WHO experiences in Causality Assessment of Individual Adverse Events

With focus on Adverse Events Following Maternal Immunization (AEFMI)

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WHO Experiences in Individual CA Vaccines & Medicines

Context → **Core Concepts** → **Tool linkage** → **Practical Application** → **Global Collaboration**

WHO AEFI causality assessment algorithm (10+ years)

Maternal/ neonatal AEFMI pilot (complex, multifactorial contexts)

Since 2023 – Phase 1 and Phase 2 development completed

Adverse Drug Event (ADE) causality Assessment – Concept approved at ACSoMP – Development started - 2025

What do we mean when we say Vaccine “causes” an adverse event?

Population
(Can it?)

Does the Vaccine increase the risk of occurrence of the event in the community?

Individual
(Did it?)

Was the Vaccine a factor in the individual developing the event?

Case Based Approach

2005

WORLD HEALTH ORGANIZATION

ADVERSE EVENTS FOLLOWING IMMUNIZATION (AEFI): CAUSALITY ASSESSMENT

AIDE MEMOIRE

Purpose: This *aide-mémoire* serves as a guide to a systematic, standardized causality assessment process for serious adverse events following immunization (including clusters). It is intended to be used by staff at the national (or first sub-national) level.

AEFI causality assessment overview

All reported AEFIs require verification of the diagnosis, coding, review, collation and storage; if an AEFI is serious, it requires triage for systematic, standardized causality assessment. Many AEFIs, including serious ones, may be coincidental while others are well known to be vaccine related (e.g., oral polio vaccine-associated paralytic polio [VAPP]).

Causality assessment is the systematic review of data about an AEFI case to determine the likelihood of a causal association between the event and the vaccine(s) received.

Causality assessment is a critical part of AEFI monitoring and enhances confidence in national immunization programmes. Whether an AEFI is, or is not, attributable to the vaccine or the vaccination programme determines what, if any, steps need to be taken to address the event.

Causality assessment is important for:

1) identification of urgent problems for investigation/action;
2) identification of programmatic and batch problems;
3) detection of signals for potential follow up and research;
4) basis for estimation of rates of serious AEFIs;
5) comparison of AEFIs between vaccine products;
6) validation of pre-licensure AEFI data.

Causality assessment outcomes help raise awareness of vaccine-associated risks among health-care workers; this, combined with knowledge of benefits of immunization, forms the basis of vaccine information for parents and/or vaccinees.

The quality of the causality assessment depends upon (1) the quality of the AEFI case report and the effectiveness of the reporting system, and (2) the quality of the causality review process. Poor quality causality assessment can lead to erroneous conclusions, crises and loss of confidence in the national immunization programme.

Causality assessment of adverse events with vaccines versus drugs

Many safety monitoring systems deal with vaccines and drug products together yet there are important differences between them that affect causality assessment.

- **Vaccines** are given to healthy populations and mostly (infants) at a vulnerable age; they are elective, have a complex compo-sition (biological products), immunological considerations in addition to pharmacological, may cause the illness they are meant to prevent (e.g., VAPP), have a short duration of exposure, a "long" time for response, and "minor" adverse events are important as they may indicate programme error.
- **Drugs** are given to ill populations and mostly adults, they are rarely elective, challenge/dechallenge/rechallenge, chemical products, pharmacological considerations mainly, longer exposure, many adverse events reported, many classes of drugs, and minor adverse events rarely important.

Expertise needed for causality assessment of vaccine adverse events is different from that needed for causality assessment of drug adverse events.

Routine AEFI review and triage

All AEFIs need to be screened and triaged by trained immunization programme staff to determine the subsequent steps needed (follow up, action, addition to database, analysis, reference for systematic causality assessment, etc.).

AEFI must be reviewed to verify the diagnosis and the timing with respect to immunization, and to classify them on the basis of standardized national case definitions.[1]

[1] Standardized case definitions for some AEFIs are available from the Brighton Collaboration at (*http://www.brightoncollaboration.org*). Use of these definitions is encouraged, especially for serious cases where systematic standardized causality assessment is required.

Systematic causality assessment

All ***serious AEFIs*** and ***signals***, defined below, require systematic causality assessment *(see Checklist, Section C, page 2)*.

Serious AEFI[1]:

1) WHO standard definition for drug and vaccine adverse events is "any untoward medical occurrence that results in death, hospitalization or prolongation of hospitalization, persistent or significant disability/incapacity, or is life threatening".
2) Additional AEFIs that need systematic causality assessment are:
   - AEFIs that may be caused by a programme error, e.g., a ***cluster***[2] of bacterial abscesses;
   - serious ***unexplained AEFI*** occurring within 30 days after vaccination and not listed in product label;
   - events causing significant parental or community concern.

Signal: Reported information on possible causal relationship between AEFI and vaccine; relationship previously unknown or incompletely documented.

WHO categories for causality[3]

Use step-by-step guide *(see Checklist, Section C, page 2)* to determine category.

Very likely/Certain[4]: A clinical event with a plausible time relationship to vaccine administration and which cannot be explained by concurrent disease or other drugs or chemicals.

Probable: A clinical event with a reasonable time relationship to vaccine administration; is unlikely to be attributed to concurrent disease or other drugs or chemicals.

Possible: A clinical event with a reasonable time relationship to vaccine administration, but which could also be explained by concurrent disease or other drugs or chemicals.

Unlikely: A clinical event whose time relationship to vaccine administration makes a causal connection improbable, but which could be plausibly explained by underlying disease or other drugs or chemicals.

Unrelated: A clinical event with an incompatible time relationship and which could be explained by underlying disease or other drugs or chemicals.

Unclassifiable: A clinical event with insufficient information to permit assessment and identification of the cause.

[1] "Severe" is not synonymous with "serious".
[2] A "cluster" is two or more AEFIs related in time, place and/or by vaccine.
[3] Adapted for vaccines from original WHO categories available at *http://www.whoumc.org/index2.html*
[4] Can be certain in rare instances where there is a demonstrated relationship e.g., VAPP or mumps vaccine-related aseptic meningitis with isolation of the vaccine strain.

Checklist

A. Be prepared

- ☐ Develop a **centralized system** to verify diagnosis, review, code, collate, store reports and analyse AEFI data.
- ☐ Establish a **national (technical) advisory committee**. Ensure independence, breadth and depth of technical expertise needed for quality causality review. Provide administrative support to this committee.
- ☐ Adopt standard **case definitions** for AEFI (Brighton Collaboration definitions if available or national case definitions). Define **signal** for programme purposes.
- ☐ Define a **routine process** and adopt criteria for referral of AEFI cases for a systematic causality assessment by the committee.
- ☐ Define **frequency of meetings** for systematic causality assessment and triggers for exceptional (i.e., urgent) reviews.
- ☐ Develop a **process for action** on recommendations arising from causality assessment.

B. Receive and process reports at regional/national level

- ☐ **Preliminary review of AEFI**: verify diagnosis, timing of event in relation to immunization, if event meets definition, if it fits criteria for referral for systematic standardized causality assessment *(see under Systematic causality assessment, page 1)*. Code, collate, store reports and analyse data.
- ☐ For cases referred for systematic standardized causality assessment: verify case information and gather more data in a timely manner. Prepare case file for review, e.g., make information in the file anonymous.

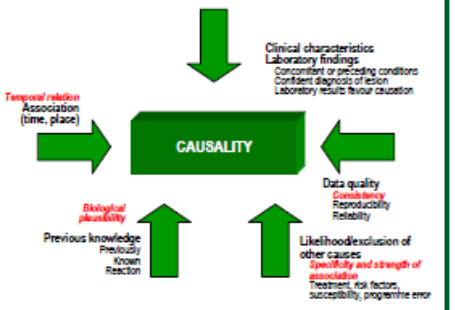
C. Conduct systematic standardized causality assessment using the step-by-step guide below

- ☐ 1. **Verify reason for reporting**: diagnosis; whether serious.
- ☐ 2. **Evaluate and assess factors.**
  - 2.1 Is this event known to be related to the vaccine? ***(Consistency of findings, strength of association.)***
  - 2.2 What is the frequency of occurrence of this adverse event? Very common (>1/10); common (>1/100); uncommon (>1/1000); rare (>1/10 000); very rare (<1/10 000), or not previously reported.
  - 2.3 Are similar events known to occur with other diseases? ***(Specificity of association.)***
  - 2.4 Is this event explainable by the biological properties of the vaccine? ***(Biological plausibility.)***
  - 2.5 Is the vaccination-to-event interval compatible with the event? ***(Temporal relation.)***
  - 2.6 Has the patient had similar symptoms in the past?
  - 2.7 Is there a history of concomitant or preceding drug therapy?
  - 2.8 Is there a history of a concomitant or preceding condition?
  - 2.9 Are there other factors that could affect the occurrence of the event?
- ☐ 3. **Determine causality category using WHO criteria** *(see page 1)*.
  - 3.1 Is this an unknown event in relation to this vaccine?
  - 3.2 Is this a new event?
  - 3.3 Is there lack of sufficient data to reach a more definite conclusion?
  - 3.4 Would the case benefit from a second review if more data became available?
  - 3.5 Based upon answers to the questions above (in this Section), in which WHO category does the case fit best? N.B. not a numerical score.
- ☐ 4. **Prepare a brief case summary.**
- ☐ 5. **Take action on recommendation(s) from the review.**
- ☐ 6. **Consider the case for education purposes.**
- ☐ 7. **Communicate findings to immunization programme staff, national regulatory authority, and others (as appropriate).**

D. Systematic causality assessment process for AEFI cluster

- ☐ Define case definition for cluster, verify if cases meet it.
- ☐ Conduct systematic causality assessment as per points 1–7 of section C above, including taking action.
- ☐ Determine if frequency of event is expected, increased, decreased, previously unrecognized or if it is a new event.

Causality assessment of serious AEFIs



Challenges and pitfalls to causality assessment

1. Causality assessment is not done, not systematic, not done by trained personnel and/or not done in a timely fashion.
2. Information in AEFI report is so limited that causality assessment cannot be done.
3. Lack of expertise and/or independence of the review committee responsible for formal causality assessment undermines credibility.
4. Non analysis of the AEFI in context after causality assessment may delay recognition of clusters and possible programme errors.
5. Lack of skilled communication of findings, not addressing all target audiences, or lack of diplomacy and/or cultural sensitivity.

All of these can damage the credibility of the immunization programme by reducing confidence in vaccine safety.

Words of advice

1. Ensure timely review of cases based on the best case information available: *solicit additional information on cases soon after receipt when memory is "fresh".*
2. Ensure timely triage and referral of serious AEFI for expert systematic causality assessment.
3. Programme expertise is needed for credible quality review, assessment and analysis.
4. Act on recommendations following causality assessment to ensure programme safety and credibility.
5. Feedback and effective communication about the process and the outcomes to stakeholders and the media is vital to avoid misinterpretation.

Assistance for causality assessment is available from the World Health Organization through the Department of Immunization, Vaccines & Biologicals. Additional information on AEFI surveillance, investigation, management and causality assessment, and on vaccine safety communication can be found on the Web at *http://www.who.int/immunization_safety/en/*

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World Health Organization
20 Avenue Appia, CH-1211 Geneva 27, Switzerland
Fax: +41 22 791 4210

2013

World Health Organization

ADVERSE EVENT FOLLOWING IMMUNIZATION

AIDE-MÉMOIRE ON CAUSALITY ASSESSMENT

Purpose: This aide-mémoire serves as a guide to a systematic, standardized process of assessing whether serious adverse events following immunization (AEFI[1]) are causally linked to vaccines/immunization or not.

Definition: AEFI causality assessment determines if a causal relationship exists between a vaccine (and/or vaccination) and an adverse event.

Rationale: Safety requirements for vaccines are stricter than those for drugs since vaccines are biological products that are more prone to lot variation and instability, they are used in healthy populations and the target groups are vulnerable. Vaccines therefore require a causality assessment process that responds in a timely manner and with scientific rigour to AEFI.

WHO SHOULD ASSESS AEFI CAUSALITY?

Ideally an AEFI review committee should be in place backed by written terms of reference. It should consist of independent experts who have no conflicts of interest. As far as possible, the experts should cover a broad range of expertise: infectious diseases, epidemiology, microbiology, pathology, immunology, neurology, forensics and vaccine programming. The committee should be supported by a secretariat (usually the national regulatory authority [NRA] and the immunization programme) that can provide supporting evidence and investigation findings to enable causality to be determined.

WHAT ARE PREREQUISITES FOR AEFI CAUSALITY ASSESSMENT?

- AEFI case investigation should be completed. Premature assessments may mislead classification.
- All relevant information should be available, including documents of investigation, laboratory and postmortem findings (if applicable).
- Valid diagnosis (unfavourable or unintended sign, abnormal laboratory finding, symptom or disease) for the AEFI must be defined, be well-founded and correspond accurately to the event being assessed.
- Information that could bias results (patient name, hospital name, etc.) should be anonymized.

POSSIBLE CAUSES OF AEFI

Related to vaccine or vaccination
- Vaccine product-related
- Vaccine quality defect-related
- Immunization error-related
- Immunization anxiety-related

Coincidental adverse event

AT WHAT LEVELS IS AEFI CAUSALITY ASSESSED?

AEFI causality assessment could be performed:

- **At population level** (is there a causal association between usage of a vaccine and a particular AEFI in the population?)
- **For an individual** (is the adverse event in the individual patient causally linked to the vaccine/vaccination?)

CONSIDERATIONS FOR ASSESSING CAUSALITY OF A SOLITARY AEFI:

- **Temporal relationship:** is it certain that the vaccination preceded the adverse event?
- **Alternate explanations:** is the event coincidental, i.e. is it due to something other than the vaccine product, immunization error or immunization anxiety?
- **Proof of association:** is there clinical or laboratory proof that the vaccine caused the event?
- **Prior evidence:** has a similar AEFI been previously reported in studies/literature or other sources?
- **Population-based evidence:** does the rate of event occurrence exceed the expected rate of the event in the population? (Refer to WHO information sheets on observed rates of known vaccine reactions.)
- **Biological plausibility:** can the association be explained by the natural history, biological mechanisms of the disease, laboratory evidence or animal studies? However this is not an important consideration.

WHICH AEFI TO SELECT FOR CAUSALITY ASSESSMENT?

All reported AEFI require verification of diagnosis, coding, review, information collation and storage. Causality assessment needs to be done for:

- **Serious AEFI** (i.e. events that are life-threatening or lead to death, hospitalization, significant disability or congenital anomaly)
- **Clusters of AEFI** (the cause for each case in the cluster should be determined separately). Line-listing of data may identify patterns that could constitute a signal
- Occurrence of **events above the expected rate** or of **unusual severity**
- **Signals** resulting from single or cluster cases
- Other AEFI as decided by the review committee or an investigation team such as **immunization errors**, significant **events of unexplained cause** occurring within 30 days after a vaccination (not listed in the product label), or events causing **significant parental or community concern.**

WHAT ARE THE STEPS[2] OF A CAUSALITY ASSESSMENT?

- Determine the eligibility of the case
- Review the checklist to ensure that all possible causes are considered
- Use algorithm to determine trend of causality
- Classify causality.

Determine eligibility → Review checklist → Use algorithm → Classify

HOW ARE CASES CLASSIFIED AT THE END OF THE ASSESSEMENT?

I. Case with adequate information

A. Consistent with causal association to immunization
- A1. Vaccine product-related
- A2. Vaccine quality defect-related
- A3. Immunization error-related
- A4. Immunization anxiety-related

B. Indeterminate
- B1 Consistent temporal relationship but insufficient definitive evidence for vaccine causing the event
- B2. Reviewing factors result in conflicting trends of consistency and inconsistency with causal association to immunization

C. Inconsistent with causal association to immunization (coincidental)

Underlying or emerging condition(s) or condition(s) caused by exposure to something other than vaccine

II. Case without adequate information

It is categorized as "unclassifiable" since it requires additional information to determine causality (the available information on such cases should be archived in a repository or an electronic database and classified when additional information becomes available)

WHAT ARE THE ACTIONS AFTER CAUSALITY ASSESSMENT?

They include providing feedback, training, modifying systems, refining tools, research, etc. to avoid and/or minimize recurrences. Based on outcomes of assessment, the following need to be considered:

A. Consistent with causal association to immunization

A1 Vaccine product-related reaction: Follow protocols adopted by each country.

A Vaccine quality defect-related reaction: Inform the NRA, manufacturer and relevant stakeholders. Take decision on existing vaccine stock.

A3 Immunization error-related reaction: Training and capacity-building are critical to avoid recurrences.

A4 Immunization anxiety-related reaction: Vaccinating in an ambient and safe environment.

B. Indeterminate

B1 The temporal relationship is consistent but there is insufficient evidence for vaccine causing the event: A national database of such AEFI cases could help to identify signals.

B2 Reviewing factors result in conflicting trends of consistency and inconsistency with causal association to immunization: If additional information becomes available, the classification can move into more definitive categories; if not, they are to be archived.

C. Inconsistent with causal association to immunization (coincidental)

Confirm diagnosis; information on why the case is classified as coincidental to be provided to the patients, relatives, care provider and community.

KEY RESOURCES FOR CAUSALITY ASSESSMENT

Causality assessment of an AEFI - User manual for the revised WHO classification
http://www.who.int/vaccine_safety/publications/gvs_aefi/en/

WHO vaccine reaction rates information sheets
http://www.who.int/vaccine_safety/initiative/tools/vaccinfosheets/en/

Brighton Collaboration
https://brightoncollaboration.org/public.html

[1] AEFI definition: any untoward medical occurrence which follows immunization and which does not necessarily have a causal relationship with the usage of the vaccine. The adverse event may be any unfavourable or unintended sign, abnormal laboratory finding, symptom or disease. http://whqlibdoc.who.int/publications/2012/9789290360834_eng.pdf

[2] For detailed description of the steps, please refer to the Causality assessment of an AEFI - User manual for the revised WHO classification shown in key resources

Contact us: Essential Medicines and Health Products (EMP) Department, World Health Organization, 20 Avenue Appia, CH-1211 Geneva 27, Switzerland. Fax: +41 22 791 42 10
http://www.who.int/vaccine_safety/en/ E-mail: vaccsafety@who.int.

Approach to the development – AEFI vs AEFMI

AEFI (2012 – 2013)

- WHO with GACVS sub-committee developed methodology
- Introduced in countries after development
- Software developed later
- Piloted in the Indo-Zimbabwe study

AEFMI (2023 – 2026)

- WHO with GACVS, global experts and experts from 5 countries developed methodology in parallel
- Validated by 6 countries as the method was developed and modifications made concurrently
- Software developed simultaneously
- Piloted in the Egypt Study

What is an AEFMI?

An adverse event following maternal immunization (AEFMI) is any untoward medical occurrence (sign, symptom, abnormal lab finding, or disease) or adverse pregnancy outcome in a woman (or fetus) or the neonate that occurs following vaccination during pregnancy which does not necessarily have a causal relationship with the usage of the vaccine

SYMPTOM

Something that a person feels or experiences that may indicate that they have a disease or condition

SIGN

Something found during a physical or clinical examination by the health care provider

LAB FINDING

Physiological or anatomic findings in medically acceptable and validaded laboratory diagnostic methods

DISEASE

A disorder of structure or function that can cause a distinctive group of symptoms, signs, physiological or psychological changes.

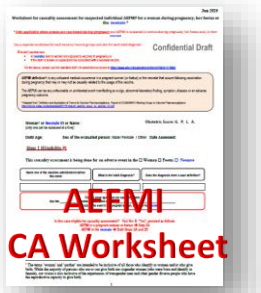
ADVERSE PREGNANCY OUTCOME

.An adverse outcome of the pregnancy involving the mother, fetus, or newborn.

* Adapted from

Definition and Application of Terms for Vaccine Pharmacovigilance; Report of CIOMS/WHO Working Group on Vaccine Pharmacovigilance

Case Based AEFMI Approach



Feedback

AEFMI Detection

OR

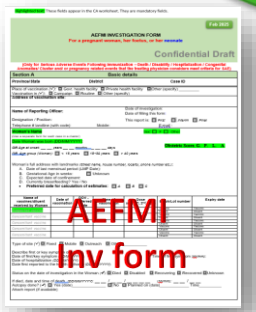
Notification

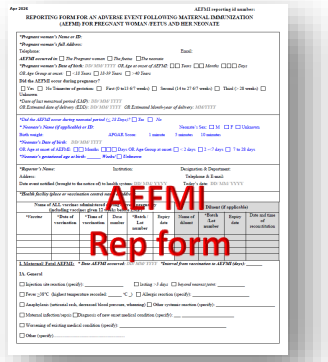
Reporting

Investigation

Analysis

Causality assessment





AEFMI causality assessment classification

A. Consistent causal association to immunization

- A1. Vaccine product-related reaction (Consistent with published evidence)
- A2. Vaccine quality defect-related reaction
- A3. Immunization error related reaction
- A4. Immunization stress related response (ISRR)

B. Indeterminate*

- B1. Any event, including adverse pregnancy outcome, with a temporal association to immunization but insufficient evidence to establish or refute a causal association (may or may not be a new vaccine- associated event)
- B2. Any event, including adverse pregnancy outcome, for which the qualifying factors outlined in the checklist yield conflicting evidence regarding consistency and inconsistency with a causal association to immunization

C. Inconsistent causal association to immunization

- C1. Coincidental, underlying or emerging condition, or condition caused by exposure to something clearly documented as other than the vaccine
- C2. Event is a common adverse pregnancy outcome unlikely to be a vaccine reaction as supported by existing evidence for this this particular vaccine and outcome

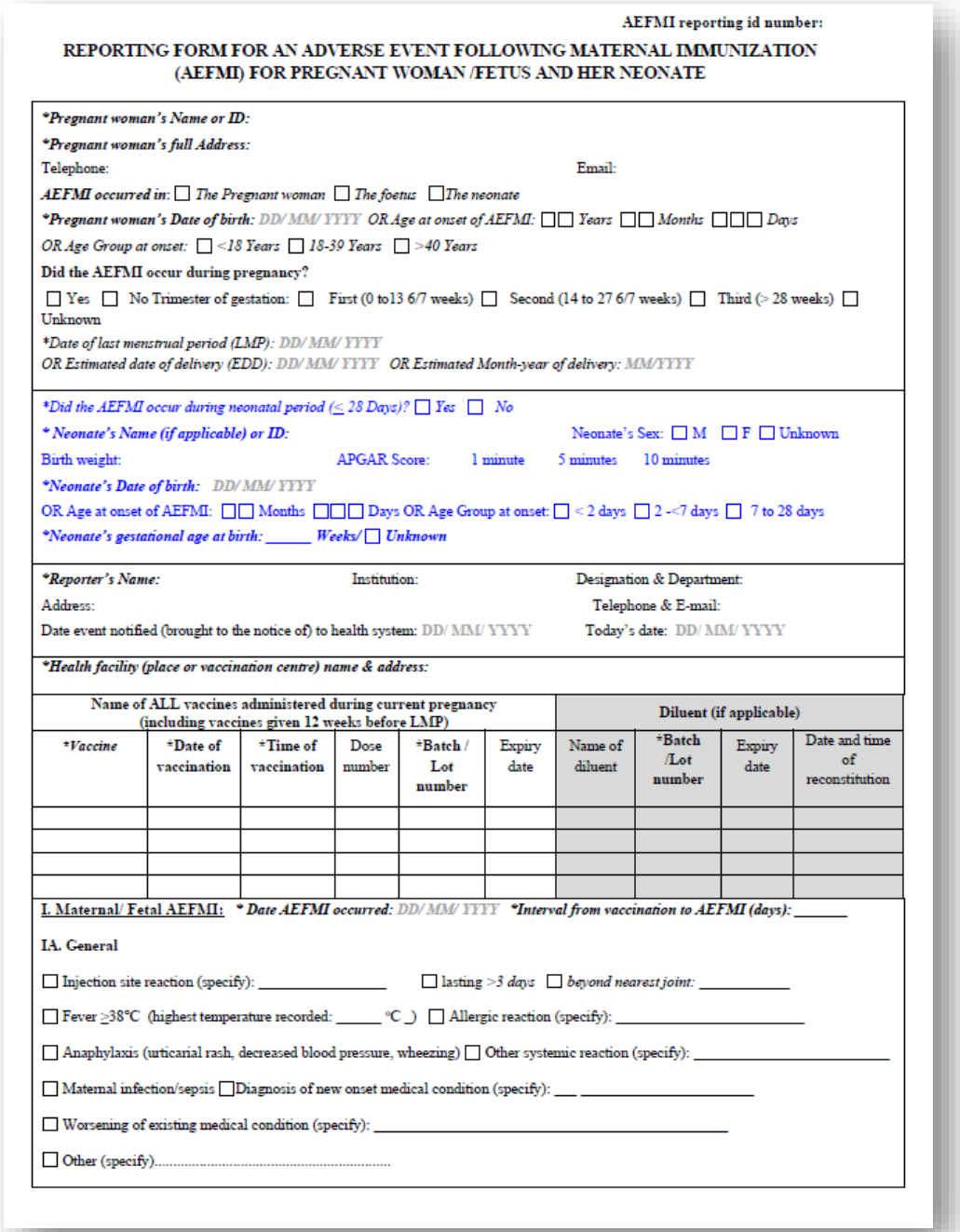
Unclassifiable

Specify the additional information required for classification

*Potential signal and maybe considered for further investigation, particularly if clustering or reporting trend suggests need to assess population-based incidence.

The AEFMI reporting form

- Retains the traditional overall structure as AEFI reporting form
- Customized to collect **preliminary information** on the AEFMI in pregnant woman, foetus and the neonate
- Separates pregnancy outcomes from general AEFMI



AEFMI reporting id number:

REPORTING FORM FOR AN ADVERSE EVENT FOLLOWING MATERNAL IMMUNIZATION (AEFMI) FOR PREGNANT WOMAN /FETUS AND HER NEONATE

**Pregnant woman's Name or ID:*

**Pregnant woman's full Address:*

Telephone: Email:

AEFMI occurred in: ☐ *The Pregnant woman* ☐ *The foetus* ☐ *The neonate*

**Pregnant woman's Date of birth: DD/ MM/ YYYY OR Age at onset of AEFMI:* ☐☐ *Years* ☐☐ *Months* ☐☐☐ *Days*

OR Age Group at onset: ☐ *<18 Years* ☐ *18-39 Years* ☐ *>40 Years*

Did the AEFMI occur during pregnancy?

☐ Yes ☐ No Trimester of gestation: ☐ First (0 to13 6/7 weeks) ☐ Second (14 to 27 6/7 weeks) ☐ Third (> 28 weeks) ☐ Unknown

**Date of last menstrual period (LMP): DD/ MM/ YYYY*

OR Estimated date of delivery (EDD): DD/ MM/ YYYY OR Estimated Month-year of delivery: MM/YYYY

**Did the AEFMI occur during neonatal period (≤ 28 Days)?* ☐ *Yes* ☐ *No*

** Neonate's Name (if applicable) or ID:* Neonate's Sex: ☐ M ☐ F ☐ Unknown

Birth weight: APGAR Score: 1 minute 5 minutes 10 minutes

**Neonate's Date of birth: DD/ MM/ YYYY*

OR Age at onset of AEFMI: ☐☐ Months ☐☐☐ Days OR Age Group at onset: ☐ < 2 days ☐ 2 -<7 days ☐ 7 to 28 days

**Neonate's gestational age at birth: _____ Weeks/* ☐ *Unknown*

**Reporter's Name:* Institution: Designation & Department:

Address: Telephone & E-mail:

Date event notified (brought to the notice of) to health system: DD/ MM/ YYYY Today's date: DD/ MM/ YYYY

**Health facility (place or vaccination centre) name & address:*

Name of ALL vaccines administered during current pregnancy (including vaccines given 12 weeks before LMP)						Diluent (if applicable)			
**Vaccine*	**Date of vaccination*	**Time of vaccination*	Dose number	**Batch / Lot number*	Expiry date	Name of diluent	**Batch /Lot number*	Expiry date	Date and time of reconstitution

I. Maternal/ Fetal AEFMI: ** Date AEFMI occurred: DD/ MM/ YYYY *Interval from vaccination to AEFMI (days): _____*

IA. General

☐ Injection site reaction (specify): _____ ☐ lasting *>3 days* ☐ *beyond nearest joint:* _____

☐ Fever ≥38°C (highest temperature recorded: _____ °C) ☐ Allergic reaction (specify): _____

☐ Anaphylaxis (urticarial rash, decreased blood pressure, wheezing) ☐ Other systemic reaction (specify): _____

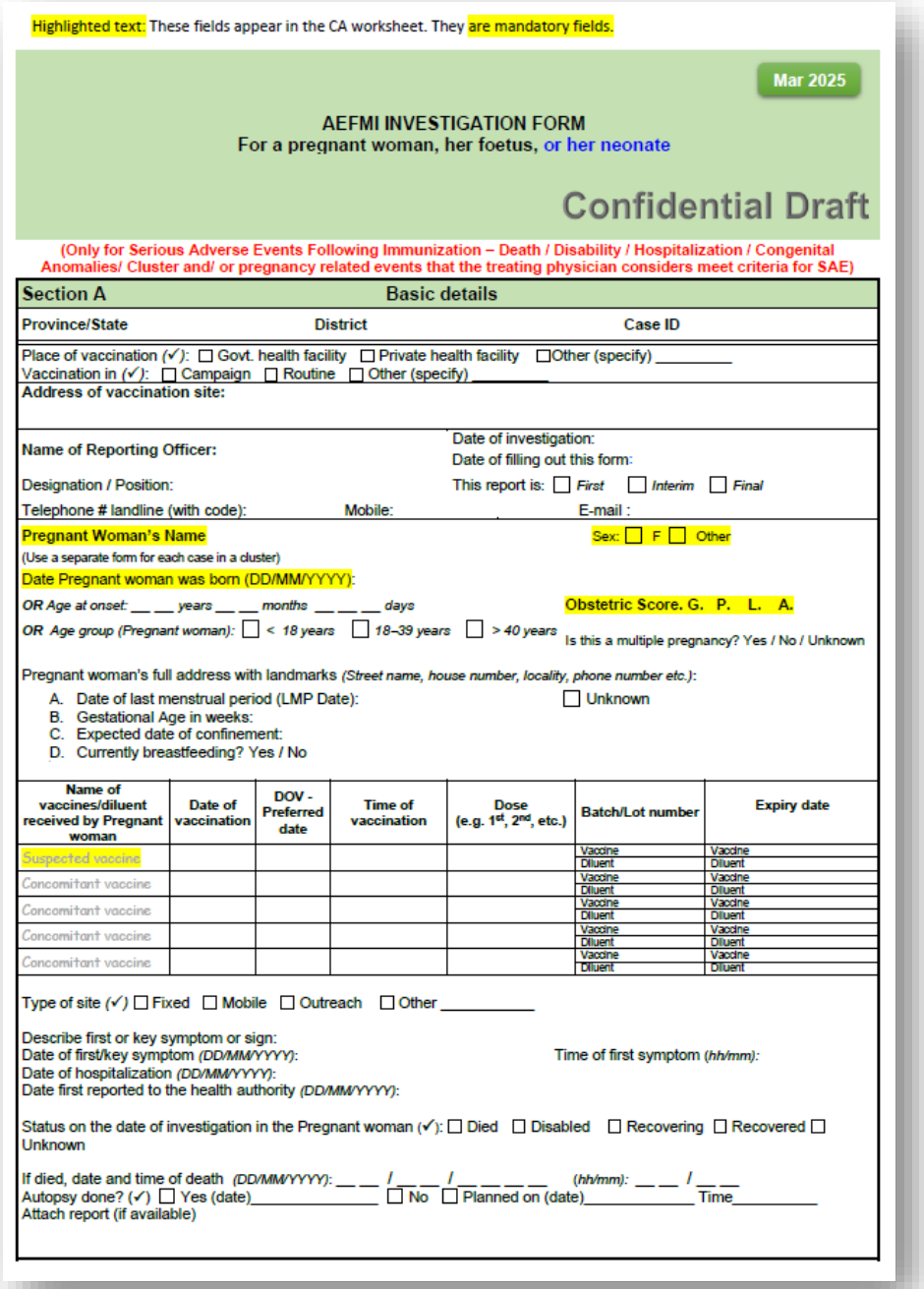
☐ Maternal infection/sepsis ☐ Diagnosis of new onset medical condition (specify): ___ _____

☐ Worsening of existing medical condition (specify): _____

☐ Other (specify).....

The AEFMI investigation form

- Retains the overall sections of the traditional AEFI investigation form
- 2 types
  - Generic (developed)
  - Adverse Pregnancy Outcome Specific (developed for Hypertension (eclampsia), Preterm Birth and AN Bleeding)
- Separate sections for pregnant woman (foetus) and neonate



Highlighted text: These fields appear in the CA worksheet. They are mandatory fields.

Mar 2025

AEFMI INVESTIGATION FORM
For a pregnant woman, her foetus, or her neonate

Confidential Draft

(Only for Serious Adverse Events Following Immunization – Death / Disability / Hospitalization / Congenital Anomalies/ Cluster and/ or pregnancy related events that the treating physician considers meet criteria for SAE)

Section A **Basic details**

Province/State **District** **Case ID**

Place of vaccination (✓): ☐ Govt. health facility ☐ Private health facility ☐Other (specify) _____
Vaccination in (✓): ☐ Campaign ☐ Routine ☐ Other (specify) _____
Address of vaccination site:

Name of Reporting Officer:
Date of investigation:
Date of filling out this form:
Designation / Position:
This report is: ☐ *First* ☐ *Interim* ☐ *Final*
Telephone # landline (with code): Mobile: E-mail :

Pregnant Woman's Name Sex: ☐ F ☐ Other
(Use a separate form for each case in a cluster)
Date Pregnant woman was born (DD/MM/YYYY):
OR Age at onset: __ __ years __ __ months __ __ __ days **Obstetric Score. G. P. L. A.**
OR Age group (Pregnant woman): ☐ *< 18 years* ☐ *18–39 years* ☐ *> 40 years* Is this a multiple pregnancy? Yes / No / Unknown

Pregnant woman's full address with landmarks *(Street name, house number, locality, phone number etc.)*:

A. Date of last menstrual period (LMP Date): ☐ Unknown
B. Gestational Age in weeks:
C. Expected date of confinement:
D. Currently breastfeeding? Yes / No

Name of vaccines/diluent received by Pregnant woman	Date of vaccination	DOV - Preferred date	Time of vaccination	Dose (e.g. 1st, 2nd, etc.)	Batch/Lot number	Expiry date
Suspected vaccine					Vaccine Diluent	Vaccine Diluent
Concomitant vaccine					Vaccine Diluent	Vaccine Diluent
Concomitant vaccine					Vaccine Diluent	Vaccine Diluent
Concomitant vaccine					Vaccine Diluent	Vaccine Diluent
Concomitant vaccine					Vaccine Diluent	Vaccine Diluent

Type of site (✓) ☐ Fixed ☐ Mobile ☐ Outreach ☐ Other _____

Describe first or key symptom or sign:
Date of first/key symptom *(DD/MM/YYYY)*: Time of first symptom *(hh/mm)*:
Date of hospitalization *(DD/MM/YYYY)*:
Date first reported to the health authority *(DD/MM/YYYY)*:

Status on the date of investigation in the Pregnant woman (✓): ☐ Died ☐ Disabled ☐ Recovering ☐ Recovered ☐ Unknown

If died, date and time of death *(DD/MM/YYYY)*: __ __ / __ __ / __ __ __ __ *(hh/mm)*: __ __ / __ __
Autopsy done? (✓) ☐ Yes (date)_____ ☐ No ☐ Planned on (date)_____ Time_____
Attach report (if available)

The AEFMI Causality Assessment worksheet

March 2024

Worksheet for causality assessment for suspected individual AEFMI[1] for women during or after pregnancy and/ or their neonate *

* Only applicable when women are vaccinated during pregnancy and AEFMI is suspected in women during or after pregnancy and/ or their neonate
Use a separate worksheet for each vaccine/ vaccine groups and also for each valid diagnosis

Confidential Draft

Do NOT use this form
- In neonates born to women not exposed to vaccines in pregnancy or lactation or
- If the AEFI is known or suspected to be associated with a neonatal vaccine

For the above, please use the standard AEFI CA worksheet accessed at https://www.who.int/pu

AEFMI definition[1]: Any untoward medical occurrence in a pregnant or lactating woman during pregnancy, that may or may not be causally related to the usage of the vaccine.

An AEFMI can be any unfavorable or unintended event manifesting as a sign, abnormal l

[1] Adapted from' Definition and Application of Terms for Vaccine Pharmacovigilance; Report of CIOMS/WHO W https://cioms.ch/wp-content/uploads/2017/01/report_working_group_on_vaccine_LR.pdf

Woman[1] or Neonate ID or Name :
(only one can be assessed at a time)

DoB/ Age: **Sex of the evaluated person:** Male/ Female /

Step 1 (Eligibility #)

This causality assessment is being done for an adverse event in the

Name one of the vaccines administered before this event	What is the Valid Diagnosis?

Create your question on causality her
Has the _____ vaccine / vaccination caused _____
(The valid diagnosis for the event in the pregnant or lactating woman or her

Is this case eligible for causality assessment? Yes/ No; If,
AEFI in a pregnant or lactating woman →
AEFI in the neonate → Both Steps 2A a

Eligibility

[1] The terms 'woman' and 'mother' are intended to be inclusive of all those wh birth. While the majority of persons who are or can give birth are cisgender w female), our vision is also inclusive of the experiences of transgender men and the reproductive capacity to give birth.

1

Page 1

Step 2 A (Checklist for the event in the PREGNANT/ LACTATING WOMAN)

(✓ Check) all boxes that apply

I. Is there strong evidence for other causes?	Y	N	UK	NA	Remar
1. In this woman, does the medical history, clinical examination and/ or investigations, confirm another cause for the event?	□	□	□	□	
II. Is there a known causal association with the vaccine or vaccination?					
Vaccine product					
2. Is there evidence in published peer reviewed literature that this vaccine may cause such an event in a pregnant or lactating woman even if administered correctly?	□	□	□	□	
3. Is there a biological plausibility that this vaccine could cause such an event in a pregnant or lactating woman?	□	□	□	□	
4. In this pregnant or lactating woman, did a specific test demonstrate the causal role of the vaccine?	□	□	□	□	
Vaccine quality					
5. Could the vaccine given to this wo substandard or falsified?	□	□	□	□	
Immunization error					
6. Was there an error in prescribing o vaccine (e.g., use beyond the expiry administered to this woman during he	□	□	□	□	
7. Was the vaccine (or diluent) admin during her pregnancy?	□	□	□	□	
8. Was the vaccine's physical conditi etc.) abnormal when administered to	□	□	□	□	
9. Was there an error in vaccine cons wrong diluent, improper mixing, impro during her pregnancy?	□	□	□	□	
10. Was there an error in vaccine ha storage and/or immunization session pregnancy?	□	□	□	□	
11. Was the vaccine administered incorrectly (e.g., wrong dose, site or route of administration; wrong needle size etc.) when given to this woman during her pregnancy?	□	□	□	□	
Immunization stress related responses (ISRR)					
12. In this pregnant woman, could this event be a stress response related to immunization (e.g., acute stress response, vasovagal reaction, hyperventilation or anxiety)?	□	□	□	□	
II (time). If "yes" to any question in II, was the event within the time window of increased risk?					
13. In this pregnant or lactating woman, did the event occur within a plausible time window after vaccine administration?	□	□	□	□	
III. Is there strong evidence against a causal association?					
14. Is there a body of published evidence (systematic reviews, GACVS reviews, Cochrane reviews etc.) against a causal association between the vaccine and the event in the pregnant or lactating woman?	□	□	□	□	
IV. Other qualifying factors for classification					
Current pregnancy					
15. In this pregnant or lactating woman, did such an event occur during the current pregnancy after administration of any vaccine?	□	□	□	□	
16. In this pregnant or lactating woman, did such an event occur during the current pregnancy without the administration of any vaccine?	□	□	□	□	
17. During this pregnancy, did the pregnant or lactating woman have an illness, pre-existing condition or risk factor that could have contributed to the event?	□	□	□	□	
18. During this pregnancy, was this woman taking any medication prior to the vaccination?	□	□	□	□	

2

Page 2

Checklist for Pregnant woman(or foetus)

19. During this pregnancy, was the woman exposed to a potential risk factor (e.g., allergen, herbal product, narcotic drugs etc.)?	□	□	□	□
20. Could the current event have occurred in this pregnant or lactating woman without vaccination (background rate in				
Prior to current pregnancy				
21. In this pregnant or lactating w of any vaccine when she was no				
22. In this pregnant or lactating w of any vaccine during her previ				
23. Did this pregnant or lactating intervention or risk factor when she was not pregnant that could have contributed to the event?				
an illness, pre-existing con ion, prior pregnancy(ies) that could have contributed to				
or to the pregnancy?	□	□	□	□
posed to a potential risk fa r (e.g., allergen,	□	□	□	□

Note the Royal Blue font for Neonate

Checklist for Neonate

Step 2 B (Checklist for the event in the NEONATE)** ✓ (check) all boxes that a

(** Please note that it is important to complete the woman's checklist prior to completing this checkl

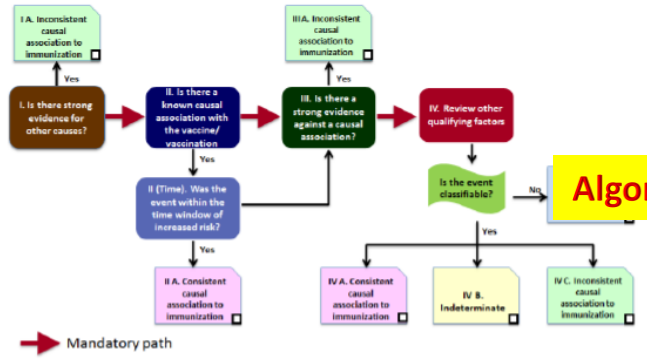
I. Is there strong evidence for other causes?	Y	N	UK	NA
1. In this neonate, does the medical history, clinical examination and/ or investigations, confirm another cause for the event?	□	□	□	□
II. Is there a known causal association with the vaccine or vaccination?				
Vaccine product				
2. Is there evidence in published peer reviewed literature that this vaccine may cause such an event in the neonate if administered correctly to the woman during her pregnancy?	□	□	□	□
3. Is there a biological plausibility that this vaccine could cause such an event in the neonate if administered to the woman during her pregnancy?	□	□	□	□
4. In this neonate, did a specific test demonstrate the causal role of the vaccine administered to the woman during her pregnancy?	□	□	□	□
II (time). If "yes" to any question in II, was the event within the time window of increased risk?				
5. In this neonate, did the event occur within a plausible time window after vaccine administration to the woman during her pregnancy?	□	□	□	□
III. Is there strong evidence against a causal association?				
6. Is there a body of published evidence (systematic reviews, GACVS reviews, Cochrane reviews etc.) against a causal association between the vaccine and the event in the neonate?	□	□	□	□
IV. Other qualifying factors for classification				
7. Could the current event have occurred in this neonate without vaccination in the pregnant or lactating woman or the neonate (background rate)?	□	□	□	□
8. Was this neonate taking any medication since birth?	□	□	□	□
9. Was this neonate exposed to a potential factor prior to the event (e.g., allergen, drug, herbal product etc.)?	□	□	□	□
10. Could any procedure in the neonate such as resuscitation procedures or surgical intervention, have contributed to the occurrence of this event?	□	□	□	□
11. Could any procedure in the pregnant or lactating woman (e.g., Lower Segment Caesarean Section, vacuum, forceps, medical intervention etc) contributed to the occurrence of this event?	□	□	□	□
12. If this neonate is breastfed, was the lactating woman exposed to a potential risk factor after delivery (e.g., radiation, ultrasound, blunt trauma, hallucinogenic drugs and tobacco etc.)?	□	□	□	□

3

Page 3

Page 4

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



Algorithm

Notes for Step 3:

Step 4 (Classification) ✓ all boxes that apply

	A. Consistent with causal association to immunization	B. Indeterminate	C. Inconsistent with causal association to immunization
Adequate information available	A1. Vaccine product-related reaction (As per published literature) A2. Vaccine quality defect-related reaction A3. Immunization error-related reaction A4. Immunization anxiety-related reaction (ISRR**)	B1. *Temporal relationship is consistent but there is insufficient definitive evidence for vaccine causing event (may be new vaccine-linked event) B2. Reviewing factors result in conflicting trends of consistency and inconsistency with causal association to immunization	C.
Adequate information not available	Unclassifiable Specify the additional information required for classification :		

*B1: This is a potential signal and maybe considered for investigation
** Immunization stress related response

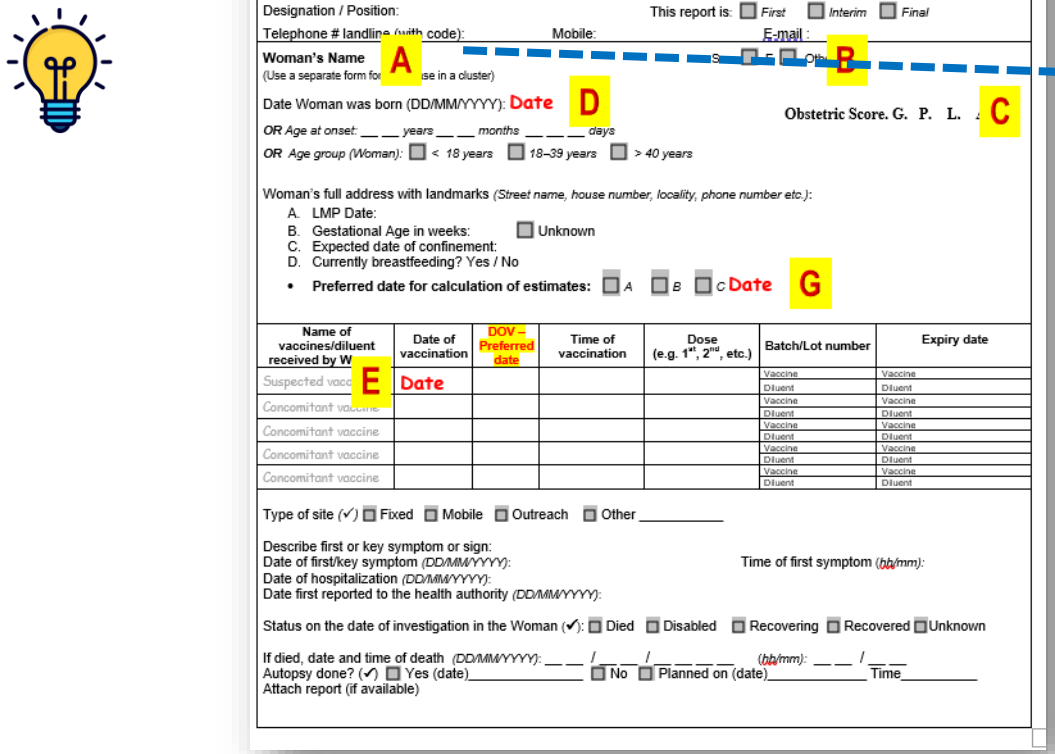
Classification

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:_____

4

Linking AEFMI Investigation with AEFMI CA



Confidential Draft

AEFMI INVESTIGATION FORM
For a pregnant woman, her foetus, or her neonate

(Only for Serious Adverse Events Following Immunization – Death / Disability / Hospitalization / Congenital Anomalies/ Cluster and/ or pregnancy related events that the treating physician considers meet criteria for SAE)

Section A **Basic details**

Province/State | District | Case ID

Place of vaccination (✓): ☐ Govt. health facility ☐ Private health facility ☐ Other (specify) _____
Vaccination in (✓): ☐ Campaign ☐ Routine ☐ Other (specify) _____
Address of vaccination site:

Name of Reporting Officer:
Date of investigation:
Date of filling this form:
Designation / Position:
This report is: ☐ First ☐ Interim ☐ Final
Telephone # landline (with code): Mobile: E-mail :

Woman's Name A B
(Use a separate form for each woman in a cluster)

Date Woman was born (DD/MM/YYYY): Date D
Obstetric Score. G. P. L. A. C
OR Age at onset: __ __ years __ __ months __ __ __ days
OR Age group (Woman): ☐ < 18 years ☐ 18–39 years ☐ > 40 years

Woman's full address with landmarks (Street name, house number, locality, phone number etc.):

A. LMP Date:
B. Gestational Age in weeks: ☐ Unknown
C. Expected date of confinement:
D. Currently breastfeeding? Yes / No

- Preferred date for calculation of estimates: ☐ A ☐ B ☐ C Date G

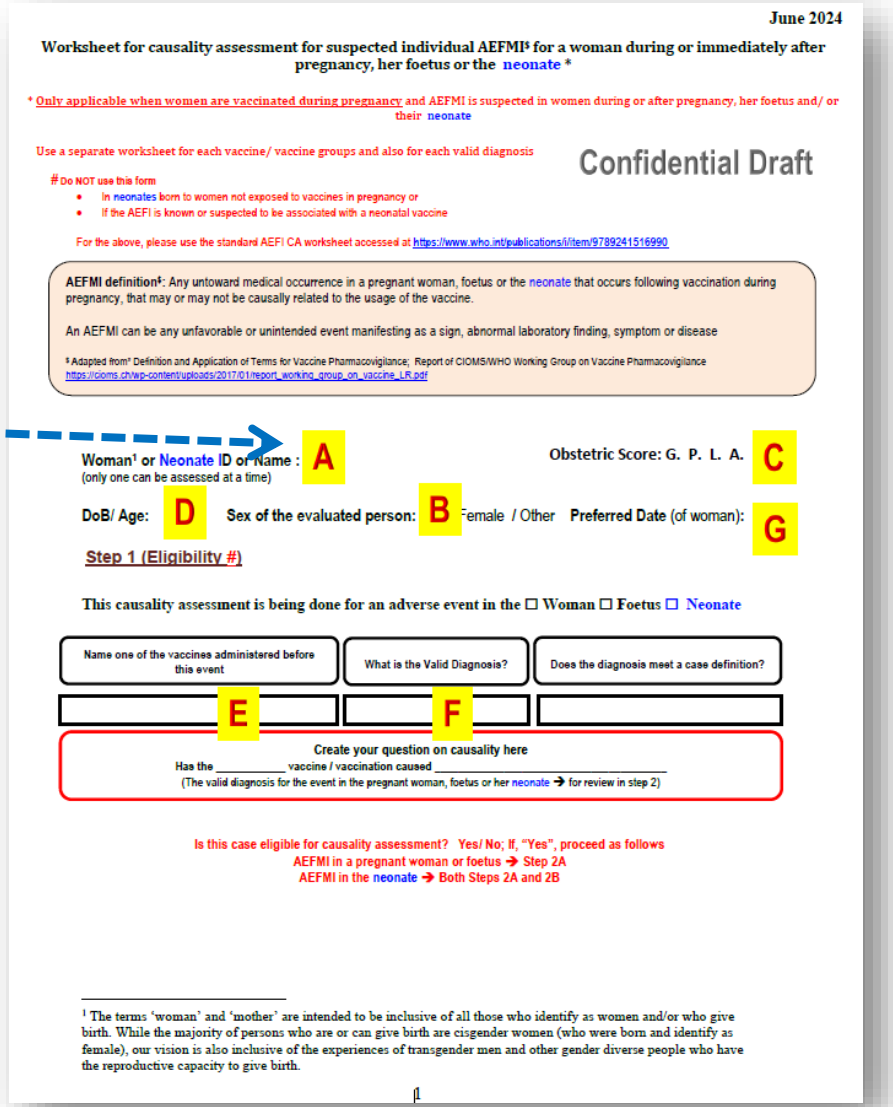
Name of vaccines/diluent received by W	Date of vaccination	DOV – Preferred date	Time of vaccination	Dose (e.g. 1st, 2nd, etc.)	Batch/Lot number	Expiry date
Suspected vacc E	Date				Vaccine / Diluent	Vaccine / Diluent
Concomitant vaccine					Vaccine / Diluent	Vaccine / Diluent
Concomitant vaccine					Vaccine / Diluent	Vaccine / Diluent
Concomitant vaccine					Vaccine / Diluent	Vaccine / Diluent
Concomitant vaccine					Vaccine / Diluent	Vaccine / Diluent

Type of site (✓) ☐ Fixed ☐ Mobile ☐ Outreach ☐ Other _____

Describe first or key symptom or sign:
Date of first/key symptom (DD/MM/YYYY):
Time of first symptom (hh/mm):
Date of hospitalization (DD/MM/YYYY):
Date first reported to the health authority (DD/MM/YYYY):

Status on the date of investigation in the Woman (✓): ☐ Died ☐ Disabled ☐ Recovering ☐ Recovered ☐ Unknown

If died, date and time of death (DD/MM/YYYY): __ __ / __ __ / __ __ __ __ (hh/mm): __ __ / __ __
Autopsy done? (✓) ☐ Yes (date)_____ ☐ No ☐ Planned on (date)_____ Time_____
Attach report (if available)



June 2024

Worksheet for causality assessment for suspected individual AEFMI[1] for a woman during or immediately after pregnancy, her foetus or the neonate *

* Only applicable when women are vaccinated during pregnancy and AEFMI is suspected in women during or after pregnancy, her foetus and/ or their neonate

Use a separate worksheet for each vaccine/ vaccine groups and also for each valid diagnosis

Confidential Draft

Do NOT use this form
- In neonates born to women not exposed to vaccines in pregnancy or
- If the AEFI is known or suspected to be associated with a neonatal vaccine

For the above, please use the standard AEFI CA worksheet accessed at https://www.who.int/publications/i/item/9789241516990

AEFMI definition[1]: Any untoward medical occurrence in a pregnant woman, foetus or the neonate that occurs following vaccination during pregnancy, that may or may not be causally related to the usage of the vaccine.

An AEFMI can be any unfavorable or unintended event manifesting as a sign, abnormal laboratory finding, symptom or disease

[1] Adapted from[2] Definition and Application of Terms for Vaccine Pharmacovigilance; Report of CIOMS/WHO Working Group on Vaccine Pharmacovigilance https://cioms.ch/wp-content/uploads/2017/01/report_working_group_on_vaccine_LR.pdf

Woman[1] or Neonate ID or Name : A (only one can be assessed at a time)
Obstetric Score: G. P. L. A. C

DoB/ Age: D Sex of the evaluated person: B Female / Other Preferred Date (of woman): G

Step 1 (Eligibility #)

This causality assessment is being done for an adverse event in the ☐ Woman ☐ Foetus ☐ Neonate

Name one of the vaccines administered before this event	What is the Valid Diagnosis?	Does the diagnosis meet a case definition?
E	F	

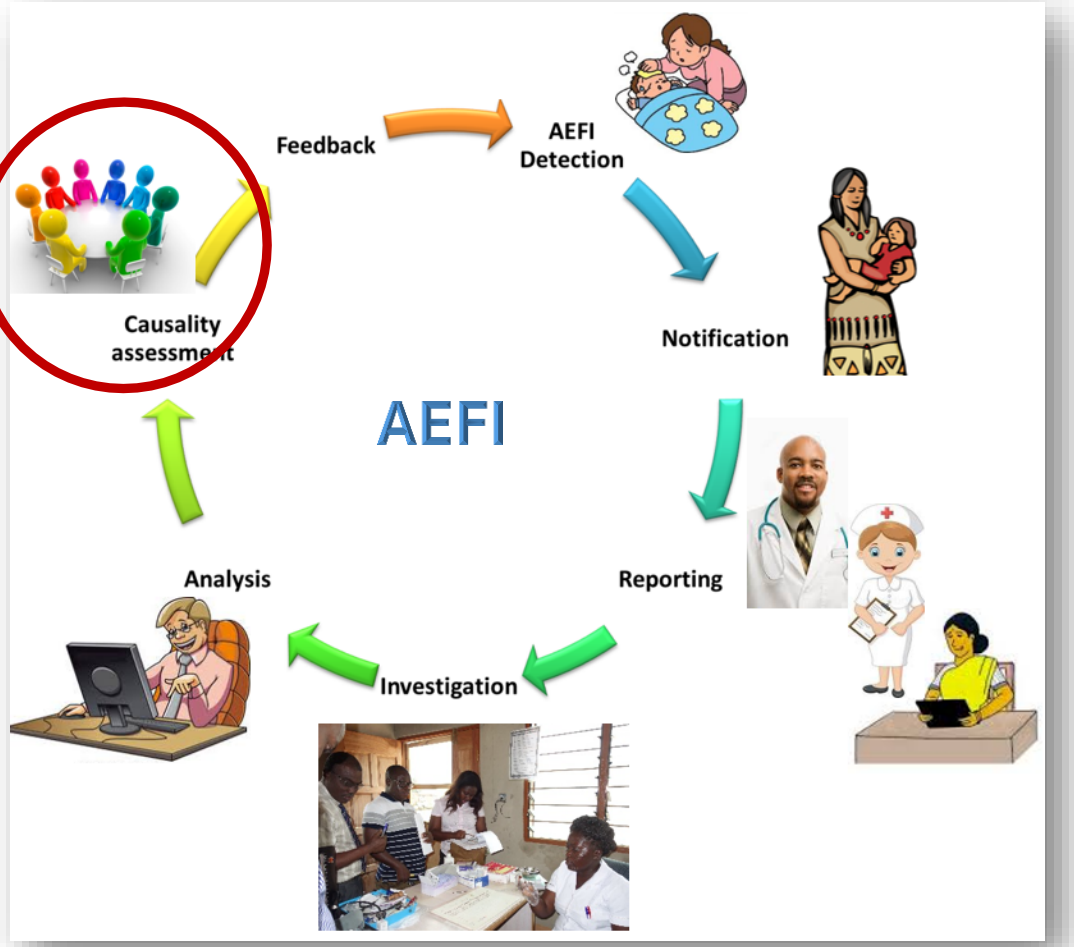
Create your question on causality here
Has the _____ vaccine / vaccination caused _____
(The valid diagnosis for the event in the pregnant woman, foetus or her neonate → for review in step 2)

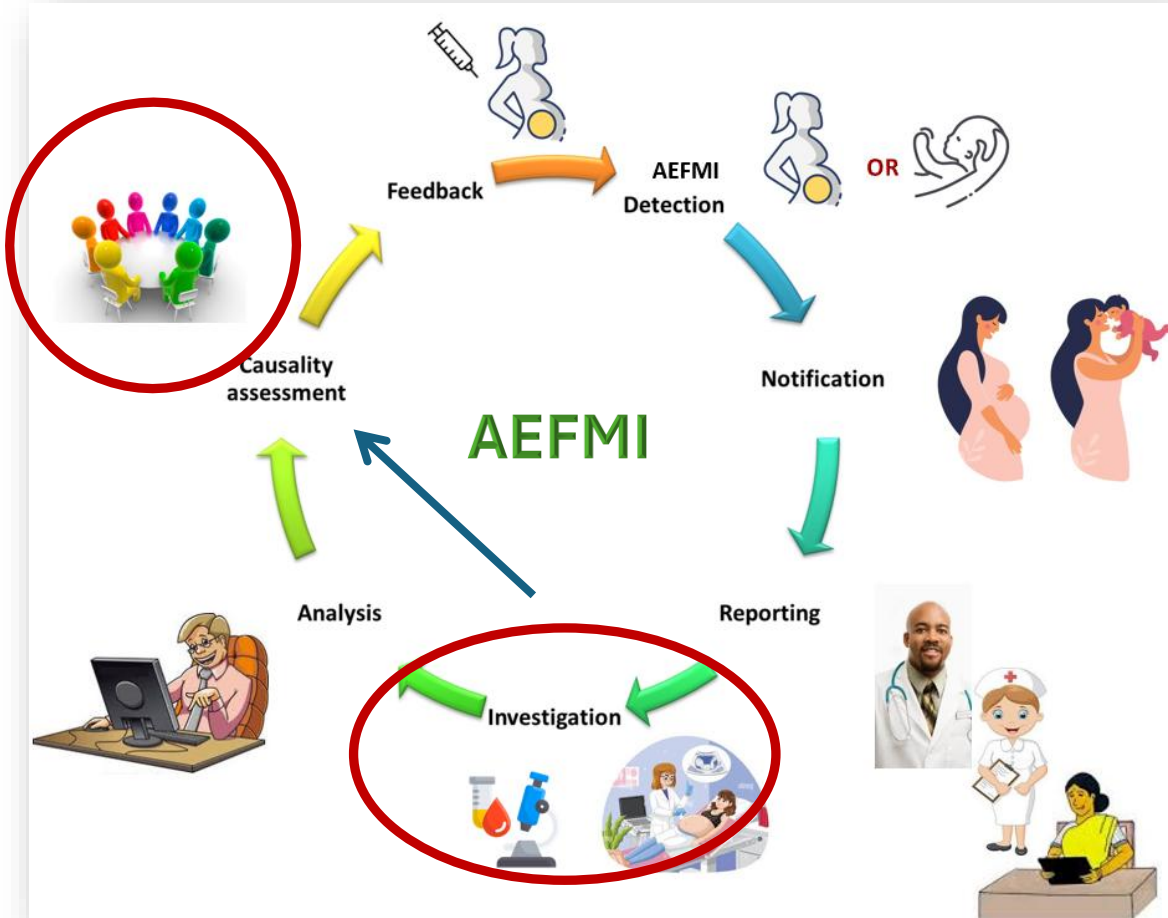
Is this case eligible for causality assessment? Yes/ No; If, "Yes", proceed as follows
AEFMI in a pregnant woman or foetus → Step 2A
AEFMI in the neonate → Both Steps 2A and 2B

[1] The terms 'woman' and 'mother' are intended to be inclusive of all those who identify as women and/or who give birth. While the majority of persons who are or can give birth are cisgender women (who were born and identify as female), our vision is also inclusive of the experiences of transgender men and other gender diverse people who have the reproductive capacity to give birth.

1

AEFI Vs AEFMI





Causality assessment of an adverse event following maternal immunization (AEFMI)*

Research Language

(Only for Serious Adverse Events Following Immunization - Death/Disability/Hospitalization/Congenital Anomalies/Cluster and/or pregnancy related outcomes that the treating physician considers meet criteria for SAE)

An adverse event following maternal immunization (AEFMI) is any untoward medical occurrence in a pregnant woman (or foetus) or the neonate that occurs following vaccination during pregnancy that may or may not be causally related to the usage of the vaccine.

The AEFMI can be any unfavorable or unintended event manifesting as a sign, abnormal laboratory finding, symptom, disease or an adverse pregnancy outcome.

The purpose of this assessment is to ascertain if the event assessed is coincidental, caused by the vaccination process, by the vaccine or if the assessor(s) is/are uncertain.

AEFMI

https://aefmi.duredemos.com/aefmi/

SYMPTOM

Cough, Rash, Vaginal Bleeding Etc

SIGN

Small For Gestational Age, Abnormal Foetal Position Etc

LAB FINDING

Placenta Previa, Multiple Pregnancies Etc

DISEASE

e.g. Intussusception, Meningitis Etc

ADVERSE PREGNANCY, FETAL/NEONATAL OUTCOMES

Abortion, APH Etc

- ***Only applicable when women* were vaccinated during pregnancy** and AEFMI is suspected in women during pregnancy and/or their *neonate (new born baby <=28 days old)

  ***IMPORTANT** : The terms 'woman' and 'mother' are intended to be inclusive of all those who identify as women and/or who give birth. While the majority of persons who are or can give birth are cisgender women (who were born and identify as female), our vision is also inclusive of the experiences of transgender men and other gender diverse people who have the reproductive capacity to give birth.

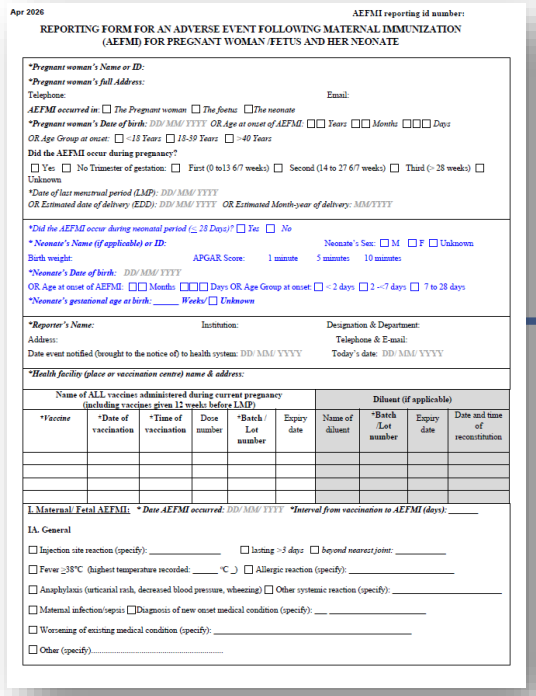
  #Do NOT use this software

  - In neonate born to women not exposed to vaccines in pregnancy or
  - If the AEFMI is known or suspected to be associated with a neonatal vaccine

  For the above, please use the standard AEFI CA worksheet accessed at https://gvsi-aefi-tools.org/

Click here to proceed

Case Based AEFMI Approach



Apr 2026 AEFMI reporting id number:

REPORTING FORM FOR AN ADVERSE EVENT FOLLOWING MATERNAL IMMUNIZATION (AEFMI) FOR PREGNANT WOMAN /FETUS AND HER NEONATE

*Pregnant woman's Name or ID:
*Pregnant woman's full Address:
Telephone: Email:
AEFMI occurred in: ☐ The Pregnant woman ☐ The foetus ☐ The neonate
*Pregnant woman's Date of birth: DD/ MM/ YYYY OR Age at onset of AEFMI: ☐☐ Years ☐☐ Months ☐☐☐ Days
OR Age Group at onset: ☐ <18 Years ☐ 18-39 Years ☐ >40 Years
Did the AEFMI occur during pregnancy?
☐ Yes ☐ No Trimester of gestation: ☐ First (0 to13 6/7 weeks) ☐ Second (14 to 27 6/7 weeks) ☐ Third (> 28 weeks) ☐ Unknown
*Date of last menstrual period (LMP): DD/ MM/ YYYY
OR Estimated date of delivery (EDD): DD/ MM/ YYYY OR Estimated Month-year of delivery: MM/YYYY

*Did the AEFMI occur during neonatal period (<= 28 Days)? ☐ Yes ☐ No
* Neonate's Name (if applicable) or ID: Neonate's Sex: ☐ M ☐ F ☐ Unknown
Birth weight: APGAR Score: 1 minute 5 minutes 10 minutes
*Neonate's Date of birth: DD/ MM/ YYYY
OR Age at onset of AEFMI: ☐☐ Months ☐☐☐ Days OR Age Group at onset ☐ < 2 days ☐ 2 --7 days ☐ 7 to 28 days
*Neonate's gestational age at birth: _____ Weeks/ ☐ Unknown

*Reporter's Name: Institution: Designation & Department:
Address: Telephone & E-mail:
Date event notified (brought to the notice of) to health system: DD/ MM/ YYYY Today's date: DD/ MM/ YYYY

*Health facility (place or vaccination centre) name & address:

Name of ALL vaccines administered during current pregnancy (including vaccines given 12 weeks before LMP)						Diluent (if applicable)			
*Vaccine	*Date of vaccination	*Time of vaccination	Dose number	*Batch / Lot number	Expiry date	Name of diluent	*Batch /Lot number	Expiry date	Date and time of reconstitution

I. Maternal/ Fetal AEFMI: * Date AEFMI occurred: DD/ MM/ YYYY *Interval from vaccination to AEFMI (days): _____

IA. General

☐ Injection site reaction (specify): _____ ☐ lasting >3 days ☐ beyond nearest joint: _____
☐ Fever ≥38°C (highest temperature recorded: _____ °C) ☐ Allergic reaction (specify): _____
☐ Anaphylaxis (urticarial rash, decreased blood pressure, wheezing) ☐ Other systemic reaction (specify): _____
☐ Maternal infection/sepsis ☐Diagnosis of new onset medical condition (specify): ___ _____
☐ Worsening of existing medical condition (specify): _____
☐ Other (specify).....

AEFMI Reporting Form reviewed & decision to investigate

Generate condition specific AEFMI Investigation form online & Printout

World Health Organization

Case Based AEFMI Approach

AEFMI Causality assessment is done in two stages

Stage 1: Stage of uploading AEFMI investigation findings (Point of care Data collectors)

This stage allows you to upload the information that you collected during your AEFMI investigation into the software.

For new causality assessments, please start here → Stage 1

Stage 2: Stage of Classification (Expert causality assessors)

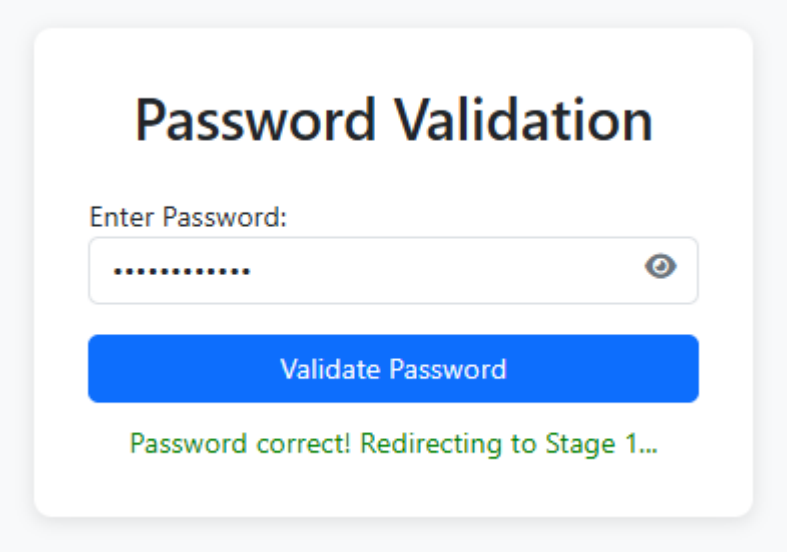
This stage helps the assessor to use the information from stage 1 to perform AEFMI causality assessment.

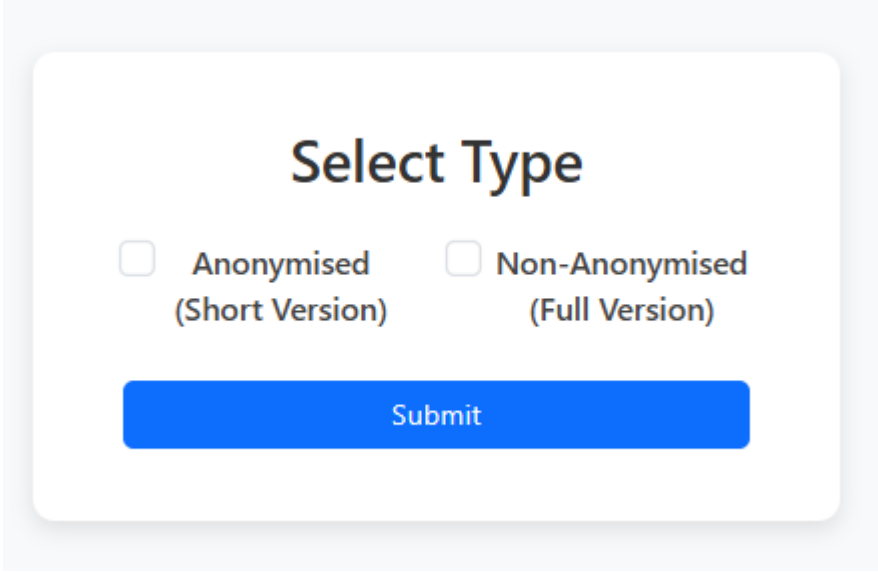
You may proceed directly to this stage if you already have a "saved Stage 1 file" to upload. → Stage 2

This is a screenshot from the software

World Health Organization

Stage 1: Stage of uploading AEFMI investigation findings





AEFMI

Home

Stage 1 Stage of investigation

Select who is directly affected by the event, and what is the suspected diagnosis of the event?

Black text pertains to the mother (pregnant woman) / fetus, and blue text pertains to the neonate

Pregnant woman*

Hypertension

Foetus

Select event

Neonate

Select event

Generating a condition specific AEFMI Investigation form

acknowledgement

ingredients, and should be interpreted in the broader context of evidence, such as population-based studies.

Back

If you require printable versions of the case investigation form, please select from the following options:

Download AEFMI investigation form for Hypertension

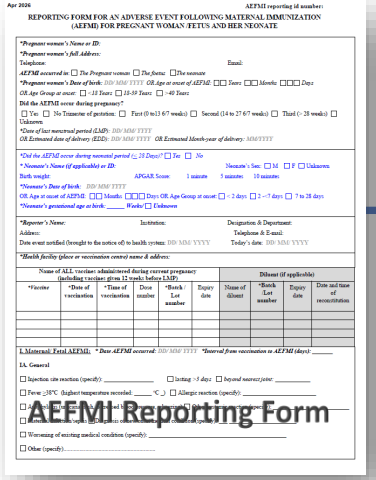
PDF

Word Doc

Download Key Considerations For Hypertension

Continue

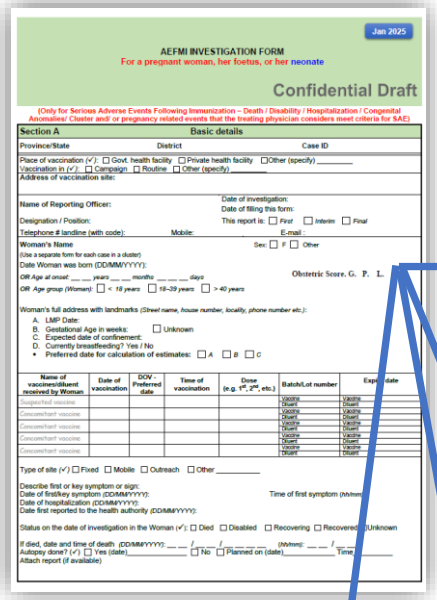
World Health Organization



AEFMI Reporting Form

AEFMI Reporting Form reviewed & decision to investigate

Generate condition specific AEFMI Investigation form online & Printout



Blank AEFMI Investigation form

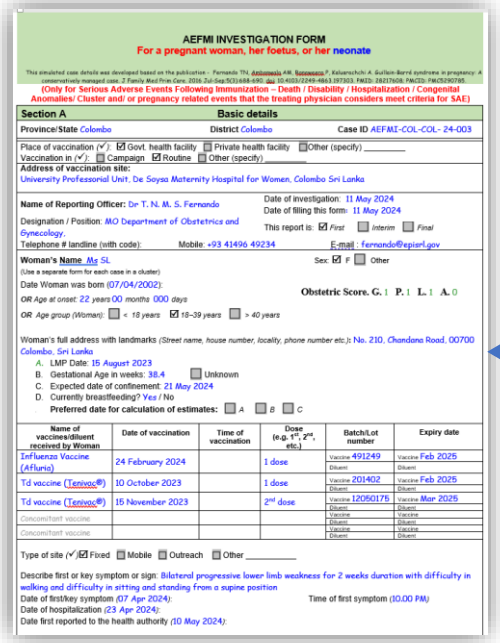
Interview Pregnant woman & doctor/ HCP

Verify vaccine storage & Transport

Visit vaccination site & Interview vaccinator

Check status of others vaccinated (pregnant women at the same time and the other pregnant women in the area)

Stage 1: Stage of uploading AEFMI investigation findings

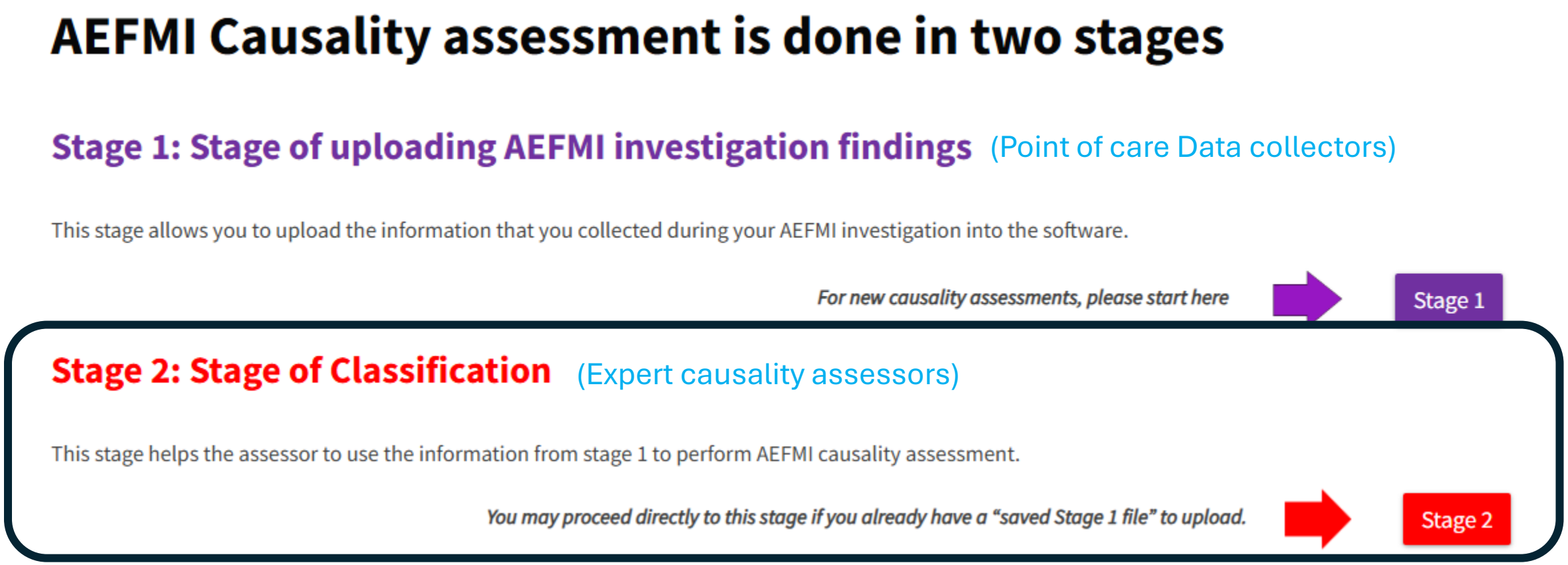


Completed AEFMI Investigation form

Upload investigation form to website

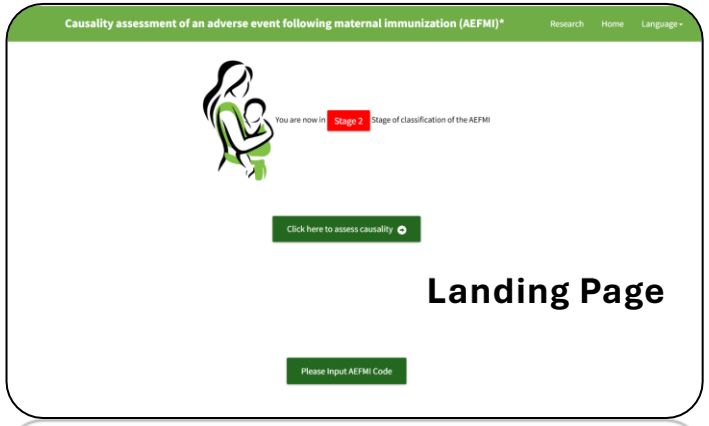
Generate Code AEFMI – 123 & Download completed form

So… how is this operationalized?



This is a screenshot from the software

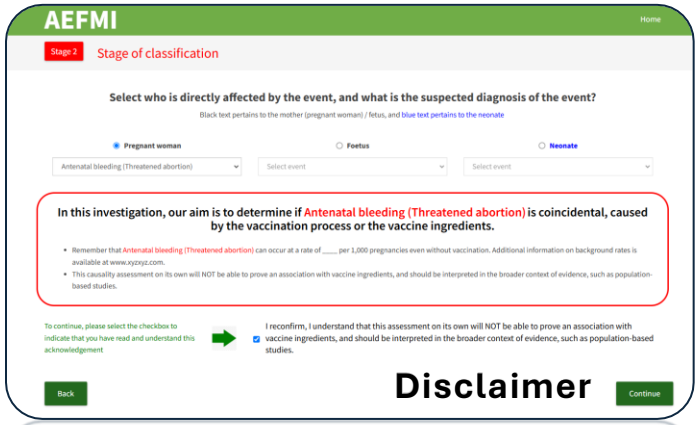
Stage 2: Stage of Classification



Landing Page

Classification with Investigation Code

Upload Code AEFMI – 123



Disclaimer

Causality Question Creation

1. Eligibility
2. Checklist
3. Algorithm
4. Classification

ADVERSE EVENT FOLLOWING MATERNAL IMMUNIZATION

This report is prepared using inputs and decisions made by Madhav

Report on AEFMI causality Assessment using the tool developed by WHO for the revised AEFMI causality assessment methodology

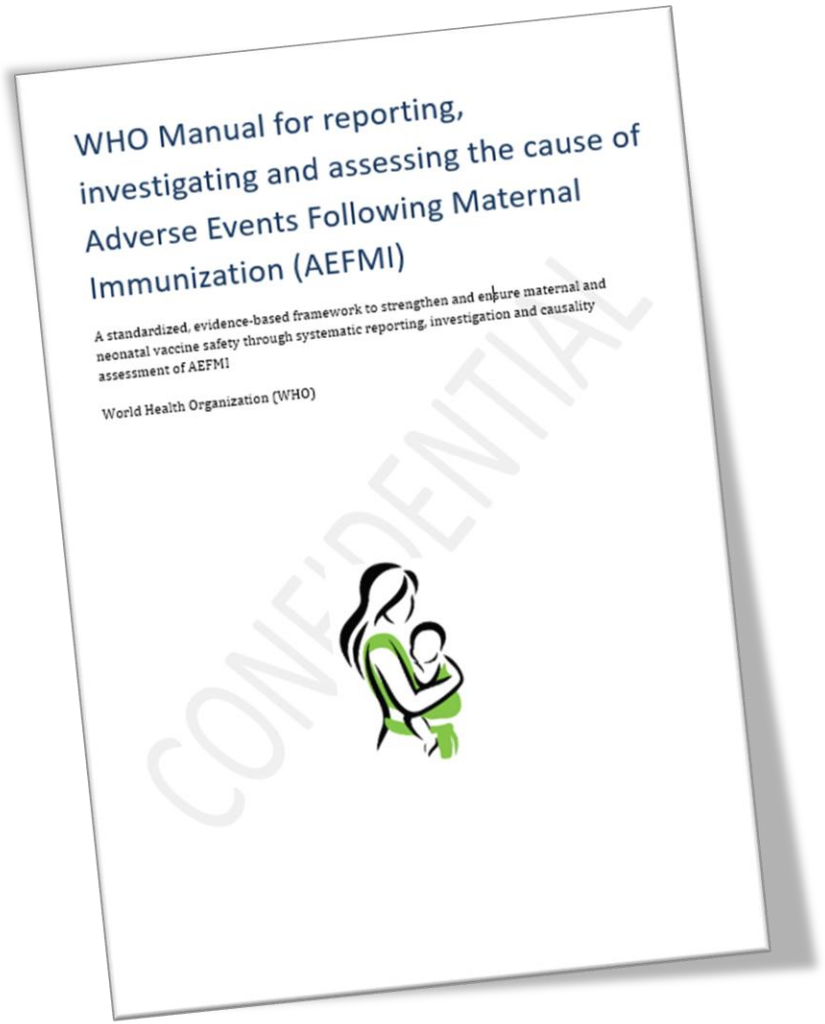
This assessment is done for Mother

PDF report generated & archived

Step 1 *(Eligibility)*

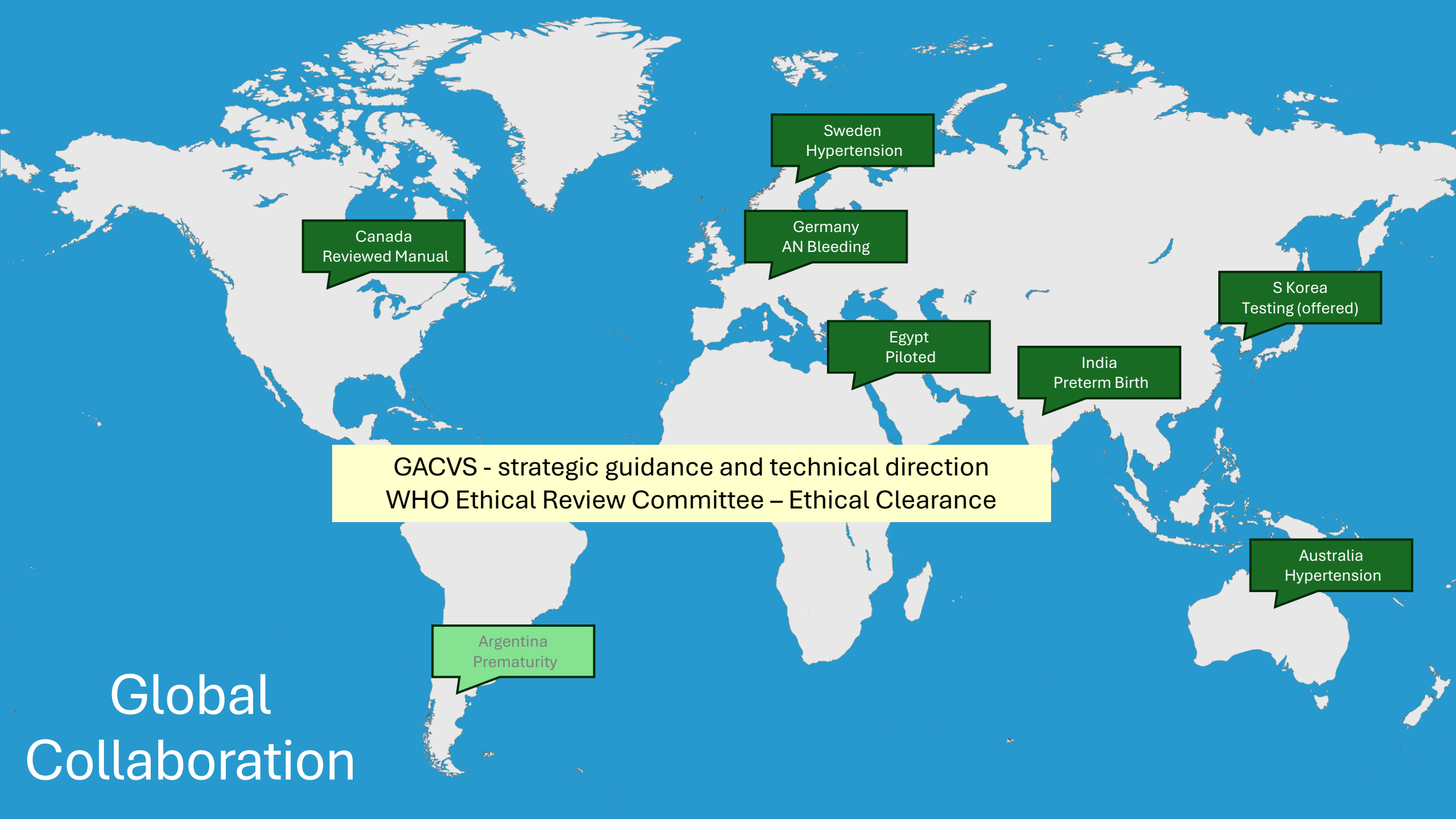
Name of the pregnant woman	Ms SL
pregnant woman Id	
Sex	Female
Age in years	22 years 10 months
Name of one or more vaccines administered before this event	Influenza, seasonal
Brand Name	Afluria
What is the Valid Diagnosis?	Gullian Barre Syndrome
Does the diagnosis meet a case definition?	Yes
Case definition is	Guillain-Barré syndrome (GBS) is a rare condition in which a person's immune system attacks the peripheral nerves. People of all ages can be affected,

Manual reviewed by GACVS and in last stages of finalization



10 Chapters

1. Introduction and Background
2. Basic Concepts of Vaccines in the Context of AEFMI
3. Challenges in Linking Vaccination and Adverse pregnancy outcomes
4. Approaches for reporting and investigating the cause of an AEFMI
5. Steps for Reporting and Investigating AEFMI using a Case-Based Approach
6. Approach to AEFMI using a Population-Based Approach
7. AEFMI Causality Assessment
8. Summarizing the logic of AEFMI causality assessment
9. Initiating action after causality assessment of an AEFMI
10. Conclusion



Global Collaboration

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Thank You

- Optional slides

The AEFI causality assessment software

Research | **Adverse Event Following Immunization (AEFI)** | Home | E-Learning | Language

EN
FR
AR
ES
RU
CH
POR

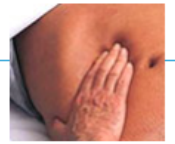
AEFI is any untoward medical occurrence which follows immunization and which does not necessarily have a causal relationship with the usage of the vaccine.

The adverse event may be any unfavorable or unintended sign, abnormal laboratory finding, symptom or disease.

This AEFI causality assessment is performed as per the WHO's revised causality assessment methodology which can be accessed at

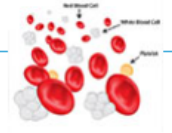
SYMPTOM

e.g. Cough, Rash, Pain Etc



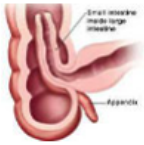
SIGN

e.g. Icterus, Hepatomegaly Etc



LAB FINDING

e.g. Thrombocytopenia, ECG Changes Etc



DISEASE

e.g. Intussusception, Meningitis Etc

Click here to access causality

Global Vaccine Safety

Usage (24 May 2021 to 24 May 2026)