

Causality assessment report of 155 reported Serious Adverse Events Following Immunization (AEFI) cases, approved by National AEFI Committee

The Immunization Division of Ministry of Health & Family Welfare has taken several steps to improve the National AEFI surveillance system, both the quality of investigation of cases at state level and their causality assessment at national level. Considering the importance and critical nature of the task, SOPs for causality assessment (CA) have been laid down as quality assurance. The CA subcommittee is housed at Lady Harding Medical College which is also the National AEFI Technical Collaborating Centre. The first round of Causality Assessment is undertaken by this subcommittee.

AEFI deaths, attributed to the vaccine or programme error are reviewed again by a specially constituted review panel comprising of the chairs of the 4 subcommittees of the National AEFI Committee (i.e. Causality assessment, investigation, media and laboratory subcommittees) chaired by Chairman, National AEFI committee. The causality assessment reports are presented to the National AEFI Committee.

The results of the Causality Assessment for 155 cases completed over the past few months after thorough review, deliberation and approval by the National AEFI Committee is placed below (The anonymized line list of the causality assessment done by the National AEFI Committee as annexure).

Many of the reported serious AEFIs are **Consistent Causal Relation to Immunization (73)** and **Inconsistent Causal Relation to Immunization (Coincidental) (50)** and none have been found to be due to quality defect in manufacturing vaccines.

CAUSALITY CLASSIFICATION OF 155 AEFI CASES APPROVED BY THE NATIONAL AEFI COMMITTEE
25th SEPTEMBER 2017 - (NEW DELHI)

S. NO.	NATIONAL ID	YEAR	STATE	AGE IN YEAR MONTHS	SEX	REASON FOR REPORTING	DATE OF VACCINATION (DD/MM/YYYY)	ANTIGENS	ROUTINE, SIA OR CAMPAIGN	CLASSIFICATION BY NATIONAL AEFI COMMITTEE
1	IND(AEFI)MPTNI2001	2012	MADHYA PRADESH	1 Y 3 M	F	DEATH	6/06/2012	MEASLES	ROUTINE	A3
2	IND(AEFI)MPTNI2002	2012	MADHYA PRADESH	1 Y 2 D	M	DEATH	6/06/2012	MEASLES	ROUTINE	A3
3	IND(AEFI)HAKTL4002	2014	HARYANA	5 Y 6 M 13 D	F	HOSPITALIZED	26/05/2014	DPT	ROUTINE	B2
4	IND(AEFI)KACHK14001	2014	KARNATAKA	1 M 19 D	M	DEATH	20/11/2014	OPV PENTA	ROUTINE	A1
5	IND(AEFI)WBWNP14003	2014	WEST BENGAL	1 Y 5 M 21 D	M	HOSPITALIZED	17/07/2014	DPT OPV	ROUTINE	A1
6	IND(AEFI)WBWNP14008	2014	WEST BENGAL	3 M 19 D	F	DEATH	14/09/2014	OPV	SIA	C
7	IND(AEFI)WBSFG14001	2014	WEST BENGAL	3 Y 5 M 25 D	F	DEATH	6/04/2014	OPV	SIA	C
8	IND(AEFI)WBSFG14002	2014	WEST BENGAL	1 M 16 D	F	DEATH	27/03/2014	DPT OPV HEP-B	ROUTINE	C
9	IND(AEFI)WBSFG14004	2014	WEST BENGAL	11 D	M	DEATH	28/05/2014	OPV BCG	ROUTINE	C
10	IND(AEFI)DCEIN15025	2015	DELHI	5 M	M	HOSPITALIZED	10/04/2015	OPV PENTA	ROUTINE	C
11	IND(AEFI)DUNWE15006	2015	DELHI	1 M 18 D	M	DEATH	19/12/2015	PENTA	ROUTINE	D
12	IND(AEFI)DLSOE15002	2015	DELHI	9 M 1 D	M	SEVERE	2/09/2015	MEASLES VIT-A	ROUTINE	A1
13	IND(AEFI)GJIND15001	2015	GUJARAT	2 Y 1 M 23 D	F	DEATH	10/10/2015	OPV/DPT MEASLES VIT-A	ROUTINE	B2
14	IND(AEFI)GJIND15003	2015	GUJARAT	0 D	F	DEATH	5/11/2015	OPV BCG HEP-B	ROUTINE	C
15	IND(AEFI)HAPKL15002	2015	HARYANA	3 M 25 D	M	HOSPITALIZED	27/05/2015	OPV PENTA	ROUTINE	C
16	IND(AEFI)HAPNP15001	2015	HARYANA	2 M 25 D	F	DEATH	18/04/2015	OPV PENTA	ROUTINE	C
17	IND(AEFI)HARTKI15001	2015	HARYANA	1 M 20 D	F	DEATH	15/04/2015	BCG PENTA	ROUTINE	D
18	IND(AEFI)HASP15001	2015	HARYANA	2 M 29 D	M	HOSPITALIZED	6/05/2015	OPV PENTA	ROUTINE	C
19	IND(AEFI)HPRLU15001	2015	HIMACHAL PRADESH	3 D	M	HOSPITALIZED	10/12/2015	HEP-B	ROUTINE	A3
20	IND(AEFI)JKGDR15001	2015	JAMMU & KASHMIR	1 M 15 D	F	HOSPITALIZED	3/06/2015	OPV PENTA	ROUTINE	B2
21	IND(AEFI)JKPUL15003	2015	JAMMU & KASHMIR	2 M 21 D	M	HOSPITALIZED	7/10/2015	OPV PENTA	ROUTINE	A1
22	IND(AEFI)JKSGR15001	2015	JAMMU & KASHMIR	3 M 27 D	F	HOSPITALIZED	7/10/2015	OPV PENTA	ROUTINE	C
23	IND(AEFI)MPRTM15001	2015	MADHYA PRADESH	1 D	M	HOSPITALIZED	3/12/2015	HEP-B	ROUTINE	A3
24	IND(AEFI)MPSH15002	2015	MADHYA PRADESH	2 M 13 D	F	DEATH	2/10/2015	OPV PENTA	ROUTINE	C
25	IND(AEFI)MPSVP15001	2015	MADHYA PRADESH	2 M 11 D	M	DEATH	16/02/2015	OPV PENTA	ROUTINE	D
26	IND(AEFI)PBLD15001	2015	PUNJAB	1 M 26 D	F	DEATH	9/12/2015	OPV PENTA	ROUTINE	D
27	IND(AEFI)PPTL15001	2015	PUNJAB	9 Y 6 D	F	HOSPITALIZED	14/05/2015	TT	ROUTINE	A4
28	IND(AEFI)RAJAM15001	2015	RAJASTHAN	1 Y 4 M 7 D	M	CLUSTER	10/12/2015	OPV DPT MEASLES	ROUTINE	C
29	IND(AEFI)RAJAM15002	2015	RAJASTHAN	3 M 2 D	F	DEATH	10/12/2015	OPV PENTA	ROUTINE	C
30	IND(AEFI)RAJAM15003	2015	RAJASTHAN	3 M 6 D	M	DEATH	10/12/2015	OPV PENTA	ROUTINE	D

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A1 - VACCINE PRODUCT RELATED REACTION
A2 - VACCINE ADMINISTRATION RELATED REACTION
A3 - IMMUNIZATION ANXIETY RELATED REACTION
B1 - TEMPORAL RELATIONSHIP IS CONSISTENT BUT THERE IS INSUFFICIENT DEFINITIVE EVIDENCE FOR VACCINE CAUSING EVENT
B2 - TEMPORAL RELATIONSHIP IS CONSISTENT BUT THERE IS INSUFFICIENT DEFINITIVE EVIDENCE FOR VACCINE CAUSING EVENT
C - CONFIDENTIAL - UNDERLYING OR EMERGING CONDITIONAL OR CONDITIONS CAUSED BY EXPOSURE TO SOMETHING OTHER THAN VACCINE
D - UNCLASSIFIABLE

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31	IND(AEFI)TNTR15001	2015	TAMIL NADU	1 Y 6 M 8 D	M	HOSPITALIZED	7/01/2015	OPV DPT BCG MEASLES TT	ROUTINE	A1
32	IND(AEFI)TNTR15003	2015	TAMIL NADU	2 M 16 D	M	HOSPITALIZED	12/01/2015	OPV PENTA	ROUTINE	B2
33	IND(AEFI)TNTR15004	2015	TAMIL NADU	1 M 15 D	F	DEATH	12/01/2015	OPV PENTA	ROUTINE	C
34	IND(AEFI)TNTR15013	2015	TAMIL NADU	2 M 1 D	F	HOSPITALIZED	4/12/2015	OPV PENTA	ROUTINE	C
35	IND(AEFI)TNTR15014	2015	TAMIL NADU	1 Y 6 M 7 D	M	HOSPITALIZED	9/12/2015	OPV DPT MEASLES JE	ROUTINE	A1
36	IND(AEFI)TNTR15001	2015	TAMIL NADU	9 M 3 D	F	HOSPITALIZED	29/04/2015	MEASLES	ROUTINE	C
37	IND(AEFI)TNTR15002	2015	TAMIL NADU	1 M 18 D	F	HOSPITALIZED	22/07/2015	OPV PENTA	ROUTINE	C
38	IND(AEFI)TNTR15002	2015	TAMIL NADU	2 M 1 D	M	HOSPITALIZED	18/03/2015	OPV PENTA	ROUTINE	C
39	IND(AEFI)UPALG15002	2015	UTTAR PRADESH	4 M 28 D	F	SEVERE	10/12/2015	DPT OPV HEF-B	ROUTINE	A1
40	IND(AEFI)UPMZN15001	2015	UTTAR PRADESH	5 D	M	DEATH	7/10/2015	OPV BCG	ROUTINE	C
41	IND(AEFI)WBHRA15007	2015	WEST BENGAL	8 M 2 D	F	DEATH	26/04/2015	OPV	ROUTINE	C
42	IND(AEFI)WBHRA15008	2015	WEST BENGAL	1 Y 3 M 27 D	F	HOSPITALIZED	13/08/2015	OPV DPT MEASLES VIT-A JE	ROUTINE	C
43	IND(AEFI)BBGSS16007	2016	BHAR	2 M 25 D	M	SEVERE	14/09/2016	OPV PENTA	ROUTINE	A1
44	IND(AEFI)DLCCN16002	2016	DELHI	3 M 27 D	M	HOSPITALIZED	20/02/2016	OPV PENTA	ROUTINE	C
45	IND(AEFI)DLCCN16003	2016	DELHI	2 Y 7 M 7 D	M	HOSPITALIZED	6/05/2016	TYPHOID	ROUTINE	B2
46	IND(AEFI)DLCCN16004	2016	DELHI	4 M 1 D	F	HOSPITALIZED	7/06/2016	OPV PENTA	ROUTINE	C
47	IND(AEFI)DLCCN16001	2016	DELHI	1 M 19 D	M	DEATH	7/12/2016	OPV PENTA	ROUTINE	D
48	IND(AEFI)DLCCN16004	2016	DELHI	1 Y 6 M 13 D	F	HOSPITALIZED	10/08/2016	OPV DPT MMR	ROUTINE	A1
49	IND(AEFI)GUIND16010	2016	GUJARAT	2 M 2 D	M	HOSPITALIZED	17/11/2016	OPV PENTA	ROUTINE	A3
50	IND(AEFI)GUJKOA16001	2016	GUJARAT	19 Y	M	CLUSTER	3/09/2016	CHOLERA	CAMPAIGN	A3
51	IND(AEFI)GUJKOA16002	2016	GUJARAT	25 Y	M	CLUSTER	3/09/2016	CHOLERA	CAMPAIGN	A3
52	IND(AEFI)GUJKOA16003	2016	GUJARAT	22 Y	F	CLUSTER	3/09/2016	CHOLERA	CAMPAIGN	A3
53	IND(AEFI)GUJKOA16004	2016	GUJARAT	27 Y	M	CLUSTER	3/09/2016	CHOLERA	CAMPAIGN	A3
54	IND(AEFI)GUJKOA16005	2016	GUJARAT	19 Y 10 M	M	CLUSTER	3/09/2016	CHOLERA	CAMPAIGN	A3
55	IND(AEFI)GUJKOA16006	2016	GUJARAT	52 Y	M	CLUSTER	3/09/2016	CHOLERA	CAMPAIGN	A3
56	IND(AEFI)GUJKOA16007	2016	GUJARAT	18 Y	M	CLUSTER	3/09/2016	CHOLERA	CAMPAIGN	A3
57	IND(AEFI)GUJKOA16008	2016	GUJARAT	19 Y	M	CLUSTER	3/09/2016	CHOLERA	CAMPAIGN	A3
58	IND(AEFI)GUJKOA16009	2016	GUJARAT	21 Y	M	CLUSTER	3/09/2016	CHOLERA	CAMPAIGN	A3
59	IND(AEFI)GUJKOA16010	2016	GUJARAT	35 Y	F	CLUSTER	3/09/2016	CHOLERA	CAMPAIGN	A3
60	IND(AEFI)GUJKOA16011	2016	GUJARAT	25 Y 4 M	F	CLUSTER	3/09/2016	CHOLERA	CAMPAIGN	A3