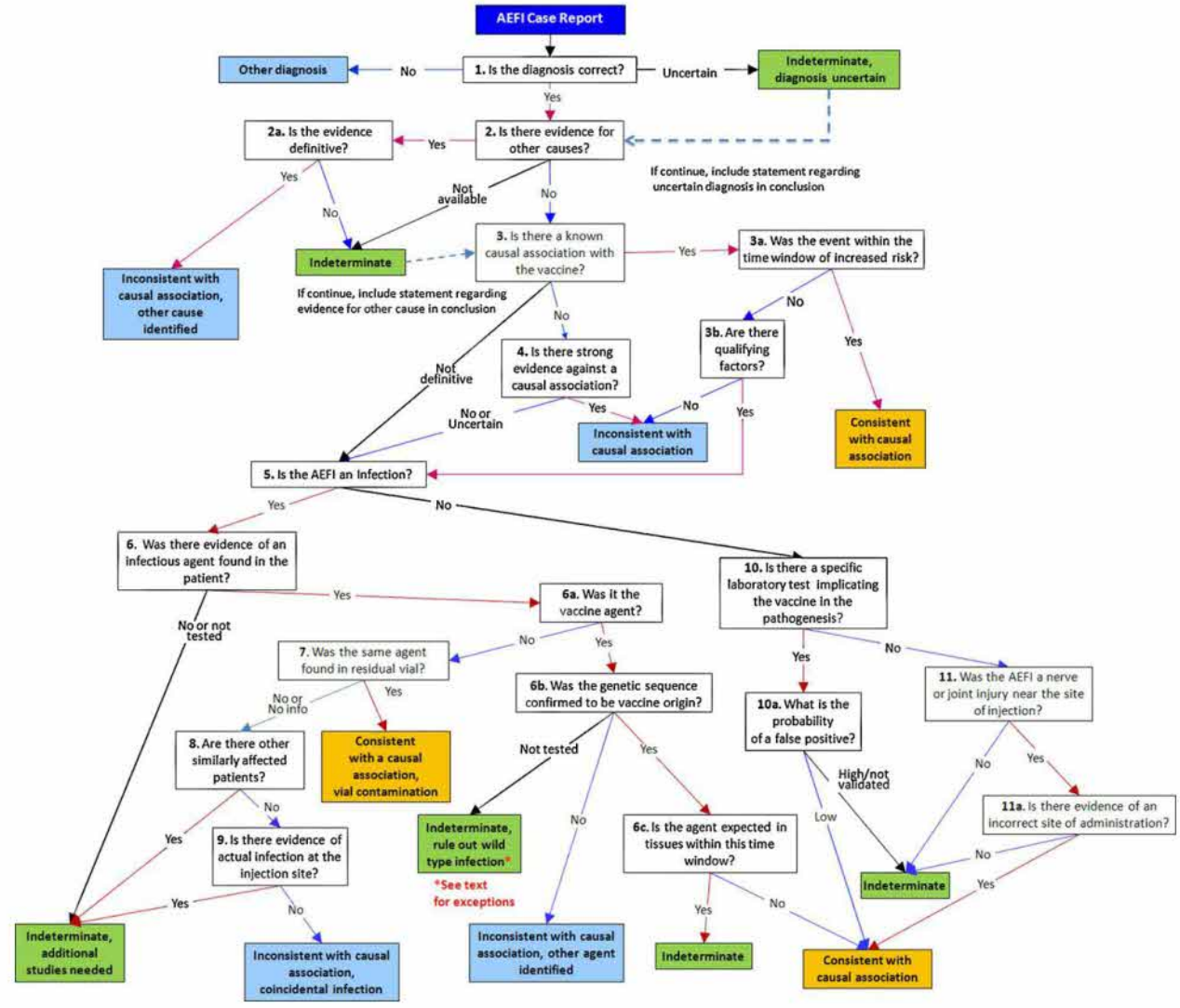
(b)(3):42 U.S.C. §242m(d), (b)(6)

References

(b)(3):42 U.S.C. §242m(d); (b)(6)



(b)(3):42 U.S.C. §242m(d), (b)(6)

June 23, 2021

(b)(3):42 U.S.C. §242m(d), (b)(6)

On behalf of the Clinical Immunization Safety Office (CISA) Project, thank you for the opportunity to review the case of your (b)(3):42 U.S.C. (b)(3):4 patient who developed a (b)(3):42 U.S.C. followed by (b)(3):42 U.S.C with symptom onset beginning approximately 24 hours after receiving dose 1 of the Moderna COVID-19 vaccine on March 27, 2021. CISA was asked to provide guidance as to whether the administration of the Moderna COVID-19 vaccine was a direct causation of the patient's (b)(3):42 U.S.C (b)(3):42

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 April 28, 2021 by the CISA Clinical Consultation Case Review Working Group, which includes vaccine safety experts, as well as subject matters experts (SMEs) in (b)(3):42 U.S.C. §242m(d), (b)(6)

The following questions were posed:

1. Is the diagnosis correct?
2. Did the vaccine cause or contribute to the AEFI?
3. What are the recommendations for future vaccines?
    a. Routine vaccines
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, literature on (b)(3):42 and vaccines, and FDA emergency use authorization information on the mRNA COVID-19 vaccines. Results from Vaccine Adverse Event Reporting Systems (VAERS) data mining and Vaccine Safety Datalink (VSD) analysis on (b)(3):42 U.S.C. were also reviewed.

The SMEs agreed that the patient's symptoms and lab work were consistent with (b)(3):42 U.S.C. There was no evidence of acute COVID-19 infection or prior COVID-19 infection. The SMEs assessed whether the diagnosis was causally related to the receipt of the Moderna COVID-19 vaccine using the causality algorithm (see diagram and reference below). The application of the causality algorithm resulted in "Indeterminate", due to the limited data available, and possibility of other etiologies. Although currently there are no safety concerns or signals for (b)(3):42 U.S.C at this time, more data are needed to conclude that a (b)(3):42 U.S.C is not directly associated with the Moderna COVID-19 vaccine.

CDC's Interim Clinical Considerations for Use of COVID-19 vaccines https://www.cdc.gov/vaccines/covid-19/info-by-product/clinical-considerations.html does not consider a (b)(3):42 U.S.C. as a

(b)(3):42 U.S.C. §242m(d); (b)(6)

contraindication or precaution to COVID-19 vaccine. However, ACIP General Best Practices recommends that the presence of a moderate or severe acute illness with or without a fever is a precaution to administration of all vaccines (https://www.cdc.gov/vaccines/hcp/acip-recs/general-recs/contraindications.html.

The SMEs agreed that there were insufficient data to establish a causal relationship between the Moderna vaccine and the patient's (b)(3):42 U.S.C. However, as a safety precaution, the SMEs felt that the patient should not receive dose 2 of the Moderna COVID-19 vaccine due to the lack of other identifiable etiologies for (b)(3):42 In this particular case, the patient has stated that (b)(3):42 is not interested in receiving additional doses of COVID vaccine.

Additionally, CISA SMEs discussed the potential benefit of conducting an extended (b)(3):42 U.S.C. §242m(d); (b)(6) (b)(3):42 U.S.C. §242m(d); (b)(6) frozen serum or urine were available from the time of admission, to see if there was some other substance that could have contributed to the patient's (b)(3):42 U.S.C.

We hope that we have fully addressed your questions and concerns. Please feel free to contact us if you have any further questions. 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 within the next six months to assess whether the patient has received additional vaccines and how (b)(3):42 U.S.C. tolerated them.

Sincerely,

(b)(3):42 U.S.C. §242m(d); (b)(6)

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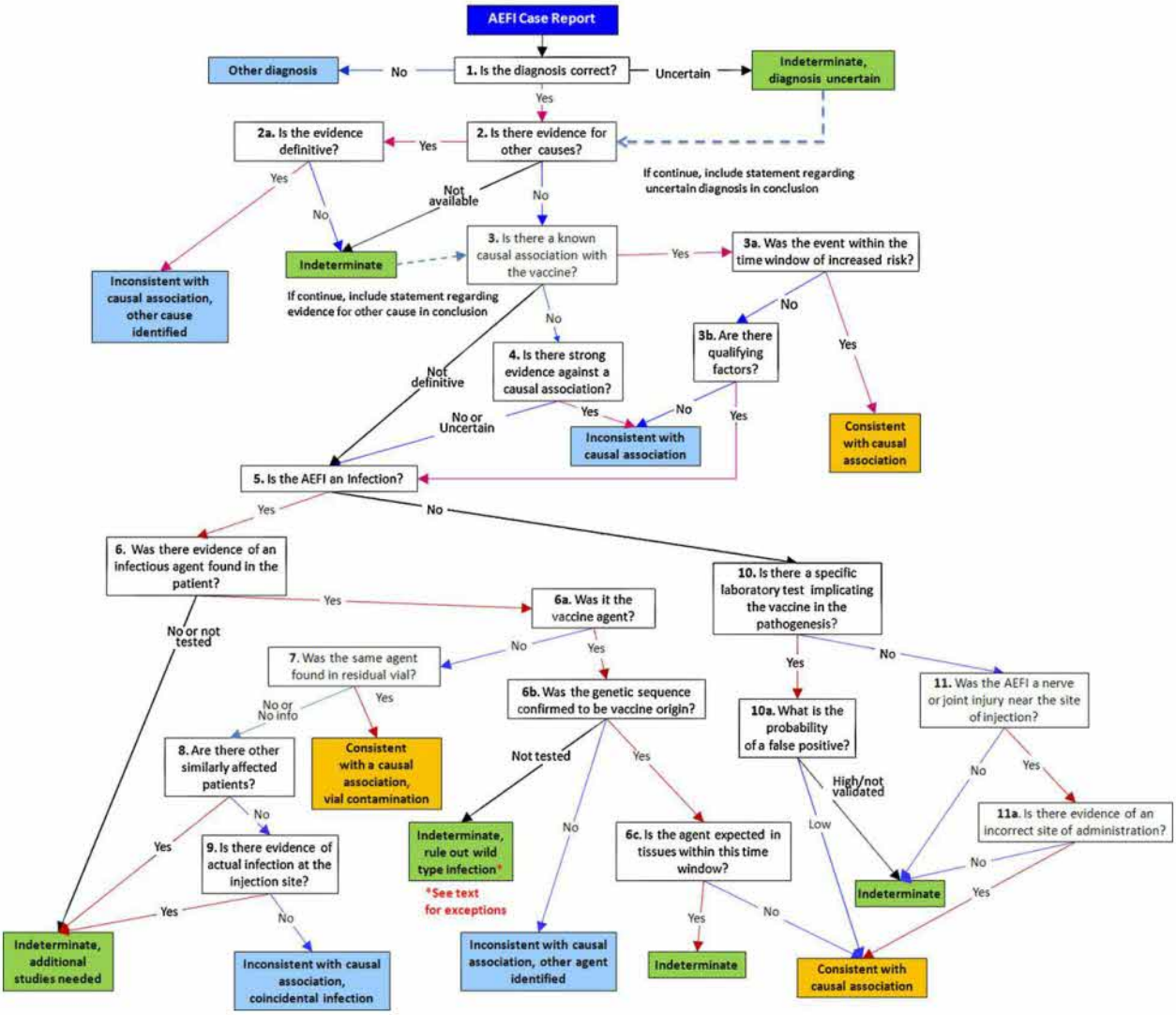
References

1. Halsey NA, Edwards KM, et al, Causality Working Group of the Clinical Immunization Safety Assessment network, Vaccine. 2012 Aug 24;30(39):5791-8. Epub 2012 Apr 14.



(b)(3):42 U.S.C. §242m(d); (b)(6)

June 3, 2021

(b)(3):42 U.S.C. §242m(d); (b)(6)

On behalf of the Clinical Immunization Safety Office (CISA) Project, thank you for the opportunity to review the case of your (b)(3):42 (b)(3):42 patient who developed (b)(3):42 U.S.C. approximately one day after receiving dose 2 of the PfizerBioNTech COVID-19 vaccine on March 22, 2021. CISA was asked to provide guidance as to whether the administration of the PfizerBioNTech COVID-19 vaccine was a direct causation of the patient's (b)(3):42 U.S.C.

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 April 28, 2021 by the CISA Clinical Consultation Case Review Working Group, which includes vaccine safety experts, as well as subject matters experts (SMEs) in i (b)(3):42 U.S.C. §242m(d); (b)(6)

The following questions were posed:

1. Is the diagnosis correct?
2. Did the vaccine cause or contribute to the AEFI?
3. What are the recommendations for future vaccines?
    a. Routine vaccines
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, literature on (b)(3):42 U.S.C. and vaccines, and FDA emergency use authorization information on the mRNA COVID-19 vaccines. Results from Vaccine Adverse Event Reporting Systems (VAERS) data mining and Vaccine Safety Datalink (VSD) analysis on (b)(3):42 U.S.C. were also reviewed.

The SMEs agreed that the patient's symptoms and lab work were consistent with (b)(3):42 U.S.C. The SMEs assessed whether the diagnosis was causally related to the receipt of the PfizerBioTech COVID-19 vaccine using the causality algorithm (see diagram and reference below). The application of the causality algorithm resulted in "Indeterminate for causation, but likely as contributing", due to the limited data available. Although currently there are no safety concerns or signals for (b)(3):42 U.S.C. at this time, more data are needed to conclude that a (b)(3):42 U.S.C. is not directly associated with the Pfizer COVID-19 vaccine. However, the SMEs agreed that a causal relationship between the Pfizer COVID-19 vaccine and (b)(3):42 U.S.C. is biologically plausible, based off the reactogenicity of the vaccine.
CDC's Interim Clinical Considerations for Use of COVID-19 vaccines https://www.cdc.gov/vaccines/covid-19/info-by-product/clinical-considerations.html does not conside (b)(3):42 U.S.C. §242m(d); (b)(6) as a contraindication or precaution to COVID-19 vaccine. ACIP General Best Practices recommends that the presence of a moderate or severe acute illness with or without a fever is a precaution to administration of all vaccines

(https://www.cdc.gov/vaccines/hcp/acip-recs/general-recs/contraindications.html.

CISA experts provided opinions regarding (b)(3):42 U.S.C. use at the time of administering the COVID vaccine. The SMEs agreed that stress (b)(3):42 U.S.C due to presumed (b)(3):42 U.S.C. §242m(d), is unnecessary at the time when administering the COVID vaccine. However, the CISA experts did agree that increasing (b)(3):42 U.S.C. for patients who had a significant reaction to dose 1 of an mRNA vaccine would be recommended.

Additionally, CISA SMEs discussed whether it would be beneficial to routinely test for COVID-19 antibody response for patients who had used (b)(3):42 for their symptoms. The SMEs agreed that serologic testing was not recommended, as CDC guidance states that antibody testing is not recommended to assess immunity: https://www.cdc.gov/coronavirus/2019-ncov/lab/resources/antibody-tests-guidelines.html

We hope that we have fully addressed your questions and concerns. Please feel free to contact us if you have any further questions. 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 within the next six months to assess whether the patient has received additional vaccines and how (b)(3):42 tolerated them.

Sincerely,

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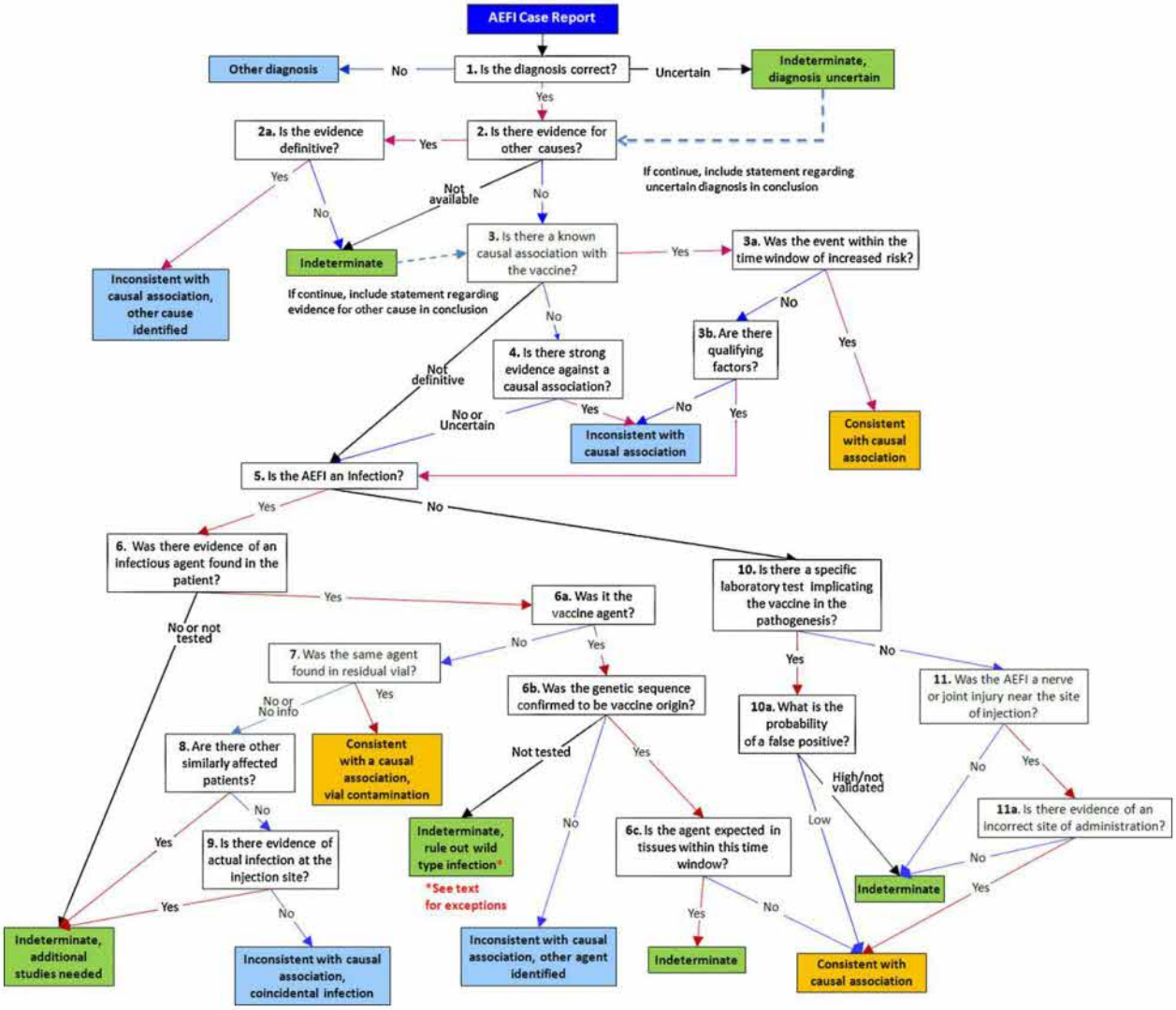
References

(b)(3):42 U.S.C. §242m(d); (b)(6)



(b)(3):42 U.S.C. §242m(d); (b)(6)

May 6, 2021

(b)(3):42 U.S.C. §242m(d); (b)(6)

On behalf of the Clinical Immunization Safety Office (CISA) Project, thank you for the opportunity to review the case of your (b)(3):42 [b)(3)] patient who was diagnosed with (b)(3):42 U.S.C. §242m(d); (b)(6) following receipt of the first dose of the Moderna COVID-19 vaccine. CISA was asked to review the case to assess whether the diagnosis was correct, if receipt of the 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 April 30, 2021 by the CISA Clinical Consultation Case Review Working Group, which includes vaccine safety experts, as well as subject matters experts (SME) in (b)(3):42 U.S.C. §242m(d); (b)(6)

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. Further COVID-19 vaccination?
    b. Routine vaccines?
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, and Vaccine Adverse Event Reporting Systems (VAERS) search results, and FDA emergency use authorization information on both the Pfizer and Moderna COVID-19 vaccines. The (b)(3):42 SMEs on the call agreed unanimously that the patient did indeed have (b)(3):42 (b)(3):42 U.S.C. (a classic case). As you brought to our attention, (b)(3):42 U.S.C. §242m(d); (b)(6) (b)(3):42 U.S.C. §242m(d); (b)(6) (b)(3):42 U.S.C. However, there is no known causal association, or clear biologic pathway for a vaccine to cause (b)(3):42 U.S.C. §242m(d); (b)(6)

There was significant discussion on the fact that the etiology of this disorder and the pathophysiology are not well understood, so it is difficult to determine a causal relationship between the vaccine and the illness. When we used the causality algorithm developed by Neal Halsey and colleagues (diagram and

reference below), we ended up with an outcome of "Indeterminate" as to whether the vaccine contributed to the adverse event.

The FDA EUA and CDC Interim Clinical Considerations for Use of COVID-19 Vaccines (https://www.cdc.gov/vaccines/covid-19/info-by-product/clinical-considerations.html) lists the contraindications and precautions for COVID-19 vaccination. Based on the guidance in that document, your patient does not have a contraindication to receipt of the second dose of the COVID-19 vaccine and would fall into the Green category. The SMEs did recommend unanimously that (b)(3):42 receive that second dose.

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 within the next few months to assess whether the patient has received additional vaccines and how (b)(3):42 tolerated them.

Sincerely,

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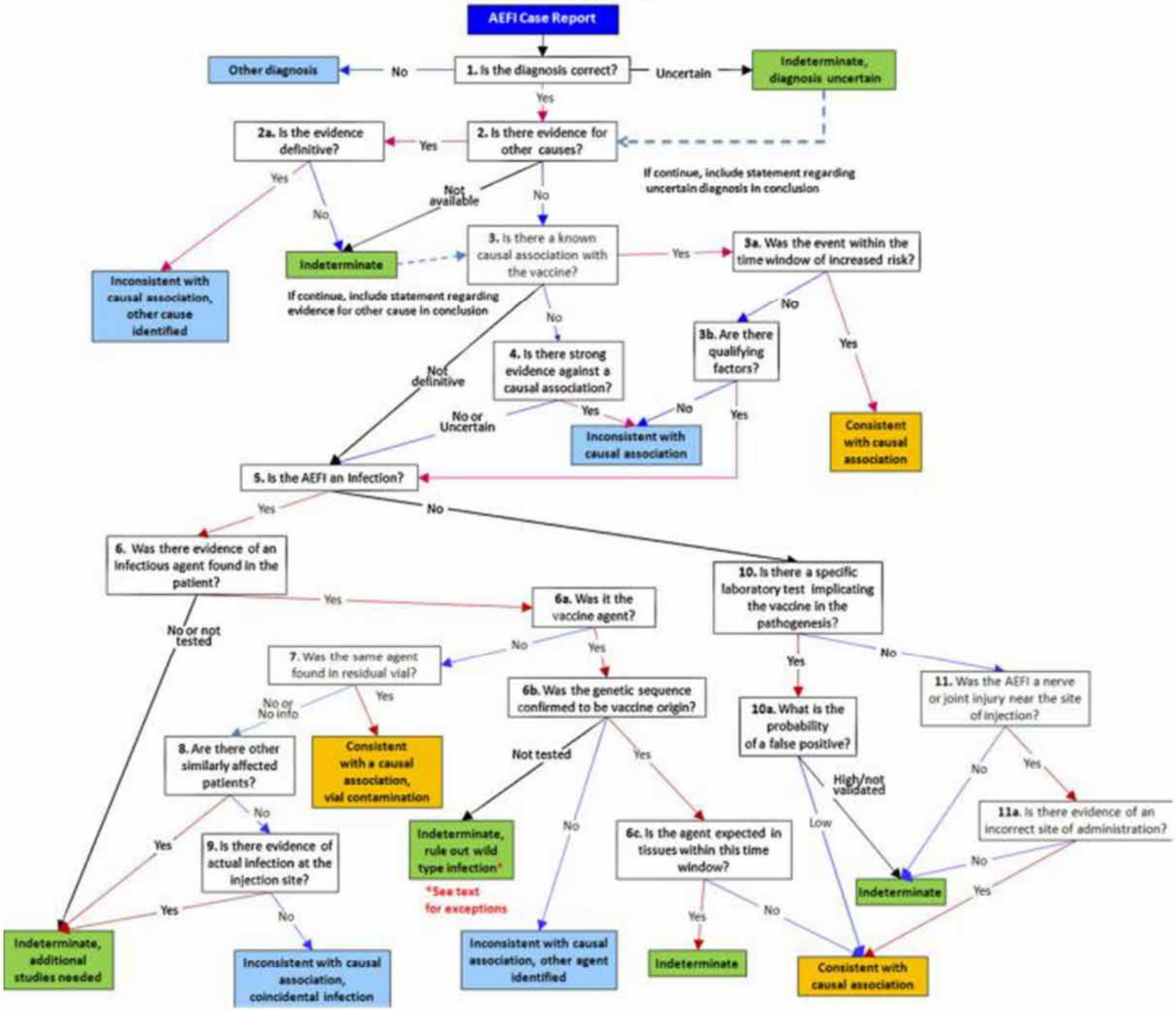
References

1. Halsey NA, Edwards KM, et al, Causality Working Group of the Clinical Immunization Safety Assessment network, *Vaccine*. 2012 Aug 24;30(39):5791-8. Epub 2012 Apr 14.

Review of Case Reports of Adverse Events Following Immunizations
February 28, 2012
Causality Work Group of CISA



(b)(3):42 U.S.C. §242m(d); (b)(6)

June 16, 2021

(b)(3):42 U.S.C. §242m(d); (b)(6)

On behalf of the Clinical Immunization Safety Office (CISA) Project, thank you for the opportunity to review the case of your (b)(3):42 (b)(3):42 patient who developed (b)(3):42 U.S.C. §242m(d); (b)(6) approximately 13 hours after receiving dose 1 of the Moderna COVID-19 vaccine on April 1, 2021. CISA was asked to provide guidance as to whether the administration of the Moderna COVID-19 vaccine was a direct causation of the patient's (b)(3):42 U.S.C. §242m(d); (b)(6)

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 May 19, 2021 by the CISA Clinical Consultation Case Review Working Group, which includes vaccine safety experts, as well as subject matters experts (SMEs) in (b)(3):42 U.S.C. §242m(d); (b)(6)

The following questions were posed:

1. Is the diagnosis correct?
2. Did the vaccine cause or contribute to the AEFI?
3. What are the recommendations for future vaccines?
    a. Routine vaccines
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, literature on (b)(3):42 U.S.C. §242m(d); (b)(6) and vaccines, and FDA emergency use authorization information on the mRNA COVID-19 vaccines. Results from Vaccine Adverse Event Reporting Systems (VAERS) data mining and Vaccine Safety Datalink (VSD) analysis on (b)(3):42 U.S.C. (b)(3):42 were also reviewed.

The SMEs agreed that the patient's symptoms and lab work were consistent with (b)(3):42 U.S.C. (b)(3):42 U.S.C. The SMEs assessed whether the diagnosis was causally related to the receipt of the Moderna COVID-19 vaccine using the causality algorithm (see diagram and reference below). The application of the causality algorithm resulted in "Consistent with causal association", due to the sudden acute stress of receiving the Moderna COVID-19 vaccine, leading to (b)(3):42 U.S.C. §242m(d); (b)(6). Of note, the SMEs agreed that they could not specify if the patient's recurrence of (b)(3):42 U.S.C. §242m(d); (b)(6) was a direct (b)(3):42 U.S.C. §242m(d); (b)(6) response from vaccination, or occurred due to the patient's anxiety and stress levels around the vaccination process.

(b)(3):42 U.S.C. §242m(d); (b)(6)

CDC's Interim Clinical Considerations for Use of COVID-19 vaccines https://www.cdc.gov/vaccines/covid-19/info-by-product/clinical-considerations.html does not consider (b)(3):42 U.S.C. §242m(d); (b)(6) as a contraindication or precaution to COVID-19 vaccine. ACIP General Best Practices recommends that the presence of a moderate or severe acute illness with or without a fever is a precaution to administration of all vaccines (https://www.cdc.gov/vaccines/hcp/acip-recs/general-recs/contraindications.html.

The SMEs agreed that the patient should receive dose 2 of the Moderna COVID-19 vaccine. However, the experts agreed that the patient should receive a follow-up (b)(3):42 U.S.C to ensure the patient's full recovery, prior to administering dose 2 of the Moderna COVID-19 vaccine. The SMEs also suggested potentially raising the patient's (b)(3):42 levels to potentially avoid a repeat occurrence of (b)(3):42 U.S.C

Additionally, CISA SMEs discussed the potential benefit of prescribing (b)(3):42 U.S.C. §242m(d); (b)(6)

(b)(3):42 U.S.C. §242m(d); (b)(6)

We hope that we have fully addressed your questions and concerns. Please feel free to contact us if you have any further questions. 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 within the next six months to assess whether the patient has received additional vaccines and how (b)(3):42 U.S.C. tolerated them.

Sincerely,

(b)(3):42 U.S.C §242m(d); (b)(6)

Disclaimer:

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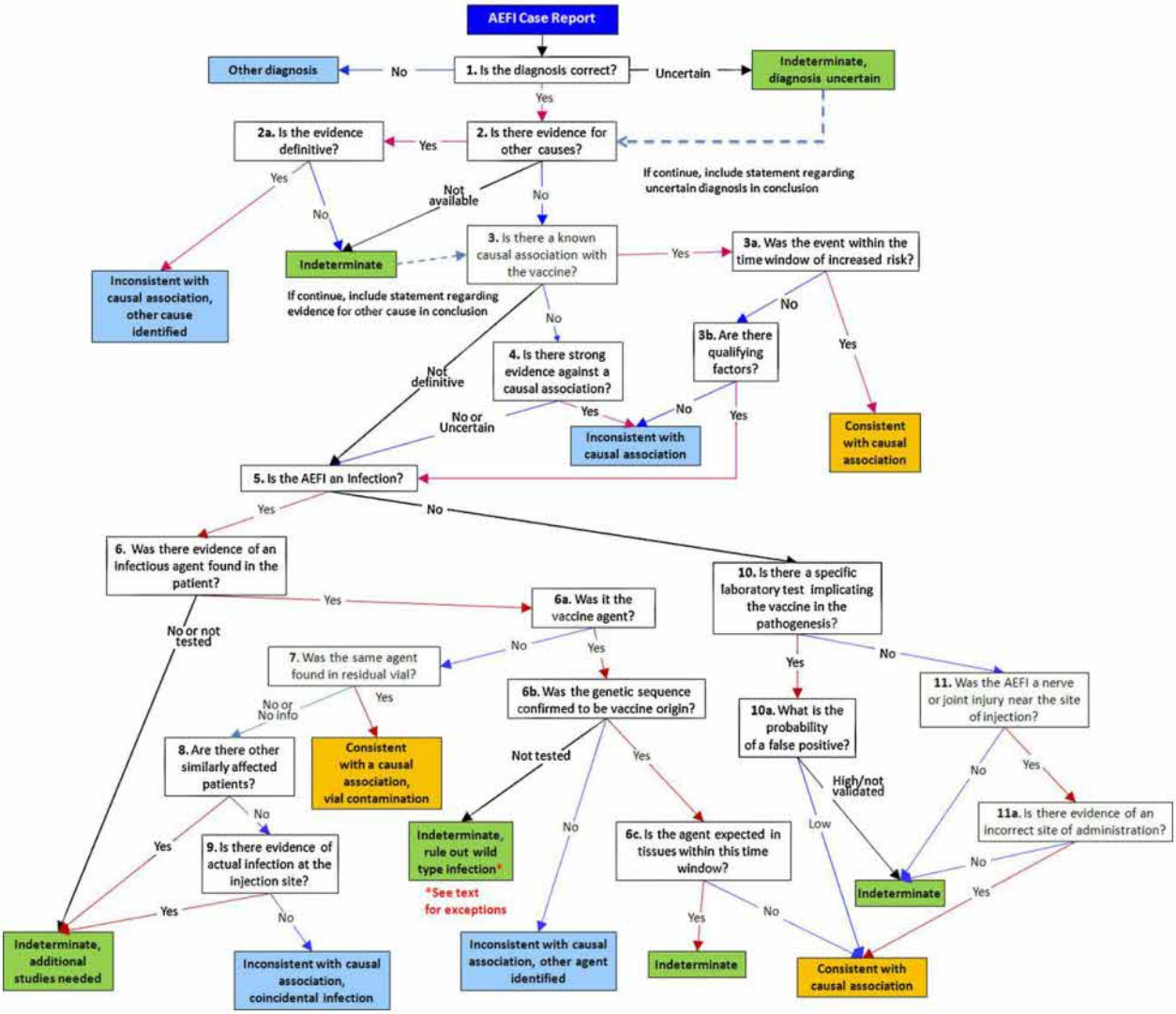
(b)(3) 42 U.S.C. §242m(d), (b)(6)

References

(b)(3) 42 U.S.C. §242m(d), (b)(6)



(b)(3):42 U.S.C. §242m(d), (b)(6)

June 4, 2021

(b)(3):42 U.S.C. §242m(d), (b)(6)

On behalf of the Clinical Immunization Safety Office (CISA) Project, thank you for the opportunity to review the case of your (b)(3):42 U.S.C. §242m(d), (b)(3) who developed (b)(3):42 U.S.C. §242m(d), following receipt of the first dose of the Moderna COVID-19 vaccine. CISA was asked to review the case to assess whether the diagnosis was correct, if receipt of the 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 May 19, 2021 by myself, Dr. T (b)(3):42 U.S.C. of the CDC CISA Team, and Dr. (b)(3):42 U.S.C. a r (b)(3):42 U.S.C. §242m(d), (b)(6) expert.

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. Further COVID-19 vaccination?
    b. Routine vaccines?
4. Is any additional testing warranted?
5. When to schedule follow-up?

Collectively, we reviewed the including the patient's medical and family history, Dr. (b)(3):42 U.S.C. summarized (b)(3) and we reviewed vaccine safety literature, and Vaccine Adverse Event Reporting Systems (VAERS) search results, and CDC's Interim Clinical Considerations and CDC's general guidance for completing vaccination with the same series that a patient begins with. Dr. (b)(3):42 confirmed that your patient did meet the criteria for (b)(3):42 U.S.C. §242m(d), (b)(6) and that (b)(would be categorized as a Brighton Criteria Level 2 (see reference) as (b)(did not have (b)(3):42 U.S.C. §242m(d), (b)(6) . Given (b)(3):42 preceding (b)(3):42 U.S.C. , Dr. (b)(3):42 felt that it was the most likely the trigger for the (b)(3) and so using the causality algorithm developed by Neal Halsey and colleagues (diagram and reference below), we ended up with an outcome of "Inconsistent with causal association" as to whether the vaccine contributed to the adverse event.

We did recommend that your patient receiv (b)(3):42 econd dose of vaccine, once the acute illness that you had brought to our attention has resolved. You mentioned that the (b)(3):42 does not have the Moderna COVID-19 vaccine available, but does have Pfizer. While the CDC recommends continuing with the same vaccine when possible, in exceptional circumstances it is possible to change vaccine brand. In

this case, we felt that it was better for your patient to receive the Pfizer vaccine as the second dose and not to switch to the Janssen vaccine, once (b)(3): 42 (b)(3):42 U.S.C. §242m(d); has cleared.

It is also fine fo (b)(3): 42 to receive any routine vaccinations that (b) needs.

The FDA EUA and CDC Interim Clinical Considerations for Use of COVID-19 Vaccines (https://www.cdc.gov/vaccines/covid-19/info-by-product/clinical-considerations.html) lists the contraindications and precautions for COVID-19 vaccination.

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 within the next few months to assess whether the patient has received additional vaccines and how (b)(3): 42 olerated them.

Guidance regarding COVID-19 vaccines is frequently being updated, and we suggest that you check the following sites for the most updated guidance regarding CDC and ACIP guidance for COVID-19 vaccines:

- For updated information on COVID-19 vaccines that have received a recommendation from the Advisory Committee on Immunization Practices, please see: https://www.cdc.gov/vaccines/hcp/acip-recs/vacc-specific/covid-19.html

- For the most up-to-date information, CDC will continue to post information online at: https://www.cdc.gov/coronavirus/2019-ncov/index.html

Sincerely,

(b)(3):42 U.S.C. §242m(d); (b)(6)

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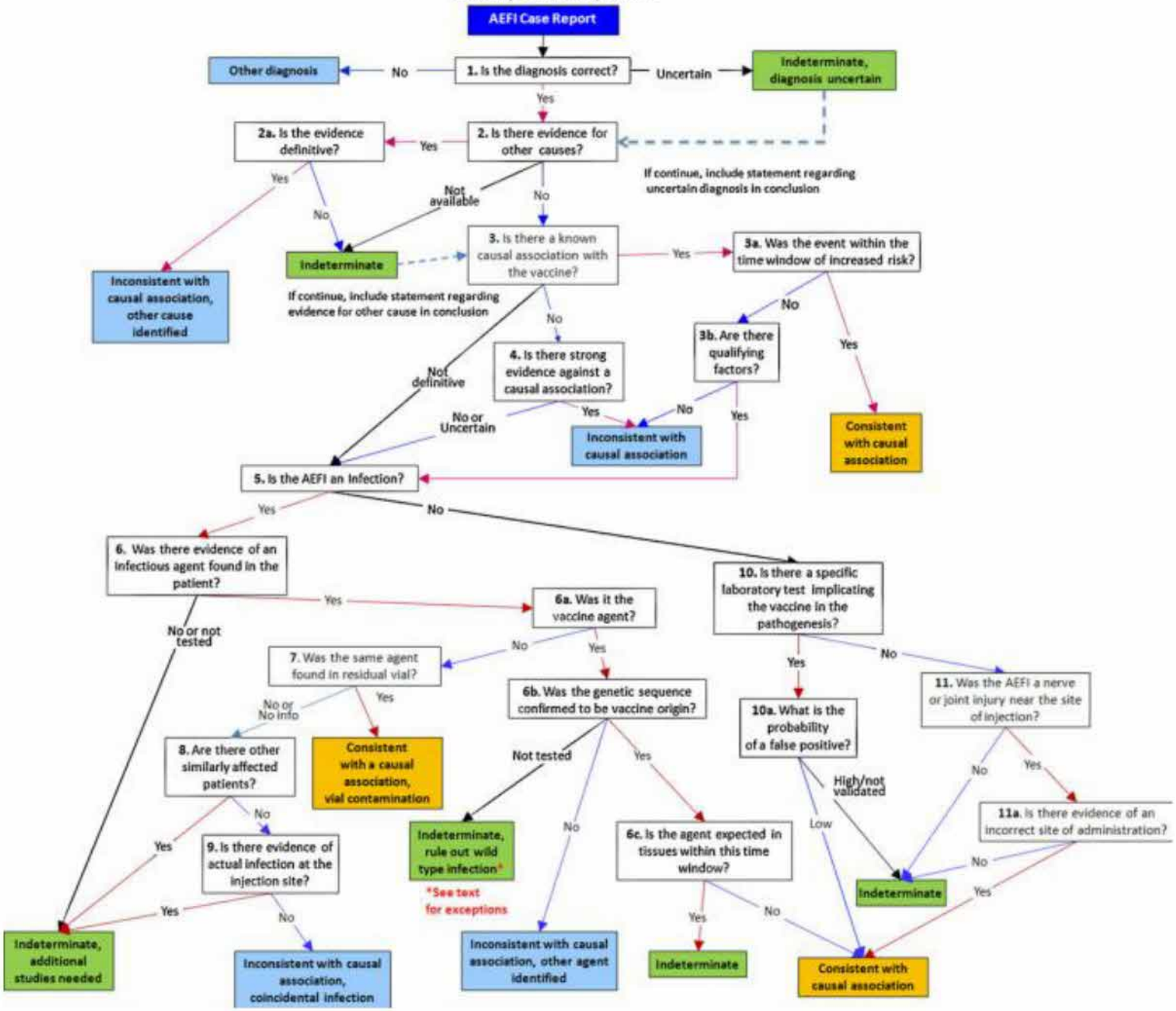
References

1. Halsey NA, Edwards KM, et al, Causality Working Group of the Clinical Immunization Safety Assessment network, *Vaccine*. 2012 Aug 24;30(39):5791-8. Epub 2012 Apr 14.

(b)(3):42 U.S.C. §242m(d); (b)(6)

Review of Case Reports of Adverse Events Following Immunizations
February 28, 2012
Causality Work Group of CISA



(b)(3) 42 U.S.C. §242m(d), (b)(6)

June 29, 2021

(b)(3) 42 U.S.C. §242m(d), (b)(6)

On behalf of the Clinical Immunization Safety Office (CISA) Project, thank you for the opportunity to review the case of your (b)(3) 42 (b)(3) 42 patient who was diagnosed with (b)(3) 42 U.S.C. §242m(d), (b)(6) (b)(3) 42 following receipt of the first dose of Pfizer COVID-19 vaccine. CISA was asked to review the case to assess whether the diagnosis was correct, if receipt of the 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 June 15, 2021 by the CISA Clinical Consultation Case Review Working Group, which includes vaccine safety experts, as well as subject matters experts (SME) in (b)(3) 42 U.S.C. §242m(d), (b)(6)

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. COVID-19 Vaccine dose 2?
    b. Routine vaccines?
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, and Vaccine Adverse Event Reporting Systems (VAERS) search results, and the FDA emergency use authorization information on the Pfizer COVID-19 vaccine.

The SMEs agreed that (b)(was the correct diagnosis and assessed whether the diagnosis was causally related to the receipt Pfizer mRNA COVID-19 vaccine using the causality algorithm (see diagram and reference below). The application of the causality algorithm resulted in **Indeterminate** because while there is no known causal association between the vaccine and (b)(3 there is not strong evidence of there was no clear evidence of another cause of the (b)(and there is not strong evidence against a causal association.

The SMEs did suggest that it would be good to test the patient for previous COVID-19 infection by looking for anti-nucleocapsid antibodies. This may help in determining if the first dose of vaccine boosted antibody titers which may have contributed to (b)(Additionally, there is increasing evidence that in those with previous infection, one dose of vaccine is likely sufficient for protection however

current guidance still supports two doses of an mRNA vaccine to be fully vaccinated, even in those with previous COVID infection. Additionally, you can consider testing (b)(3):42 U.S.C. §242m(d); (b)(6) has been associated with (b)(

Given (b)(3): 42 reluctance to receive a second dose of vaccine, it is recommended that the second dose be deferred. However, the decision to receive a second dose should be revisited should the epidemiology of circulating variants change. Recent data has shown that two doses of mRNA vaccine provide significantly greater protection against the Delta variant of SARS-CoV-2 than a single dose. Shared decision making should be utilized if the epidemiology of COVID supports revisiting the decision to defer the second vaccination.

The FDA EUA and CDC Interim Clinical Considerations for Use of COVID-19 Vaccines (https://www.cdc.gov/vaccines/covid-19/info-by-product/clinical-considerations.html) lists the contraindications and precautions for COVID-19 vaccination. Based on the guidance in that document, your patient does not have a contraindication to receipt of the second dose of the COVID-19 vaccine and would fall into the Green category.

In regards to routine vaccinations, (b)(3): 42 can receive any other vaccine according to need/schedule.

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 within the next few months to assess whether the patient has received additional vaccines and how (b)(3):4 tolerated them.

Sincerely,

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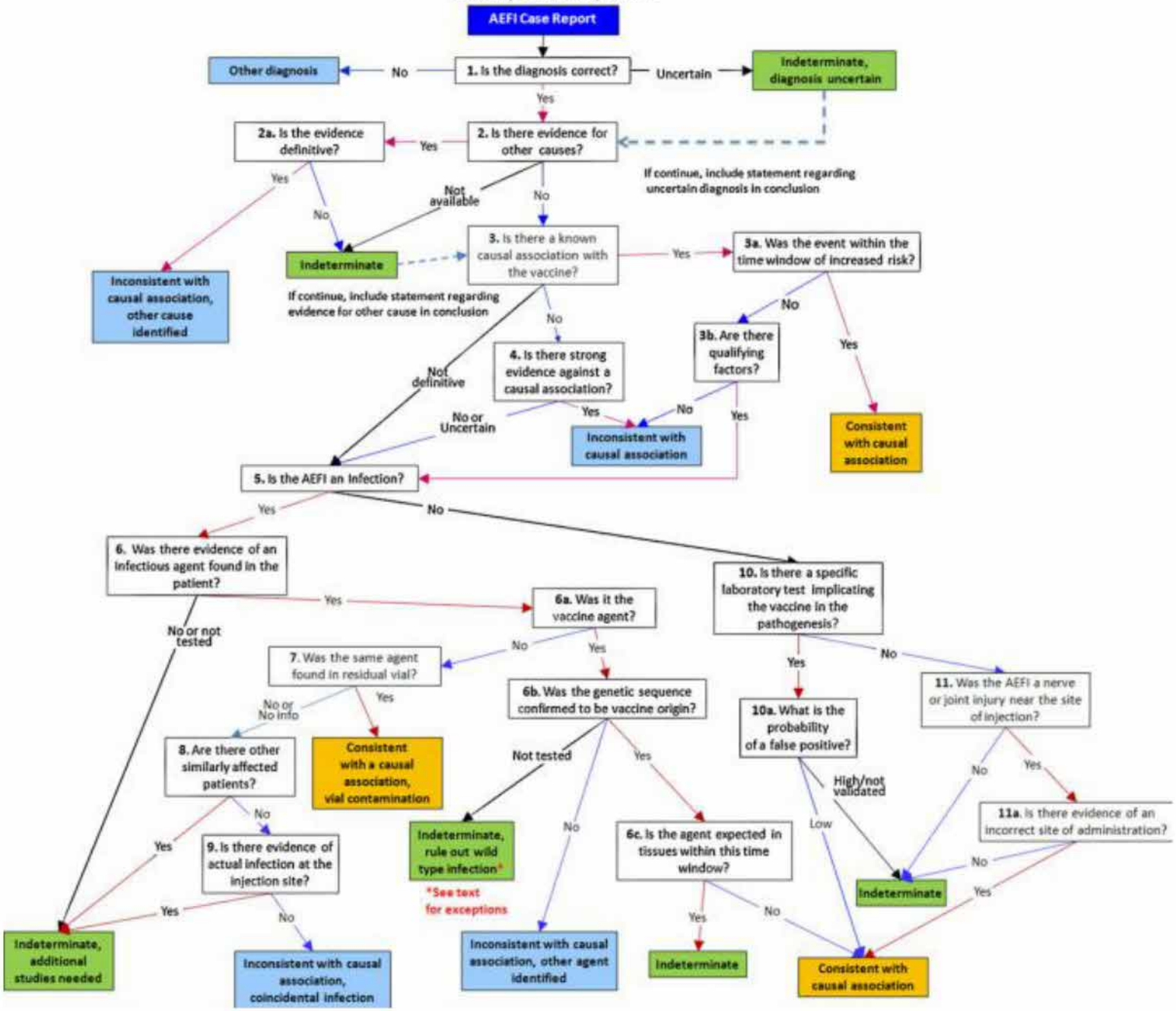
References

1. Halsey NA, Edwards KM, et al, Causality Working Group of the Clinical Immunization Safety Assessment network, *Vaccine*. 2012 Aug 24;30(39):5791-8. Epub 2012 Apr 14.

Review of Case Reports of Adverse Events Following Immunizations
February 28, 2012
Causality Work Group of CISA



(b)(3):42 U.S.C. §242m(d); (b)(6)

June 29, 2021

(b)(3):42 U.S.C. §242m(d); (b)(6)

On behalf of the Clinical Immunization Safety Office (CISA) Project, thank you for the opportunity to review the case of your (b)(3):42 U.S.C. (b)(3):4 patient who experienced (b)(3):42 U.S.C. §242m(d); (b)(6) 2 weeks following the receipt of the first dose of the Moderna COVID-19 mRNA vaccine. CISA was asked to review the case to assess whether the diagnosis was correct, if receipt of the Pfizer COVID-19 mRNA 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 June 25, 2021 by a sub-group of the CISA Clinical Consultation Case Review Working Group, which included myself, Dr. (b)(3):42 U.S.C. , a (b)(3):42 U.S.C. §242m(d); (b)(6) (b)(3):42 U.S.C. , Dr. (b)(3):42 U.S.C. §242m(d); (b)(6) , and Drs. (b)(3):42 U.S.C. §242m(d); (b)(6) (b)(3):42 U.S.C. §242m(d); of the CDC CISA team.

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. COVID-19 vaccine?
    b. Routine vaccines?
4. Is any additional testing warranted?
5. When to schedule follow-up?

Together we reviewed available evidence, including the patient's medical history, vaccine safety literature, and Vaccine Adverse Event Reporting Systems (VAERS) search results, and the FDA emergency use authorization information on the Pfizer COVID-19 vaccine.

The causality algorithm (see diagram and reference below) was applied using a diagnosis of (b)(3):42 U.S.C. syndrome to assess whether this patient's AEFI was causally related to the receipt of the Pfizer COVID-19 mRNA vaccine. The application of the causality algorithm resulted in "Indeterminate" because the diagnosis is uncertain, there is no evidence to support other causes, and there is not a definitive known association between the vaccine and AEFI.

The FDA EUA and CDC Interim Clinical Considerations for Use of COVID-19 Vaccines (https://www.cdc.gov/vaccines/covid-19/info-by-product/clinical-considerations.html) lists the contraindications and precautions for COVID-19 vaccination. Based on the guidance in that document, your patient does not have a contraindication to receipt of the second dose of the COVID-19 vaccine and would fall into the Green category.

Regarding routine vaccinations, CISA agreed that no contraindications exist, and this patient can receive other vaccines according to need/schedule.

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 within the next few months to assess whether the patient has received the second dose, additional vaccines and how s[redacted] tolerated them.

Sincerely,

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References

1. Halsey NA, Edwards KM, et al, Causality Working Group of the Clinical Immunization Safety Assessment network, *Vaccine*. 2012 Aug 24;30(39):5791-8. Epub 2012 Apr 14.

Review of Case Reports of Adverse Events Following Immunizations
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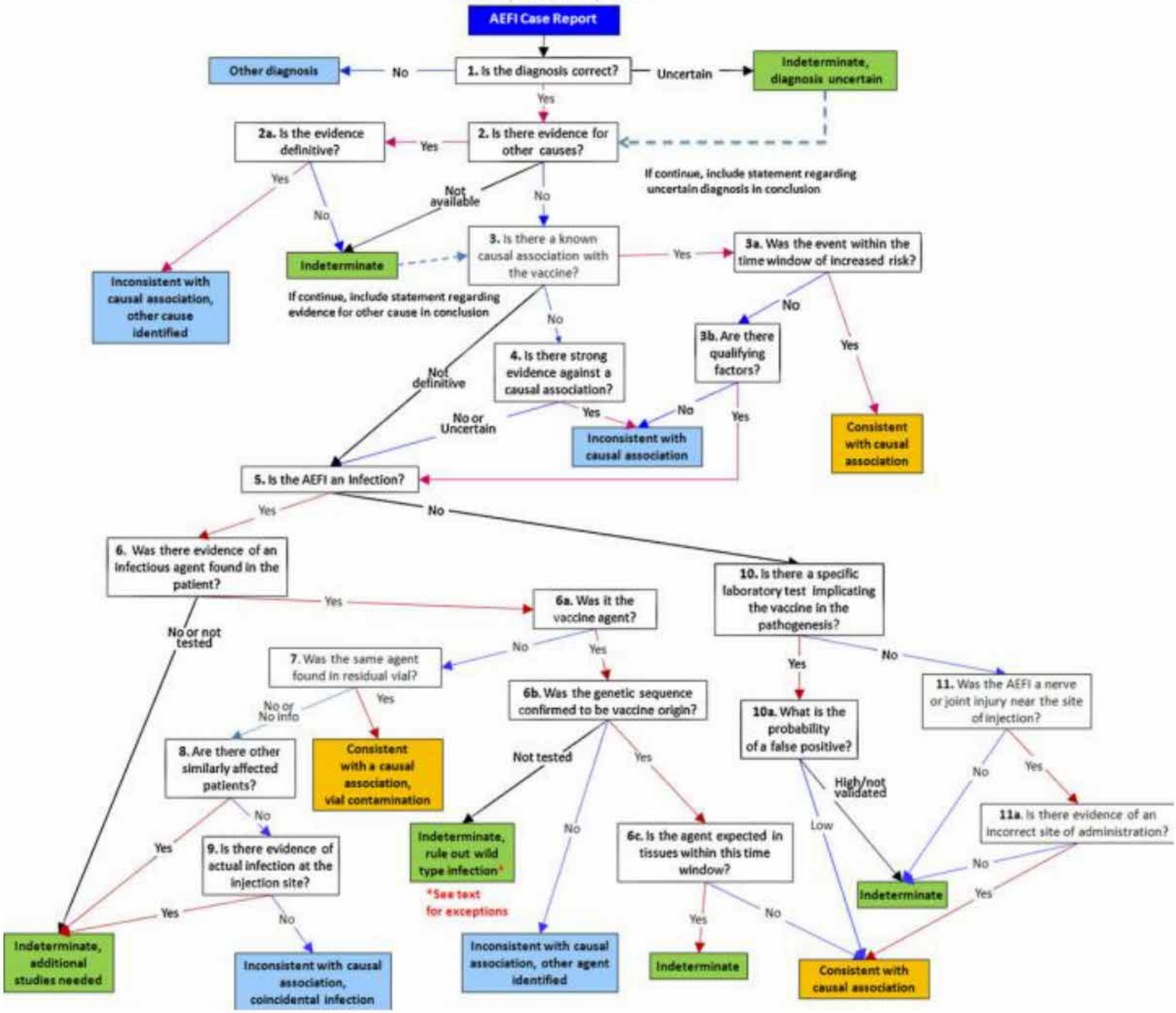
Causality Work Group of CISA



(b)(3):42 U.S.C. §242m(d), (b)(6)

July 21, 2021

(b)(3):42 U.S.C. §242m(d); (b)(6)

On behalf of the Clinical Immunization Safety Office (CISA) Project, thank you for the opportunity to review the case of your (b)(3):42 (b)(3) patient who experienced (b)(3):42 U.S.C. 4 days following the receipt of the first dose of the Pfizer COVID-19 mRNA vaccine, followed by (b)(3):42 U.S.C. §242m(d), (b)(6) and then (b)(3):4 (b)(3):42 U.S.C. §242m(d), (b)(6). CISA was asked to review the case to assess whether the diagnosis was correct, if receipt of the Pfizer COVID-19 mRNA 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 June 30, 2021 by the CISA Clinical Consultation Case Review Working Group, which includes vaccine safety experts, as well as subject matters experts (SME) in (b)(3):42 U.S.C. §242m(d); (b)(6)

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. COVID-19 vaccine?
    b. Routine vaccines?
4. Is any additional testing warranted?
5. When to schedule follow-up?

Together we reviewed available evidence, including the patient's medical history, vaccine safety literature, and Vaccine Adverse Event Reporting Systems (VAERS) search results, and the FDA emergency use authorization information on the Pfizer COVID-19 vaccine.

The causality algorithm (see diagram and reference below) was applied using a diagnosis of (b)(3):42 (b)(3):42 to assess whether this patient's AEFI was causally related to the receipt of the Pfizer COVID-19 mRNA vaccine. The subject matter experts on the call were polled later to see whether they thought that the evidence was sufficient to state that the diagnosis is inconsistent with a causal relationship or whether it was indeterminate. The only reason for it being potentially indeterminate that was given was that no organism was identified as a cause of (b)(3) (b)(3):42 due to (b)(3):42 U.S.C. §242m(d); (b)(6) Despite this, 11 of 12 of the SMEs who responded agreed that there was sufficient evidence to suspect another etiology in the case of your patient, and that this AEFI was inconsistent with a causal association with the vaccine; 1 said that she would prefer to have a definitive organism and would put it between inconsistent and indeterminate.

The FDA EUA and CDC Interim Clinical Considerations for Use of COVID-19 Vaccines (https://www.cdc.gov/vaccines/covid-19/info-by-product/clinical-considerations.html) lists the contraindications and precautions for COVID-19 vaccination. Based on the guidance in that document, your patient does not have a contraindication to receipt of the second dose of the COVID-19 vaccine and would fall into the Green category.

Regarding routine vaccinations, CISA agreed that no contraindications exist, and this patient can receive other vaccines according to need/schedule.

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 within the next few months to assess whether the patient has received the second dose, additional vaccines and how (b)(3):42 tolerated them.

Sincerely,

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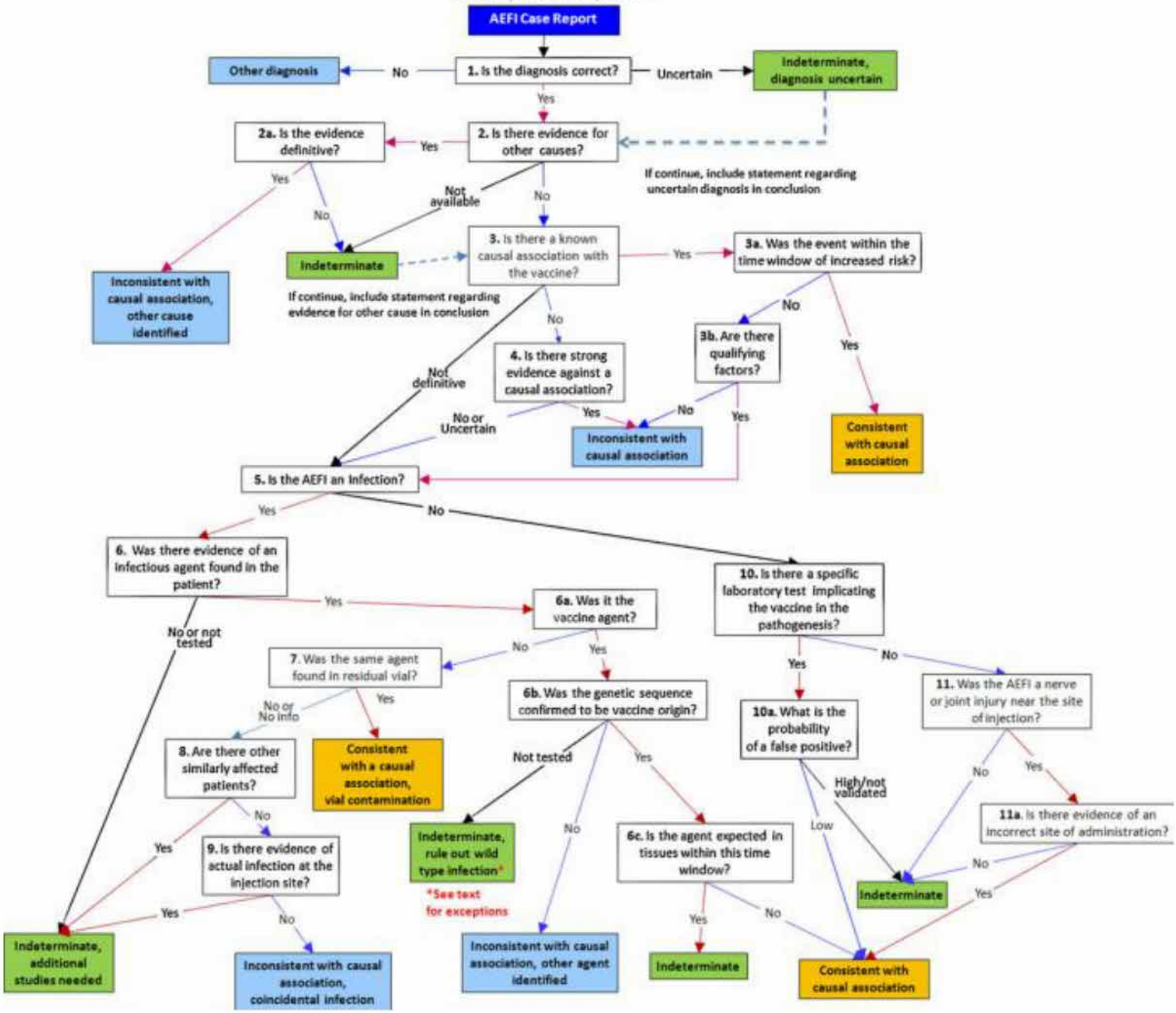
References

1. Halsey NA, Edwards KM, et al, Causality Working Group of the Clinical Immunization Safety Assessment network, *Vaccine*. 2012 Aug 24;30(39):5791-8. Epub 2012 Apr 14.

Review of Case Reports of Adverse Events Following Immunizations
February 28, 2012
Causality Work Group of CISA



(b)(3):42 U.S.C. §242m(d); (b)(6)

July 30, 2021

(b)(3):42 U.S.C. §242m(d); (b)(6)

On behalf of the Clinical Immunization Safety Office (CISA) Project, we thank you for the opportunity to review the case of your patient who was diagnosed with (b)(3):42 U.S.C. after COVID-19 mRNA vaccine. CISA was asked to review the case to assess whether the diagnosis of (b)(3):42 U.S.C. was correct, if receipt of (b)(3): 42 vaccines 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), CISA is a national research network that provides healthcare providers with expert opinions on adverse events following immunizations. This case was reviewed on July 20th, 2021 by the CISA Clinical Consult Case Review Working Group, which includes vaccine safety experts, as well as subject matter experts in (b)(3):42 U.S.C. §242m(d); (b)(6)

The following questions were posed and the answers presented in bold italics:

1. Is the diagnosis correct? ***After discussions, the CISA subject matter experts assessed that the diagnosis can best be characterized as*** (b)(3):42 U.S.C. §242m(d); (b)(6)
2. Did the vaccines cause or contribute to the AEFI? ***Indeterminate***
3. What is CISA guidance regarding future vaccines for this patient? ***Patient received one dose and is interested in receiving a second dose to be fully vaccinated in college. CISA PIs/SMEs in attendance on this call opined that they would give second dose. Informed decision-making between patient and provider is recommended when deciding on optimal time to administration dose #2. Guidance was shared that dose #2 could be administered after the patient has recovered from the recent illness, and could be now, if the patient has recovered.***
4. Is any additional testing warranted? ***One could test the original sample(s) of CSF (if there is sample available) with PCRs specific for*** (b)(3):42 U.S.C. §242m(d); (b)(6) (b)(3):42 U.S.C. ***The rationale for this guidance is that sometimes large panel screening tests are as not as sensitive and specific for identifying the etiology of a viral infection as single-virus tests.***
5. When to schedule follow-up? ***This was not addressed on the call, but we plan to reach out in 2-3 months for patient outcome survey.***

6. What is the guidance for this patient regarding receipt of subsequent doses of these vaccines? ***CISA PIs/SMEs would feel comfortable administering the second dose of the COVID-19 mRNA Pfizer vaccine.***

CISA's primary aim is not to establish causality; however, based on a published causality algorithm (see figure and reference #1 in the attached summary) and expert opinion, we assessed the likelihood that receipt of the vaccine was causally related to the reaction. Application of the algorithm resulted in the causality determination of "**Indeterminate**" as to whether this event was causally related to the vaccine.

Please see the appended below the CISA Vaccine Adverse Event Causality Algorithm, and bibliography that might be of use to you in the future. We hope that this review will be helpful in the management of your patient.

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 to you in approximately two to three months to assess how the patient tolerated future vaccinations.

Sincerely,

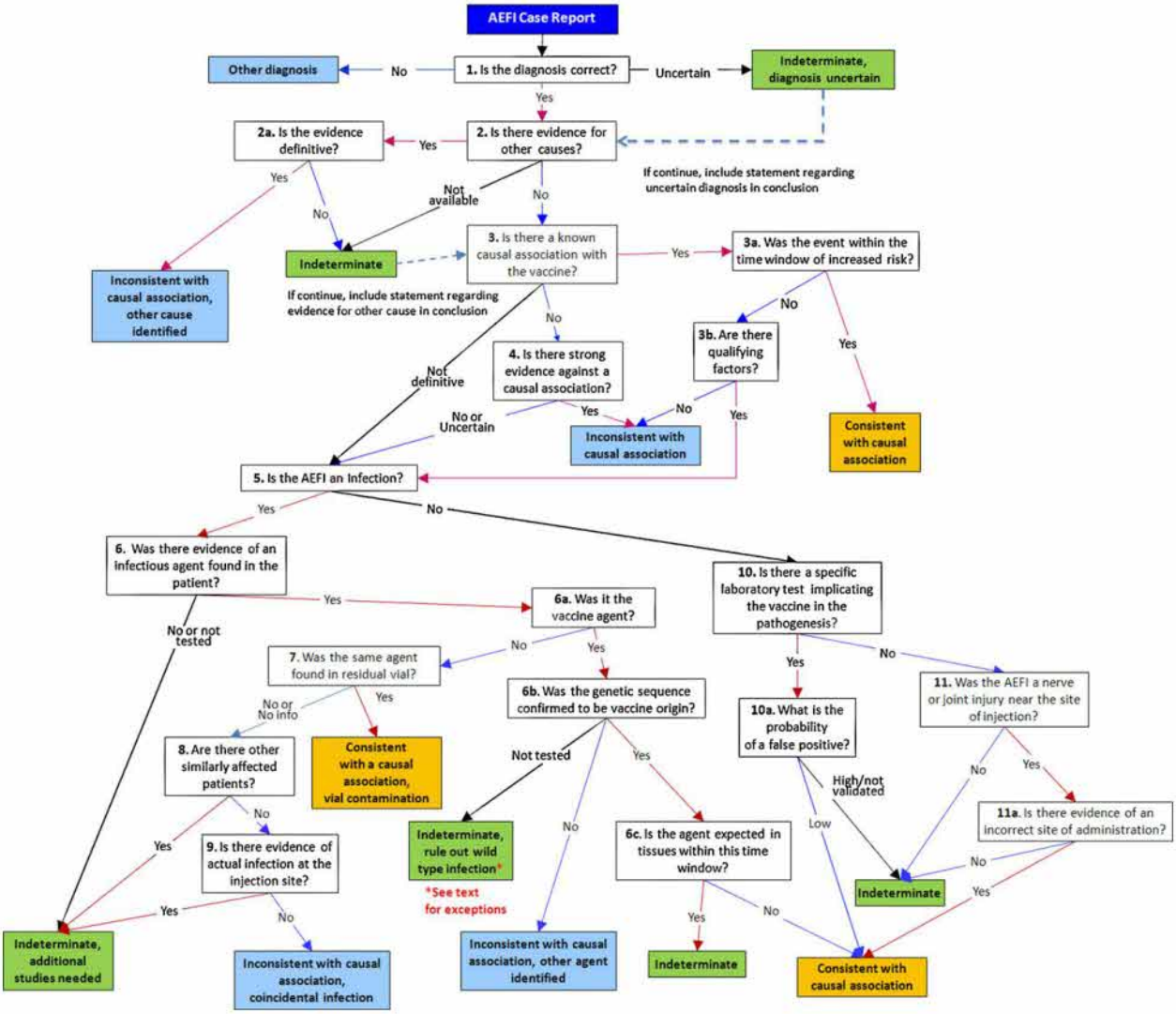
Disclaimer:

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.

(b)(3):42 U.S.C. §242m(d), (b)(6)

References

1. Halsey NA, Edwards KM, et al, Causality Working Group of the Clinical Immunization Safety Assessment network, Vaccine. 2012 Aug 24;30(39):5791-8. Epub 2012 Apr 14.



(b)(3):42 U.S.C. §242m(d); (b)(6)

August 23, 2021

(b)(3):42 U.S.C. §242m(d); (b)(6)

On behalf of the Clinical Immunization Safety Office (CISA) Project, thank you for the opportunity to review the case of your (b)(3):42 U.S.C (b)(3) patient who developed (b)(3):42 U.S.C §242m(d); (b)(6) with symptom onset beginning approximately 19 days after receiving dose 1 of the Pfizer-BioNTech COVID-19 vaccine on June 3, 2021. CISA was asked to provide guidance as to whether the administration of the Pfizer-BioNTech COVID-19 vaccine was a direct causation of the patient's (b)(3):42 U.S.C

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 August 13, 2021 by the CISA Clinical Consultation team at (b)(3):4 and CDC, which includes vaccine safety experts, as well as subject matters experts (SMEs) in (b)(3):42 U.S.C

The following questions were posed:

1. Is the diagnosis correct?
2. Did the vaccine cause or contribute to the AEFI?
3. What are the recommendations for future vaccines?
    a. Routine vaccines
4. Is any additional testing warranted?
5. When to schedule follow-up?

CISA vaccine safety and (b)(3): SMEs reviewed available evidence, including the patient's medical and family history, literature on (b)(3):42 U.S.C. §242m(d); (b)(6) and vaccines, and FDA emergency use authorization information on the mRNA COVID-19 vaccines. Results from Vaccine Adverse Event Reporting Systems (VAERS) data mining were also reviewed.

The SMEs agreed that the patient's symptoms and lab work were consistent with (b)(3):42 U.S.C. There was no evidence of acute COVID-19 infection or prior COVID-19 infection. The SMEs assessed whether the diagnosis was causally related to the receipt of the Pfizer-BioNTech COVID-19 vaccine using the causality algorithm (see diagram and reference below). The application of the causality algorithm resulted in "inconsistent with a causal association", based off the patient's medical history, literature review, and VAERS search. The SMEs assessed this adverse event as '(b)(3):42 U.S.C. §242m(d); (b)(6) due to (b)(3):42 U.S.C. §242m(d); (b)(6) (b)(3) (b)(3):42 U.S.C. §242m(d); (b)(6) (b)(3):42 U.S.C. §242m(d); (b)(6)

CDC's Interim Clinical Considerations for Use of COVID-19 vaccines https://www.cdc.gov/vaccines/covid-19/info-by-product/clinical-considerations.html does not consider (b)(3):42 U.S.C as a contraindication or precaution to COVID-19 vaccine. However, ACIP General Best Practices recommends that the

(b)(3):42 U.S.C. §242m(d); (b)(6)

presence of a moderate or severe acute illness with or without a fever is a precaution to administration of all vaccines (https://www.cdc.gov/vaccines/hcp/acip-recs/general-recs/contraindications.html.

The SMEs agreed that there was not a causal relationship between the Pfizer-BioNTech vaccine and the patient's (b)(3):42 U.S.C. Although the patient's (b)(3):42 U.S.C. §242m(d); (b)(6) the SMEs agreed that due to the determination that there was no causation between the patient's developed (b)(3):42 U.S.C and the Pfizer-BioNTech COVID-19 vaccine, the patient should receive the second dose of the Pfizer-BioNTech vaccine without delay. The SMEs agreed that the benefit of the patient (b)(3):42 U.S.C fully vaccinated outweighed the patient's slightly (b)(3):42 U.S.C.

Additionally, CISA SMEs agreed that the patient should get (b)(3) (b)(3):42 U.S.C. §242m(d); (b)(6) echecked in approximately four weeks. The SMEs agreed that the patient should be referred to (b)(3):42 U.S.C if the (b)(levels had not decreased.

We hope that we have fully addressed your questions and concerns. Please feel free to contact us if you have any further questions. 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 within the next six months to assess whether the patient has received additional vaccines and how (b)(3):4 tolerated them.

Sincerely,

(b)(3):42 U.S.C. §242m(d); (b)(6)

Disclaimer:
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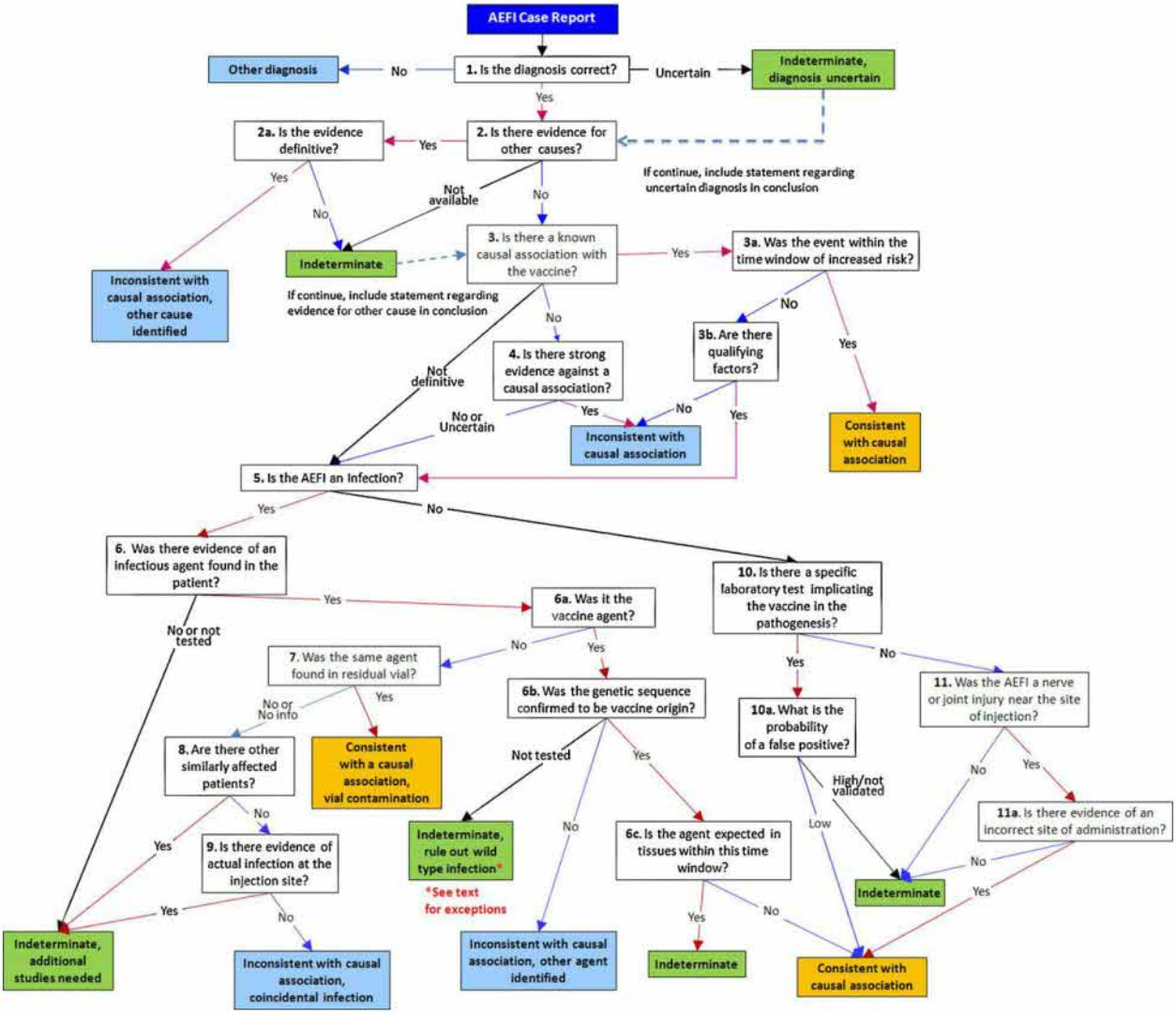
References

1. Halsey NA, Edwards KM, et al, Causality Working Group of the Clinical Immunization Safety Assessment network, Vaccine. 2012 Aug 24;30(39):5791-8. Epub 2012 Apr 14.



(b)(3):42 U.S.C. §242m(d), (b)(6)

September 20, 2021

(b)(3):42 U.S.C. §242m(d), (b)(6)

On behalf of the Clinical Immunization Safety Office (CISA) Project, we thank you for the opportunity to review the case of your (b)(3): (b)(3):42 patient who was diagnosed with (b)(3):42 U.S.C (b)(3):42 U.S.C. §242m(d), (b)(6) with laboratory evidence of (b)(3):42 U.S.C. The (b)(3):42 symptoms began 3 weeks after receipt of the first dose of the Pfizer COVID-19 mRNA vaccine. CISA was asked to review the case to assess whether the diagnoses of (b)(3):42 U.S.C. §242m(d), and (b)(3):42 U.S.C. were correct, if receipt of the Pfizer mRNA COVID-19 vaccine might have caused or contributed to the adverse event following immunization (AEFI), and to provide guidance regarding the second dose of the Pfizer mRNA COVID-19 vaccine and other non-COVID future vaccines.

As part of our mission under the Centers for Disease Control and Prevention (CDC), CISA is a national research network that provides healthcare providers with expert opinions on adverse events following immunizations. This case was reviewed on September 2nd, 2021 by the CISA COVID Vaccine (COVIDvax) Clinical Consult Case Review Working Group, which includes vaccine safety experts, as well as subject matter experts in (b)(3):42 U.S.C. §242m(d), (b)(6) (b)(3):42 U.S.C. §242m(d), (b)(6)

The following questions were posed and the answers presented in bold italics:

1. Is the diagnosis correct? ***Yes- patient clinically showed clinical symptoms, laboratory, and imaging findings consistent with*** (b)(3):42 U.S.C. §242m(d), (b)(6) ***. Based on the*** (b)(3):42 U.S.C. §242m(d), (b)(6) ***, Brain MRI and CSF findings,*** (b)(3):42 U.S.C. ***is also a diagnosis.***
2. Did the vaccine cause or contribute to the AEFI? ***Indeterminate- however, due to the onset of symptoms being 3 weeks following vaccination, there is evidence from both the clinical presentation and timing of onset strongly suggesting a non-vaccine*** (b)(3):42 ***etiology.***

(b)(3):42 U.S.C. §242m(d), (b)(6)

Reassessment is needed once the patient has fully recovered.

3. What is CISA guidance regarding future vaccines for this patient?
    - COVID- 19 vaccine? ***Second dose of COVID- 19 vaccine might be possible once the patient has fully recovered. Reassess patient in 1 to 3 months.***
    - Routine vaccines? ***Proceed as usual.***
4. Is any additional testing warranted? ***Recommended by Dr. [redacted] to culture patient's [redacted] (if possible) to look for additional [redacted] (e.g., enteroviruses).***
5. When to schedule follow-up? ***In 1 to 3 months when patient has fully recovered.***
6. What is the guidance for this patient regarding receipt of subsequent doses of these vaccines? ***CISA [redacted] SMEs said that they would not proceed with dose #2 of the Pfizer COVID-19 vaccine while the [redacted] is still recovering from [redacted] PIs/SMEs might feel comfortable proceeding with the second dose of the COVID-19 mRNA Pfizer vaccine after patient has been determined by [redacted] and other specialists involved in [redacted] case to have fully recovered. Though the timing of onset of symptoms and laboratory and imaging studies are more consistent with an [redacted] etiology, since CISA could not absolutely exclude the COVID-19 vaccine as being a contributing factor to the immune response, proceeding with Pfizer mRNA COVID-19 vaccine should be shared decision-making between the providers and the [redacted] weighing risks of infection (especially in the setting of the circulating prevalent SARS CoV-2 delta variant) vs. vaccination.***

CISA's primary aim is not to establish causality; however, based on a published causality algorithm (see figure and reference #1 in the attached summary) and expert opinion, we assessed the likelihood that receipt of the vaccine was causally related to the reaction. Application of the algorithm resulted in the causality determination of "**Indeterminate**" as to whether this event was causally related to the vaccine.

Please see the appended below the CISA Vaccine Adverse Event Causality Algorithm[1], and bibliography that might be of use to you in the future[2-14]. We hope that this review will be helpful inthe management of your patient.

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 to you in approximately two to three months to assess how the patient tolerated future vaccinations.

(b)(3):42 U.S.C. §242m(d), (b)(6)

Sincerely,

(b)(3):42 U.S.C. §242m(d), (b)(6)

Disclaimer:

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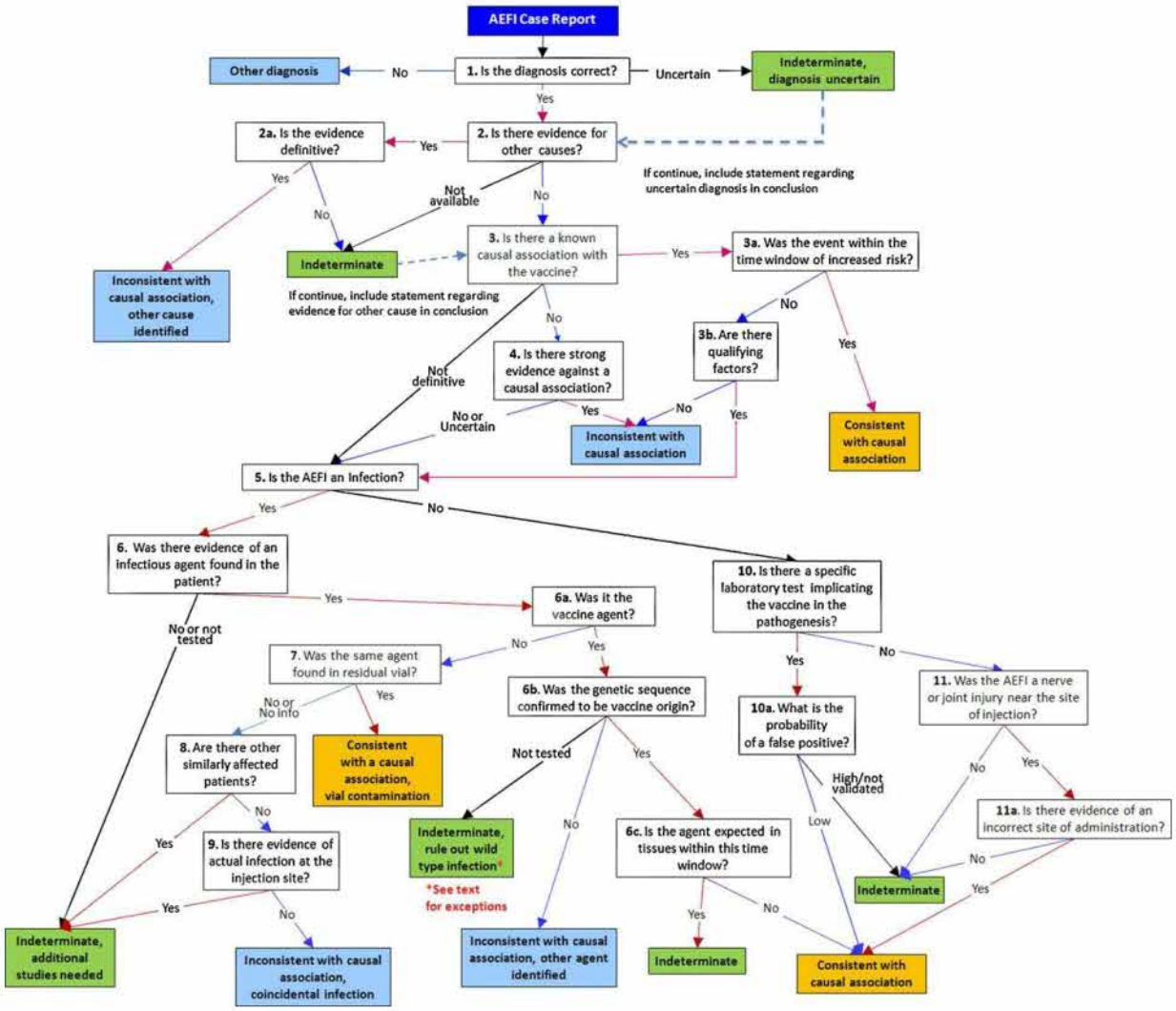
(b)(3):42 U.S.C. §242m(d) , (b)(6)

(b)(3):42 U.S.C. §242m(d), (b)(6)



(b)(3):42 U.S.C. §242m(d); (b)(6)

November 3, 2021

(b)(3):42 U.S.C. §242m(d); (b)(6)

On behalf of the Clinical Immunization Safety Office (CISA) Project, we thank you for the opportunity to review the case of your (b)(3): (b)(3):42 patient who was diagnosed with M (b)(3):42 U.S.C. §242m(d); (b)(6) The (b)(3):42 symptoms began two days after receipt of the first dose of the Pfizer COVID-19 mRNA vaccine. CISA was asked to review the case to provide guidance regarding the second dose of the Pfizer mRNA COVID-19 vaccine.

As part of our mission under the Centers for Disease Control and Prevention (CDC), CISA is a national research network that provides healthcare providers with expert opinions on adverse events following immunizations. This case was reviewed on September 15, 2021, by the CISA COVID Vaccine (COVIDvax) Clinical Consult Case Review Working Group, which includes vaccine safety experts, as well as subject matter experts in (b)(3):42 U.S.C. §242m(d); (b)(6) (b)(3):42 U.S.C. §242m(d); (b)(6).

Though CISA investigators continue to recommend shared decision-making between the patient's family and the patient's physician, the CISA investigators who provided individual input advised against a second dose of COVID-19 vaccine at this time. These investigators expressed hope that additional data may become available in the upcoming months that may shed further light on this question. Regarding receipt of other (non-COVID-19) vaccines, the investigators who provided individual input on this question felt comfortable with giving other vaccines as needed.

Sincerely,

Disclaimer:

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[redacted]
(b)(3):42 U.S.C. §242m(d); (b)(6)

References

1. Halsey NA, Edwards KM, Dekker CL, et al. Algorithm to assess causality after individual adverse events following immunizations. Vaccine 2012;30:5791-8.

[redacted]
(b)(3):42 U.S.C. §242m(d); (b)(6)

(b)(3):42 U.S.C. §242m(d), (b)(6)

November 29, 2021

(b)(3):42 U.S.C. §242m(d), (b)(6)

On behalf of the Clinical Immunization Safety Office (CISA) Project, thank you for the opportunity to review the case of your (b)(3):42 (b)(3):42 patient with reported history of (b)(3):42 U.S.C. §242m(d), (b)(6) and history of (b)(3):42 (b)(3):42 U.S.C. §242m(d), (b)(6) who experienced (b)(3):42 U.S.C. §242m(d), (b)(6) (which the patient described as (b)(3):42 U.S.C. within minutes following receipt of the Janssen COVID-19 vaccine. Over days to weeks after vaccination, the patient experienced a variety of other symptoms including (b)(3):42 U.S.C. §242m(d), (b)(6) (b)(3):42 U.S.C. §242m(d), (b)(6)

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 October 22, 2021 by the CISA Clinical Consultation Case Review Working Group, which includes vaccine safety experts, as well as subject matters experts (SME) in (b)(3):42 U.S.C. (b)(3):42 U.S.C. §242m(d), (b)(6)

We reviewed available primary care and subspecialist medical records where your patient has sought care, pertinent literature, relevant reports to the Vaccine Adverse Event Reporting System (VAERS) and discussed all of this information with the CISA SMEs. We have summarized our findings and guidance below.

CISA was asked to review this case to assess if receipt of the Janssen single-dose, replication-incompetent, recombinant adenovirus type 26 (Ad26) vaccine might have caused or contributed to the adverse events following immunization. We divided our investigation into two parts: 1) an assessment of the (b)(3):42 U.S.C. §242m(d), (b)(6) (b)(3):42; and 2) the varied (b)(3):42 U.S.C. §242m(d), (b)(6) (b)(3):42 symptoms.

The following questions were posed:

1. What is/are the diagnoses?
2. Did the vaccine(s) cause or contribute to the AEFI?
3. What is CISA guidance regarding future vaccines for this patient?

(b)(3):42 U.S.C. §242m(d), (b)(6)

[redacted]

a. COVID-19 vaccine: Can the patient proceed with a booster dose of the Janssen COVID-19 vaccine or an mRNA COVID-19 vaccine?
b. Routine vaccines?

4. Is any additional testing warranted?
5. When to schedule follow-up?

We have summarized our findings and guidance below:

1. We began our review by assessing the patient's [redacted] reaction that occurred shortly following receipt of the Janssen vaccine. The diagnosis of [redacted] after receipt of the Janssen vaccine was noted in the patient's medical records based on patient report to her primary healthcare providers; however, the nurse vaccinator's documentation in the [redacted] records noted that the patient reported onset within ~20 minutes after vaccination of a sensation of [redacted] This was treated on-site with [redacted]. There was no report of [redacted] noted on-site. The vaccination nurse's notes stated, "[redacted]" The patient's symptoms would not meet major or minor Brighton Collaboration case definition for [redacted][2] but the subjective symptoms would qualify as a "[redacted]."[3] According to CDC's *Interim Clinical Considerations for Use of COVID-19 Vaccines Currently Approved or Authorized in the United States*, *Appendix B*: [redacted]. Of note, this patient had a [redacted] See below for our guidance regarding additional doses of COVID vaccines.

The information below summarizes CISA guidance for the various longer-term symptoms this patient has reported, and for which she has sought clinical evaluation:

2. [redacted] We understand from review of the medical records that the patient has a long history of both [redacted] is a frequent symptom during the first 24-72 hours after any COVID-19 vaccine, including the Janssen vaccine. The patient's medical records indicate

[redacted]

(b)(3):42 U.S.C. §242m(d); (b)(6)

that (b)(3) (b)(3):42 U.S.C. were well-controlled when (b)(3): 42 takes (b)(3):42 U.S.C. (b)(3):42 U.S.C. §242m(d); (b)(6) but that if (b)(6 misses a dose, (b)(3):4 2 has return of (b)(3):42 U.S.C. §242m(d); (b)(6) , including (b)(3):42 U.S.C. §242m(d); (b)(6) might explain some of the persistent (b)(3):42 U.S.C. §242m(d); (b)(6) s the patient has experienced.

3. (b)(3):42 U.S.C. §242m(d)

a. The (b)(3):42 U.S.C. reviewed the symptom of (b)(3):42 U.S.C. §242m(d); (b)(6) (b)(3):42 U.S.C. §242m(d); which was described as ' (b)(6) ' by the patient. The prolonged (b)(3):42 U.S.C. §242m(d); (b)(6) and other symptoms could be explained by (b)(3):42 U.S.C. §242m(d); (b)(6) ; however, the patient tested

(b)(3):42 U.S.C. §242m(d); (b)(6)

b. One of the CISA site (b)(3):42 U.S.C. shared his impression that the multiple, prolonged (b)(3):42 U.S.C. §242m(d); may represent a diagnosis of (b)(3):42 U.S.C. (b)(3):42 U.S.C. §242m(d);

i. Many of the patient's symptoms are (b)(3):42 in nature, and extensive investigation was undertaken into each and every symptom the patient mentioned. The CISA (b)(3):42 U.S.C. thought the correct diagnosis is (b)(3):42 U.S.C. §242m(d); (b)(6) The (b)(3):42 U.S.C. shared that (b)(3):42 U.S.C. §242m(d); (b)(6) has taken the lead on this concept, which is best discussed on these websites: (b)(3):42 U.S.C. §242m(d); (b)(6) (b)(3):42 U.S.C. §242m(d); (b)(6) The paper referenced below[4] is interesting, as the list of symptoms is nearly identical to those of this (b)(3):42 patient.

4. (b)(3):42 U.S.C. §242m(d); (b)(6) : Our CISA expert on (b)(3):42 U.S.C. §242m(d); (b)(6) reviewed the detailed data from the patient's (b)(3):42 U.S.C. and shared the following expert impression:

(b)(3):42 U.S.C. §242m(d); (b)(6)

(b)(3):42 U.S.C. §242m(d); (b)(6)

a.

b.

(b)(3):42 U.S.C. §242m(d); (b)(6)

c.

5. **Patient history of** (b)(3):42 U.S.C. After the CISA consultation call, one of the CISA (b)(3):42 U.S.C. §242m(d); (b)(6) was asked to assess whether the patient's symptoms could be caused by (b)(3) (b)(3):42 U.S.C. §242m(d); (b)(6) The (b)(3):42 made several points which we have listed below:

a.

b.

(b)(3):42 U.S.C. §242m(d); (b)(6)

c.

(b)(3):42 U.S.C. §242m(d); (b)(6)

(b)(3):42 U.S.C. §242m(d), (b)(6)

d. (b)(3):42 U.S.C. §242m(d), (b)(6)

6. **Assessment of Causality**:

CISA subject matter experts assessed the early-onset and later-onset symptoms that were described as most bothersome to the patient.

a. Using (b)(3):42 U.S.C. §242m(d), (b)(6) instead of (b)(3):42 U.S.C. (see 1st paragraph above) as the 1st diagnosis, the CISA Causality algorithm arrives at a designation of "consistent with a causal relationship". This would lead to a contraindication for the patient to receive any additional doses of the Janssen vaccine, and a precaution for (b)(3) to receive to either of the mRNA COVID-19 vaccines (see below).

b. Using (b)(3):42 U.S.C. §242m(d), (b)(6) (patient described as "(b)(3):42 U.S.C.") as the 2nd diagnosis, the CISA causality algorithm leads to an "indeterminate" designation regarding causality. While most of the vaccine experts on the call agreed with an Indeterminate designation, two SMEs thought that while the evidence was not conclusive, they were inclined to believe that the vaccine was not responsible for the (b)(3):42 U.S.C. symptoms.

CISA GUIDANCE:

1) (b)(3):42 U.S.C. §242m(d), (b)(6) CISA assessed that it is most likely that this patient experienced an (b)(3):42 U.S.C. §242m(d), (b)(6) that could be classified according to the CDC Interim Clinical Considerations, Appendix B as a (b)(3):42 U.S.C. (b)(3):42 U.S.C. CISA assessed that the patient's (b)(3):42 U.S.C. §242m(d), (b)(6) was unlikely to have been (b)(3):42 U.S.C.. After this consultation call, the FDA authorized use of mRNA COVID-19 booster doses, including use of the Janssen or either of the mRNA

(b)(3):42 U.S.C. §242m(d), (b)(6)

[redacted]

COVID-19 vaccines for persons who received the Janssen vaccine. In light of our interpretation of the post-Janssen vaccine reaction as being a [redacted] a COVID-19 booster vaccination with either of the mRNA vaccines (Moderna or Pfizer) would be a precaution. A re-evaluation of risk/benefit assessment by the [redacted] prudence dictates caution in the choice of vaccine and the need for informed consent and careful monitoring. Your patient, along with [redacted] treating physicians, should consider the far greater adverse impact that natural COVID infections would likely have on [redacted] health, both in the short- and long-term. If this patient chooses to proceed with a booster vaccination with a COVID mRNA vaccine, observation for a 30-minute period is recommended.

2) [redacted] This patient has a longstanding history of [redacted] [redacted] has experienced relief of symptoms with a combination [redacted] however, [redacted] has experienced intermittent [redacted] The [redacted] could represent a [redacted] CISA SMEs would encourage that the patient be formally evaluated and treated by a [redacted] specialist who may be able to help with [redacted] if this continues to be an issue.

3) [redacted]: CISA suggests that the diagnosis of [redacted] be considered for this patient. The patient's [redacted] could evaluate the patient for this diagnosis. This diagnosis also includes [redacted] that the patient has been experiencing.

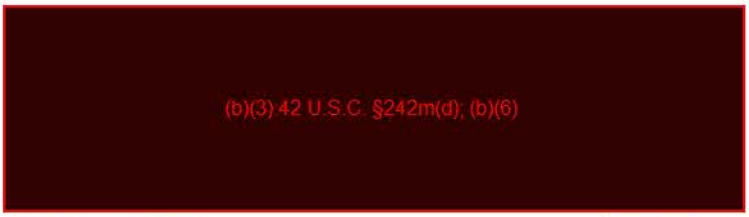
4) [redacted]: The patient has undergone a complete [redacted] evaluation. CISA experts agreed with the recommendations made by the [redacted] evaluation ([redacted]. CISA SMEs agree with the patient's provider that [redacted]

5) [redacted]: If [redacted] symptoms persist, the CISA [redacted] expert would suggest performing a regular [redacted] Your patient's [redacted] lasted only 15 minutes, which is not sufficient to assess and differentiate between these etiologies.

6) **Patient history of** [redacted] **and use of** [redacted] since ingestion of [redacted] CISA suggests that an evaluation of your patient's [redacted] could be considered. [redacted]

If your patient chooses to stop taking [redacted] our CISA [redacted] suggested that it may be worthwhile to get a [redacted] In the [redacted] clinical

[redacted]



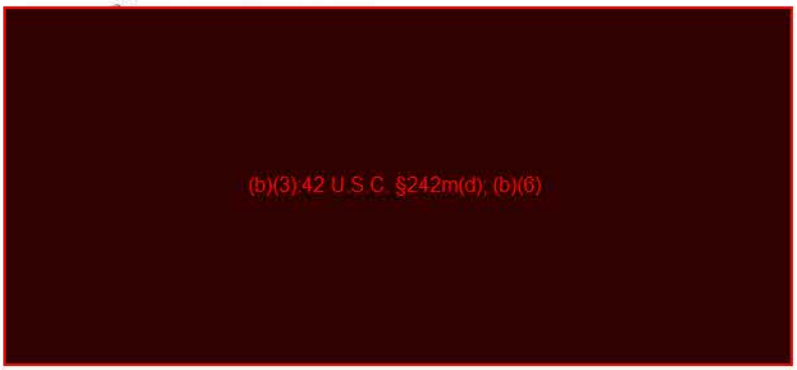
opinion, if the (b)(3):42 U.S.C. §242m(d); is normal at baseline, there's n (b)(3):42 U.S.C. §242m(d); (b)(6) for your patient to take (b)(3):42 U.S.C. §242m(d); (b)(6) if (b)(3):4 eels that it is needed due to the (b)(3):42 U.S.C. §242m(d); (b)(6) However, for (b)(3):42 (b)(3):42 U.S.C. §242m(d); (b)(6) are often recommended, but not at excessive levels.

General considerations:

7) The CISA SMEs feel that it may be very beneficial if a multidisciplinary a care team, rather than one provider, could help this patient navigate through (b)(3): 42 ongoing health issues, given the (b)(3):42 U.S.C. §242m(d); of (b)(3 clinical symptoms (b)(3): 42 would benefit from a team and plan to take care o (b)(3):4 2 ymptoms. The patient may be able to receive COVID-19 vaccines in the future, but prudence dictates caution in the choice of vaccine and the need for informed consent and careful monitoring. (b)(3): must, along with (b)(3 treating physicians, also consider the far greater adverse impact that natural COVID infection would likely have on (b)(3): 42 ealth, both in the short- and long-term.

8) Recommendations for non-COVID vaccines: the CISA experts stated that the patient may receive all of the other non-COVID vaccines that are recommended for (b)(3):4 2 This would include the 2021-2022 seasonal influenza vaccine. On November 29, 2021, the CDC released a media statement about boosters for everyone (https://www.cdc.gov/media/releases/2021/s1129-booster-recommendations.html)

Sincerely,



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Citations:

(b)(3):42 U.S.C. §242m(d), (b)(6)

February 14, 2022

(b)(3):42 U.S.C. §242m(d), (b)(6)

On behalf of the Clinical Immunization Safety Assessment (CISA) Project, thank you for the opportunity to review the case of your (b)(3):42 U.S.C. §242m(d), (b)(6) (b)(3):42 patient presenting with (b)(3):42 U.S.C. following receipt of dose 1 of Pfizer COVID-19 vaccine on July 27, 2021.

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 December 7, 2021 by the CISA Clinical Consultation Case Review Working Group, which includes vaccine safety experts, as well as subject matters experts (SME) in (b)(3):42 U.S.C. §242m(d), (b)(6). CISA was asked to review this case to assess if receipt of the Pfizer COVID-19 mRNA vaccine might have caused or contributed to the adverse events following immunization.

We reviewed available primary care and subspecialist medical records where your patient has sought care, pertinent literature, relevant reports to the Vaccine Adverse Event Reporting System (VAERS) and discussed all of this information with the CISA SMEs, and you on the call. We have summarized our findings and guidance below.

The following questions were posed, discussed, and adjudicated:

1. **What is/are the diagnoses?** The experts agreed with your diagnosis of (b)(3):42 (b)(3):42 U.S.C. §242m(d), (b)(6)

2. **Did the vaccine(s) cause or contribute to the AEFI?** The SMEs assessed whether the diagnosis was causally related to the receipt of Pfizer COVID-19 mRNA using the causality algorithm (see diagram and reference below). As a (b)(3):42 is a well-described contributor to t (b)(3):42 U.S.C e, it was felt that there was evidence of another cause, but that the evidence was not definitive. Therefore, application of the causality algorithm resulted in an "indeterminate" determination.

3. **What is CISA guidance regarding future vaccines for this patient?**
   a. **COVID-19 vaccine**: The experts agreed that your patient does not have contraindication to receipt of COVID-19 mRNA vaccines. Some experts stated that they would not recommend the Janssen COVID-19 vaccine because of (b)(gender, age and prior history of t (b)(3):42 U.S.C. According to CDC's *Interim Clinical Considerations for Use of COVID-19 Vaccines*, a two-dose mRNA COVID-19 vaccine

(b)(3):42 U.S.C. §242m(d), (b)(6)

[redacted]

series is currently preferred over Janssen COVID-19 vaccine for both the primary vaccination and booster dose. One expert mentioned that if the patient is resistant to receiving another mRNA COVID-19 vaccine [redacted] may consider the Novavax product if FDA-authorized, however CDC cannot provide recommendations on vaccines that are not authorized at this time. Finally, since [redacted] was thought to play a contributory role in [redacted] symptoms, appropriate interventions/medications could be considered to lessen [redacted]

b. Routine vaccines? The experts agreed the patient has no known contraindications to receiving other vaccines. However, it would be useful to clarify what was meant by the patient's report that the flu shot '[redacted] in order to exclude features of a [redacted]

4. **Is any additional testing warranted?** The experts agreed with your plan to get an [redacted] There was less consensus about the utility of a [redacted] to evaluate for [redacted] given the time since symptom onset. The group also agreed with your assessment that a [redacted] was not warranted.

5. **When to schedule follow-up?** The experts agreed with your plan to follow-up with [redacted] at one and six months. We would be interested in updates regarding [redacted] condition and vaccination status.

Finally, thank you for the opportunity to discuss your patient with the CISA group and we would be happy to assist in evaluating any new vaccine-related developments in this patient with you. 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 within the next three months to assess whether the patient has received additional vaccines and how [redacted] tolerated them.

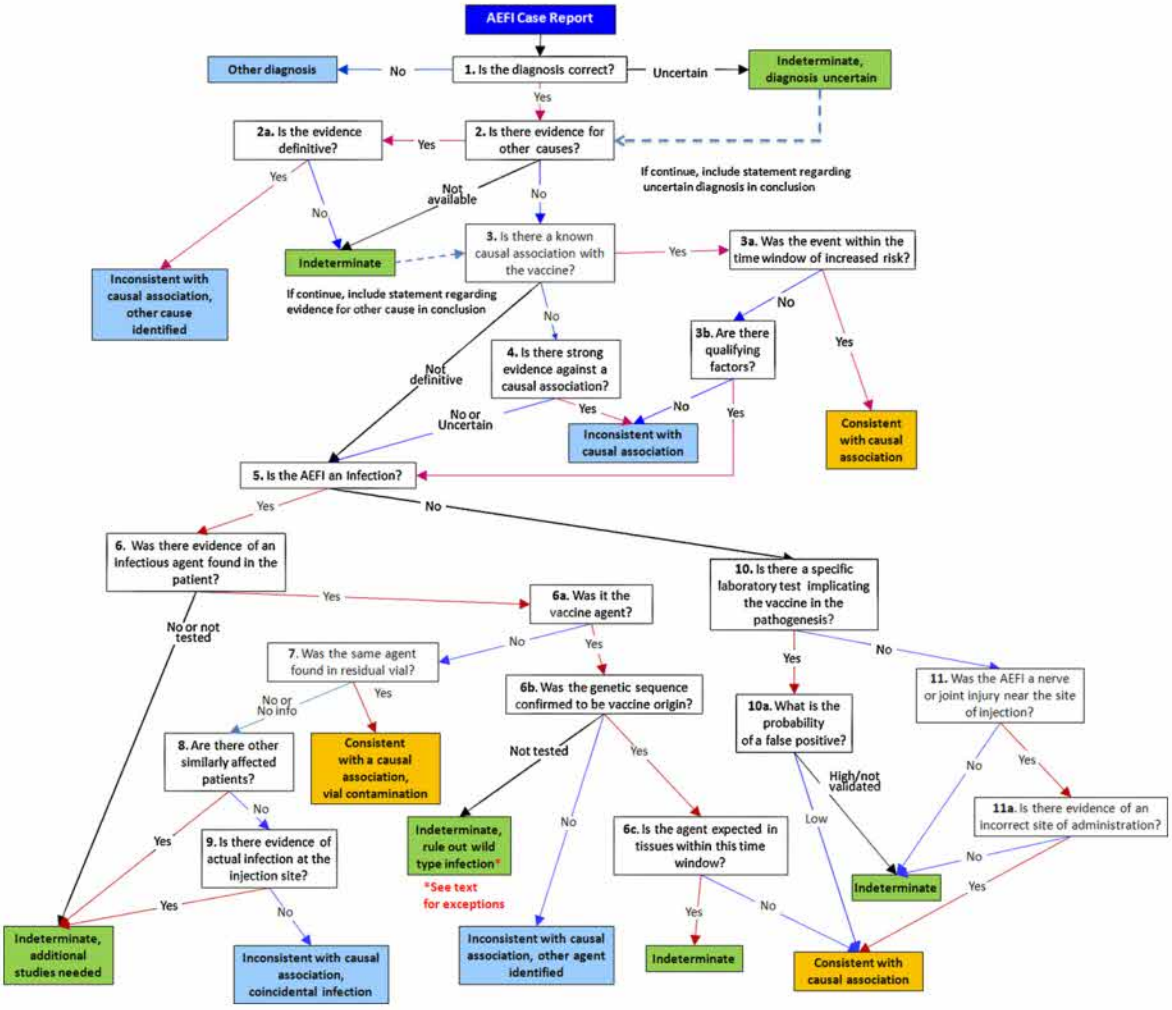
Sincerely,

[redacted]

[redacted]

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.*

1. Interim Clinical Considerations for Use of COVID-19 Vaccines | CDC



Halsey NA, Edwards KM, et al, Causality Working Group of the Clinical Immunization Safety Assessment network, *Vaccine*. 2012 Aug 24;30(39):5791-8. Epub 2012 Apr 14.

[redacted]

(b)(3):42 U.S.C. §242m(d), (b)(6)

January 18, 2022

(b)(3):42 U.S.C. §242m(d), (b)(6)

On behalf of the Clinical Immunization Safety Assessment (CISA) Project, thank you for the opportunity to review the case of your [redacted] patient who experienced [redacted] following the receipt of the first dose of the Pfizer COVID-19 mRNA vaccine, and who is presumed to have [redacted]. CISA was asked to review the case to assess whether the diagnosis was correct, if receipt of the Pfizer COVID-19 mRNA 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 December 20, 2021 by the CISA Clinical Consultation Case Review Working Group, which includes vaccine safety experts, as well as subject matters experts (SME) in [redacted], as well as by experts from the CDC Immunization Safety Office.

The following questions were posed:

1. Did the vaccine contribute to his symptoms and potential [redacted]
2. Are there specific characteristics associated with the development of [redacted] following covid-19 vaccination?
3. What is the present CDC guidance for future COVID-19 vaccines?
4. What is CISA guidance regarding future vaccines for this patient?
    a. COVID-19 vaccine?
    b. Routine vaccines?
5. Is any additional testing warranted?
6. When to schedule follow-up?

Together we reviewed available evidence, including the patient's medical history, vaccine safety literature, and Vaccine Adverse Event Reporting Systems (VAERS) search results, and the FDA emergency use authorization information on the Pfizer COVID-19 vaccine.

The causality algorithm (see diagram and reference below) was applied with and without the diagnosis of [redacted] to assess whether this patient's AEFI was causally related to the receipt of the Pfizer COVID-19 mRNA vaccine. The application of the causality algorithm resulted in "Indeterminate" because the diagnosis is uncertain, there is no evidence to support other causes, and there is not a definitive known association between the vaccine and AEFI.

More importantly, the FDA EUA and CDC Interim Clinical Considerations for Use of COVID-19 Vaccines lists the contraindications and precautions for COVID-19 vaccination. Based on the guidance in that document, your patient does not have a contraindication to receipt of the second dose of the COVID-19 vaccine. In addition, the SMEs on the call strongly felt that the risk of COVID-19 infection was higher than the potential risk from another dose of vaccine, and that [redacted] should receive the second dose of vaccine. There was some preference among the SMEs favoring vaccination with the Pfizer vaccine, as it potentially has a lower risk of

(b)(3):42 U.S.C. §242m(d); (b)(6) however, rates of (b)(3):42 following mRNA COVID-19 vaccine are under study. CDC's *Interim Clinical Considerations for Use of COVID-19 Vaccines Currently Approved or Authorized in the United States* states, "In general, the same mRNA vaccine product (i.e., the same manufacturer) should be used for all doses in the primary series, including an additional primary dose; thus, our guidance would be for your patient to complete the COVID-19 vaccine series with the Pfizer mRNA COVID-19 vaccine. The CISA SMEs favored avoiding the Johnson and Johnson vaccine because of the (b)(3):42 U.S.C. §242m(d); (b)(6) group, and the (b)(3):42 U.S.C. §242m(d); (b)(6) There was also an opinion by (b)(3):42 U.S.C. §242m(d); (b)(6) (b)(3):42 U.S.C. §242m(d); (b)(6), that the patient should get a properly performed (b)(3):42 U.S.C. (b)(3):42 U.S.C. §242m(d); (b)(6) although this was not necessary to be done before vaccination. Proper technique is essential when (b)(3):42 U.S.C. §242m(d); (b)(6) and there are only a couple of laboratories in the U.S. with specific expertise in (b)(3):42 U.S.C. §242m(d); (b)(6) mentioned that both (b)(3):42 U.S.C. §242m(d); (b)(6) have the expertise in evaluating these (b)(3):42 If it is helpful, and you would like to use the (b)(3): lab, I can help to facilitate this.

Regarding routine vaccinations, CISA agreed that no contraindications exist, and this patient can receive other vaccines according to need/schedule.

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 within the next few months to assess whether the patient has received the second dose, additional vaccines and how (b)(3):4 tolerated them.

Sincerely,

(b)(3):42 U.S.C. §242m(d), (b)(6)

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.

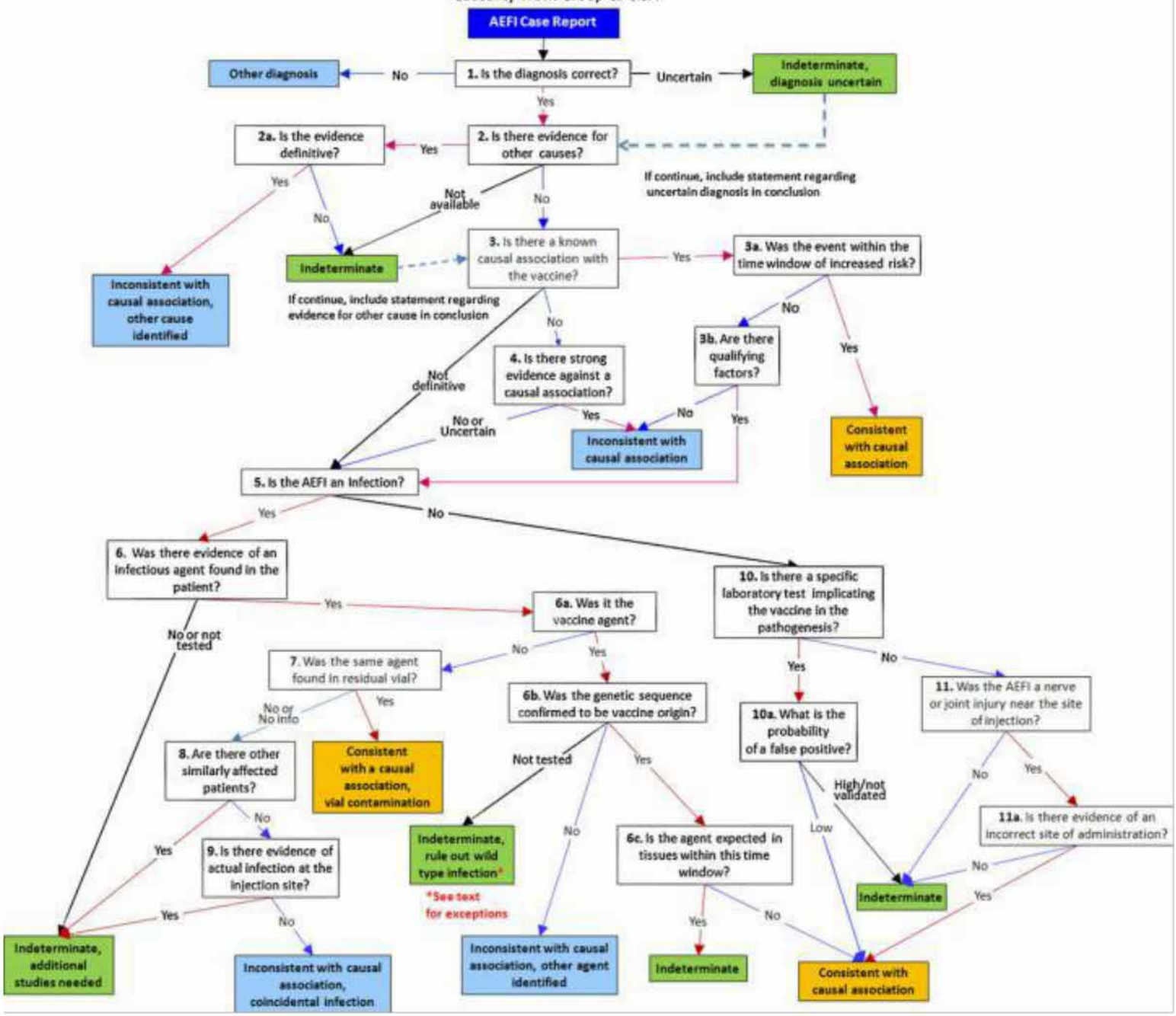
References

1. Halsey NA, Edwards KM, et al, Causality Working Group of the Clinical Immunization Safety Assessment network, *Vaccine*. 2012 Aug 24;30(39):5791-8. Epub 2012 Apr 14.

Review of Case Reports of Adverse Events Following Immunizations

February 28, 2012

Causality Work Group of CISA



(b)(3):42 U.S.C. §242m(d); (b)(6)

January 24, 2022

(b)(3):42 U.S.C. §242m(d); (b)(6)

On behalf of the Clinical Immunization Safety Office (CISA) Project, we thank you for the opportunity to review the case of your (b)(3):42 patient who was diagnosed with (b)(3):42 U.S.C. (b)(3):42 U.S.C. §242m(d); (b)(6) CISA was asked to review the case and to assess whether or not the patient would be a suitable recipient of the Pfizer mRNA COVID-19 vaccine. CISA investigators provided guidance regarding the Pfizer mRNA COVID-19 vaccine and other future non-COVID vaccines.

As part of our mission under the Centers for Disease Control and Prevention (CDC), CISA is a national research network that provides healthcare providers with expert opinions on adverse events following immunizations. This case was reviewed on December 22nd, 2021, by the CISA COVID Vaccine (COVIDvax) Clinical Consult Case Review Working Group, which includes vaccine safety experts, as well as subject matter experts in (b)(3):42 U.S.C. §242m(d); (b)(6) (b)(3):42 U.S.C. §242m(d); (b)(6)

With shared decision-making between the patient's family and the patient's physician, the CISA investigators who provided individual input felt that the benefit/risk balance was in favor of administering a first dose of Pfizer COVID-19 vaccine to this patient given the ongoing risk for COVID-19 infection due to the patient's (b)(3):42 U.S.C. §242m(d); (b)(6)

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 to you in approximately two to three months to assess how the patient tolerated future vaccinations.

[redacted]

Sincerely,

[redacted]

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.

[redacted]

References

1. Lucas, J. London Med J. 1790;11:325–331

[redacted]

14. Klein, Nicola P., et al. Surveillance for adverse events after COVID-19 mRNA vaccination. JAMA. 2021;326(14):1390-1399.

(b)(3):42 U.S.C. §242m(d), (b)(6)

March 16, 2022

(b)(3):42 U.S.C. §242m(d), (b)(6)

On behalf of the Clinical Immunization Safety Assessment (CISA) Project, thank you for the opportunity to review the case of your previously healthy (b)(3):42 U.S.C. (b)(3): patient with an (b)(3):42 U.S.C. §242m(d), (b)(6) following the first dose of Pfizer mRNA COVID-19 vaccine, which was received on 9/30/21.

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 February 9, 2022 by the CISA Clinical Consultation Case Review Working Group, which includes vaccine safety experts, as well as subject matter experts (SME) in i (b)(3):42 U.S.C. §242m(d), (b)(6) CISA was asked to review this case to assess if receipt of the Pfizer COVID-19 mRNA vaccine might have caused or contributed to the adverse events following immunization and to provide guidance regarding future vaccinations.

We reviewed available primary care and subspecialist medical records where your patient has sought care, pertinent literature, relevant reports to the Vaccine Adverse Event Reporting System (VAERS) and discussed all of this information with the CISA SMEs, and you on the call. We have summarized our findings, the call, and guidance below.

The following questions were posed, discussed, and adjudicated:

1. **What is/are the diagnoses?** The (b)(3):42 U.S.C. agree that your patient had an (b)(3):42 (b)(3):42 U.S.C. §242m(d), but the consensus was that at this point in the disease process it was not possible to determine whether this represents (b)(3):42 U.S.C. §242m(d), (b)(6) (b)(3):42 U.S.C. §242m(d), (b)(6) . During the discussion it was noted that (b)(3): 42 presentation was not consistent with (b)(3):42 U.S.C. §242m(d). A more definitive diagnosis may be possible after additional follow-up (b)(3):42 U.S.C. 6 months after the initial event (May 2022).

2. **Did the vaccine(s) cause or contribute to the AEFI?** The SMEs assessed whether the diagnosis was causally related to the receipt of Pfizer COVID-19 mRNA using the causality algorithm (see diagram and reference below). Since there is not a definitive diagnosis at this time, it is not possible to determine causality. The review of the literature presented did note the lack of association between (b)(3):42 U.S.C. events and

(b)(3):42 U.S.C. §242m(d), (b)(6)

(b)(3):42 U.S.C. §242m(d), (b)(6)

vaccinations, and the VAERS search also did not find a signal for (b)(3):42 U.S.C. §242m(d), temporally associated with the COVID-19 mRNA vaccines. Finally, application of the causality algorithm using the two potential diagnoses of (b)(3):42 U.S.C. §242m(d), (b)(6) both resulted in an "indeterminate" determination for causality.

3. **What is CISA guidance regarding future vaccines for this patient?**
   a. **COVID-19 vaccine**: It was noted that your patient received the 2nd dose of the Pfizer mRNA COVID vaccine on 11/9/21 without incident. However, it was also noted that (b)(3):42 U.S.C. §242m(d); (b)(6) (b)(3):42 U.S.C. §242m(d), (b)(6) followed by an (b)(3):42 U.S.C. may have clouded the significance of this negative finding. Current CDC guidance for COVID-19 vaccines[1] is updated and reviewed regularly. At the present time, the only potentially applicable precaution for vaccination in this case would be for moderate or severe acute illness, with or without fever. Most experts agreed that your patient does not currently have a contraindication or a precaution to receipt of COVID-19 mRNA vaccines. Your patient will be eligible for a Pfizer COVID-19 booster dose five months after dose 2. There was a discussion about the timing of the booster dose. Some experts indicated that they would wait to see if the follow-up (b)(3):42 U.S.C. resulted in a more definitive diagnosis, the treatment of which might affect the immunogenicity of the booster dose. Most experts agreed with proceeding with the booster after more is known about the patient's condition and its potential treatment. The group also suggested that (b)(3):42 U.S.C. §242m(d); (b)(6) specialists weigh in on the booster dose decision once a more definitive diagnosis is made.
   b. **Routine vaccines?** The experts agreed the patient has no known contraindications to receiving other vaccines.

4. **Is any additional testing warranted?** The experts agreed with your plan to repeat (b)(3):42 U.S.C. §242m(d), (b)(6) about 6 months after the initial clinical presentation to better define the (b)(3):42 U.S.C. §242m(d), . In addition, the following suggestions were made:
   a.
   b.

(b)(3):42 U.S.C. §242m(d), (b)(6)

(b)(3):42 U.S.C. §242m(d), (b)(6)

(b)(3) 42 U.S.C. §242m(d); (b)(6)

c. (b)(3) 42 U.S.C. §242m(d); (b)(6)

d.

5. **When to schedule follow-up?** The experts agreed with your plan to follow-up with (b)(3) at six months after initial presentation. We would be interested in updates regarding (b)(3): 42 condition and vaccination status.

(b)(3) 42 U.S.C. §242m(d); (b)(6)

(b)(3):42 U.S.C. §242m(d); (b)(6)

Finally, thank you for the opportunity to discuss your patient with the CISA group and we would be happy to assist in evaluating any new vaccine-related developments in this patient with you. We have included in the body of the email accompanying this letter, a link to a survey for you to evaluate the CISA consultation process. An additional patient follow-up survey will be sent within the next three months to assess whether the patient has received additional vaccines and how (b)(3):42 tolerated them.

Sincerely,

(b)(3):42 U.S.C. §242m(d); (b)(6)

(b)(3):42 U.S.C. §242m(d); (b)(6)

[redacted]

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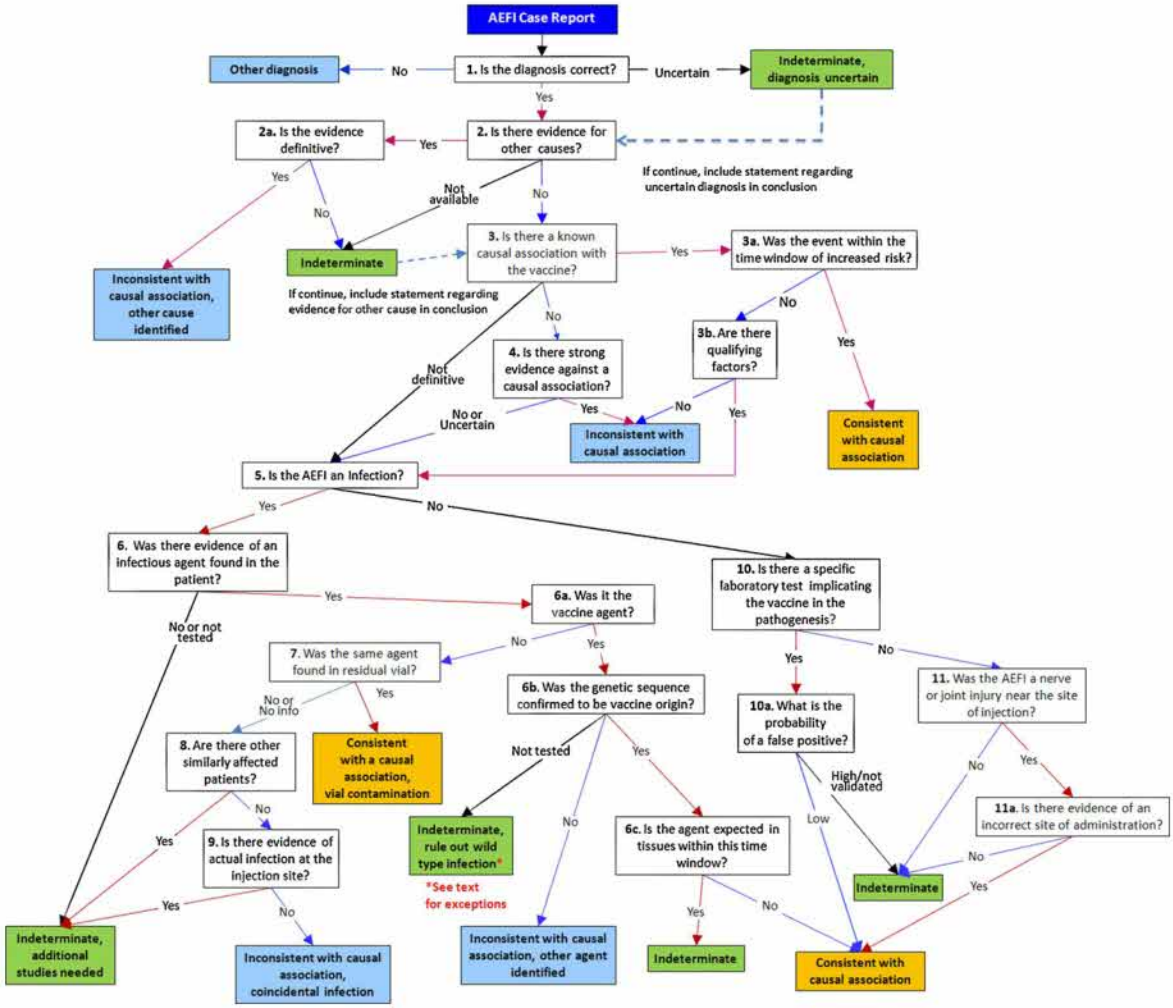
1. Interim Clinical Considerations for Use of COVID-19 Vaccines | CDC



Halsey NA, Edwards KM, et al, Causality Working Group of the Clinical Immunization Safety Assessment network, *Vaccine*. 2012 Aug 24;30(39):5791-8. Epub 2012 Apr 14.

[redacted]