

Annexure 14A: State Causality Assessment Form

STATE	DISTRICT	CASE ID	NAME OF PATIENT
AGE / SEX	VACCINE (S) GIVEN		OUTCOME
DATES & TIMES OF		IF DEATH CASE:	
BIRTH : VACCINATION : FIRST SYMPTOM ONSET : HOSPITALISATION : DISCHARGE :		DATE & TIME OF DEATH : AEFI VERBAL AUTOPSY REPORT : YES / NO FIRST POST MORTEM REPORT : YES / NO FINAL POST MORTEM REPORT : YES / NO	
AEFI FORMS RECEIVED	SUPPORTING DOCUMENTS RECEIVED	REMARKS	
CRF: YES/NO CIF: YES/NO	HOSPITAL RECORDS: YES/NO DIAGNOSTIC REPORTS: YES/NO Others (name please):		
KEY FINDINGS AIDING ARRIVING AT VALID DIAGNOSIS:			

Step 1 (Eligibility)

List all vaccines administered before this event	What is the valid diagnosis?	Diagnosis meets a case definition?
Level of certainty (if diagnosis included in Brighton's Collaboration):		
<u>Create your question on causality here:</u>		
Has the _____ vaccine / vaccination caused _____ <div style="text-align: right;">(event for review in step 2-valid diagnosis)</div>		
Co-administered vaccines, if any:		

Is this case eligible for causality assessment? Yes / No; If "Yes", proceed to step 2.

If "No", mention missing information required:

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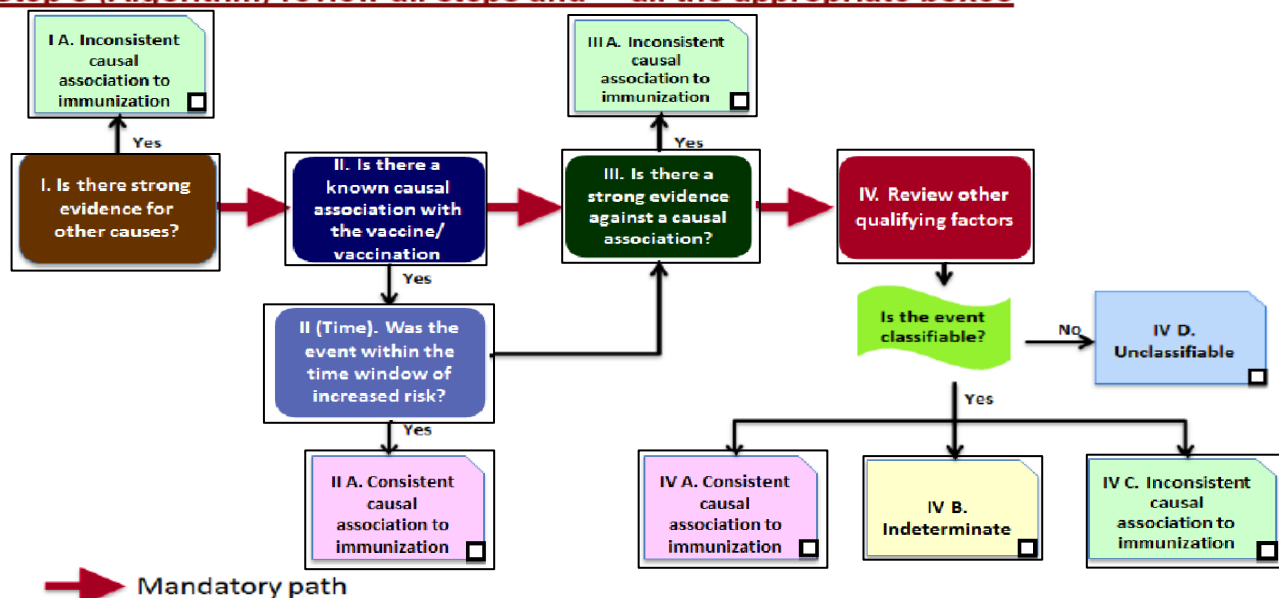
Step 2 (Event Checklist) ✓ (check) all boxes that apply

I. Is there strong evidence for other causes?	Y	N	UK	NA	Remarks
1. In this patient, does the medical history, clinical examination and/ or investigations, confirm another cause for the event?	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	
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 even if administered correctly?	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	
2. Is there a biological plausibility that this vaccine could cause such an event?	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	
3. In this patient, did a specific test demonstrate the causal role of the vaccine ?	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	
Vaccine quality					
4. Could the vaccine given to this patient have a quality defect or is substandard or falsified?	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	
Immunization 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.)?	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	
6. In this patient, was the vaccine (or diluent) administered in an unsterile manner?	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	
7. In this patient, was the vaccine's physical condition (e.g. colour, turbidity, presence of foreign substances etc.) abnormal when administered?	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	
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.)	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	
9. In this patient, was there an error in vaccine handling (e.g. a break in the cold chain during transport, storage and/or immunization session etc.)?	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	
10. In this patient, was the vaccine administered incorrectly (e.g. wrong dose, site or route of administration; wrong needle size etc.)?	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	
Immunization anxiety (Immunization Triggered Stress Response - ITSr)					
11. In this patient, could this event be a stress response triggered by immunization (e.g. acute stress response, vasovagal reaction. hyperventilation or anxiety)?	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	
II (time). If "yes" to any question in II, was the event within the time window of increased risk?					
12. In this patient, did the event occur within a plausible time window after vaccine administration?	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	
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?	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	
IV. Other qualifying factors for classification					
1. In this patient. did such an event occur in the past after administration of a similar vaccine?	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	
2. In this patient did such an event occur in the past independent of vaccination?	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	
3. Could the current event have occurred in this patient without vaccination (background rate)?	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	
4. Did this patient have an illness, pre-existing condition or risk factor that could have contribute to the event ?	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	
5. Was this patient taking any medication prior to the vaccination?	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	
6. Was this patient exposed to a potential factor (other than vaccine) prior to the event (e.g. allergen, drug, herbal product etc.)?	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	

Y: Yes N: No UK: Unknown NA: Not applicable or Not available

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Step 3 (Algorithm) review all steps and ✓ all the appropriate boxes



Notes for Step 3:

Step 4 (Classification) ✓ all boxes that apply

Adequate information available	A. Consistent with causal association to immunization <input type="checkbox"/> A1. Vaccine product-related reaction (As per published literature) <input type="checkbox"/> A2. Vaccine quality defect-related reaction <input type="checkbox"/> A3. Immunization error-related reaction <input type="checkbox"/> A4. Immunization anxiety-related reaction (ITSR**)	B. Indeterminate <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"/> B2. Reviewing factors result in conflicting trends of consistency and inconsistency with causal association to immunization	C. Inconsistent with causal association to immunization <input type="checkbox"/> C. Coincidental Underlying or emerging condition(s), or conditions caused by exposure to something other than vaccine
	Unclassifiable Specify the additional information required for classification:		

*B1: This is a potential signal and maybe considered for investigation

** Immunization Triggered Stress Response

Summarize the classification logic in the order of priority:

With available evidence, we could conclude that the classification is _____ because:

With available evidence, we could NOT classify the case because: _____

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Feedback on the case for district / others (specify):

S.N.	Name of experts	Designation	Signature	Date
1				
2				
3				
4				
5				
6				

T h a n k y o u

- Notes: 1. All necessary documents should be available before the meeting.
2. Ensure that the Quorum is complete for state AEFI committee meeting.
3. All columns need to be filled.
4. Write N.A. if not applicable