

Z.16025/02/2018-IMM-Part(1)
Government of India
Ministry of Health & Family Welfare
Immunization Division

Nirman Bhawan, New Delhi

Date: 18th Nov 2024

Causality assessment results of 311 reported Serious Adverse Events Following Immunization (AEFI) cases approved by the National AEFI Committee on the 24th & 27th Sep 2024

The Immunization Division of the Ministry of Health & Family Welfare has taken several steps to improve the National AEFI surveillance system, for 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 for 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 311 cases completed on **24th and 27th Sep 2024** after thorough review, deliberation, and approval by the National AEFI Committee are given in the annexure (anonymized line list of the causality assessment done by the National AEFI Committee).

234 out of 311 cases for which a Causality assessment has been done were found to have **a consistent causal association with immunization**. Of these 234 cases, 109 cases (1 death) were vaccine product-related reactions, 121 cases were immunization error-related reactions and 4 cases were anxiety-related reactions. 62 cases have inconsistent causal association to immunization (**coincidental - not linked to vaccination**), which included 30 death cases. 6 cases (1 death) were in indeterminate categories and 9 cases were in the 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 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 occurrences that, despite investigation, lack sufficient evidence for a definitive diagnosis due to missing critical 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 are being constantly tracked and reviewed periodically.

CAUSALITY ASSESSMENT CLASSIFICATION OF 293 AEFI CASES APPROVED BY THE NATIONAL AEFI COMMITTEE ON 24 SEP 2024

- 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
280	INDIAEFIWBTML23022	2023	WEST BENGAL	0 Y 9 M 26 D	MALE	CLUSTER HOSPITALIZED AND RECOVERED	16-03-2023	IPV,JE,MR	ROUTINE	A3	INJECTION SITE ABSCESS
281	INDIAEFIWBTML23023	2023	WEST BENGAL	1 Y 0 M 20 D	MALE	CLUSTER HOSPITALIZED AND RECOVERED	16-03-2023	JE,MR	ROUTINE	A3	INJECTION SITE ABSCESS
282	INDIAEFIWBTML23024	2023	WEST BENGAL	0 Y 10 M 10 D	FEMALE	CLUSTER HOSPITALIZED AND RECOVERED	16-03-2023	JE,MR	ROUTINE	A3	INJECTION SITE ABSCESS
283	INDIAEFIWBTML23025	2023	WEST BENGAL	3 Y 9 M 23 D	MALE	CLUSTER SIGNIFICANT P/C/H/P CONCERN	16-03-2023	JE,MR	ROUTINE	A3	INJECTION SITE ABSCESS
284	INDIAEFIWBTML23026	2023	WEST BENGAL	1 Y 6 M 13 D	FEMALE	CLUSTER SIGNIFICANT P/C/H/P CONCERN	16-03-2023	JE,MR	ROUTINE	A3	INJECTION SITE ABSCESS
285	INDIAEFIWBTML23043	2023	WEST BENGAL	0 Y 9 M 10 D	FEMALE	CLUSTER SIGNIFICANT P/C/H/P CONCERN	01-11-2023	IPV,JE,MR,PCV,VIT-A	ROUTINE	C	PSEUDOTUMOR CEREBRI
286	INDIAEFIWBTML23044	2023	WEST BENGAL	0 Y 9 M 17 D	FEMALE	CLUSTER SIGNIFICANT P/C/H/P CONCERN	01-11-2023	IPV,JE,MR,PCV,VIT-A	ROUTINE	C	PSEUDOTUMOR CEREBRI
287	INDIAEFIWBTML23045	2023	WEST BENGAL	0 Y 9 M 30 D	MALE	CLUSTER SIGNIFICANT P/C/H/P CONCERN	01-11-2023	IPV,JE,MR,PCV,VIT-A	ROUTINE	C	PSEUDOTUMOR CEREBRI
288	INDIAEFIWBTML23046	2023	WEST BENGAL	0 Y 10 M 4 D	MALE	CLUSTER SIGNIFICANT P/C/H/P CONCERN	01-11-2023	IPV,JE,MR,PCV,VIT-A	ROUTINE	C	PSEUDOTUMOR CEREBRI
289	INDIAEFIWBTML23047	2023	WEST BENGAL	0 Y 10 M 18 D	FEMALE	CLUSTER SIGNIFICANT P/C/H/P CONCERN	01-11-2023	IPV,JE,MR,PCV,VIT-A	ROUTINE	C	PSEUDOTUMOR CEREBRI
290	INDIAEFIWBTML23048	2023	WEST BENGAL	0 Y 9 M 26 D	FEMALE	CLUSTER SIGNIFICANT P/C/H/P CONCERN	01-11-2023	IPV,JE,MR,PCV,VIT-A	ROUTINE	C	PSEUDOTUMOR CEREBRI
291	INDIAEFIWBML24003	2024	WEST BENGAL	5 Y 0 M 8 D	MALE	HOSPITALIZED AND RECOVERED	08-02-2024	DPF	ROUTINE	C	LOWER RESPIRATORY TRACT INFECTION WITH SEPSIS
292	INDIAEFIWBUD22002	2022	WEST BENGAL	0 Y 9 M 10 D	MALE	HOSPITALIZED AND RECOVERED	06-07-2022	MR	ROUTINE	A4	BREATH HOLDING SPELL
293	INDIAEFIWBUD23022	2023	WEST BENGAL	1 Y 4 M 6 D	FEMALE	HOSPITALIZED AND RECOVERED	21-06-2023	DPV,JE,MR,OPV,VIT-A	ROUTINE	A3	INJECTION SITE ABSCESS

Approved by Dr. Anju Seth on 15-10-2024

CAUSALITY ASSESSMENT CLASSIFICATION OF 18 ADULT RI AEFI CASES APPROVED BY THE NATIONAL AEFI COMMITTEE ON 27 SEPT 2024

- 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	SEX	REASON FOR REPORTING / OUTCOME	DATE OF VACCINATION (DD/MM/YYYY)	ANTIGENS	ROUTINE, SIA, CAMPAIGN & OTHERS	CLASSIFICATION BY NACM	VALID DIAGNOSIS
1	INDIAEFI01BHA24001	2024	BIHAR	19 Y 11 M	FEMALE	SEVERE AND RECOVERED	09.03.2024	TD	ROUTINE	C	SPONTANEOUS ABORTION
2	INDIAEFI01BKH20111	2022	BIHAR	20 Y 0 M	FEMALE	HOSPITALIZED AND RECOVERED	14.12.2022	TD	ROUTINE	C	SPONTANEOUS ABORTION
3	INDIAEFI01GRR23007	2023	CHHATTISGARH	32 Y 4 M	FEMALE	SEVERE AND RECOVERED	16.09.2023	TD	ROUTINE	A1	LOCAL REACTION
4	INDIAEFI01DND123006	2023	DELHI	35 Y 2 M	MALE	HOSPITALIZED AND RECOVERED	16.10.2023	YELLOW FEVER	OTHER	A1	ANAPHYLAXIS
5	INDIAEFI01GJAMC22006	2022	GUJARAT	35 Y 7 M	MALE	SEVERE AND RECOVERED	26.09.2022	OPV, YELLOW FEVER	OTHER	A1	ANAPHYLAXIS IN A K/C/O BRONCHIAL ASTHMA
6	INDIAEFI01GJAMC30008	2023	GUJARAT	23 Y 6 M	MALE	SEVERE AND RECOVERED	12.07.2023	YELLOW FEVER	OTHER	A1	ALLERGIC REACTION
7	INDIAEFI01GJAMC22030	2022	GUJARAT	56 Y 2 M	MALE	HOSPITALIZED AND RECOVERED	12.12.2022	YELLOW FEVER	OTHER	A1	GUILLAIN-BARRE SYNDROME (GBS)
8	INDIAEFI01KAUDJ24003	2024	KARNATAKA	26 Y 0 M	FEMALE	HOSPITALIZED AND RECOVERED	06.04.2024	HPV	OTHER	C	ACUTE MENINGOENCEPHALITIS SYNDROME
9	INDIAEFI01KJKD24002	2024	LAKSHADWEEP	31 Y 2 M	FEMALE	SEVERE AND RECOVERED	30.05.2024	TD	ROUTINE	A1	LOCAL REACTION
10	INDIAEFI01MHBM24014	2024	MAHARASHTRA	31 Y 10 M	MALE	SEVERE AND RECOVERED	16.05.2024	ANTIRABIES	OTHER	A1	ALLERGIC REACTION
11	INDIAEFI01MHBL24001	2024	MAHARASHTRA	21 Y 10 M	FEMALE	DEATH	03.02.2024	ANTIRABIES	OTHER	C	RABIES MENINGOENCEPHALITIS
12	INDIAEFI01MPCN23011	2023	MAHARASHTRA	24 Y 1 M	FEMALE	SEVERE AND RECOVERED	27.09.2023	ANTIRABIES	OTHER	A1	ALLERGIC REACTION
13	INDIAEFI01TNCN20076	2022	TAMIL NADU	25 Y 11 M	FEMALE	HOSPITALIZED AND RECOVERED	25.10.2022	TD	ROUTINE	A1	ALLERGIC REACTION IN A K/C/O BRONCHIAL ASTHMA
14	INDIAEFI01TNCN20093	2022	TAMIL NADU	19 Y 1 M	FEMALE	HOSPITALIZED AND RECOVERED	22.11.2022	QUADRIVALENT INACTIVATED INFLUENZA	OTHER	A1	ALLERGIC REACTION
15	INDIAEFI01TRRN23003	2023	TRIPURA	28 Y 1 M	FEMALE	SEVERE AND RECOVERED	07.06.2023	TD	ROUTINE	A1	FEVER AND SWELLING
16	INDIAEFI01TSQP2006	2022	TELANGANA	42 Y 2 M	MALE	SEVERE AND RECOVERED	16.07.2022	TD	ROUTINE	B2	ALLERGIC REACTION
17	INDIAEFI01UPAUR21001	2021	UTTAR PRADESH	27 Y 2 M	FEMALE	SEVERE AND RECOVERED	07.08.2021	TD	ROUTINE	A4	ANXIETY RELATED
18	INDIAEFI01WBMP23032	2023	WEST BENGAL	18 Y 0 M	FEMALE	HOSPITALIZED AND RECOVERED	20.01.2023	MR	OTHER	A1	ANAPHYLAXIS

Approved by Dr. Anil Gurtoo on 4th October 2024