

Causality assessment report of 108 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 108 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 coincidental (33) and none have been found to be due to quality defect in manufacturing vaccines.

CAUSALTY CLASSIFICATION OF 108 AEFI CASES REVIEWED AND APPROVED BY THE NATIONAL AEFI COMMITTEE
3rd - 4th AUGUST 2015 - (PATNA-BIHAR)

- 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. NO.	NATIONAL ID	YEAR	STATE	AGE IN MONTH*	SEX	REASON FOR REPORTING	DATE OF VACCINATION	ANTIGENS	ROUTINE VS CAMPAIGN	CLASSIFICATION BY CA SUBCOMMITTEE
1	IND/AEFI/PAKMM12001	2012	ANDHRA PRADESH	8 D	F	DEATH	21-07-2012	BCG	ROUTINE	C
2	IND/AEFI/PAKRN12001	2012	ANDHRA PRADESH	14 M	M	DEATH	11-01-2012	OPV, DPT, HEP-B	ROUTINE	D
3	IND/AEFI/AFRGY12001	2012	ANDHRA PRADESH	19 M	M	DEATH	07-03-2012	OPV, DPT, HEP-B	ROUTINE	D
4	IND/AEFI/BIGS12001	2012	BIHAR	3 D	M	DEATH	27-01-2012	OPV, DPT, HEP-B	ROUTINE	D
5	IND/AEFI/BINZF12001	2012	BIHAR	105.2 M	F	CLUSTER	06-12-2012	MEASLES	SIA	A4
6	IND/AEFI/BMZP12003	2012	BIHAR	109 M	F	CLUSTER	06-12-2012	MEASLES	SIA	A1
7	IND/AEFI/HAPAL12001	2012	HARYANA	4.1 M	F	DEATH	16-04-2012	DPT	ROUTINE	D
8	IND/AEFI/KABLUI2005	2012	KARNATAKA	14 M	F	HOSPITALIZED	15-03-2012	OPV, DPT, HEP-B	ROUTINE	A1
9	IND/AEFI/KABLUI2004	2012	KARNATAKA	15 M	F	HOSPITALIZED	19-07-2012	OPV, DPT, HEP-B,	ROUTINE	C
10	IND/AEFI/KABLUI2003	2012	KARNATAKA	1.6 M	M	HOSPITALIZED	06-07-2012	OPV, DPT, HEP-B,	ROUTINE	C
11	IND/AEFI/KABLUI2006	2012	KARNATAKA	2.7 M	M	HOSPITALIZED	06-09-2012	OPV, DPT, HEP	ROUTINE	A1
12	IND/AEFI/KACBP12001	2012	KARNATAKA	14 M	F	DEATH	11-10-2012	OPV, DPT, HEP	ROUTINE	D
13	IND/AEFI/KAJAS12001	2012	KARNATAKA	3.9 M	M	HOSPITALIZED	01-03-2012	OPV, DPT, HEP-B	ROUTINE	A1
14	IND/AEFI/KAKOD12003	2012	KARNATAKA	1.8 M	M	DEATH	10-08-2012	OPV, DPT, HEP-B	ROUTINE	D
15	IND/AEFI/KAMYS12003	2012	KARNATAKA	18 M	F	CLUSTER	02-08-2012	DPT, MEASLES	ROUTINE	D
16	IND/AEFI/KAMYS12004	2012	KARNATAKA	18 M	M	CLUSTER	02-08-2012	DPT, MEASLES	ROUTINE	D

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17	IND/AEFI/KEAP212002	2012	KERALA	17 M	F	HOSPITALIZED	27-02-2012	PENTA	ROUTINE	D
18	IND/AEFI/KEAP212008	2012	KERALA	13 M	M	HOSPITALIZED	25-07-2012	PENTA	ROUTINE	C
19	IND/AEFI/KEAP212010	2012	KERALA	55.9 M	F	HOSPITALIZED	03-10-2012	DPT	ROUTINE	B2
20	IND/AEFI/KEAP212011	2012	KERALA	5 D	F	HOSPITALIZED	17-07-2012	BCG HEP-B OPV	ROUTINE	A1
21	IND/AEFI/KEENK12005	2012	KERALA	17.4 M	M	HOSPITALIZED	10-10-2012	OPV, DPT, VIT-A	ROUTINE	A1
22	IND/AEFI/KEENK12006	2012	KERALA	1.8 M	F	HOSPITALIZED	12-12-2012	PENTA	ROUTINE	A1
23	IND/AEFI/KEKLM12002	2012	KERALA	53.4 M	M	HOSPITALIZED	21-06-2012	DPT	ROUTINE	A3
24	IND/AEFI/KEKOT12005	2012	KERALA	18.6 M	M	HOSPITALIZED	28-10-2012	DPT	ROUTINE	C
25	IND/AEFI/KEKOT12006	2012	KERALA	18.7 M	F	HOSPITALIZED	09-11-2012	DPT	ROUTINE	A3
26	IND/AEFI/KEKZK12002	2012	KERALA	17.1 M	M	HOSPITALIZED	13-10-2012	OPV	ROUTINE	A1
27	IND/AEFI/KEPMM12005	2012	KERALA	63.2 M	M	HOSPITALIZED	17-11-2012	DPT	ROUTINE	C
28	IND/AEFI/KEPMM12003	2012	KERALA	6.7 M	M	HOSPITALIZED	25-09-2012	OPV	ROUTINE	C
29	IND/AEFI/KEPLK12001	2012	KERALA	15 M	F	HOSPITALIZED	17-08-2012	MMR	ROUTINE	C
30	IND/AEFI/KEPLK12003	2012	KERALA	3.1 M	M	HOSPITALIZED	27-12-2012	PENTA	ROUTINE	C
31	IND/AEFI/KETRM12011	2012	KERALA	1.4 M	M	HOSPITALIZED	24-12-2012	PENTA	ROUTINE	A1
32	IND/AEFI/KETRM12010	2012	KERALA	2.2 M	F	HOSPITALIZED	27-11-2012	OPV, PENTA	ROUTINE	C

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33	IND/AEFI/KETRI12009	2012	KERALA	2.6 M	F	HOSPITALIZED	19-12-2012	OPV,PENTA	ROUTINE	C
34	IND/AEFI/KETRI12002	2012	KERALA	1.5 M	M	HOSPITALIZED	05-12-2012	OPV,PENTA	ROUTINE	B2
35	IND/AEFI/MAHAMI12001	2012	MAHARASHTRA	1.4 M	M	DEATH	13-12-2012	OPV, HEP	ROUTINE	C
36	IND/AEFI/MAHABD12001	2012	MAHARASHTRA	60.7 M	M	HOSPITALIZED	24-12-2012	DPT	ROUTINE	B2
37	IND/AEFI/MAHBM12033	2012	MAHARASHTRA	17.4 M	M	HOSPITALIZED	09-02-2012	OPV, DPT	ROUTINE	D
38	IND/AEFI/MAHBM12003	2012	MAHARASHTRA	15 M	M	HOSPITALIZED	14-02-2012	OPV, DPT	ROUTINE	A1
39	IND/AEFI/MAHBM12008	2012	MAHARASHTRA	1.6 M	F	HOSPITALIZED	13-03-2012	OPV, DPT, HEP B	ROUTINE	A1
40	IND/AEFI/MAHBM12025	2012	MAHARASHTRA	1.8 M	M	HOSPITALIZED	07-09-2012	OPV,DPT,HEP-B	ROUTINE	C
41	IND/AEFI/MAHBM12026	2012	MAHARASHTRA	1.6 M	F	HOSPITALIZED	12-09-2012	OPV,DPT	ROUTINE	B2
42	IND/AEFI/MAHBM12028	2012	MAHARASHTRA	3.2 M	M	HOSPITALIZED	21-09-2012	OPV,DPT,HEP	ROUTINE	B2
43	IND/AEFI/MAHBM12030	2012	MAHARASHTRA	1.9 M	M	HOSPITALIZED	18-09-2012	OPV, DPT, HEP	ROUTINE	D
44	IND/AEFI/MAHBM12031	2012	MAHARASHTRA	4.8 M	M	HOSPITALIZED	18-12-2012	OPV,DPT,HEP	ROUTINE	A1
45	IND/AEFI/MAHBM12032	2012	MAHARASHTRA	10.6 M	F	HOSPITALIZED	21-12-2012	DPT HEP-B	ROUTINE	A1
46	IND/AEFI/TMNCN12007	2012	TAMIL NADU	17.7 M	F	HOSPITALIZED	29-09-2012	OPV,DPT,MEASLES	ROUTINE	C
47	IND/AEFI/TRTRS12001	2012	TRIPURA	1.5 M	F	DEATH	19-12-2012	OPV,DPT,HEP	ROUTINE	D
48	IND/AEFI/UPPER12001	2012	UTTAR PRADESH	7 M		HOSPITALIZED	09-05-2012	DPT,HEP-B	ROUTINE	A3

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49	IND/AEFI/JPFER12003	2012	UTTAR PRADESH	4.9 M	M	HOSPITALIZED	30-06-2012	OPV, DPT, VIT-A	ROUTINE	D
50	IND/AEFI/JPGZA12001	2012	UTTAR PRADESH	2.5 M	M	HOSPITALIZED	21-11-2012	OPV, DPT, HEP B	ROUTINE	D
51	IND/AEFI/JPGND12002	2012	UTTAR PRADESH	22 D	F	DEATH	24-09-2012	BCG	ROUTINE	D
52	IND/AEFI/JPHPR12004	2012	UTTAR PRADESH	15 D	M	DEATH	01-09-2012	OPV, BCG	ROUTINE	D
53	IND/AEFI/JPHTR12001	2012	UTTAR PRADESH	30 D	F	DEATH	11-09-2012	OPV	SIA	C
54	IND/AEFI/JPMZN12002	2012	UTTAR PRADESH	120 M	F	CLUSTER	04-12-2012	MEASLES	SIA	A4
55	IND/AEFI/JPMZN12001	2012	UTTAR PRADESH	120 M	M	CLUSTER	04-12-2012	MEASLES	SIA	A4
56	IND/AEFI/JPMZN12003	2012	UTTAR PRADESH	120 M	F	CLUSTER	04-12-2012	MEASLES	SIA	A4
57	IND/AEFI/JPHIL12004	2012	UTTAR PRADESH	91.5 M	M	HOSPITALIZED	13-12-2012	MEASLES	SIA	C
58	IND/AEFI/JUPVRN12002	2012	UTTAR PRADESH	1 M	F	CLUSTER	22-02-2012	OPV	SIA	C
59	IND/AEFI/JUPVRN12003	2012	UTTAR PRADESH	1 M	F	CLUSTER	22-02-2012	OPV	SIA	C
60	IND/AEFI/JWBHPG12002	2012	WEST BENGAL	3.5 M	M	DEATH	18-11-2012	OPV	SIA	D
61	IND/AEFI/JWBSPG12006	2012	WEST BENGAL	9.1 M	F	DEATH	09-09-2012	OPV	SIA	D
62	IND/AEFI/JWBSPG12001	2012	WEST BENGAL	22 D	M	HOSPITALIZED	20-02-2012	OPV	SIA	D
63	IND/AEFI/JWBSPG12007	2012	WEST BENGAL	20 D	M	DEATH	05-09-2012	OPV, BCG	ROUTINE	D
64	IND/AEFI/JWBSPG12006	2012	WEST BENGAL	15.7 M	F	DEATH	23-08-2012	OPV, DPT, VIT-A	ROUTINE	D

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65	IND/AEFI/WBSPG12002	2012	WEST BENGAL	2 M	M	HOSPITALIZED	10-05-2012	DPT, HEP-B	ROUTINE	D
66	IND/AEFI/WBSPG12004	2012	WEST BENGAL	60.7 M	M	DEATH	26-07-2012	DPT	ROUTINE	D
67	IND/AEFI/WBSPG12003	2012	WEST BENGAL	9.3 M	F	DEATH	24-05-2012	MEASLES	ROUTINE	D
68	IND/AEFI/WBSPG12008	2012	WEST BENGAL	9.1 M	M	DEATH	27-09-2012	OPV, DPT	ROUTINE	D
69	IND/AEFI/WBBDN12002	2012	WEST BENGAL	1.7 M	F	DEATH	01-08-2012	OPV, DPT, HEP-B	ROUTINE	D
70	IND/AEFI/WBBBM12002	2012	WEST BENGAL	1.4 M	M	DEATH	28-08-2012	OPV, DPT, HEP-B	ROUTINE	C
71	IND/AEFI/WBBBM12001	2012	WEST BENGAL	1.6 M	F	DEATH	22-08-2012	OPV, DPT, HEP-B, BCG	ROUTINE	D
72	IND/AEFI/WBHRP12001	2012	WEST BENGAL	1 D	F	DEATH	27-12-2012	BCG	ROUTINE	D
73	IND/AEFI/WBHGL12002	2012	WEST BENGAL	1.8 M	F	HOSPITALIZED	18-04-2012	OPV, DPT, HEP-B	ROUTINE	A3
74	IND/AEFI/WBHGL12005	2012	WEST BENGAL	4 M	M	DEATH	12-12-2012	OPV, DPT, HEP-B	ROUTINE	D
75	IND/AEFI/WBALD12001	2012	WEST BENGAL	2.3 M	M	DEATH	04-01-2012	DPT, BCG	ROUTINE	D
76	IND/AEFI/WBMDA12001	2012	WEST BENGAL	1.6 M	M	CLUSTER	05-12-2012	OPV, DPT	ROUTINE	C
77	IND/AEFI/WBMDA12003	2012	WEST BENGAL	2.5 M	M	DEATH	19-12-2012	OPV, DPT, HEP	ROUTINE	D
78	IND/AEFI/WBMANP12004	2012	WEST BENGAL	2.7 M	M	HOSPITALIZED	16-05-2012	OPV, DPT	ROUTINE	C
79	IND/AEFI/WBMANP12003	2012	WEST BENGAL	5.9 M	F	DEATH	16-05-2012	OPV, DPT, HEP-B	ROUTINE	D
80	IND/AEFI/WBPRL12002	2012	WEST BENGAL	4.5 M	M	DEATH	01-02-2012	OPV, DPT	ROUTINE	D

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81	IND/AEFI/WBPR12001	2012	WEST BENGAL	2.7 M	F	DEATH	04-01-2012	OPV, DPT, HEP-B	ROUTINE	D
82	IND/AEFI/WBPR12005	2012	WEST BENGAL	22 D	M	DEATH	20-12-2012	BCG	ROUTINE	D
83	IND/AEFI/APCDP13001	2013	ANDHRA PRADESH	3.7 M	M	DEATH	19-01-2013	OPV DPT HEP-B	ROUTINE	C
84	IND/AEFI/APFKM13001	2013	ANDHRA PRADESH	2.8 M	M	DEATH	20-11-2013	OPV DPT HEP-B	ROUTINE	C
85	IND/AEFI/BIMZF13002	2013	BIHAR	2.4 M	F	DEATH	27-12-2013	OPV DPT HEP-B	ROUTINE	D
86	IND/AEFI/BIMZF13003	2013	BIHAR	1.4 M	F	DEATH	01-03-2013	DPT HEP-B	ROUTINE	D
87	IND/AEFI/BISAM13003	2013	BIHAR	2.3 M	M	DEATH	18-09-2013	OPV DPT HEP-B	ROUTINE	D
88	IND/AEFI/BISIT13002	2013	BIHAR	1.4 M	F	DEATH	11-11-2013	DPT OPV/HEP-B	ROUTINE	D
89	IND/AEFI/BIVSL13002	2013	BIHAR	17 M	F	DISABILITY	17-06-2013	BOpV	SIA	C
90	IND/AEFI/BIVSL13003	2013	BIHAR	2.6 M	F	DISABILITY	19-11-2013	OPV	SIA	C
91	IND/AEFI/BIVSL13004	2013	BIHAR	180 M	M	HOSPITALIZED	28-11-2013	JE	SIA	A4
92	IND/AEFI/BIVSL13007	2013	BIHAR	180.5 M	F	CLUSTER	28-11-2013	JE	SIA	C
93	IND/AEFI/BIVSL13009	2013	BIHAR	183.8 M	F	HOSPITALIZED	02-12-2013	JE	SIA	C
94	IND/AEFI/BIVSL13014	2013	BIHAR	187 M	F	HOSPITALIZED	04-12-2013	JE	SIA	A4
95	IND/AEFI/BIVAR13011	2013	BIHAR	132 M	F	CLUSTER	17-12-2013	JE	SIA	A4
96	IND/AEFI/BICPE13004	2013	BIHAR	108 M	F	CLUSTER	09-12-2013	JE	SIA	A4

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97	IND/AEFI/BIHARR13023	2013	BIHAR	133.8 M	F	CLUSTER	17-12-2013	JE	SIA	A4
98	IND/AEFI/BIHARR13024	2013	BIHAR	144 M	F	CLUSTER	17-12-2013	JE	SIA	A4
99	IND/AEFI/KETHR13008	2013	KERALA	2.3 M	M	HOSPITALIZED	14-03-2013	OPV PENTA	ROUTINE	C
100	IND/AEFI/APQTR14001	2014	ANDHRA PRADESH	6 D	F	DEATH	02-04-2014	OPV BCG	ROUTINE	C
101	IND/AEFI/ASSPR14002	2014	ASSAM	5.6 M	M	HOSPITALIZED	06-08-2014	DPT HEP-B BCG	ROUTINE	B2
102	IND/AEFI/BIMLUN14002	2014	BIHAR	4.7 M	F	DEATH	19-01-2014	TOPV	SIA	C
103	IND/AEFI/BIMLUN14003	2014	BIHAR	16.3 M	F	HOSPITALIZED	10-05-2014	OPV DPT MEASLES	ROUTINE	B2
104	IND/AEFI/BNVSL14003	2014	BIHAR	1.5 M	M	DEATH	17-12-2014	OPV DPT HEP-B	ROUTINE	C
105	IND/AEFI/BISSKP14001	2014	BIHAR	121 M	F	CLUSTER	15-05-2014	JE	SIA	A4
106	IND/AEFI/BISSKP14002	2014	BIHAR	144 M	F	CLUSTER	15-05-2014	JE	SIA	A4
107	IND/AEFI/MPRJG14001	2014	MADHYA PRADESH	3.8 M	F	HOSPITALIZED	11-11-2014	OPV PENTA	ROUTINE	C
108	IND/AEFI/MPJBP14001	2014	MADHYA PRADESH	2.6 M	M	HOSPITALIZED	09-12-2014	OPV PENTA BCG	ROUTINE	C

* Age less than 31 days mentioned in days