Australian Government
Department of Health
Therapeutic Goods Administration

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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	**AU-TGA-0000**s 47F
Patient initials	s22
Age at time of event	75 years
Gender	Male
Sources of information	s22
Quality of information	s22

Vaccine and AEFI diagnosis details

Vaccine involved	ChAdOx1-S COVID-19 Vaccine AstraZeneca
Vaccine brand name	VAXZEVRIA
Date(s) administered	s22
Event/Diagnosis	s22 transverse myelitis s22
Does the diagnosis meet a case definition?	s22 Brighton Collaboration Classification: Level 1 GBS References: • s22 • https://brightoncollaboration.us/wp-content/uploads/2021/03/SPEAC_D2.5.2.1-GBS-Case-Definition-Companion-Guide_V1.0_format12062-1.pdf

s22

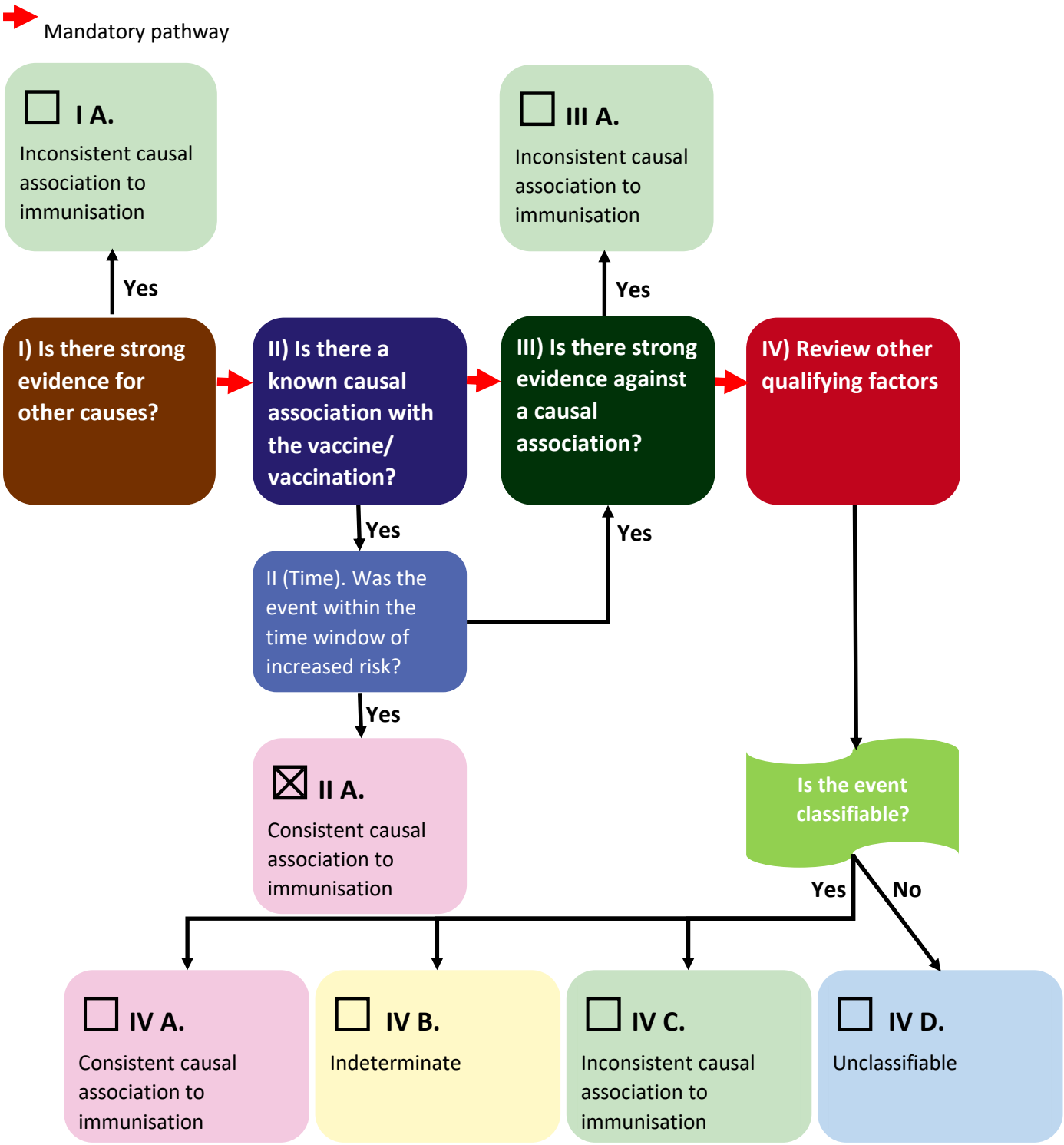
s22

s22

s22

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**
☒ **A1.** Vaccine product-related reaction (As per published literature)	☐ **B1.** *Temporal relationship is consistent but there is insufficient definitive evidence for vaccine causing event (may be new vaccine-linked event)	☐ **C.** Coincidental Underlying or emerging condition(s), or condition(s) caused by exposure to something other than vaccine	☐ **U.** *Specify the additional information required for classification:* Click or tap here to enter text.
☐ **A2.** Vaccine quality defect-related reaction	☐ **B2.** Qualifying factors result in conflicting trends of consistency and inconsistency with causal association to immunisation		
☐ **A3.** Immunisation error- related reaction			
☐ **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	Vaccine product-related reaction	**because:**

s22 [redacted]

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

Signature

- To setup your signature: Right click the X → 'Signature Setup'
- To sign: Right click the X → 'Sign'

X

<Name>
VSIG Chair

Return completed form via email to Committees@health.gov.au and Cc TGAVaccineSurveillance@health.gov.au.