



Vaccine Safety Investigation Group Causality Assessment Expert Panel Worksheet for AEFI Causality Assessment

This template has been developed in line with the World Health Organization Causality Assessment of an Adverse Event Following Immunization (AEFI): User manual for the revised WHO classification, 2nd ed., p59-60, 2019 update. World Health Organization. <https://apps.who.int/iris/handle/10665/340802>.

Patient details

TGA ICSR	<insert ICSR>
Patient initials	<insert initials>
Date of birth	<DD MMMM YYYY>
Age at time of event	<insert>
Gender	<insert>
Sources of information	Click or tap here to enter text.
Quality of information	Click or tap here to enter text.

Vaccine and AEFI diagnosis details

Vaccine involved	<insert>
Vaccine brand name	<insert>
Date(s) administered	<insert>
Event/Diagnosis	<insert>
Does the diagnosis meet a case definition?	<insert>

Complete all steps

The AEFI causality assessment process

Is guided by the following 3 steps:

1. **Checklist:** the checklist is designed to assemble key information on the AEFI.
2. **Algorithm:** information from the checklist is applied to the algorithm to assist in the decision-making of the reviewers. The algorithm helps to determine if the AEFI could be consistent or inconsistent with an association to immunisation, an indeterminate outcome or unclassifiable.
3. **Classification:** the final classification of the AEFI is determined based on the findings from step 1 and 2.

Step 1: Checklist

Diagnosis question

What are the diagnoses for this acute medical condition(s)?

Click or tap here to enter text.

Causality question

Has the <vaccine name> caused <the adverse event / outcome>?

Is this case eligible for causality assessment?

- Yes → proceed to the Event Checklist
- No → provide comment: Click or tap here to enter text.

Event Checklist (check all that apply)

Instructions:

- All questions are to be answered with a “Yes”, “No”, “Unknown” or “Not applicable” response.
- You may provide comments for your answer in the space provided.
- Comment for other responses may also be important in assessing causality.

1) Is there strong evidence for other causes?

1. In this patient, does the medical history, clinical examination and/or investigations confirm another cause for the event?

Yes No Unknown Not Applicable

Comments: Click or tap here to enter text.

II) Is there a known causal association with the vaccine or vaccination?

Vaccine Product

1. Is there evidence in published peer reviewed literature that this vaccine may cause such an event if administered correctly?

Yes No Unknown Not Applicable

Comments: Click or tap here to enter text.

2. Is there a biological plausibility that this vaccine could cause such an event?

Yes No Unknown Not Applicable

Comments: Click or tap here to enter text.

3. In this patient, did a specific test demonstrate the causal role of the vaccine?

Yes No Unknown Not Applicable

Comments: Click or tap here to enter text.

Vaccine Quality

4. Could the vaccine given to this patient have a quality defect or is substandard or falsified?

Yes No Unknown Not Applicable

Comments: Click or tap here to enter text.

Immunisation error

5. In this patient, was there an error in prescribing or non-adherence to recommendations for use of the vaccine (e.g. use beyond the expiry date, wrong recipient etc.)?

Yes No Unknown Not Applicable

Comments: Click or tap here to enter text.

6. In this patient, was the vaccine (or diluent) administered in an unsterile manner?

Yes No Unknown Not Applicable

Comments: Click or tap here to enter text.

7. In this patient, was the vaccine's physical condition (e.g. colour, turbidity, presence of foreign substances etc.) abnormal when administered?

Yes No Unknown Not Applicable

Comments: Click or tap here to enter text.

8. When this patient was vaccinated, was there an error in vaccine constitution/ preparation by the vaccinator (e.g. wrong product, wrong diluent, improper mixing, improper syringe filling etc.)?

Yes No Unknown Not Applicable

Comments: Click or tap here to enter text.

9. In this patient, was there an error in vaccine handling (e.g. a break in the cold chain during transport, storage and/or immunisation session etc.)?

Yes No Unknown Not Applicable

Comments: Click or tap here to enter text.

10. In this patient, was the vaccine administered incorrectly (e.g. wrong dose, site or route of administration; wrong needle size etc.)?

Yes No Unknown Not Applicable

Comments: Click or tap here to enter text.

Immunisation anxiety (Immunisation stress related responses - ISRR)

11. In this patient, could this event be a stress response triggered by immunization (e.g. acute stress response, vasovagal reaction, hyperventilation, dissociative neurological symptom reaction etc)?

Yes No Unknown Not Applicable

Comments: Click or tap here to enter text.

II (time): Was the event in section II within the time window of increased risk (i.e. 'Yes' response to questions from II 1 to II 11 above)

12. In this patient, did the event occur within a plausible time window after vaccine administration?

Yes No Unknown Not Applicable

Comments: Click or tap here to enter text.

III) Is there strong evidence against a causal association?

1. Is there a body of published evidence (systematic reviews, GACVS reviews, Cochrane reviews etc.) against a causal association between the vaccine and the event?

Yes No Unknown Not Applicable

Comments: [Click or tap here to enter text.](#)

IV) Other qualifying factors for classification

1. In this patient, did such an event occur in the past after administration of a similar vaccine?

Yes No Unknown Not Applicable

Comments: [Click or tap here to enter text.](#)

2. In this patient, did such an event occur in the past independent of vaccination?

Yes No Unknown Not Applicable

Comments: [Click or tap here to enter text.](#)

3. Could the current event have occurred in this patient without vaccination (background rate)?

Yes No Unknown Not Applicable

Comments: [Click or tap here to enter text.](#)

4. Did this patient have an illness, pre-existing condition or risk factor that could have contributed to the event?

Yes No Unknown Not Applicable

Comments: [Click or tap here to enter text.](#)

5. Was this patient taking any medication prior to the vaccination?

Yes No Unknown Not Applicable

Comments: [Click or tap here to enter text.](#)

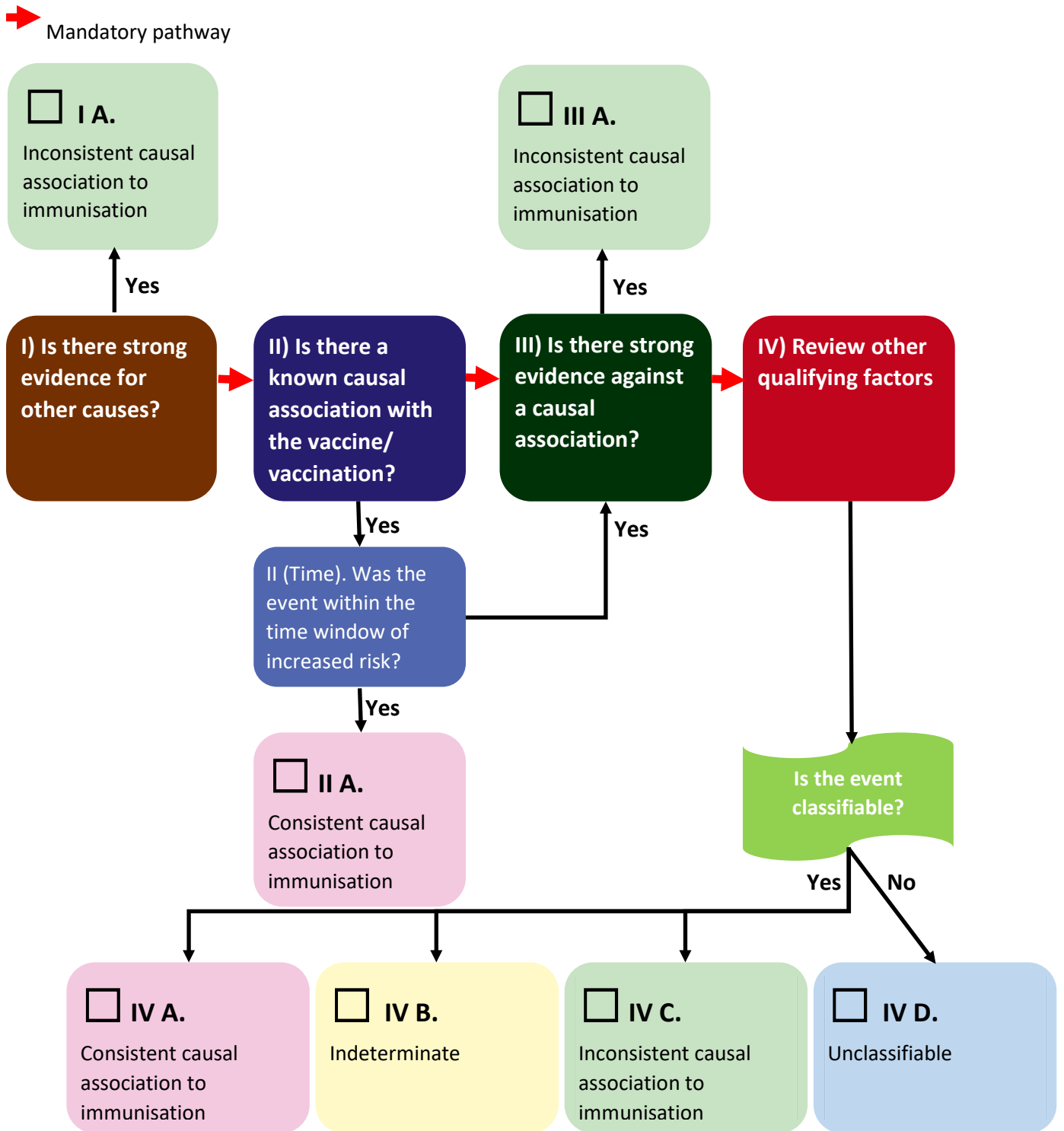
6. Was this patient exposed to a potential factor (other than vaccine) prior to the event (e.g. allergen, drug, herbal product etc.)?

Yes No Unknown Not Applicable

Comments: [Click or tap here to enter text.](#)

Step 2: The algorithm

Review all steps and check the appropriate boxes:



Notes for Step 3:

Click or tap here to enter text.

Step 3: Classification and Outcome

Classification

Check all boxes that apply:

Adequate information			Adequate information not available
A. Consistent with causal association to immunisation	B. Indeterminate	C. Inconsistent with causal association to immunisation	U. Unclassifiable
<input type="checkbox"/> A1. Vaccine product-related reaction (As per published literature)	<input type="checkbox"/> B1. *Temporal relationship is consistent but there is insufficient definitive evidence for vaccine causing event (may be new vaccine-linked event)	<input type="checkbox"/> C. Coincidental Underlying or emerging condition(s), or condition(s) caused by exposure to something other than vaccine	<input type="checkbox"/> U. Specify the additional information required for classification: Click or tap here to enter text.
<input type="checkbox"/> A2. Vaccine quality defect-related reaction	<input type="checkbox"/> B2. Qualifying factors result in conflicting trends of consistency and inconsistency with causal association to immunisation		
<input type="checkbox"/> A3. Immunisation error-related reaction			
<input type="checkbox"/> A4. Immunisation anxiety-related reaction (ISRR**)			
* B1: Potential signal and maybe considered for investigation ** Immunisation stress related response			

Outcome

Summarise the classification logic in the order of priority:

With available evidence, we could conclude that the classification is	<u><E.g. A4></u>	because:
Click or tap here to enter text.		

With available evidence, we could NOT classify the case because:
Click or tap here to enter text.

Return completed form via email to Committees@health.gov.au and Cc TGA Vaccine Surveillance@health.gov.au.