

**Government of India
Ministry of Health & Family Welfare
Immunization Division**

**Nirman Bhawan, New Delhi
Date: 2nd Sep 2024**

Causality assessment results of 561 reported Serious Adverse Events Following Immunization (AEFI) cases approved by the National AEFI Committee on 18th Jun 2024

The Immunization Division of the Ministry of Health & Family Welfare has taken several steps to improve the National AEFI surveillance system, both the quality of investigation of cases at the state level and their causality assessment at the national level. Considering the importance and critical nature of the task, SOPs for causality assessment (CA) have been laid down as quality assurance. The results of the causality assessment done by the CA subcommittee are discussed in the national AEFI committee meeting for final approval.

The results of the causality assessment for 561 cases completed on **18th Jun 2024** after thorough review, deliberation, and approval by the National AEFI Committee is given in the annexure (anonymized line list of the causality assessment done by the National AEFI Committee).

346 out of 561 cases for which Causality assessment was been done were found to have **a consistent causal association to immunization**. Of these 346 cases, 237 cases were vaccine product-related reactions, 69 cases were immunization error related reaction and 40 cases were anxiety related reaction. 192 cases have inconsistent causal association to immunization (**coincidental - not linked to vaccination**), including 65 death cases. Two cases were in indeterminate categories and 21 cases were in unclassifiable category (all death cases).

Vaccine product-related reactions are expected reactions that can be attributed to vaccination based on current scientific evidence. Examples of such reactions are allergic reactions, anaphylaxis, etc.

Indeterminate reactions are reactions that have occurred soon after vaccination but there is no definitive evidence in current literature or clinical trial data that this event could have been caused due to the vaccine. Further observations, analysis, and studies are required.

Unclassifiable events are events that have been investigated but there is not enough evidence for assigning a diagnosis due to missing crucial information. When this relevant information becomes available, the case may be reconsidered for causality assessment.

Coincidental events are events that are reported following immunization but for which a clear cause other than vaccination is found in the investigation.

Overall, the benefits of vaccination are overwhelmingly greater than the small risk of harm. However, as a measure of utmost precaution, all emerging signals of harm are being constantly tracked and reviewed periodically.

CAUSALITY ASSESSMENT CLASSIFICATION OF 561 AEFI CASES TO BE APPROVED BY THE NATIONAL AEFI COMMITTEE

- A1 - VACCINE PRODUCT RELATED REACTION
- A2 - VACCINE QUALITY DEFECT RELATED REACTION
- A3 - IMMUNIZATION ERROR RELATED REACTION
- A4 - IMMUNIZATION ANXIETY RELATED REACTION
- B1 - TEMPORAL RELATIONSHIP IS CONSISTENT BUT THERE IS INSUFFICIENT DEFINITIVE EVIDENCE FOR VACCINE CAUSING EVENT
- B2 - REVIEWING FACTORS RESULT IN CONFLICTING TRENDS OF CONSISTENCY AND INCONSISTENCY WITH CAUSAL ASSOCIATION TO IMMUNIZATION
- C - COINCIDENTAL - UNDERLYING OR EMERGING CONDITION(S), OR CONDITIONS CAUSED BY EXPOSURE TO SOMETHING OTHER THAN VACCINE
- D - UNCLASSIFIABLE

S.N.	NATIONAL ID	YEAR	STATE	AGE IN YEAR MONTHS DAYS	SEX	REASON FOR REPORTING / OUTCOME	DATE OF VACCINATION (DD/MM/YYYY)	ANTIGENS	ROUTINE, SIA, CAMPAIGN & OTHERS	CLASSIFICATION BY NACM	VALID DIAGNOSIS
558	INDIAEFIPBARI122002	2022	PUNJAB	0 Y 1 M 16 D	FEMALE	HOSPITALIZED AND RECOVERED	11-05-2022	IPV,OPV,PCV,PENTA,RVV	ROUTINE	A1	ACUTE GASTROENTERITIS
559	INDIAEFIRJGGN23006	2023	RAJASTHAN	0 Y 0 M 17 D	MALE	HOSPITALIZED AND RECOVERED	27-07-2023	BCG	ROUTINE	A3	INJECTION SITE ABSCESS
560	INDIAEFIKETHR23032	2023	KERALA	1 Y 6 M 16 D	MALE	SEVERE AND RECOVERED	20-09-2023	DPT,MR,OPV, VIT A	ROUTINE	A3	CELLULITIS
561	INDIAEFIKATUM23002	2023	KARNATAKA	0 Y 1 M 30 D	MALE	DEATH	08-06-2023	IPV,OPV,PCV,PENTA,RVV	ROUTINE	C	ASPIRATION ASPHYXIA

Approved by Dr. Anju Seth on 22-06-2024