AEFI

Adverse Event Following Immunization

Standard Operating Procedures (SOPs)

NATIONAL RURAL HEALTH MISSION
राष्ट्रीय ग्रामीण स्वास्थ्य मिशन

Ministry of Health and Family Welfare
Government of India
New Delhi
2010

सत्यमेव जयते

AEFI

Adverse Event Following Immunization

Standard Operating Procedures (SOPs)
Investigation of Adverse Events Following Immunization (AEFI)

Ministry of Health and Family Welfare
Government of India
New Delhi
2010

Table of Content

Abbreviations

AC	Assistant Commissioner of Immunization Division
AEFI	Adverse Event Following Immunization
AE	Adverse Event
AFP	Acute Flaccid Paralysis
ANM	Auxiliary Nurse Midwife
ASHA	Accredited Social Health Activist
CHC	Community Health Center
CDSCO	Central Drug Standard Control Organization
CMO/ CS	Chief Medical Officer/ Civil Surgeon
DCG (I)	Drug Controller General of India
DIO	District Immunization Officer
DIR	Detailed investigation report
DPT	Diphtheria -Pertussis (whole-cell) -Tetanus vaccine
EPI	Expanded Programme on Immunization
FDA	Food & Drugs Administration
FIR	First information report
GoI	Government of India
HA	Health Assistant
HIV	Human Immunodeficiency Virus
ILR	Ice Lined Refrigerator
MO	Medical officer
MO (PHC)	Medical Officer (Primary Health Center)
MoHFW	Ministry of Health & Family Welfare
NCL	National Control Laboratory
NRA	National Regulatory Authority
OPV	Oral Polio Vaccine
PHC	Primary health center
PIR	Preliminary investigation report
SC	Sub center
SEPIO	State Immunization Officer/State EPI Officer
SRA	State Regulatory Authority
SOPs	Standard Operating Procedures
VPD	Vaccine Preventable Disease
WHO	World Health Organization
UHC	Urban Health Center
UIP	Universal Immunization Program
UNICEF	United Nations children's Fund
UT	Union territory
VVM	Vaccine Vial Monitor

Glossary

Adverse event following immunization (AEFI): A medical incident that takes place after an immunization, causes concern, and is believed to be caused by immunization

AEFI surveillance: monitoring, detecting and responding to adverse events following immunization (AEFI); Implementing appropriate and immediate action to correct any unsafe practices detected through the AEFI surveillance system, in order to lessen the negative impact on the health of individuals and the reputation of the immunization programme.

Serious AEFIs: AEFIs that are life threatening and those that result in hospitalization, disability or death.

Non serious AEFI: A reaction that is not "serious".

Trigger event: A medical incident that stimulates a response, usually a case investigation.

Causal association/ link: An AEFI which is caused by administration of a particular vaccine. Causally associated events are also temporally associated, but events which are temporally associated may not necessarily be causally associated. Causality is usually based on Laboratory findings (e.g. isolation of vaccine virus strain), and/or Unique clinical syndrome (e.g. anaphylaxis), and/or Epidemiological studies showing an increased incidence in vaccinated groups as compared with unvaccinated groups.

Coincidental adverse event: A medical event that occurs after immunization but is not caused by the vaccine. This is due to a chance temporal association.

Cluster: Two or more cases of the same or similar events, which are related in time, and have occurred within specific geographical area, or associated with the same vaccine, the same batch number or the same vaccinator.

Injection safety: Injection safety is the safe handling of all injection equipment, routine monitoring of the availability and use of safe injection equipment, and correct disposal of contaminated injection equipment.

Immunization safety: Includes vaccine safety and quality, Safe injections and waste disposal and AEFI surveillance.

Program error: An event caused by an error in the transportation, storage, handling, or administration of a vaccine.

Temporal association: If the putative (presumed) causal event precedes the onset of the suspected adverse event then they are temporally associated. Temporal association is independent of causal association, and an event which is temporally associated with vaccine administration may or may not be caused by the vaccine.

Vaccine: Biological substance that is administered to individuals to elicit immunity (protection) against a specific disease. Combination vaccines (e.g. DTP) protect against more than one disease.

Live viral vaccines (e.g. poliomyelitis, measles) contain attenuated (weakened) version of the disease -causing virus. The vaccine virus causes a mild infection, usually with no or minimal symptoms, that creates immunity against that virus.

Vaccine reaction: An event caused or precipitated by the active component or one of the other components of the vaccine (e.g. adjuvant, preservative of stabilizer). This is due to inherent properties of the vaccine.

Standard operating procedure (SOP) for investigation of adverse events following immunization (AEFI)

An adverse event following immunization (AEFI) is defined as a medical incident that takes place after an immunization, causes concern, and is believed to be caused by immunization.

1. Types of AEFI

AEFIs can be classified into five types (Table 1)

1. Vaccine Reaction
2. Program error
3. Coincidental reactions
4. Injection reaction
5. Unknown

Table 2.1: Types of AEFIs

Type	*Definition*	*Example*
	***1. Vaccine reaction*** An event caused or precipitated by the active component or one of the other components of the vaccine (e.g. adjuvant, preservative and stabilizer). This is due to the inherent properties of the vaccine.	• High grade fever following DPT vaccination • Anaphylaxis
	***2. Program Error*** An event caused by an error in vaccine preparation, handling or administration.	Bacterial abscess due to un-sterile injection / wrong diluent
	***3. Coincidental*** An event that occurs after immunization but is not caused by the vaccine. This is due to a chance temporal association	Pneumonia after oral polio vaccine administration
	4. Injection Reaction Event caused by anxiety about, or pain from the injection itself rather than the vaccine	Fainting spell after immunization
	5. Unknown The cause of the event cannot be determined	Does not fit into any of the above four types

Table 2: Frequency and nature of non serious vaccine reactions

Vaccine	*Local reaction (pain, swelling, redness)*	*Fever (greater than 38°C)*	*Irritability, malaise and non-specific symptoms*
BCG	Common	-	-
Hepatitis B	Adults up to 30% Children up to 5%	1 – 6%	
Hib	Up to 25%	-	
Measles/MMR	Up to 10%	5-15%	Up to 5%(rash)

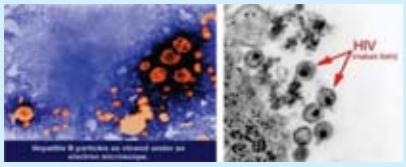
OPV	-	Less than 1%	Less than 1%[a]
Tetanus/DT/Td	Up to 10%[b]	Up to 10%	Up to 25%
Pertussis (DPT-Whole cell)[c]	Up to 50%	Up to 50%	Up to 60%
Management	• Cold cloth at injection site • Paracetamol	• Give extra fluids • Wear light clothing • Tepid sponge or bath • Paracetamol	• Symptomatic

[a] Diarrhea, headache and/or muscle pains
[b] Rate of local reaction likely to increase with booster doses up to 50-85%
[c] Acellular Pertussis vaccine causes lower rates of reaction.

Table 3: Frequency and nature of serious vaccine reactions

Vaccine	*Reaction*	*Interval between vaccination and onset*	*Number of events per million doses*
BCG	Suppurative adenitis	2-6 months	100-1000
	BCG Osteitis	Up to several years	-
	Disseminated BCG infection	1-12 months	-
Hib	None known	-	-
Hep B	Anaphylaxis	0-1 hour	1-2
Measles/MMR[a]	Febrile seizures	5-12 days	330
	Thrombocytopenia (low platelets)	60 days	30
	Anaphylaxis	0-1 hour	1
OPV	Vaccine-Associated Paralytic Poliomyelitis[b]	4-30 days	Up to 0.4[b]
Tetanus	Brachial Neuritis	2-28 days	5-10
	Anaphylaxis	0-1 hour	1-6
	Sterile abscess	1-6 weeks	6-10
DPT	Persistent (>3hours) inconsolable screaming	0-48 hours	1,000-60,000
	Seizures	0-3 days	600[c]
	Hypotonic Hypo Responsive Episode (HHE)	0-24 hours	30 - 990
	Anaphylaxis/Shock	0-1 hour	1 -6
Japanese Encephalitis	Serious allergic reaction	0 – 2 weeks	10 - 1000
	Neurological events	0 – 2 weeks	1 – 2.3

[a] Reactions (except anaphylaxis) do not occur if already immune (~ 90% of those receiving a second dose): children over six years are unlikely to have febrile seizures
[b] VAPP risk is higher for first dose (12 per 1.4 to 3.4 million doses) compared to 1 per 5.9 million for subsequent doses and 1 per 6.7 million doses for subsequent contacts.
[c] Seizures are mostly febrile in origin, and the rate depends on past history, family history and age, with a much lower risk in infants under the age of 4 months

Table 4: Common program errors leading to AEFIs		
	Program Errors	*Possible AEFI*
Non-sterile injection		
	• Contact of needle with unsterile surface e.g. finger, swab, table etc. • Contaminated vaccine or diluent • Administering injection over clothes • Improper handling of vaccine vials like touching of septum	 Infection e.g. local abscess at site of injection, sepsis
	• Use of reconstituted vaccines beyond the stipulated time (4 hrs for BCG and Measles, 2 Hrs for JE) • Reuse of reconstituted vaccine at subsequent sessions	Toxic shock syndrome or death.
	• Reuse of disposable syringe & needle • Improper storage and handling of syringes and needles leading to loss of sterility • Syringes and needles used after expiry date	 Blood-borne infections e.g. Hep B, HIV, Hep C etc., Abscess 
Reconstitution error/ Wrong vaccine preparation		
	• Reconstitution with incorrect diluent • Reuse of the reconstitution syringe • Use of expired vaccine or diluents	Less vaccine effectiveness
	• Drug substituted for diluent	Drug reaction; Death
	• Inadequate shaking of T-series vaccines	Local abscess
Injection at incorrect site/route		
	• Injection into gluteal region (buttocks)	 Sciatic nerve damage, paralysis
	• BCG/T series vaccine given subcutaneously	Local reaction or abscess

Vaccine transportation/storage incorrect		
	• Improper storage of vaccines like freezing of T-series vaccines and subsequent administration of frozen and thawed freeze-sensitive vaccine	Increased local reaction such as sterile abscess Less Vaccine effectiveness
Contraindications ignored		
	• DPT2 given after history of convulsions with DPT1	More severe convulsions

2. Isolated and Clusters of AEFI

2.1 Isolated AEFI:

This is a solitary medical incident that takes place after immunization, causes concern and is believed to be caused by immunization

2.2 Cluster AEFI:

A cluster is defined as two or more cases of the same or similar event, which is related in time, and has occurred within the same district or geographical unit, or associated with the same vaccine, same batch number administered or same vaccinator.

3. Channels of reporting of AEFIs

It is essential that the health staff identify and report all serious and non serious adverse events following immunization. The details of reporting system of AEFI has been provided in the National AEFI Surveillance and response Operational Guidelines, 2010. The non-serious AEFI should be reported "routinely" on a monthly basis and the serious AEFI should be reported immediately and also included in the monthly report and the line list (refer to pg 111-112 of National AEFI Guidelines, 2010). The case definitions of the reportable AEFI are given in the Annex 5.

There are two channels of reporting AEFIs:

1. Monthly routine reporting
2. Immediate serious AEFI reporting

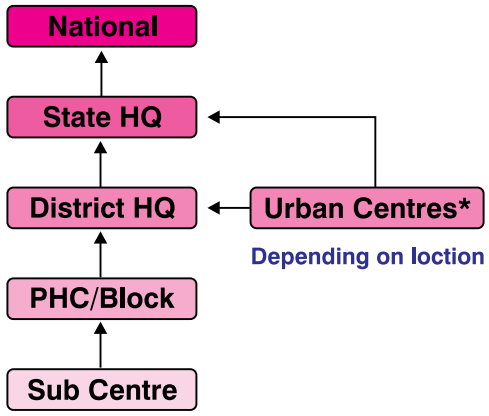
3.1 Monthly routine reporting:

This includes reporting of all non-serious and serious AEFIs outlined in table 2 and 3 from the level of Health worker (Auxiliary Nurse Midwife or ANM) up to the National level (coordinated by the district) through monthly progress reports (fig 3.1) using existing immunization monthly progress reports / forms (vary from state to state). It is necessary for the ANM to submit "Nil" report in case no AEFI case detected from her area during the month. This information is collated and compiled by health workers in monthly reporting formats under the heading of "Any untoward reactions or reportable AEFIs" and forwarded to the next level. These include,

1. Deaths
2. Injection site Abscesses
3. High Grade Fever (> 1020 F)

4. Persistent inconsolable screaming (> 3 hours)
5. Seizure
6. Hypotonic Hypo responsive episode (HHE)
7. Other complications (including the cases not listed above such as severe local reaction, brachial neuritis, thrombocytopenia, lymphadenitis, disseminated BCG infection, osteitis/ osteomyelitis and any untoward incident that the vaccinator, ANM, Medical Officer think is a result of Immunization –both immediate and/or delayed.)

Fig 3.1 AEFI Monthly Reporting - Data Flow



* Monthly reports to be sent to the respective district OR state HQ through the Asst Health Officer (EPI) / Corporation Immunization Officer I/C

3.2 Immediate notification of Serious AEFI

The serious AEFI is defined as "any untoward medical occurrence that results in death, hospitalization or prolongation of hospitalization, persistent or significant disability/ incapacity, or is life threatening". All serious AEFI are to be immediately notified by the first person who identifies the event. This 'first' person should notify the case to the nearest government PHC, CHC and / or the District Immunization Officer (DIO) / by quickest means of communication e.g. telephone, messenger etc. All persons involved in reporting AEFI should be aware of the timeline and channels of reporting. Notification should be followed up with a First Information Report (FIR - Annex 1).

Serious AEFIs:

1. Death
2. Hospitalization
3. Disability
4. Life threatening events
5. Cluster of 2 or more cases

3.3 The process of reporting serious AEFIs:

These events are an emergency and need to be immediately investigated, managed and reported on standardized AEFI formats. Each serious event(s) should be followed up to determine the cause for its occurrence (causality assessment).

In India, the following reporting reports are used to guide AEFI investigation and causality assessment.

1. First Information Report (FIR): Annex 1
2. Preliminary Investigation Report (PIR): Annex 2
3. Detailed Investigation Report (DIR): Annex 3

4. Reporting and Investigation of AEFI

At Field Level:

- ANMs, Health Assistants (HAs) and other field level health workers (including ASHA) and Medical Officers of Primary Health Centers (MO-PHC) should follow-up all children and mothers vaccinated, during the next vaccination session or follow-up field/ home visits (or post and ante-natal visits), to monitor the occurrence of any AEFI.

- During the vaccination session, vaccinators should inform all parents and guardians about the risk of mild AEFIs that could occur and encourage them to report AEFIs described or any illness that causes concern after the immunization to the respective ANM/Accredited Social Health Activist (ASHA)/ Anganwadi Worker (AWW) or to the MO (PHC).
- Parents and guardians should be given instructions to manage fever with sponge baths, paracetamol, and extra oral fluids. In cases of fever that doesn't subside (with or without a febrile seizure) and for other severe illness, the child should be taken to a treatment facility for immediate consultation and treatment.
- In case of a serious AEFI or other AEFI which warrants investigation, the MO (PHC) should be informed by telephone immediately.
- On receipt of information about any other AEFI, the ANM should report the same in the monthly reporting form as per the existing timeline for monthly reports.

At PHC level:

- Once information regarding an AEFI, including any concerns reported by the parents, is received by the MO (PHC), s/he should personally initiate an investigation to verify the facts. For any serious event, s/he will fill the First Information Report (FIR) (Annex 1).
- If the event is a serious AEFI, the FIR should be filled in duplicate and a copy should be sent to the DIO as soon as possible. For serious events (as above), the completed form should be sent within 24 hours of the report. For all other events, the report should be sent monthly.
- If the reported AEFI is an event that needs investigation, the MO/PHC should inform the DIO of the case(s) by telephone or fax immediately. The MO (PHC) will keep a copy of FIR at PHC level.
- At times, Lab testing is required to confirm or rule out the suspected cause. In such cases, the incriminated vial of vaccine and the syringe used to administer vaccine should be collected and sent under cold chain to the DIO. The details on sample collection are provided in the section 6 of these SOPs. If required, a post-mortem should be conducted to assist with the investigation.
- If the event is due to a programmatic error, actions should be initiated to correct wrong practices in the area and lessons to be shared with all other health facilities.
- In situations where no reports of AEFIs are received during the month, a 'Nil' report should be prepared by writing word 'NIL' across the monthly reporting form and sent to the DIO and a copy kept in a separate file at the PHC.

At Medical Institutions/District Hospital Level:

- All medical officers treating patients with conditions, as given in the list of reportable AEFIs, (especially among the children admitted to pediatric units and children with injection site abscess in the surgical units) should ascertain their immunization history.
- If the event is a serious AEFI, then the FIR should be filled in duplicate and sent to the DIO within 24 hours. Rest of the events should be reported in the monthly reporting form.
- If the AEFI is an event that needs investigation, it should be informed to the DIO by telephone or fax immediately and followed up by FIR within 24 hours.
- Medical officers should give their fullest cooperation to DIOs and District AEFI Committee to investigate AEFI by providing clinical information and by carrying out the appropriate laboratory investigation, and facilitating postmortem investigation, where needed.

- At times, Lab testing is required to confirm or rule out the suspected cause. In such cases, the incriminated vial of vaccine and the syringe used to administer vaccine should be collected and sent under cold chain to the DIO. The details on sample collection are provided in the section 6 of these SOPs. If required, a post-mortem should be conducted to assist with the investigation.

At District or District Immunization Officer (DIO) Level:

- On receipt of FIR from MO (PHC) or hospitals for cases that warrant investigation, the DIO should initiate an investigation following review by the District AEFI Committee.
- The FIR should be sent to directly to the State EPI Officer (SEPIO) and Assistant Commissioner (Immunization Division in MoHFW) within 48 hours of occurrence of the case, the PIR within 7 days of the FIR. The DIR to be sent to the SEPIO within 90 days. The SEPIO will get the causality assessment done, on the basis of all reports following the receipt of DIR and will submit the completed DIR (with causality assessment) to national level within additional 30 days (A total of 120 days for receiving DIR at national level). The original copies of FIR/PIR and DIR should be maintained in a separate file at district level.
- When applicable, the Assistant Commissioner in Immunization division in MoHFW, New Delhi should always be informed of the investigation to take place; s/he will assist in the investigation, whenever possible.
- In the event of death following AEFI, the incriminated vial of vaccine and diluents should be collected and sent under cold chain requirement to Central Drug Laboratory Kasauli for laboratory investigation (Annex 7).
- On completion of the investigation, the DIO should provide feedback on the outcome of the investigation to the MO (PHC) and HA with appropriate corrective measures. The DIO should maintain a line listing of all cases of AEFI reported to him/her through FIR/PIR/monthly reports.

5. District and State AEFI committees

All districts need to have a district AEFI committee to streamline and support AEFI surveillance and case investigation process at the local level. These District AEFI Committees are supported by the State AEFI Committees. The detailed composition and terms of reference of AEFI committees have been given in National AEFI guidelines, 2010 on pg 79-82. It has been noticed in various review meetings that though there are existing committees in majority of the districts in the country, these committees need to be revived and activated, to enable them in supporting AEFI surveillance function.

5.1 District AEFI Committee

Every District must constitute and establish a functioning AEFI committee with DIO as member secretary. The members in the committee should include from the locally available resources persons, representing the above mentioned field, where ever possible. The concerned Block Medical Officers (in charge), where AEFI has occurred could be the special invitee to the District AEFI committee meeting. The committee should meet once in every quarter or earlier as per need. The committee should:

- Analyze the FIR and plan for investigation of the AEFI as a team,
- Provide appropriate information to the drug authority on the important aspects of temporary suspension of the implicated batch of vaccine/ logistics
- Prepare DIR based on the finding of the investigation of the AEFI
- Monitor and analyze non serious AEFI data every quarter

- To support the spokesperson for media communication
- Communicate and share the conclusions and results of investigation with health workers and the community where warranted
- Any other responsibility in context to vaccine safety that the committee would like to add.

5.2 State AEFI Committee

The SEPIO will be the member secretary in State AEFI Committee. The committee to meet at least once every quarter or earlier as per need to do following activities:

- Desk review of the FIR, PIR and DIR for causality assessment
- Inspection of the site visit and interview with the parents of the AEFI case and also interview of the Districts AEFI committee members, if required
- Analysis of similar cases or clustering of cases in the State
- Periodic review of the data base of AEFI case

The details about the AEFI committees can be read in National AEFI Guidelines, 2010.

6. Specimen collection and handling for AEFI

The investigation of a few serious AEFI cases may require the collection of a specimen. The decision on what to be collected can be taken in consultation with District AEFI Committee. Only the appropriate specimen in the correct quantity required for the investigation should be collected. Laboratory specimens should be accompanied by clear supporting documents (LRF, FIR, PIR and other relevant document), reasons for specimen collection and any specific additional request for information by the investigators.

Though it is difficult to generalize what specimens will be required in a given situation as it will depend on the symptoms and signs of the patient and the clinical decisions made by the doctor in charge of the case. Table 6.1 below gives a general outline of some of the specimens that could be collected. The list is not exhaustive.

Table 6.1 Biological specimens to be collected for testing following AEFI

Event	***Specimen from the patient***
Severe Local Reaction Abscess Lymphadenitis	Swab , Blood
CNS Adverse events CNS Symptoms, No paralysis CNS Symptoms, with paralysis	Cerebrospinal fluid (CSF), blood Stool *
Other Anaphylaxis Toxic Shock Syndrome Death	Blood, Blood culture, Post mortem tissue specimen (as directed by physician)

* If paralysis follows administration of OPV, stool specimens are important. These are to be collected as per the guidelines for stool collection in AFP case

The activities and responsibilities for sample collection are described in details in National AEFI guidelines of India, 2010 on pg 51-62. A summary of those activities is given below:

Table 6.2 Activities and responsibilities for specimen collection following an AEFI		
	Activity	***Responsibility***
1	Decision to collect sample (samples should be collected as soon as possible and sent only if the district AEFI committee decides)	• District AEFI committee that includes local Drug Inspector. If required consult state AEFI committee
2	Decision to temporarily suspend the use of implicated batch of the vaccine/diluent/logistics	• MoHFW, Govt. of India. • The local drug authority representative after discussion with the AEFI committee.
3	Collection and sending of samples	• The Drug Inspector and DIO
4	Decision on type of samples that need to be collected	• Based on recommendations of the District AEFI committee. • The Drug Inspector may also collect additional samples as he considers appropriate.
5	Transportation of samples to laboratories	• Preferably DIO and/ or Drug Inspector
6	Funding	• The expenses for activities related to AEFI surveillance, AEFI case management, transportation of vaccine and other AEFI related activities can be made from the available funds under Part C (Immunization) of NRHM PIP (under the provision for 'State specific activities') after due approval by competent authority at block/district/state level. • All expenses towards testing of vaccines in CDL Kasauli and Kolkata will be borne by the respective laboratories. • NIV Pune and NIV Gorakhpur will bear the expenses related to testing of samples for adverse events occurring following JE vaccination.
7	Feedback of Laboratory results	• DIO to share with - District cold chain officer, - Drug Inspector - Block Medical officer reporting the case - Private health facility reporting the case.

7. Monitoring and feedback

At Community Level:

- Whenever a parent, public or any other interested group bring any AEFI to the notice of any member of the health team, they should be assured that after an investigation, they will be informed about the true facts of the situation.

At PHC Level:

- At every monthly meetings, MO (PHC) should discussed the types of AEFI reported, results of investigations, action taken and corrective measures adopted with ANM/ HAs and other field health staff.
- Contents of the Quarterly and annual feedback reports received from district and state level should also be a part of feedback to field health staff during these meetings, whenever these are received.

At District (DIO) Level

- DIO should maintain a log to monitor the completeness and timeliness of FIR/PIR/DIR/ Monthly report received from MO (PHC), and from the reporting hospitals come under his/her purview.
- When Monthly report or the FIR/PIR is not received from a particular hospital or from a PHC by the deadline, reminder should be sent and DIO should make sure that he receives all reporting forms in reasonable time.
- At the end of every quarter, the DIO should convene a meeting of district AEFI committee to discuss all the reported cases in the meeting. The DIO should regularly analyze the data available in FIR/PIR/ DIR/ Monthly reports, a summary report of this should be sent to the MO (PHC) and to the SEPIO.

At State Level

- The SEPIO should maintain a log to monitor the completeness and timeliness of all reporting forms received from the DIOs.
- When reports are not received from a particular DIO, before the timeline, reminder should be sent and SEPIO should make sure that s/he has received all AEFI forms in reasonable time.
- The state should call a meeting of the state AEFI committee to conduct causality assessment of all serious AEFI cases reported from the districts. After the causality assessment, the completed DIRs should be sent to the National level. The assistance of the immunization division from MoHFW may also be sought in the causality assessment process.
- At the end of every quarter and annum, SEPIO should analyze the data available from all the districts and compile a report, and feed back it to the DIOs, reporting Hospitals, expert committee, to the national level, and to all interested officials and institutions. It's contains should be discussed at least Quarterly at the DIO review meetings.

8. Report writing:

The investigation of a serious AEFI at any level should be well documented by mode of collecting information in the standardized formats. A summary report following investigation may also be prepared and shared with the various stakeholders. The report should follow the basic principle of epidemiological investigation and have section on the corrective actions suggested.

Section A **FIRST INFORMATION REPORT (FIR)**

(To be completed by the person reporting the AEFI and sent to MO - Immediately)

(Only for Serious Adverse Events Following Immunization)

Serious AEFI category (Encircle): **Death** / **Hospitalized** / **Cluster*** / **Disability**

State	**District**
Block/ Ward	**Village/ Urban Area**
Address of the site:	
Reported by (Name) :	Today's Date:
Posted at: Designation:	Time of preparing this form: AM / PM
Contact phone number (with STD Code) :	Time sent to MO: AM / PM

Patient Name																								
Age (in months) / Date of Birth																				Sex		Male		Female
Father/Mother Name																								

Complete Address of the Case with landmarks *(Street name, house number, village, block, Tehsil, PIN No., Telephone No. etc.)*

P	I	N	-							P	H	O	N	E	-									

Date of Vaccination	D	D	M	M	Y	Y	Y	Y	Time of Vaccination	H	H	M	M	(	AM	PM	)							
Name of recent Vaccine(s) given:																								
Date of first symptom	D	D	M	M	Y	Y	Y	Y	Time of first symptom	H	H	M	M	(	AM	PM	)							
Current status **(encircle)**	**Death** / **Still Hospitalized** / **Recovered & Discharged** / **Left Against Medical Advice** **(LAMA)**																							
Date of Death	D	D	M	M	Y	Y	Y	Y	Time of Death	H	H	M	M	(	AM	PM	)							
Additional Information:																								

* use separate form for each case in a cluster

Section B: **FIRST INVESTIGATION REPORT (FIR)**

(To be reported by MO to District HQ within 24 hours of AEFI case notification)

(Only for Serious Adverse Events Following Immunization)

AEFI Case ID (To be assigned by DIO): **IND (AEFI)** / *State Code* / *District Code* / *Year* / *Serial No.*

Reporting Medical Officer (Dr.) Name :	Date of filling FIR by MO :
Posted at: Designation:	Mobile No. Fax No.:
Land Line (with STD Code) :	Case Informed By :

If MO disagrees with information in Section A, please record details (with justification) here	

Patient Name																								
Date of Birth	D	D	M	M	Y	Y	Y	Y		Age (in months)				Sex		Male		Female						

Date of Notification	D	D	M	M	Y	Y	Y	Y	Date of Investigation	D	D	M	M	Y	Y	Y	Y		
Date of Vaccination	D	D	M	M	Y	Y	Y	Y	Time of Vaccination	H	H	M	M	(	AM	PM	)		
Date of Onset	D	D	M	M	Y	Y	Y	Y	Time of Onset	H	H	M	M	(	AM	PM	)		

Hospitalization No/ Yes Date	D	D	M	M	Y	Y	Y	Y	Time of Hospitalization	H	H	M	M	(	AM	PM	)

Name and Address of hospital:

Outcome **(encircle)**	**Death / Still Hospitalized / Recovered & Discharged / Left Against Medical Advice (LAMA)**

If died, Date of Death	D	D	M	M	Y	Y	Y	Y	Time of Death	H	H	M	M	(	AM	PM	)

Post mortem done? (*encircle*)	Yes**/ No / Planned on (date) _____	If Yes, Date_____ Time_____

** Attach report (if available) with FIR

Details of vaccine, diluents & Vitamin-A given to the patient

(*In the doses administered column write the dose received by beneficiary like 1st, 2nd, 3rd, booster and any other)

Vaccine/Vit-A/ Diluent	*Dose Administered	Name of Manufacturer (in BLOCK Letters)	Batch No.	Manufacturing Date	Expiry Date
BCG					
BCG Diluent					
DPT					
OPV					
Measles					
Measles Diluent					
Hep-B					
DT					
TT					
Vit-A					
Others					

Place of Vaccination: Govt. Health Facility /Outreach / Private Health Facility/ Other____**Session**: SIA / Routine/ Other ___

Total number of beneficiaries immunized at session site: Pregnant women _____ Children _____

Number of other beneficiaries who received vaccine from the SAME VIAL: _____

Signature of Reporting Medical officer …… **Email id**……

Section C: The following information is to be completed by DIO & forwarded to GoI and State within 24 hours of receiving the above information.

Proposed date of District AEFI committee review meeting for this case	D	D	M	M	Y	Y
Proposed date of preliminary investigation	D	D	M	M	Y	Y

Notes/comments:

DIO/ District Nodal Person ***(Officer forwarding this report)***

Name …… Date.....Designation……..…

Mobile No…….…… Landline (with STD code)…….…… Fax No. ……

Emailid…….. Complete Office address (with Pin code)……

……

……Signature/ Seal

To be sent to : State Immunization Officer & Assistant commissioner
Immunization division of Govt. of India, MOHFW,
Nirman Bhawan, New Delhi – 110108. (Fax No. – 011 23062728 / e mail: aefiindia@gmail.com

Appendix 2

Section A **PRELIMINARY INVESTIGATION REPORT (PIR)**
(To be reported to State & GoI within 7 days of submitting FIR)

(Only for Serious Adverse Events Following Immunization - Death / Hospitalized / Cluster / Disability)

DIO/RCHO/District Nodal Officer to complete all details in BLOCK letters only

State **District** **Case ID** **IND (AEFI) /** *State Code* / *District Code* / *Year* / *Serial No.*

Block/ Ward **Village/ Urban Area**

Place of Vaccination *(encircle)* : Govt. Health Facility/ Private Health Facility/ Other Specify _____
Vaccination in *(encircle)* : SIA / Routine
Type of site *(encircle)* Outreach/ SC/ PHC/ CHC/ BPHC/ Dist Hospital State Hospital/ Medical College/ Other specify _____
Site Address:

Name of Reporting Officer : Date of filling PIR :

Designation: Posted at:

Land Line (with STD Code) : Mobile No. Fax No.:

Patient Name*

* use separate form for each case in a cluster

Date of Birth *D D M M Y Y Y Y* Age (in months) Sex Male Female

Father's Name

Mother's Name

Complete Residential Address of the Case with landmarks *(Street name, house number, village, block, Tehsil, PIN No. etc.)*

P I N - PHONE -

Details of vaccine, diluents & Vitamin-A given to the patient at this session site on the day of the event

Vaccine/Vit-A/ Diluent	*Dose Administered	Name of Manufacturer (in BLOCK Letters)	Batch No.	Manufacturing Date	Expiry Date
BCG					
BCG Diluent					
DPT					
OPV					
Measles					
Measles Diluent					
Hep-B					
DT					
TT					
Vit-A					
Others					

(*In the doses administered column write the dose received by beneficiary like 1st, 2nd, 3rd, booster and any other)

Date of First Information *D D M M Y Y Y Y* Date of Preliminary Investigation *D D M M Y Y Y Y*

Date of Vaccination *D D M M Y Y Y Y* Time of Vaccination *H H M M (AM PM)*

Date of first symptom *D D M M Y Y Y Y* Time of first symptom *H H M M (AM PM)*

Date of Hospitalization *D D M M Y Y Y Y* Time of Hospitalization *H H M M (AM PM)*

Outcome (encircle) **Death /Still Hospitalized /Discharged /Left Against Medical Advice (LAMA)/Not Hospitalized**

Date of Death *D D M M Y Y Y Y* Time of Death *H H M M (AM PM)*

Post mortem done? (*encircle*) Yes/ No / Planned on (date) _____ If Yes**, Date_____ Time_____
** Attach report (if available) with FIR

Section B	**Relevant information of the patient prior to immunization:**	
		If 'Yes', specify
Past H/o similar event	Yes / No	
Reaction after previous vaccination	Yes / No	
H/o allergy	Yes / No	
Pre-existing illness / disorder	Yes / No	
H/o hospitalization in last 30 days with cause	Yes / No	
Recent H/o trauma with date, time, site and mode	Yes / No	
For adult women Currently pregnant? Currently Breastfeeding	 Yes / No Yes / No	
Family History of any disease or allergy	Yes / No	
Natal history Delivery	Full term / pre mature / post dated Normal / Caesarian / Assisted birth / any complication (specify)	
Was the patient on any concurrent medication for any illness (if Yes : name the drug, indication & Doses)	Yes / No /Unknown	

Section C	**Details of first examination* of serious AEFI case**
***Instructions – Attach copies of ALL available documents and then complete additional information NOT AVAILABLE in existing documents** (case sheet, discharge summary, case notes, post mortem reports etc). i.e. If Patient has taken medical care - Attach copies of all available documents (including case sheet, discharge summary, laboratory reports and post mortem reports - if available) and complete only additional unavailable information below If patient has not taken medical care – Complete this form fully **If the investigator has disagreement with the findings in any of the document(s) mentioned above, the same may be expressed here with justification**	
Source of information (*encircle all that apply*): **Examination by the investigator/ Documents/ Verbal autopsy/ Other _____**	
If from verbal autopsy, please mention the source (encircle)	Name of the person who first examined the child:_____ Other sources (specify)
Signs and Symptoms in Chronological order:	
The clinical details below are filled up by_____	Designation:
Date and time of onset of 1st symptoms:	Date and time of examination:

Findings on initial examination that are NOT documented in the available documents or if the investigator disagrees with the information documented please record details (with justification) here

Consciousness	Alert / drowsy / Unconscious other (specify)_____ Describe:
Vitals	Pulse Temperature Respiratory rate BP
Skin	Rash / cyanosis / petechiae / pallor / jaundice / others (specify)_____ Describe:
Eyes	Vision: Normal / Impaired Pupil : Normal / Constricted / Dilated / Reacting to light
Hearing Speech	Normal / Impaired (Describe) Normal / Abnormal (Describe)

Neck	Neck Stiffness: Present / Absent
Chest	Auscultation Normal / Crepts / Rhonchi Heart sounds Normal / Murmur (Describe)
Respiratory	Normal / Cough / Shortness of breath / others (specify)_____ Describe:
GI	Pain abdomen / Vomiting / diarrhea / dysentery / others (specify)_____ Describe:
Abdomen	Normal / Distended / Tender Liver : Not palpable / Palpable (If palpable specify size) Spleen : Not palpable / Palpable (If palpable specify size) (Describe)
Limbs	Tone Upper Limbs Normal / Increased / Decreased Lower Limbs Normal / Increased / Decreased Reflexes Biceps Normal / Increased / Decreased / Absent Triceps Normal / Increased / Decreased / Absent Supinator Normal / Increased / Decreased / Absent Plantar Extensor / Flexor

Any other abnormal signs.

Treatment provided:

Provisional diagnosis:

Add additional pages if needed

Section D	**Details of immunization provided at the site on the day AEFI reported**										
Number of beneficiaries immunized for each antigen at session site. Attach record if available.	BCG	Hep-B1	OPV Birth	Hep B Birth	DPT-1	DPT-2	DPT-3	DPT-B1	DPT-B2	OPV-1	OPV-2
	OPV-3	OPV-B	Hep-B2	Hep-B3	Measles	DT	TT-1	TT-2	TT-B	Vit-A	Others

a) Number of beneficiaries immunized from the implicated vaccine vial/ampoule	
b) When was the patient immunized? (*encircle below*)	
Within the first vaccinations of the RI session / Within the last vaccinations of the RI session / Unknown	
Within the first few doses of the vial administered/ Within the last doses of the vial administered/ Unknown	
c) Number of OTHER beneficiaries immunized with the implicated vaccine vial in the same session	
d) Number of OTHER beneficiaries immunized with the implicated vaccine having the same batch number in the PHC/ CHC / district hospital/ other location specify _____	
c) Is this case a part of a cluster?	Yes / No
a. If yes, How many other cases have been detected in the cluster?	
b. Did all the cases receive vaccine from the same vial?	Yes / No
c. If No, Number of vials implicated	

Section E **Immunization practices <u>at the location (s) where implicated vaccine was used</u>**
(fill up this section by asking & or observing practice)

Last vaccine storage point:

Temp of ILR (^{0}C)		
Temp of deep freezer (^{0}C)		
Correct procedure of storing vaccines, diluents and syringes followed?	Yes	No
Any other item (other than RI vaccines and diluents) in the ILR or freezer?	Yes	No
Partially used reconstituted vaccines in the ILR?	Yes	No
Unusable vaccines (expired, no label, VVM stage 3 & 4, frozen) in the ILR?	Yes	No
Unusable diluents (expired, manufacturer not matched, cracked, dirty ampoule) in the store?	Yes	No
Specific key findings/additional observations and comments:		

Vaccine Transportation:

Type of vaccine carrier used		
Vaccine carrier sent to the RI site on the same day of vaccination?	Yes	No
Vaccination carrier returned from the RI site on the same day of vaccination?	Yes	No
Conditioned ice-pack used?	Yes	No
Specific key findings/additional observations and comments:		

Syringes and Needles Used:

Are AD syringes used fro immunization?	Yes	No
If No, specify the type of syringes used: Glass/ Disposable/ Recycled disposable/ other specify _____		
Specific key findings/additional observations and comments:		

Reconstitution: (complete only if applicable, write NA if not applicable)

Reconstitution procedure (*encircle*)			
Same reconstitution syringe used for multiple vials of same vaccine?	Yes	No	NA
Same reconstitution syringe used for reconstituting different vaccines?	Yes	No	NA
Separate reconstitution syringe for each vaccine vial?	Yes	No	NA
Separate reconstitution syringe for each vaccination?	Yes	No	NA
Are the vaccines and diluents from the same manufacturer?	Yes	No	NA
Specific key findings/additional observations and comments:			

Injection technique: (Observe another session in the same locality – same or different place)

Correct dose and route?	Yes	No
Time of reconstitution mentioned on vial *(in case of BCG, Measles, JE)?*	Yes	No
Non-touch technique followed?	Yes	No
Contraindication screened prior to vaccination?	Yes	No
How may AEFI reported from the centre that distributed the vaccine in last 30 days?		
Training on RI received by the vaccinator : *(If Yes specify date of last training_____)*	Yes	No
Specific key findings/additional observations and comments:		

Private practitioner: (complete only if applicable, write NA for not applicable)

Source of vaccine (*encircle*)	Government Supply	Procured from manufacturer	Pharmacy (Chemist)	Others
Address of source from where vaccine was obtained for this patient				

Status of cold chain at private clinic (*encircle*)	Satisfactory***/ Unsatisfactory/ Not observed (specify why_____)
Status of cold chain at procurement site (*encircle*)	Satisfactory***/ Unsatisfactory/ Not observed (specify why_____)

***If it complies with ALL criteria in section E "Last vaccine storage point"

Additional observations and comments:

Section F Community Investigation (Please visit locality and interview parents/ others)

Any similar events reported recently in the locality? Yes / No
If Yes, Describe:

If Yes, How many events / Episodes?

Of those effected, How many are
Vaccinated:_____
Not Vaccinated:_____
Unknown:_____

Section G	**District AEFI Committee Review & Investigation Report**						
a) District AEFI committee review held?					Yes		No
If Yes, then date of review by district AEFI committee					D D M		M Y Y
b) Any implicated samples sent for testing following District AEFI committee review?					Yes		No

Details of Vaccine/ Diluent samples sent to CDL Kasauli

Vaccine/Diluent Name	Used Vial/Amp. Quantity	Batch no, Lot no, date of expiry	Date Sent	Unused Vial/Amp. Quantity	Batch no, Lot no, date of expiry	Date Sent

Details of Syringe/ Needle samples sent to CDL Kolkata

Type of Syringes	Quantity	Batch no, Lot no, date of expiry	Date Sent	Type of Needles	Quantity	Batch no, Lot no, date of expiry	Date Sent

c) Any **biological product** (CSF, Blood, Urine, etc) sent for testing? *If yes , specify details of the lab; attach copy of report if available* *Note: for AEFI resulting within 28 days following JE vaccine ,send sample of CSF, Serum to nearest NIV lab in Pune or Gorakhpur.*	Yes	No
d) Was local drug inspector involved in collecting additional samples?	Yes	No
e) Other investigation, specify the findings and attach report.		

Section H	**Preliminary Assessment (working hypothesis of AEFI committee):**				
Probable underlying cause of the adverse event:					
Type of Adverse Event suspected based on preliminary findings *(encircle)*	Programme Error	Vaccine Reaction*	Coincidental	Injection Reaction	Unknown

Specific reasons for suspecting the above:

Corrective actions/recommendations:

If an event is suspected to be related to vaccine(s)/ diluent(s), immediate efforts should be initiated by DIO/ District Cold chain Officer to collate the information related to - Number of blocks supplied with the suspected batch and Number of beneficiaries vaccinated with the suspected batch.

Attached copies of reports / documents etc with this PIR:

1.
2.
3.
4.
5.
6.

District AEFI Committee that conducted the preliminary investigation

Name	Designation	Phone #	Signature
1.			
2.			
3.			
4.			
5.			
6.			
7.			

Section I **DIO/ District Nodal Person** ***(Officer forwarding this report)***

Name …… Designation……..…Date of submission to state/ national level……

Mobile No…….. Landline (with STD code)…… Fax No. ……

Email id……. Complete Office address (with Pin code)……

……

……Signature/ seal……..Date

Please ensure that this PIR form (ALL 7 pages) reach:
State Immunization Officer & Assistant commissioner, Immunization division of Govt. of India, MOHFW, Nirman Bhawan, New Delhi – 110108.
(Fax No. – 011 23062728 / Email: aefiindia@gmail.com)

Important Laboratory Addresses:

Send Vaccines and Diluents to	Send syringes and needles to	Send Biological specimens to	
CDL Kasauli	CDL Kolkata	NIV Gorakhpur	NIV Pune
Director. Central Drugs Laboratory Central Research Institute Kasauli – 173204. Himachal Pradesh.	Director Central Drugs Laboratory Ministry of Health & Family Welfare Govt. of India 3, KYD Street Kolkata-700016	Director Officer In-Charge National Institute of Virology Gorakhpur Unit. BRD Medical College Campus Gorakhpur – 273013.	Director National Institute of Virology 20/ A, Dr. Ambedkar Road. Post Box No. 11, Pune - 411001 Maharashtra
Email : nclkasauli@bsnl.in	Email: cdlkol@gmail.com	Email: cdlkol@gmail.com	E-mail : nivicl@pn3.vsnl.net.in
Phone: 0179-2272046 0179-2272060	Phone: 033-22299021 033-22870513	Phone : 0551-2506698	Phone : 020-26127301 020-26006290
Fax: 0179-2272049 0179-2272016	Fax : 033-222 99380 033-222 99541	Fax : 0551-2506698	Fax: 020-26122669 020-26126399

For State level use only

Note: *If an event is suspected to be related to vaccine(s)/ diluent(s), then immediate efforts should be initiated by State Immunization Officer and State Cold chain Officer to collate the information related to the districts supplied with the suspected batch and number of beneficiaries vaccinated with the suspected batch. The consolidated data needs to be sent to the govt of India as early as possible

Section A ***DETAILED INVESTIGATION REPORT (DIR)***

(To be reported by district AEFI committee to State & GoI within 90 days of filling FIR)

(Only for Serious Adverse Events Following Immunization - Death / Hospitalized / Cluster / Disability)

DIO to fill page 1 to 4 and SEPIO to fill page 4 & 5 to complete all details in BLOCK letters only

State **District** **Case ID** **IND (AEFI) /** *State Code* / *District Code* / *Year* / *Serial No.*

Block/ Ward **Village/ Urban Area**

Place of Vaccination *(encircle)* : Govt. Health Facility/ Private Health Facility/ Other Specify _____
Vaccination in *(encircle)* : SIA / Routine
Type of site *(encircle)* Outreach/ SC/ PHC/ CHC/ BPHC/ Dist Hospital State Hospital/ Medical College/ Other specify _____
Site Address:

Name of Reporting Officer : Date of filling this **DIR** :

Designation: Posted at:

Land Line (with STD Code) : Mobile No. Fax No.:

Patient Name*

* use separate form for each case in a cluster

Date of Birth *D D M M Y Y Y Y* Age (in months) Sex Male Female

Father's Name

Mother's Name

Complete Residential Address of the Case with landmarks *(Street name, house number, village, block, Tehsil, PIN No. etc.)*

P I N - P H O N E -

Date of Vaccination *D D M M Y Y Y Y* Time of Vaccination *H H M M (AM PM)*

Date of Onset *D D M M Y Y Y Y* Time of Onset *H H M M (AM PM)*

Date of Hospitalization *D D M M Y Y Y Y* Time of Hospitalization *H H M M (AM PM)*

Outcome **(encircle)** **Death/Still Hospitalized / Discharged / Left Against Medical Advice (LAMA)/ Not Hospitalized**

Date of Death *D D M M Y Y Y Y* Time of Death *H H M M (AM PM)*

Date of Post Mortem *D D M M Y Y Y Y* Time of Post Mortem *H H M M (AM PM)*

Documents attached with this DIR: (Please retain the original and enclose ONLY COPIES)

Sl. No.	Documents	Date of submission/ completion	Attached with this document? *(encircle)*	Remarks (if any) and in case response is "No" then give reason
1.	First Information Report (FIR)		Yes / No	
2.	Preliminary Investigation Report (PIR)		Yes / No	
3.	Post Mortem Report done? *(in case of death)*		Yes / No	
4.	Result of any Pathology/Microbiology (Blood, CSF and Urine) Test done?		Yes / No	
5.	Doctor's prescription/treatment record for this AEFI		Yes / No	
6	Doctor's prescription/treatment record for other illness		Yes / No	
7.	Report of Laboratory test of vaccine/ diluent (if sent for testing)		Yes / No	

8.	Report of Laboratory result of syringes/other drugs (if sent for testing)		Yes / No	
9.	Any other document relevant to case		Yes / No	*If Yes, specify & attach report*

Refer to FIR & PIR for writing the following case summary. Remember to include the following points, add additional sheet as necessary:

1. Detailed history of signs and symptoms and signs in chronological order
2. Additional relevant information prior to immunization:
3. Status of immunization on the day of AEFI reported (Completed doses before the event):
4. Vaccines administered on the day of the event:
5. Examination findings on first examination of serious AEFI case:
6. Any other abnormal signs (if any observed during initial examination). Add additional pages if needed:
7. Progress of the patient's condition, treatment provided and diagnosis:
8. Details of Community investigation if conducted:

CASE SUMMARY

Please add additional sheets to complete…

Please add additional sheets to complete…

DIO's report on District Assessment (working hypothesis of AEFI committee)					
Probable underlying cause of the adverse event:					
Type of Adverse Event suspected based on preliminary findings *(encircle)*	Programme Error	Vaccine Reaction*	Coincidental	Injection Reaction	Unknown

Specific reasons for suspecting the above:
Corrective actions/recommendations:

Details of District AEFI Committee members who conducted the preliminary investigation		
Name	**Designation**	**Phone #**
1.		
2.		
3.		
4.		
5.		
6.		
7.		

****If an event is suspected to be related to vaccine(s)/ diluent(s), then immediate efforts should be initiated by DIO/ District Cold chain Officer to collate the information related to - Number of blocks supplied with the suspected batch and Number of beneficiaries vaccinated with the suspected batch and the consolidated data needs to be reported in the following table:***

Name of Vaccine/Diluent	Batch of suspected vaccine/diluent	Total number of blocks supplied with suspected vaccine/diluent in the district	Total number of beneficiaries vaccinated with suspected batch in the district	
			Children	Adults/ Preg women

DIO/ District Nodal Person *(Officer forwarding this report)*

Name …… Designation……..…Date of submission to state/ national level……

Mobile No…… Landline (with STD code)…… Fax No. ……

Email id…… Complete Office address (with Pin code)……

……..…

……Signature/ seal……..Date

Section B	**To be completed at State Level** *(Office of State Immunization Officer)*

Date of receipt of this DIR at State	D	D	M	M	Y	Y	Y	Y

State/UT Causality Assessment Report

Note: *State vaccine safety (AEFI) committee to complete causality assessment exercise and forward the report to GoI within 90 days of filling FIR.*

Preparation for causality assessment check list for state EPI officer:

Sl. No.	List of document copies sent to the Govt of India	Availability *(encircle)*	Remarks (if any) / (if no why)
1.	First Information Report (FIR)	Yes / No	
2.	Preliminary Investigation Report (PIR)	Yes / No	
3.	Is the case summary completed in this DIR?	Yes / No	
4.	Report of Post Mortem Report done? *(in case of death)*	Yes / No	
5.	Report of any Pathology/Microbiology (Blood, CSF, Urine) Test done?	Yes / No	
6.	Doctor's prescription/treatment record for AEFI	Yes / No	
7.	Doctor's prescription/treatment record for other illness	Yes / No	
8.	Laboratory result of vaccine (if sent for testing)	Yes / No	
9.	Laboratory result of syringes/other drugs (if sent for testing)	Yes / No	
10.	Any other document relevant to case	Yes / No	*If Yes, specify & attach report*

Conclusion of State AEFI committee on causality					
Probable underlying cause of the adverse event:					
Type of Adverse Event suspected based on findings *** *(encircle)*	Programme Error	Vaccine Reaction	Coincidental	Injection Reaction	Unknown

*****Causality: Very likely/Certain/ Probable/Possible/ Unlikely/Unrelated/Unclassifiable**

(*** Refer to the relevant section on the Operational Guidelines on AEFI Surveillance – 2010 MoHFW – Government of India)

Specific reasons for suspecting the above:
Corrective actions/recommendations:

Details of State AEFI Committee members who conducted the causality assessment			
Name	**Designation**	**Phone #**	**Signature**
1.			
2.			
3.			
4.			
5.			
6.			
7.			

Date of review of this case	D	D	M	M	Y	Y	Y	Y	Date of submission of report to GoI								

**If an event is suspected to be related to vaccine(s)/ diluent(s), then immediate efforts should be initiated by DIO/ District Cold chain Officer to collate the information related to - Number of blocks supplied with the suspected batch and Number of beneficiaries vaccinated with the suspected batch and the consolidated data needs to be reported in the following table:*

Name of Vaccine/Diluent	Batch of suspected vaccine/diluent	Total number of blocks supplied with suspected vaccine/diluent in the district	Total number of beneficiaries vaccinated with suspected batch in the district	
			Children	Adults/ Preg women

State Nodal Person (Officer forwarding this report)

Name …… Designation……..…Date of submission to national level……

Mobile No…….…… Landline (with STD code)…….…… Fax No. ……

Email id……. Complete Office address (with Pin code)…….

……..…
……Signature/ seal……..Date

Please ensure that this DIR form reaches:

Assistant Commissioner,
Immunization division of Govt. of India, MOHFW, Nirman Bhawan,
New Delhi – 110108.
(Fax No. – 011 23062728. or Email : aefiindia@gmail.com)

Section C ***For use at National Level (Office of Assistant Commissioner- UIP)***								
Date of receipt of DIR from District	D	D	M	M	Y	Y	Y	Y
Date of receipt of DIR from State ***(with Causality assessment report)***	D	D	M	M	Y	Y	Y	Y

AEFI – LABORATORY REQUESITION FORM (LRF)
(To be completed by Drug Inspector/DIO. LRF should be accompanied with specimens)

(For Serious Adverse Events Following Immunization)

AEFI category (Encircle): **Death / Hospitalized / Cluster / Disability**

State		**Case ID**	**IND (AEFI) /** *State Code* / *District Code* / *Year* / *Serial No.*
District			
Block			

Name of Drug Inspector/DIO: Date of filling LRF :

Designation: Mobile No.:

Land Line (with STD Code) : Fax No.:

Case Name

Date of Birth (*D D M M Y Y Y Y*) Age (in months) Sex Male Female

Complete Address of the Case with landmarks *(Street name, house number, village, block, Tehsil, PIN No., Telephone No. etc.)*

P I N - P H O N E -

Date of vaccination (*D D M M Y Y Y Y*)		Date of Onset (*D D M M Y Y Y Y*)	
Date of collection of specimen (*D D M M Y Y Y Y*)		Time of collection of specimen (*H H M M (AM PM)*)	

1. Precise description of samples:

a) For vaccine/diluents specimens: (to be transported in reverse cold chain)

Mention vaccine/diluent	Quantity Sent	Name of Manufacturer (in BLOCK Letters)	Batch No.	Manufacturing Date	Expiry Date

b) For logistics specimens: (AD, Reconstitution, Disposable syringes)

Mention Logistics	Quantity Sent	Name of Manufacturer (in BLOCK Letters)	Batch No.	Manufacturing Date	Expiry Date

c) For Biological product specimen: (CSF, Blood, Urine, etc)

2. Test requested:

Name of AEFI Case:	**Case ID** **IND (AEFI)** / *State Code* / *District Code* / *Year* / *Serial No.*

3. Preliminary clinical diagnosis (working hypotheses) of district AEFI committee:

4. Name & complete address of officials to whom laboratory results should be sent:

Send to	Complete address	Phone/Fax	Mobile	Email-ID
State Drug Controller				
State Cold Chain Officer				
State EPI Officer				
District Immunization Officer (DIO)				
Others (specify)				

To be completed by lab officials after receiving the specimen

Date of receipt of specimen at laboratory	*D*	*D*	*M*	*M*	*Y*	*Y*	*Y*	*Y*
Name of person receiving specimen(s) at laboratory								
Condition of specimen upon receipt at lab (*encircle*)	Good*		Poor		Unknown			
Comments by pathologist, virologist or bacteriologist:								
Date specimen results sent from this lab	*D*	*D*	*M*	*M*	*Y*	*Y*	*Y*	*Y*
Name of laboratory professional								
Signature								

Landline No. :	Fax No.:	Email Id:

**** Criteria for "good" condition: Samples sent as per AEFI guidelines.***

Annex 5:

Case definitions of some reportable adverse events.

AEFI	Case definition	Vaccine
Vaccine associated paralytic poliomyelitis (presenting as AFP)	An acute flaccid paralysis 4–30 days following receipt of oral polio vaccine (OPV), or within 4–75 days after contact with a recipient of OPV, with neurological deficits remaining 60 days after onset, or death.	OPV
Anaphylactoid reaction (acute hypersensitivity reaction)	Exaggerated acute allergic reaction, occurring within 2 hours after immunization, characterized by one or more of the following: ● wheezing and shortness of breath due to bronchospasm ● laryngospasm/laryngeal edema ● One or more skin manifestations, e.g. hives, facial edema, or generalized edema. Do not report less severe allergic reactions	All
Anaphylaxis	Severe immediate (within 1 hour) allergic reaction leading to circulatory failure with or without bronchospasm and/or laryngospasm/laryngeal edema.	All
Disseminated BCG infections	Widespread infection occurring within 1 to 12 months after BCG vaccination and confirmed by isolation of Mycobacterium bovis BCG strain. Usually in immuno-compromised individuals.	BCG
Encephalopathy	Acute onset of major illness characterized by any two of the following three conditions: ● Seizures ● severe alteration in level of consciousness lasting for one day or more ● Distinct change in behavior lasting one day or more Needs to occur within 48 hours of DPT vaccine or from 7 to 12 days after measles vaccine, to be related to immunization.	Measles, Pertussis
Fever	The fever can be classified (based on temperature) such as ● Mild fever: 100.4°F to 102°F (38 to 38.9°C), ● High fever: 102°F to 104.7°F (39 to 40.4°C) and ● Extreme fever: 104.7°F or higher (>40.5°C).	All
Hypotonic, hypo responsive episode (HHE or shock-collapse)	Event of sudden onset occurring within 48 [usually less than 12] hours of vaccination and lasting from one minute to several hours, in children younger than 10 years of age. All of the following must be present: ● limpness (hypotonic) ● reduced responsiveness (hypo responsive) ● pallor or cyanosis – or failure to observe/ recall	Mainly DPT, rarely others
Injection site abscess	Fluctuant or draining fluid filled lesion at the site of injection. Bacterial if evidence of infection (e.g. purulent, inflammatory signs, fever, culture), Sterile abscess if no evidence of bacterial infection on culture. Sterile abscesses are usually due to the inherent properties of the vaccine.	All injectable vaccines

AEFI	Case definition	Vaccine
Lymphadenitis (includes Suppurative lymphadenitis)	Either at least one lymph nodes enlarged to >1.5 cm in size (one adult finger width) or a draining sinus over a lymph node. Almost exclusively caused by BCG and then occurring within 2 to 6 months after receipt of BCG vaccine, on the same side as inoculation (mostly axillary).	BCG
Osteitis/ Osteomyelitis	Inflammation of the bone with isolation of Mycobacterium bovis BCG strain.	BCG
Persistent inconsolable screaming	Inconsolable continuous crying lasting 3 hours or longer accompanied by high pitched screaming.	DPT, Pertussis
Seizures	Occurrence of generalized convulsions that are not accompanied by focal neurological signs or symptoms. Febrile seizures: if temperature elevated >100.4°F or 38°C (rectal) Afebrile seizures: if temperature is normal	All, especially Pertussis, Measles
Sepsis	Acute onset of severe generalized illness due to bacterial infection and confirmed (if possible) by positive blood culture. Needs to be reported as possible indicator of Program error.	All injectable vaccines
Severe local reaction	Redness and/or swelling centered at the site of injection and one or more of the following: ● Swelling beyond the nearest joint ● Pain, redness, and swelling of more than 3 days ● Requires hospitalization. Local reactions of lesser intensity occur commonly and are trivial and do not need to be reported.	All injectable vaccines
Toxic shock syndrome (TSS)	Abrupt onset of fever, vomiting and watery diarrhea within a few hours of immunization. Often leading to death within 24 to 48 hours. Report as a possible indicator of program error.	All injectable vaccines

Annexure 6:

Role and responsibilities in response to AEFIs

The following table summarizes the role and responsibilities in response to a AEFI case, (for details refer to page 6 and for treatment guidelines refer Annexure 6a).

Situation	Action	Person	Timeline
Village			
Mild symptoms like fever, pain after vaccination	• Advise cold sponging & Inform ANM/ HW(M)	**ASHA/AWW**	Same day
Injection Site Abscesses, excessive Crying etc	• Advise cold fomentation for abscesses & Inform ANM/HW(M)		Immediately
Serious AEFI	• Inform ANM/MO		Immediately
Sub-centre			
Mild symptoms like fever, pain after vaccination	• Appropriate treatment at local level	**ANM / HW(M)/ LHV**	Same day
Injection Site Abscesses, excessive Crying etc	• Give first –aid and refer to PHC/CHC		At the earliest/Same day
Serious AEFI	• Give first-aid and Immediately refer to nearest health facility • Inform MO-I/C of PHC		Immediate/Half hour
PHC/CHC			
Injection Site Abscesses, excessive Crying etc	• Appropriate treatment	**Medical Officer / M.O.-I/C**	Initiate treatment same day
Serious AEFI	• Appropriate management with emergency drugs. • If the patient requires further specialized treatment, stabilize the patient and refer to nearest facility (District Hospital/Medical College) for further management • Inform District Immunization Officer		Immediate
District Hospital			
Serious AEFI	• Appropriate management of patient	**Paediatrician / Medical Officer**	Immediate
	• Rush a team to the sub-centre/ village where session was conducted to find about any other similar AEFI case		At the earliest

Annex 12:

List of Key contacts

For what activity	Name and address	Contact Details
Reporting AEFI by sending FIR, PIR and DIRs	Assistant Commissioner (Immunization), Ministry of Health & Family Welfare, Nirman Bhawan, New Delhi-110011	Tel : 011- 23062126 Fax : 011-23062728, 23062126 Email : aefiindia@gmail.com
For Shipment of vaccines and diluents	Head, Central Drugs Laboratory, Central Research Institute, Kasauli – 173 204. Himachal Pradesh.	Tel : 0179-2272046, 2272060 Fax : 0179-2272049, 2272016 Email : nclkasauli@gmail.com
For Shipment of syringes, needles and vitamin A	The Director, Central Drug Laboratory, Min. of Health & Family Welfare, Govt. of India, 3, Kyd Street, Kolkata- 700016	Tel : 033- 22299541 Fax : 033-222 99380, 033- 222 98336 Email : cdlkol@gmail.com
Biological specimens for JE Vaccine	The Director, National Institute of Virology (NIV) (JE Group), MCC 130/1,Sus Road, Pashan, Pune-411021	Tel : 020-26006390, 020-26127301, 020-26006290; Fax : 020-25871895, 020-26122669, 020-26126399 Email : nivicl@pn3.vsnl.net.in, acm1750@rediffmail.com (www.niv.co.in)
	Officer In Charge NIV, Gorakhpur Unit BRD Medical College Campus Gorakhpur-273013	Tel : 0551-2506698 Fax : 0551-2506698 Email : goremilind@gmail.com

World Health Organization
Printed by WHO on behalf of Ministry of Health & Family Welfare, Government of India

Adverse Event Following Immunization
Standard Operating Procedures (SOPs)

Ministry of Health and Family Welfare
Government of India