

THE INCLEN TRUST INTERNATIONAL  
RESEARCH AND TRAINING FOR IMPROVING  
EQUITY, EFFICIENCY AND QUALITY IN HEALTH CARE

Ref: IEO-Delhi/GEN-Corres2016/INC-186

February 27, 2016

To  
**Dr Rakesh Kumar, IAS**  
Joint Secretary (RMNCHA),  
Ministry of Health and Family Welfare,  
Room No.145-A, Nirman Bhawan  
New Delhi - 110003

Sub: **Causality Assessment of 141 reported serious AEFIs finalised by the National AEFI Committee**

Dear Dr Rakesh Kumar,

In continuation with the previous letter no. IEO-Delhi/GEN-Corres 2015/INC-801 dated 3<sup>rd</sup> December 2015, please find the causality assessment of next batch of 141 reported serious AEFIs as finalised by the National AEFI Committee.

The pool of national experts trained on the globally accepted WHO/CIOMS Causality Assessment protocol have participated in monthly Causality Assessment meetings conducted at Lady Hardinge Medical College (National AEFI Technical Collaborating Centre). Considering the importance and critical nature of the task, SOPs for causality assessment have been laid down for quality assurance. This causality report has been endorsed by the National AEFI Committee in its last meeting held on 21<sup>st</sup> Dec2015.

Out of 141 cases, 36% (51 cases) of the reported serious AEFIs are consistent causal relation to immunization (A) but none is due to quality defect in manufacturing of vaccines. Out of 51 cases, 41 cases were due to vaccine product related reaction, 8 cases were due to immunization error related reaction and 2 cases due to immunization anxiety related reaction. More than one third (36%) of the reported serious AEFIs have inconsistent causal association relation to immunization (co incidental). Sixteen cases remained in unclassifiable category due to inadequate information. *Among these 141 cases, none of the reported AEFI deaths had consistent causal association with immunisation.*

It is important to note that as on 5<sup>th</sup> December 2015, 2506 cases (between 01 Jan 2012 and 05 December 2015) of serious AEFIs were reported indicating that the AEFI events are well within the expected rates though there is an overall need to further improve surveillance. The National AEFI Surveillance during this period has shown significant improvement and number of districts reporting serious AEFI is gradually increasing.

The anonymized line list of the causality assessment done by the National AEFI Committee is attached for your perusal and records. Following is the summary of the Causality Assessment Report appended with this letter.

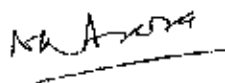
<b>Causality Assessment of AEFI cases (2012-15) reviewed by National AEFI Committee in 2015</b>	
<b>CLASSIFICATION</b>	<b>Serious AEFI cases reviewed by National AEFI Committee</b>
<b>A: CONSISTENT CAUSAL RELATION TO IMMUNIZATION</b>	<b>51</b>
A1 (VACCINE PRODUCT RELATED REACTION)	41
A2 (VACCINE QUALITY DEFECT RELATED)	0
A3 (IMMUNIZATION ERROR RELATED REACTION)	8
A4 (IMMUNIZATION ANXIETY RELATED REACTION)	2
<b>B (INDETERMINATE) EVENT FOLLOWED VACCINATION BUT POOR EVIDENCE IS AVAILABLE FOR STRENGTH OF ASSOCIATION OR EVIDENCES GIVE CONFLICTING INDICATIONS SO CAUSALITY CANNOT BE FIXED)</b>	<b>23</b>
<b>C (COINCIDENTAL) INCONSISTENT CAUSAL RELATION TO IMMUNIZATION UNDERLYING OR EMERGING CONDITION(S), OR CONDITIONS CAUSED BY EXPOSURE TO SOMETHING OTHER THAN VACCINE)</b>	<b>51</b>
<b>D (UNCLASSIFIABLE) INFORMATION IS INADEQUATE TO FORM VALID DIAGNOSIS TO THE EVENT DUE TO INCOMPLETE DOCUMENTATION/POOR CLINICAL INFORMATION)</b>	<b>16</b>
<b>TOTAL</b>	<b>141</b>

Out of 2506 reported serious AEFI cases between 01 January 2012 and 5<sup>th</sup> December 2015, the causality of 912 reported serious AEFIs has been reviewed and endorsed by the National AEFI Committee so far and submitted to your office. The National AEFI Secretariat is working systematically with all stakeholders to complete the causality assessment of remaining cases.

I shall be happy to clarify further if required.

Thanking you,

With regards,



**Narendra K Arora,**  
**Chairperson, National AEFI Committee**

Copy to:

- Dr M K Aggarwal, Deputy Commissioner (UIP), MOHFW
- Dr Pradeep Haldar, Deputy Commissioner (Imm.), MOHFW
- Dr (Director-Prof) S Aneja, Chairperson, CA subcommittee of National AEFI Committee & Technical Coordinator, National AEFI Technical Collaborating Centre, LHMC & KSCH, New Delhi
- Dr Jyoti Joshi Jain, Deputy Director and Senior Advisor-AEFI Surveillance and vaccine safety, IISU

**Causality assessment report of 141 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 141 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 (51)** and **Consistent Causal Relation to Immunization (51)** and none have been found to be due to quality defect in manufacturing vaccines.

**CAUSALITY CLASSIFICATION OF 141 AEFI CASES REVIEWED AND TO BE APPROVED BY THE NATIONAL AEFI COMMITTEE**  
**21<sup>st</sup> DECEMBER 2015 - (DELHI)**

- 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 - CONCORDANT - 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 YEAR MONTH DAY	SEX	REASON FOR REPORTING	DATE OF VACCINATION	ANTIGENS	ROUTINE vs CAMPAIGN	CLASSIFICATION BY CA SUBCOMMITTEE
1	IND/AEFI/PAVSM12002	2012	ANDHRA PRADESH	29 D	F	DEATH	15/04/2012	OPV	SIA	C
2	IND/AEFI/ASMRG12001	2012	ASSAM	2 Y	M	DEATH	09/04/2012	PENTA	SIA	C
3	IND/AEFI/ASUDG12001	2012	ASSAM	5 M	F	DEATH	09/04/2012	OPV	SIA	C
4	IND/AEFI/BIVSL12001	2012	BIHAR	2 M 26 D	F	HOSPITALIZED	11/09/2012	BOPV	SIA	A1
5	IND/AEFI/COMMD12001	2012	CHHATTISGARH	4 M 3 D	F	DEATH	01/05/2012	OPV DPT	ROUTINE	C
6	IND/AEFI/DEAST12001	2012	DELHI	6 M 24 D	M	DEATH	28/08/2012	OPV DPT HEP-B	ROUTINE	C
7	IND/AEFI/HPAPKL12001	2012	HARYANA	2 M 27 D	M	HOSPITALIZED	23/05/2012	OPV DPT HEP-B	ROUTINE	B2
8	IND/AEFI/KAMVS12001	2012	KARNATAKA	9 M	M	CLUSTER	02/09/2012	MEASLES VIT-A	ROUTINE	D
9	IND/AEFI/KAMVS12002	2012	KARNATAKA	9 M	F	CLUSTER	02/09/2012	MEASLES VIT-A	ROUTINE	D
10	IND/AEFI/KEAPZ12009	2012	KERALA	1 M 13 D	M	HOSPITALIZED	05/09/2012	OPV PENTA	ROUTINE	D
11	IND/AEFI/KEPMH12006	2012	KERALA	1 M 15 D	M	HOSPITALIZED	28/11/2012	OPV PENTA	ROUTINE	C
12	IND/AEFI/PBPTL12001	2012	PUNJAB	3 M 1 D	F	DEATH	21/11/2012	OPV DPT HEP-B	ROUTINE	D
13	IND/AEFI/UPPVRN12001	2012	UTTAR PRADESH	2 M 22 D	M	DEATH	07/01/2012	OPV DPT HEP-B	ROUTINE	D
14	IND/AEFI/UPGND12001	2012	UTTAR PRADESH	1 D	M	DEATH	12/08/2012	OPV HEP-B BCG	ROUTINE	C
15	IND/AEFI/IASCHH13001	2013	ASSAM	2 Y 4 M 28 D	F	HOSPITALIZED	22/01/2013	OPV	SIA	C
16	IND/AEFI/IASGLP13001	2013	ASSAM	4 M 18 D	F	DEATH	10/04/2013	OPV DPT HEP-B	ROUTINE	D
17	IND/AEFI/IASJHT13001	2013	ASSAM	2 Y 6 M 16 D	F	HOSPITALIZED	25/09/2013	DPT	ROUTINE	A1
18	IND/AEFI/IASPPR13001	2013	ASSAM	1 M 17 D	F	DEATH	13/11/2013	OPV DPT HEP-B	ROUTINE	D
19	IND/AEFI/BIPEP13002	2013	BIHAR	14 Y	F	CLUSTER	05/12/2013	JE	SIA	A4

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20	IND(AEFI)BICPE13003	2013	BIHAR	13 Y	F	HOSPITALIZED	07/12/2013	JE	SIA	D
21	IND(AEFI)CHCHD13001	2013	CHANDIGARH	1 M 11 D	M	DEATH	23/04/2013	PENTA	ROUTINE	C
22	IND(AEFI)DDDMN13004	2013	DAMAN & DIU	2 M 25 D	M	CLUSTER	16/05/2013	OPV DPT	ROUTINE	D
23	IND(AEFI)GOGOS13002	2013	GOA	1 D	F	HOSPITALIZED	21/10/2013	HEPB	ROUTINE	B2
24	IND(AEFI)KABLU13003	2013	KARNATAKA	6 Y 4 M 3 D	M	HOSPITALIZED	13/06/2013	DPT	ROUTINE	B2
25	IND(AEFI)KABLU13007	2013	KARNATAKA	5 Y 10 M 20 D	M	HOSPITALIZED	18/07/2013	DPT	ROUTINE	B1
26	IND(AEFI)KABLU13010	2013	KARNATAKA	7 M 6 D	F	HOSPITALIZED	03/10/2013	OPV PENTA	ROUTINE	C
27	IND(AEFI)KEPTM13002	2013	KERALA	4 M 12 D	M	HOSPITALIZED	02/01/2013	OPV PENTA	ROUTINE	C
28	IND(AEFI)KEPTM13001	2013	KERALA	15 Y 1 M 24 D	M	HOSPITALIZED	10/01/2013	TT	ROUTINE	A4
29	IND(AEFI)KETRM13002	2013	KERALA	1 Y 10 M 6 D	F	HOSPITALIZED	20/01/2013	OPV	SIA	C
30	IND(AEFI)KEPM13001	2013	KERALA	1 M 10 D	F	HOSPITALIZED	23/01/2013	OPV PENTA	ROUTINE	A1
31	IND(AEFI)KETHR13004	2013	KERALA	1 M 17 D	M	HOSPITALIZED	23/01/2013	OPV PENTA	ROUTINE	A1
32	IND(AEFI)KETRM13004	2013	KERALA	1 M 14 D	M	HOSPITALIZED	04/02/2013	OPV PENTA	ROUTINE	C
33	IND(AEFI)KETRM13003	2013	KERALA	1 M 13 D	M	HOSPITALIZED	08/02/2013	OPV PENTA	ROUTINE	B2
34	IND(AEFI)KEKSG13001	2013	KERALA	1 Y 7 M	M	HOSPITALIZED	14/02/2013	OPV DPT MEASLES VIT-A	ROUTINE	A1
35	IND(AEFI)KETHR13011	2013	KERALA	2 M 18 D	F	HOSPITALIZED	23/04/2013	OPV PENTA	ROUTINE	B2
36	IND(AEFI)KETHR13013	2013	KERALA	10 M	M	HOSPITALIZED	27/04/2013	OPV PENTA MEASLES	ROUTINE	C
37	IND(AEFI)KETHR13009	2013	KERALA	1 Y 4 M 9 D	F	HOSPITALIZED	22/05/2013	OPV PENTA	ROUTINE	A1
38	IND(AEFI)KEMPM13007	2013	KERALA	2 M 21 D	M	HOSPITALIZED	29/05/2013	OPV PENTA	ROUTINE	A1

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39	IND/AE/FI/KET/HR/13018	2013	KERALA	3 M 13 D	M	HOSPITALIZED	06/06/2013	OPV/PENTA	ROUTINE	C
40	IND/AE/FI/KEA/PZ/13009	2013	KERALA	7 D	F	HOSPITALIZED	12/06/2013	BCG	ROUTINE	D
41	IND/AE/FI/KEA/PM/13012	2013	KERALA	1 Y 8 M 14 D	M	HOSPITALIZED	18/07/2013	OPV/DPT	ROUTINE	A3
42	IND/AE/FI/KEA/PM/13011	2013	KERALA	4 M 8 D	F	HOSPITALIZED	20/07/2013	PENTA	ROUTINE	A1
43	IND/AE/FI/KE/HR/13020	2013	KERALA	1 Y 5 M 25 D	F	HOSPITALIZED	23/07/2013	OPV DPT VIT-A	ROUTINE	B2
44	IND/AE/FI/KE/KZ/K/13017	2013	KERALA	1 M 16 D	F	HOSPITALIZED	05/08/2013	OPV PENTA	ROUTINE	A3
45	IND/AE/FI/KE/MP/13006	2013	KERALA	6 M 28 D	F	HOSPITALIZED	16/08/2013	OPV DPT MEASLES PENTAT	ROUTINE	B2
46	IND/AE/FI/KE/MP/13013	2013	KERALA	9 M 29 D	F	HOSPITALIZED	24/10/2013	OPV PENTA	ROUTINE	C
47	IND/AE/FI/KE/MP/13014	2013	KERALA	9 M 10 D	M	HOSPITALIZED	05/11/2013	BCG PENTA	ROUTINE	C
48	IND/AE/FI/KE/KLM/13008	2013	KERALA	3 M 24 D	F	HOSPITALIZED	24/12/2013	OPV PENTA	ROUTINE	A1
49	IND/AE/FI/MA/HB/MC/13016	2013	MAHARASHTRA	1 M 18 D	M	HOSPITALIZED	26/09/2013	OPV DPT HEP-B	ROUTINE	B2
50	IND/AE/FI/MA/HB/MC/13015	2013	MAHARASHTRA	4 M 21 D	F	HOSPITALIZED	28/09/2013	OPV DPT HEP-B	ROUTINE	A1
51	IND/AE/FI/MA/HB/MC/13017	2013	MAHARASHTRA	1 M 26 D	M	HOSPITALIZED	21/10/2013	OPV DP <sup>+</sup> HEP-B	ROUTINE	B2
52	IND/AE/FI/MA/H/PNA/13204	2013	MAHARASHTRA	1 M 6 D	M	HOSPITALIZED	07/11/2013	BCG	ROUTINE	C
53	IND/AE/FI/MA/HB/MC/13018	2013	MAHARASHTRA	8 M 8 D	F	HOSPITALIZED	12/11/2013	OPV DPT HEP-B	ROUTINE	C
54	IND/AE/FI/MA/HB/MC/13020	2013	MAHARASHTRA	3 M 21 D	F	HOSPITALIZED	12/11/2013	OPV DPT HEP-B	ROUTINE	C
55	IND/AE/FI/MA/HT/NI/13003	2013	MAHARASHTRA	12 Y 11 M 5 D	F	HOSPITALIZED	04/12/2013	TT	ROUTINE	C
56	IND/AE/FI/MA/HB/MC/13021	2013	MAHARASHTRA	2 M 28 D	F	HOSPITALIZED	31/12/2013	OPV DPT HEP-B	ROUTINE	C
57	IND/AE/FI/PE/DP/NY/13004	2013	PUNJAB	9 M 24 D	F	HOSPITALIZED	22/08/2013	MEASLES	ROUTINE	A1

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58	IND/AEF/UP/LNO13003	2013	UTTAR PRADESH	10 Y	M	HOSPITALIZED	18/03/2013	MEASLES	SIA	C
59	IND/AEF/WB/BBM13001	2013	WEST BENGAL	1 Y 2 M 17 D	F	HOSPITALIZED	20/01/2013	OPV	SIA	C
60	IND/AEF/WB/MNP13001	2013	WEST BENGAL	1 M 18 D	M	DEATH	20/01/2013	OPV	SIA	C
61	IND/AEF/WB/BM13002	2013	WEST BENGAL	2 D	F	DEATH	03/04/2013	BCG	ROUTINE	D
62	IND/AEF/WB/DJ13002	2013	WEST BENGAL	1 D	M	HOSPITALIZED	07/10/2013	OPV, HEP-B, BCG	ROUTINE	A3
63	IND/AEF/BI/MUN14005	2014	BHAR	1 Y 11 M 24 D	F	DEATH	10/01/2014	OPV, DPT, MEASLES	ROUTINE	D
64	IND/AEF/DL/SOU14005	2014	DELHI	1 M 15 D	M	HOSPITALIZED	07/02/2014	PENTA	ROUTINE	B2
65	IND/AEF/DL/DLH14002	2014	DELHI	2 M 17 D	M	DEATH	19/03/2014	PENTA	ROUTINE	C
66	IND/AEF/DL/WES14002	2014	DELHI	2 M 20 D	F	HOSPITALIZED	05/06/2014	OPV, PENTA	ROUTINE	C
67	IND/AEF/GO/GON14002	2014	GOA	1 Y 6 M 3 D	M	HOSPITALIZED	13/02/2014	DPT	ROUTINE	A1
68	IND/AEF/GO/GON14005	2014	GOA	1 Y 7 M	M	HOSPITALIZED	08/05/2014	OPV, DPT	ROUTINE	A1
69	IND/AEF/GO/GOS14009	2014	GOA	10 M 12 D	F	HOSPITALIZED	09/05/2014	OPV, PENTA	ROUTINE	B2
70	IND/AEF/GO/GON14008	2014	GOA	1 M 18 D	F	HOSPITALIZED	15/06/2014	OPV, PENTA	ROUTINE	A1
71	IND/AEF/GO/GOS14011	2014	GOA	2 M 7 D	F	HOSPITALIZED	03/07/2014	DPT	ROUTINE	A1
72	IND/AEF/GO/GON14009	2014	GOA	3 M 5 D	M	HOSPITALIZED	09/08/2014	OPV, PENTA	ROUTINE	A3
73	IND/AEF/GO/GOS14013	2014	GOA	5 M 30 D	M	HOSPITALIZED	20/09/2014	MMR	ROUTINE	B2
74	IND/AEF/GO/GON14010	2014	GOA	1 M 16 D	F	HOSPITALIZED	09/10/2014	OPV, PENTA	ROUTINE	A1
75	IND/AEF/GO/GON14011	2014	GOA	4 M 23 D	M	HOSPITALIZED	09/10/2014	OPV, PENTA	ROUTINE	B2
76	IND/AEF/GO/GON14012	2014	GOA	1 Y 7 M 12 D	F	HOSPITALIZED	10/10/2014	OPV, DPT, JE	ROUTINE	A1

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77	IND/AEFI/GOGON14016	2014	GOA	1 Y 6 M 12 D	F	HOSPITALIZED	27/11/2014	OPV DPT JE	ROUTINE	B2
78	IND/AEFI/GOGON14015	2014	GOA	6 M 16 D	F	HOSPITALIZED	18/12/2014	OPV PENTA	ROUTINE	A1
79	IND/AEFI/GURJT14001	2014	GUJARAT	1 M 9 D	M	HOSPITALIZED	17/02/2014	OPV PENTA	ROUTINE	C
80	IND/AEFI/GURJT14002	2014	GUJARAT	2 M 7 D	F	DEATH	17/09/2014	OPV PENTA	ROUTINE	D
81	IND/AEFI/HASNPI14002	2014	HARYANA	3 M 19 D	M	HOSPITALIZED	09/07/2014	OPV PENTA	ROUTINE	C
82	IND/AEFI/HAKTL14003	2014	HARYANA	1 Y 8 M 12 D	M	HOSPITALIZED	03/09/2014	DPT MEASLES JE	ROUTINE	A1
83	IND/AEFI/HAKNL14001	2014	HARYANA	1 D	F	HOSPITALIZED	01/10/2014	OPV HEP B BCG	ROUTINE	A3
84	IND/AEFI/HALJF14007	2014	HARYANA	1 Y 5 D	M	HOSPITALIZED	17/12/2014	OPV DPT MEASLES	ROUTINE	A1
85	IND/AEFI/KETRM14005	2014	KERALA	1 M 11 D	F	HOSPITALIZED	07/02/2014	OPV PENTA	ROUTINE	C
86	IND/AEFI/KETHR14001	2014	KERALA	5 M 15 D	F	HOSPITALIZED	13/02/2014	PEVTA	ROUTINE	A3
87	IND/AEFI/KEPK14001	2014	KERALA	1 Y 3 M 26 D	F	HOSPITALIZED	05/03/2014	MMR	ROUTINE	C
88	IND/AEFI/KEKZK14010	2014	KERALA	4 M 20 D	M	HOSPITALIZED	20/03/2014	OPV PENTA	ROUTINE	A1
88	IND/AEFI/KEKZK14013	2014	KERALA	9 M 8 D	M	HOSPITALIZED	28/04/2014	MEASLES VIT-A	ROUTINE	C
90	IND/AEFI/KEKZK14015	2014	KERALA	1 Y 7 M 6 D	M	HOSPITALIZED	03/05/2014	OPV	ROUTINE	A1
91	IND/AEFI/KEKZK14014	2014	KERALA	1 M 22 D	F	HOSPITALIZED	07/05/2014	OPV PENTA	ROUTINE	A1
92	IND/AEFI/KEKZK14016	2014	KERALA	1 Y 11 M 21 D	F	HOSPITALIZED	21/05/2014	OPV DPT VIT-A	ROUTINE	A1
93	IND/AEFI/KEKZK14017	2014	KERALA	3 M 20 D	M	DEATH	24/05/2014	OPV PENTA	ROUTINE	C
94	IND/AEFI/KEKOT14013	2014	KERALA	1 Y 9 M 13 D	F	HOSPITALIZED	18/06/2014	OPV DPT	ROUTINE	C
95	IND/AEFI/KEKZK14032	2014	KERALA	3 M 6 D	F	HOSPITALIZED	15/07/2014	PENTA	ROUTINE	A3



**CAUSALTY CLASSIFICATION OF 141 AEFI CASES REVIEWED AND TO BE APPROVED BY THE NATIONAL AEFI COMMITTEE**  
**21<sup>st</sup> DECEMBER 2015 - (DELHI)**

- 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 - CONSIDERABLE - UNDERLYING OR EMERGING CONDITION(S), OR CONDITIONS CAUSED BY EXPOSURE TO SOMETHING OTHER THAN VACCINE**  
**O - UNCLASSIFIABLE**

S. NO.	NATIONAL ID	YEAR	STATE	AGE IN YEAR MONTH DAY	SEX	REASON FOR REPORTING	DATE OF VACCINATION	ANTIGENS	ROUTINE VS CAMPAIGN	CLASSIFICATION BY CA SUBCOMMITTEE
96	IND(AEFI)KEKZK14028	2014	KERALA	1 M 24 D	F	HOSPITALIZED	18/07/2014	BCG PENTA	ROUTINE	C
97	IND(AEFI)KEKZK14031	2014	KERALA	2 M 20 D	M	HOSPITALIZED	23/07/2014	OPV PENTA	ROUTINE	B2
98	IND(AEFI)KEKZK14033	2014	KERALA	2 M 8 D	M	HOSPITALIZED	30/07/2014	PENTA	ROUTINE	B2
99	IND(AEFI)KEKOT14018	2014	KERALA	1 Y 5 M	F	HOSPITALIZED	01/10/2014	OPV DPT	ROUTINE	A1
100	IND(AEFI)KEKZK14042	2014	KERALA	2 M 16 D	M	HOSPITALIZED	10/12/2014	OPV PENTA	ROUTINE	B2
101	IND(AEFI)KEKOT14023	2014	KERALA	1 Y 1 M 2 D	M	HOSPITALIZED	31/12/2014	MEASLES PENTA	ROUTINE	A1
102	IND(AEFI)MPBHD14001	2014	MADHYA PRADESH	1 M 25 D	M	DEATH	02/05/2014	OPV DPT HEP-B	ROUTINE	D
103	IND(AEFI)MPSDH14001	2014	MADHYA PRADESH	2 M 12 D	M	DEATH	06/06/2014	OPV DPT HEP-B	ROUTINE	D
104	IND(AEFI)MPSJ14001	2014	MADHYA PRADESH	2 M	M	HOSPITALIZED	13/11/2014	OPV PENTA	ROUTINE	B2
105	IND(AEFI)MHBMC14010	2014	MAHARASHTRA	2 Y 5 M 1 D	M	DISABILITY	23/07/2014	OPV DPT	ROUTINE	A1
106	IND(AEFI)MHBMC14011	2014	MAHARASHTRA	4 M 29 D	M	HOSPITALIZED	05/08/2014	OPV DPT HEP-B	ROUTINE	C
107	IND(AEFI)MHPNA14203	2014	MAHARASHTRA	2 M	F	HOSPITALIZED	07/08/2014	OPV DPT HEP-B BCG	ROUTINE	C
108	IND(AEFI)MHBMC14012	2014	MAHARASHTRA	6 M	F	HOSPITALIZED	13/09/2014	OPV DPT HEP-B	ROUTINE	A1
109	IND(AEFI)MHBMC14013	2014	MAHARASHTRA	8 M 26 D	F	HOSPITALIZED	18/09/2014	MEASLES	ROUTINE	C
110	IND(AEFI)MHBMC14017	2014	MAHARASHTRA	1 Y 7 M 29 D	F	HOSPITALIZED	27/11/2014	OPV DPT VIT-A	ROUTINE	A1
111	IND(AEFI)MHBMC14019	2014	MAHARASHTRA	1 Y 7 M 26 D	F	HOSPITALIZED	13/12/2014	OPV DPT	ROUTINE	C
112	IND(AEFI)ORBOU14001	2014	ODISHA	4 M 8 D	M	DEATH	01/01/2014	OPV DPT HEP-B BCG	ROUTINE	D
113	IND(AEFI)TNTTC14001	2014	TAMIL NADU	11 M 24 D	F	HOSPITALIZED	14/05/2014	MEASLES	ROUTINE	C
114	IND(AEFI)TNCN114008	2014	TAMIL NADU	3 M 24 D	F	HOSPITALIZED	04/06/2014	OPV PENTA	ROUTINE	C

**CAUSALITY CLASSIFICATION OF 141 AEFI CASES REVIEWED AND TO BE APPROVED BY THE NATIONAL AEFI COMMITTEE**  
**21<sup>ST</sup> DECEMBER 2015 - (DELHI)**

- 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 - CONCOMITANT - 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 YEAR MONTH DAY	SEX	REASON FOR REPORTING	DATE OF VACCINATION	ANTIGENS	ROUTINE vs CAMPAIGN	CLASSIFICATION BY CA SUBCOMMITTEE
115	IND(AEFI)TNCN14003	2014	TAMIL NADU	1 Y 7 M	F	HOSPITALIZED	07/06/2014	OPV DPT MEASLES	ROUTINE	A1
116	IND(AEFI)TNCN14005	2014	TAMIL NADU	1 Y 6 M 9 D	M	HOSPITALIZED	11/06/2014	OPV DPT MEASLES	ROUTINE	A1
117	IND(AEFI)TNTUT14002	2014	TAMIL NADU	14 Y 2 M 18 D	F	HOSPITALIZED	20/06/2014	TT	SIA	B1
118	IND(AEFI)TNTLR14003	2014	TAMIL NADU	1 Y 6 M 7 D	M	HOSPITALIZED	27/06/2014	OPV DPT	ROUTINE	A1
119	IND(AEFI)TNCN14012	2014	TAMIL NADU	3 M 20 D	F	HOSPITALIZED	03/09/2014	OPV PENTA	ROUTINE	C
120	IND(AEFI)TNTLR14004	2014	TAMIL NADU	1 Y 9 M 30 D	M	HOSPITALIZED	09/09/2014	OPV DPT H.B	ROUTINE	A1
121	IND(AEFI)TNCN14013	2014	TAMIL NADU	1 Y 8 M 30 D	M	HOSPITALIZED	17/09/2014	OPV DPT MEASLES	ROUTINE	A1
122	IND(AEFI)TNCN14014	2014	TAMIL NADU	4 M 8 D	M	HOSPITALIZED	24/09/2014	PENTA	ROUTINE	B2
123	IND(AEFI)TNCN14020	2014	TAMIL NADU	3 M 17 D	F	HOSPITALIZED	24/09/2014	OPV PENTA	ROUTINE	A1
124	IND(AEFI)TNRKN14008	2014	TAMIL NADU	1 M 23 D	F	HOSPITALIZED	24/09/2014	OPV PENTA	ROUTINE	A3
125	IND(AEFI)TNCN14015	2014	TAMIL NADU	5 Y 17 D	M	HOSPITALIZED	01/10/2014	DPT	ROUTINE	C
126	IND(AEFI)TNCN14016	2014	TAMIL NADU	1 Y 4 M 9 D	F	HOSPITALIZED	01/10/2014	OPV DPT MEASLES	ROUTINE	A1
127	IND(AEFI)TNCN14017	2014	TAMIL NADU	1 Y 5 M 20 D	M	HOSPITALIZED	01/10/2014	OPV DPT MEASLES	ROUTINE	B2
128	IND(AEFI)TNCN14018	2014	TAMIL NADU	5 Y 3 M 20 D	M	HOSPITALIZED	01/10/2014	DPT	ROUTINE	A1
129	IND(AEFI)TNCN14019	2014	TAMIL NADU	4 M 11 D	M	HOSPITALIZED	12/11/2014	OPV PENTA	ROUTINE	B2
130	IND(AEFI)TNCN14021	2014	TAMIL NADU	1 M 16 D	F	DEATH	18/11/2014	OPV PENTA	ROUTINE	C
131	IND(AEFI)TNTVLR14006	2014	TAMIL NADU	3 M 4 D	M	HOSPITALIZED	19/11/2014	OPV PENTA	ROUTINE	A1
132	IND(AEFI)TNCN14022	2014	TAMIL NADU	1 M 22 D	F	HOSPITALIZED	02/12/2014	OPV PENTA	ROUTINE	A1
133	IND(AEFI)TRGNT14001	2014	TRIPURA	1 M 14 D	F	DEATH	11/11/2014	OPV DPT HEP-B OTHER	ROUTINE	C

**CAUSALTY CLASSIFICATION OF 141 AEHI CASES REVIEWED AND TO BE APPROVED BY THE NATIONAL AERI COMMITTEE  
21<sup>ST</sup> DECEMBER 2015 - (DELHI)**

- 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 OR CONSISTENCY AND INCONSISTENCY WITH CAUSAL ASSOCIATION TO IMMUNIZATION**  
**C - COINCIDENTAL - UNBELIEVING OR EMERGING CONDITION(S), OR CONDITIONS CAUSED BY EXPOSURE TO SOMETHING OTHER THAN VACCINE**  
**D - UNCLASSIFIABLE**

S. NO.	NATIONAL ID	YEAR	STATE	AGE IN YEAR MONTH DAY	SEX	REASON FOR REPORTING	DATE OF VACCINATION	ANTIGENS	ROUTINE VS CAMPAIGN	CLASSIFICATION BY CA SUBCOMMITTEE
134	IND(AEFI)WBND14001	2014	WEST BENGAL	3 M 15 D	M	HOSPITALIZED	20/02/2014	DPT	ROUTINE	C
135	IND(AEFI)WBND14003	2014	WEST BENGAL	2 M 24 D	M	DEATH	14/09/2014	Opv	SIA	C
136	IND(AEFI)ASLKR15003	2015	ASSAM	2 M 8 D	F	DEATH	18/02/2015	OPV PENTA	ROUTINE	C
137	IND(AEFI)CHCHD15003	2015	CHANDIGARH	1 M 24 D	F	HOSPITALIZED	15/04/2015	OPV DPT HEP-B	ROUTINE	A1
138	IND(AEFI)HAKTL15001	2015	HARYANA	2 M 7 D	M	DEATH	11/02/2015	Opv PENTA	ROUTINE	C
139	IND(AEFI)MPJBA15001	2015	MADHYA PRADESH	3 M 1 D	F	DEATH	06/01/2015	OPV PENTA	ROUTINE	C
140	IND(AEFI)MPFAN15001	2015	MADHYA PRADESH	3 M 7 D	F	DEATH	10/02/2015	OPV PENTA	ROUTINE	C
141	IND(AEFI)UARRD15001	2015	UTTARAKHAND	1 M 22 D	M	HOSPITALIZED	04/02/2015	PENTA	ROUTINE	A1

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