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Ministry of Health & Family Welfare
Government of India

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AEFI SURVEILLANCE PROCESSES

A GUIDANCE DOCUMENT FOR STATES

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Ministry of Health & Family Welfare
Government of India

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Government of India
Ministry of Health & Family Welfare
Nirman Bhavan, New Delhi - 110011

MESSAGE

The Government of India's Universal Immunization Program (UIP) envisages to protect all eligible beneficiaries from vaccine preventable diseases (VPD) by administering life-saving vaccines. India has the largest cohort of eligible beneficiaries in the world i.e. 26 million children and 29 million pregnant women who are to be vaccinated every year through 12 million immunization sessions being conducted by trained health workers across the country.

With the introduction of newer vaccines such as rotavirus vaccine, pneumococcal vaccine and measles rubella vaccines, Government of India has made sustained efforts to increase the vaccine coverage among the target beneficiaries and launched Intensified Mission Indradhanush 2.0 to continue to sustain the achievements made during the previous rounds of Mission Indradhanush.

In order to ensure that safety and effectiveness of the vaccines being used under UIP, the Govt. of India has taken a series of steps to strengthen the Adverse Event Following Immunization (AEFI) surveillance in the country. The national AEFI operational guidelines aims to provide the overall direction to the national, state and district programme managers to establish and maintain sensitive AEFI surveillance. Based on the feedback and suggestions received from various stakeholders, Immunization Division, MoHFW has developed a guidance document for states to enable the state EPI officer/ programme managers to implement AEFI surveillance processes at state level including liaising and coordination with other stakeholders to further strengthen AEFI surveillance in the state.

(Vandana Gurnani)

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FOREWORD

India is committed towards saving lives by reducing morbidity and mortality caused by vaccine preventable diseases. Over the past few years, many new vaccines (rotavirus vaccine, inactivated polio vaccine, pneumococcal vaccine, measles-rubella vaccine) have been introduced in the Universal Immunization Programme (UIP). Strengthening of routine immunization vaccine coverage through campaign such as Mission Indradhanush (MI), Gram Swaraj Abhiyan (GSA), Intensified Mission Indradhanush 2.0 (IMI 2.0) have resulted in protecting vulnerable children from vaccine preventable diseases.

In order to ensure that quality and safety of vaccines being used under universal Immunization programme, the Govt. of India maintains a sensitive surveillance for Adverse Events Following Immunization (AEFI). The national AEFI guidelines, 2015 elaborates the steps to be taken by programme managers at national, state and district level in order to ensure that all suspected adverse event following immunization are reported, investigated and causally assessed by trained experts.

Subsequently, with the intent of supporting the state level programme managers to effectively implement the activities listed in national AEFI guidelines, a state guidance document has been prepared with inputs from various domain experts. It aims at guiding the state EPI officer / Programme managers to take effective steps to strengthen AEFI surveillance in state and districts.

I am thankful to all the experts who contributed to the development of this guidance document. I hope this will enable the health system to further reinforce activities aimed at maintaining vaccine safety surveillance in the state.

31/01/2020

(Manohar Agnani)

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PREFACE

Intensive efforts are currently on-going in India to strengthen and intensify the routine immunization coverage and improve the quality of immunization services. Under the Universal Immunization Program (UIP), 26 million children and 29 million pregnant women are aimed to be fully immunized through 9 million immunization sessions held in the country each year. New vaccines such as rotavirus vaccine, inactivated polio vaccine, pneumococcal vaccine, measles-rubella vaccine have also been introduced in the UIP schedule.

Continuous efforts are being made to strengthen the surveillance of Adverse Event Following Immunization. The national AEFI guidelines which are currently in use enables the national, state and district programme managers to adopt and implement activities aimed at maintaining sensitive AEFI surveillance in the country.

Based on the feedback and the recommendation of the experts, a guidance document for AEFI surveillance processes has been developed by the Immunization Division which would enable the state EPI Officer / programme manager to efficiently conduct AEFI surveillance activities at the state level. Some of the key highlights of this document are the tools, templates and SOPs to conduct state level meetings, monitor district AEFI surveillance activities, coordinate with stakeholders at state level and take necessary actions at state level to improve AEFI surveillance

I would like to congratulate the AEFI Secretariat, Immunization Technical Support Unit for developing a comprehensive document in consultation with paediatricians, public health experts and administrators, to address the queries and concerns of the state programme managers and to guide them in establishing sensitive vaccine safety surveillance.

(M K Aggarwal)

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ABBREVIATIONS

AEFI	-	Adverse Event(s) Following Immunization
AFP	-	Acute Flaccid Paralysis
AMC	-	Adverse Drug Reaction Monitoring Centre
ANM	-	Auxiliary Nurse Midwife
ASHA	-	Accredited Social Health Activist
CA	-	Causality Assessment
CBHI	-	Central Bureau of Health Intelligence
CDL	-	Central Drugs Laboratory
CDSCO	-	Central Drugs Standard Control Organization
CHC	-	Community Health Centre
CIOMS	-	Council for International Organizations of Medical Sciences
CME	-	Continuing Medical Education
CRF	-	Case Reporting Form
DACM	-	District AEFI committee meeting
DCGI	-	Drug Controller General of India
DIO	-	District Immunization Officer
DPT	-	Diphtheria, Pertussis (whooping cough), and Tetanus
DTFI	-	District Task Force for Immunization
EPID number	-	Epidemiological number
ESI	-	Employees' State Insurance
FCIF	-	Final Case Investigation Form
HMIS	-	Health Management Information System
IAP	-	Indian Academy of Pediatrics
IAPSM	-	Indian Association of Preventive and Social Medicine
IDSP	-	Integrated Disease Surveillance Project
IEC	-	Information Education and Communication
IMA	-	Indian Medical Association
ITSU	-	Immunization Technical Support Unit
MO	-	Medical Officer
MoHFW	-	Ministry of Health and Family Welfare
NCC	-	National Coordinating Centre
NCDC	-	National Centre for Disease Control
NPSP	-	National Public Health Surveillance Project
NRA	-	National Regulatory Authority
PCIF	-	Preliminary Case Investigation Form
PHC	-	Primary Health Centre
PSU	-	Public Sector Undertaking
PvPI-IPC	-	Pharmacovigilance Programme of India - Indian Pharmacopoeia Commission
QMS	-	Quality Management System
RI	-	Routine Immunization
SAFE-VAC	-	Surveillance and Action for Events following Vaccination
SEPIO	-	State Expanded Programme on Immunization Officer
STFI	-	State Task Force for Immunization
TNAI	-	Trained Nurses' Association of India
UNDP	-	United Nations Development Programme
UNICEF	-	United Nations Children's Fund
VPD	-	Vaccine Preventable Disease
WHO	-	World Health Organization


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CHAPTER

1

BACKGROUND AND SCOPE

Background

The Adverse Event Following Immunization (AEFI) Surveillance and Response Operational Guidelines guide health care providers and programme managers at national, state, district, block / PHC levels to develop and maintain the AEFI surveillance system.

Over the years, many states and districts have demonstrated significant improvement in AEFI surveillance. However, recent assessments in high priority states have shown that these improvements are not consistent over a period of time and even within a state or district. There are multiple factors which affect the quality of the AEFI surveillance system in a state or a district. Some of these factors are frequent change of programme managers at state and district level, infrequent trainings and orientation of health staff (MOs, ANMs, ASHAs) for AEFI surveillance and other competing priorities at state and district levels.

During interactions with different stakeholders in the field, it was conveyed that the AEFI Surveillance Operational Guidelines describes the **"what to do"** for the state and district programme managers. However, the guidelines do not address the "**how to do**" part. A new immunization programme manager is left to figure his way through the **"how to do"** part which acts as a barrier. To provide a comprehensive guidance on AEFI surveillance processes, Immunization Division, MoHFW has developed this guidance document for states which aims to enable SEPIOs and state program managers to understand various steps and activities related to smooth implementation of AEFI surveillance guidelines including newer developments such as use of SAFE-VAC (Surveillance and Action for Events following Vaccination) and implementation of QMS-AEFI (Quality Management System for AEFI).

Scope of the document

- Basics of AEFI and AEFI surveillance system
  - » Structure and stakeholders
  - » Process and formats
- Improving coordination with various stakeholders for enhanced reporting, thorough investigation and scientific causality assessment at state level.
- Facilitating effective state AEFI committee meetings and ensuring quality causality assessment.
- Monitoring AEFI processes, capacity-building activities and providing feedback to districts
- Support extended from National AEFI Secretariat in form of technical assistance to states by zonal AEFI senior consultants, formulation of operational guidelines, performance indicators, regular feedback in form of states specific presentations and line lists, AEFI dashboard & causality assessment results approved by the National AEFI committee.


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राष्ट्रीय कृमि मुक्ति दिवस
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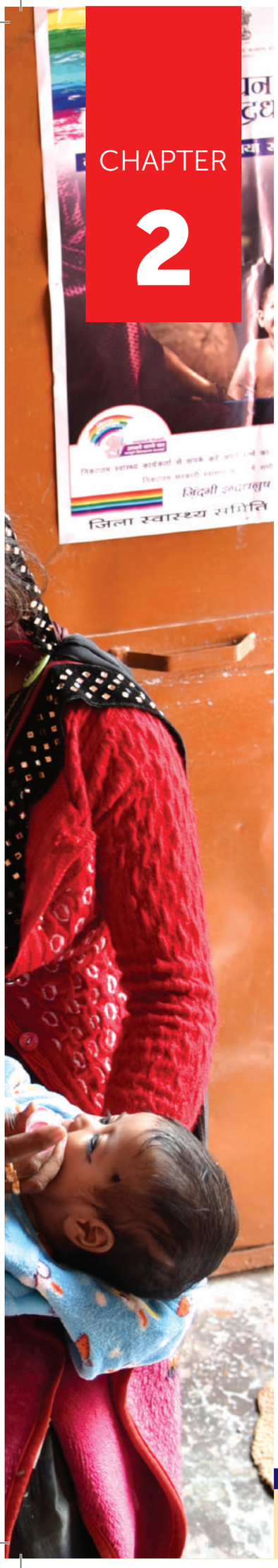


CHAPTER

2

ADVERSE EVENT FOLLOWING IMMUNIZATION (AEFI) SURVEILLANCE SYSTEM

Basics of Adverse Event Following Immunization (AEFI)

An AEFI is any untoward medical occurrence which follows immunization and which does not necessarily have a causal relationship with the usage of the vaccine. The adverse event may be any unfavorable or unintended sign, abnormal laboratory finding, symptom or disease.

The AEFI surveillance system in India, is a passive reporting system unlike the active Acute Flaccid Paralysis (AFP) reporting system. Any suspected adverse event following immunization informed to the health system (ANM, ASHA or AWW) should be recorded and reported as per the National AEFI Surveillance guidelines.

The importance of maintaining a sensitive AEFI surveillance system is that, it helps to-

- Ensure vaccine safety and build vaccine confidence in the community.
- Capture rare, serious AEFI which may not have been detected during clinical trials.
- Recognizes immunization related programmatic errors (improper storage, handling, administration of vaccines) and helps to take corrective actions to prevent future recurrence.
- Recognizes coincidental events temporally related to vaccination and prevent false blame.
- Document and convey the cause of the event to parents/community.
- Estimate rates of occurrence of AEFI in the local population

As per WHO/Council for International Organizations of Medical Sciences (CIOMS) 2012 classification (Table 1), AEFI can be categorized into 5 categories based on the cause of the AEFI.

Table 1. Cause-specific categorization of AEFI (CIOMS/WHO 2012)		
Cause-specific type of AEFI	Definition	Examples
Vaccine product-related reaction	An AEFI that is caused or precipitated by a vaccine due to one or more of the inherent properties of the vaccine product	Extensive limb swelling following DTP vaccination.
Vaccine quality defect-related reaction	An AEFI that is caused or precipitated by a vaccine due to one or more quality defects of the vaccine product, including its administration device as provided by the manufacturer	Failure by the manufacturer to completely inactivate a lot of inactivated polio vaccine leads to cases of paralytic polio.
Immunization error-related reaction (formerly "programme error")	An AEFI that is caused by inappropriate vaccine handling, prescribing or administration and thus by its nature are preventable	Transmission of infection by contaminated multidose vial
Immunization anxiety-related reaction	An AEFI arising from anxiety about the immunization	Vasovagal syncope in an adolescent following vaccination.
Coincidental event	An AEFI that is caused by something other than the vaccine product, immunization error or immunization anxiety	A fever occurs at the time of the vaccination, but is in fact caused by malaria

Based on severity and for ease of recognizing events to be recorded and reported, any adverse event can be categorized as:

- **Minor AEFI**- These are common, self-limiting reactions, e.g. pain, swelling at the injection site, fever, irritability, malaise etc.
- **Severe AEFI**- These can be disabling and, rarely, life threatening. However, they do not lead to long-term problems. Examples include non-hospitalized recovered cases of the following conditions: anaphylaxis, high fever (>102-degree F), hypotonic-hyporesponsive episodes, cellulitis, sepsis, etc.
- **Serious AEFI**- These are cases resulting in death, persistent or significant disability, requiring inpatient hospitalization, are a part of AEFI cluster or evoke significant parental/community concern.

Some of the examples of severe/serious vaccine reactions are mentioned in the table no. 2 below

Table 2. Examples of severe/serious vaccine reactions	
Vaccine	**Reactions**
BCG vaccine	Suppurative lymphadenitis
	BCG osteitis
	Disseminated BCG infection

Vaccine	Reactions
Measles/MMR/MR	Febrile seizures
	Thrombocytopenia (low platelet)
	Anaphylactoid (severe allergic) reaction
	Anaphylaxis
	Encephalopathy
Oral Poliomyelitis	Vaccine associated paralytic poliomyelitis
Hepatitis -B	Anaphylaxis
Tetanus	Brachial neuritis
	Anaphylaxis
Pertussis (DPT- whole cell)	Persistent (>3 hours) inconsolable screaming
	Seizures
	Hypotonic-hyporesponsive episode (HHE)
	Anaphylaxis

Important points to remember

- All categories of AEFI (minor, severe and serious) are to be recorded in PHC/block AEFI recording register.
- Only serious and severe type of AEFI cases are to be reported immediately in Case Reporting Formats (CRF)

AEFI Surveillance Processes

AEFI surveillance involves a series of processes which starts with notification of minor, severe and serious cases which are to be subsequently recorded in Block/ Planning unit AEFI recording register by the health worker. Cases which are ascertained to be severe or serious in nature by the medical officer are reported immediately using the case reporting form (CRF). The DIO further investigates the case using PCIF and FCIF within the timeline outlined for each, and shares the record with the state and national level. Once the case investigation is completed and all the supporting documents are submitted to the state and national level, these cases are causally assessed by trained experts in state and national AEFI committee meetings.

Notification:

- When information regarding an AEFI reaches the health worker/medical officer either from caregiver, private practitioner or others.
- All timelines for the surveillance processes i.e. case reporting and investigation are based on date of notification of case.

Recording

- **Block/Planning unit AEFI recording register**- All minor, severe and serious AEFI are to be recorded by ANMs in this register on weekly basis as per the letter issued by Government of India in 2016 (**Annexure A**). It is required that the ANM submits a "nil" monthly report in case no AEFI case is detected from her area during the month. The nodal medical officer is required to review the recording of AEFI cases in these registers and analyze the trends of minor/severe AEFI for potential immunization errors or signals.
- **Weekly VPD reporting (H002/ D001 format) for serious and severe AEFI cases**- All the designated reporting unit as per WHO AFP surveillance system are required to submit the weekly H002 report for the AEFI (serious/ severe) cases reported in the week. This information is to be collated from the planning unit AEFI register. In case, no serious or severe AEFI case is reported, a 'Nil' report is to be submitted.

Reporting

- As the AEFI case is notified, medical officer reports it to the district immunization officer (DIO) by filling up the case reporting form (CRF) within 24 hours of the notification.
- The CRF is verified by the DIO and shared with the state EPI officer and national level via **SAFE-VAC**

Other reporting channels include

- **Pharmacovigilance Programme of India**- call centre number 18001803024 (Mon- Fri 9:30am to 5:30pm)
- **Individual Case Safety Reports (ICSRs):** generated by ADR Monitoring centres under Pharmacovigilance Program of India (PvPI)
- **Infectious Disease Surveillance (IDsurv) Portal**- Used by private paediatricians for reporting of suspected AEFI cases (http://www.idsurv.org/)

S. No.	Reporting channel	Frequency	Categories of vaccine reactions to be reported
1	AEFI surveillance (CRF)	Immediately	Serious and Severe
2	Block/Planning unit AEFI recording register	Weekly	Serious, Severe and Minor.
3	VPD surveillance (H-002 & D-001)	Weekly	Serious and Severe
4	HMIS	Monthly	Serious, Severe and Minor (Death, Abscess and others)

HMIS reporting is a monthly, number-based reporting system at PHC/CHC level in which numbers of deaths, abscesses and others are reported under section 9.6.1, 9.6.2, 9.6.3 respectively.

Investigation

- The DIO reviews the CRF received from the MO and along with the members of the district AEFI committee team decides whether the case is to be investigated or not. The case details are entered in SAFE-VAC and the EPID number (IND (AEFI) - ST - DIS - YR – NUM) thus generated is allocated to the case.
- Preliminary case investigation is to be done by the members of the district AEFI committee and report to be submitted within 10 days of notification.
- The final case investigation form i.e. FCIF is to be filled along with all relevant case records (prescriptions, hospital records for hospitalized case only, post mortem report etc.) are to be shared within 70 days of notification.
- A copy of the CRF should also be sent to the local drug inspector.

Specimen of Block/Planning unit AEFI recording register

Week No.	Name of sub-centre	Name of vaccine recipient	Father's Name	Age	Date of vaccination	Name of vaccines given	Batch number of vaccines given	AEFI noted (symptoms)	Category (minor/ serious/ severe)	Case seen by MO i/c (yes/no)	CRF filled? (yes/no)
10	HSC1	Monika	Prabakaran	1 day	07-03-2018	BCG, Hep B, OPV	BCG 037G5041 Hep B 3421A91 OPV S-151	Abscess	severe	Yes	Yes
10	HSC2	Hari Prasanth	Sathiya Prakash	20 months	07-03-2018	DPT, Measles	DPT TA627B/14 Measles 003F5084	Fever, local Pain & swelling	minor	Yes	No
10	HSC3	Shanthi	Subramani	1.5 months	07-03-2018	Penta, OPV	TA651A/14	seizures, febrile	severe	Yes	Yes
11	HSC2	Kavitha	Suresh	3.5 months	07-03-2018	Penta, OPV	TA651A/14	Mild fever	minor	No	No
11	HSC1	Rajesh	Sridhar	2.5 months	07-03-2018	Penta, OPV		Fever (>102^0 F)	severe	Yes	No
11	HSC3	Hamsaveni	Baskar	9 months	07-03-2018	Measles		Local skin rash	minor	Yes	No
12	HSC3	Mayura	Madhavan	20days	07-03-2018	BCG, OPV		Death	serious	Yes	Yes
12	HSC2	Preetham	Ravikumar	18months	07-03-2018	Measles		Fever, local Pain & swelling	minor	No	No
12	HSC1	Baby of Kavitha	Venkatesh	1 day	14-03-2018	BCG, OPV	BCG 037G5041 OPV 63AS10115201	Localised skin redness	minor	Yes	No
13	HSC1	Sabari	Raja	0 day	14-03-2018	BCG, Hep B, OPV	BCG 037G5041 Hep B 3421A91 OPV S-151	Abscess	severe	Yes	Yes

The reported AEFI must be investigated, if it is any one of the following:

- Severe or serious event (death, disability and hospitalization etc.) of known or unknown cause
- Part of a cluster AEFI
- Suspected immunization error
- Appears on the list of events defined for AEFI surveillance
- Causes significant parental or public concern
- Is a previously unrecognized event associated with any vaccine, especially the newly introduced ones.

A. Cluster investigation

A cluster is described when two or more cases of the same adverse event are found to be related in time, place or vaccine administered. A cluster may occur within the same district or geographical unit, or associated with the same vaccine, same batch number administered or same vaccinator.

Clusters can be usually found to be associated within:

1. a particular provider or health facility
2. a vial/vials of vaccine that has/have been
   - Inappropriately prepared
   - Contaminated
   - Inappropriately stored (e.g. freezing vaccine during transport)

B. Investigation of reported AEFI deaths

It is recommended that investigation may be carried out by a team comprising of clinical (preferably a pediatrician), laboratory and forensic experts. In case post mortem is done, preliminary report should be submitted alongwith PCIF followed by final report to the National AEFI secretariat at the earliest.

If post mortem is not done then verbal autopsy should aim to describe all relevant events in a chronological manner from the time of vaccination to the time of death in chronological order. Verbal autopsy should always be done for all unexplained death cases including cases such as brought dead/home death/insufficient medical records/not hospitalized/clinical diagnosis not possible.

Causality assessment

- It is the systematic evaluation of the information obtained about an AEFI to determine the likelihood of the event having been caused by the vaccine/s received.
- It is done by trained experts of state and national AEFI committees

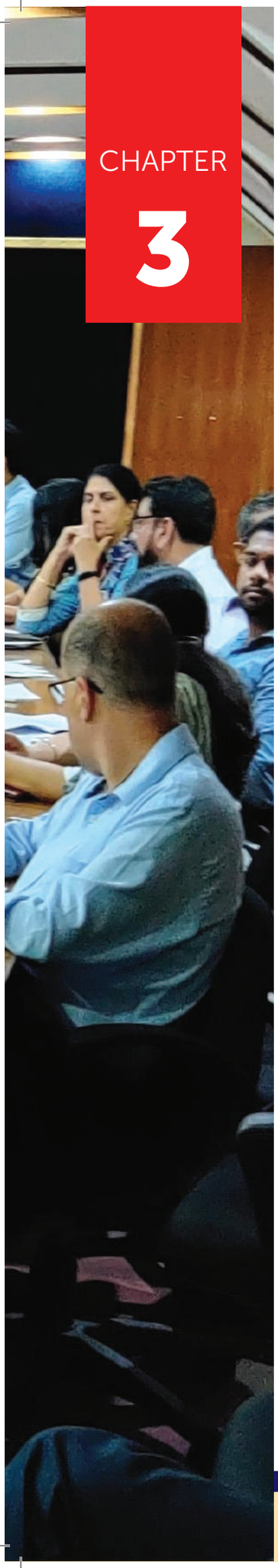
Causality assessment is important for:

- identification of vaccine-related problems
- identification of immunization error-related problems
- excluding coincidental events
- detection of signals for potential for follow-up testing of hypothesis and research
- validation of pre-licensure safety data with comparison of post-marketing surveillance safety data

Feedback and communication

During the causality assessment at state and national level, in case additional documents are required or important documents are missing, feedback is shared with the states for corrective action. Results of the causality assessment done by national experts and approved by the national AEFI committee are communicated to the states regularly for further sharing with the districts.

States are also encouraged to share with districts the feedback of AEFI cases causally assessed by state level experts. Moreover, any relevant information aimed at improving the quality of case investigation or timely submission of case records should also be shared. It is important that in events where program error is suspected suggestive actionable points are conveyed to the districts.



CHAPTER

3

IMPROVING COORDINATION BETWEEN STAKEHOLDERS

There are many stakeholders at the state level with whom the State EPI Officer has to coordinate to improve AEFI surveillance. These include doctors working at government, private medical colleges and tertiary care hospitals, state drug controller, programme managers of Integrated Disease Surveillance Project (IDSP), state cold chain officer, etc.

Other stakeholders may include - representative of partner organization (WHO, UNICEF & UNDP), municipal corporations / urban local bodies, professional associations such as IAP, IMA and TNAI (Trained Nurses Association of India).

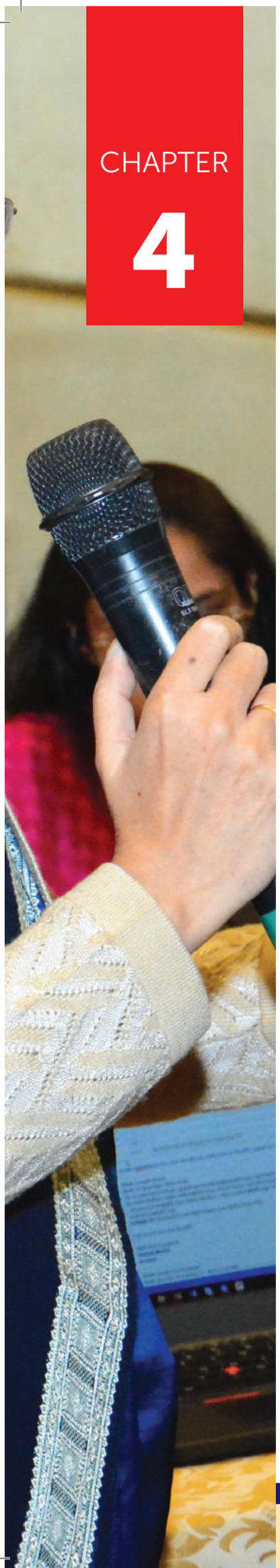
It is important for the SEPIO to reach out to these stakeholders and invite them in the state AEFI committee meetings. In addition to their involvement in state AEFI committee meeting, these stakeholders can also be involved in improving AEFI reporting from private sector and medical colleges/hospitals.

Some of the suggestive activities in this regard could be as follows -

1. For multi-speciality hospitals and medical colleges:
    - Enlist prominent multi-speciality hospitals and medical colleges preferably in the state capital (using existing AFP surveillance network). Sensitize and promote pediatricians to report any suspected AEFI case.
    - Medical colleges serving as Adverse Drug Reaction Monitoring Centre (AMC) under the PvPI may be contacted by respective DIO to sensitize the technical associate and Nodal Officer for AEFI case notification.
    - SEPIO may share the list of AMCs with the DIO with instruction to reach out to the AMC for sensitization and reporting of AEFI in CRF. DIO can share his contact details with nodal person of medical colleges and AMC, so that the hospital records and discharge summary of the reported cases may be scanned and shared with him.
    - Regular feedback for the notified case should be shared with the centre reporting the case. Also, its efforts should be appreciated to maintain its confidence in AEFI surveillance process.
2. SEPIO may advocate with state chapter of IAP, IMA and other professional associations to encourage reporting of AEFI cases
    - Immunization program manager should try to utilize the platform of CME, training workshops, panel discussions, etc., to sensitize private practitioners for reporting of suspected serious or severe AEFI cases.
    - Soft copies of the blank CRF may be provided to private practitioner for reporting of suspected AEFI cases. They may also be provided with a list of names, telephone numbers and email addresses of DIOs of neighboring districts, so that they can report cases to DIOs based on the place of vaccination.
3. For reporting from urban areas
    - Sensitize the medical officer of urban local body/ municipality, PSU hospitals such as defence, ESI, railways, etc.to report suspected AEFI cases.
4. Collaborate with state drug controller
    - Meet the state drug controller and explain his/her role in vaccine safety and AEFI surveillance.

- The State Drug Controller can be involved in special investigation of AEFI cases whenever needed. He can further direct the district drug inspectors for assisting in collecting vaccine samples for testing as per the provisions of the Drugs and Cosmetics Act, 1940.
- SEPIO may work with the state drug controller to ensure drug inspectors are members of the district AEFI committee and actively take part in meeting and investigations.

5. Utilize state and district level review meetings for sensitizing on AEFI surveillance- SEPIO and DIOs may utilize the opportunity of State and district task force for immunization (STFI and DTFI) to discuss the status of AEFI surveillance at state and district level, respectively. Data from monthly presentation and analysis of state/district line list may be used.
6. State level technical collaborating center- A collaboration may be sought with a medical college in the state, preferably at the state capital, to act as a technical collaborating center for AEFI surveillance in the state. The center would support the AEFI surveillance process by providing the technical oversight and support during the causality assessment process.
7. National Coordinating Centre (NCC) - Pharmacovigilance Programme of India (NCC-PvPI) at IPC, Ghaziabad - Representatives from the NCC-PvPI may also be invited as members to the state/ district AEFI committees.
8. Immunization partners- WHO/UNICEF/ UNDP can support in strengthening AEFI surveillance by activities such as-
   - Capacity building of health workers for AEFI surveillance
   - Monitoring of RI sessions for observing ANM injection practices.
   - Follow up for case investigation of serious/severe AEFI cases
   - May participate as special members for state/district AEFI committees
   - Present data pertaining to AEFI surveillance status during district and state task force meeting on immunization.
   - Support in implementation and roll out of SAFE-VAC across key states.



CHAPTER

4

CONDUCTING EFFECTIVE STATE AEFI COMMITTEE MEETINGS

Members of AEFI committees include clinical specialists, programme officers and representatives of professional bodies. These are ***epidemiologist/public health specialist, representative from drug authority, paediatrician, microbiologist, general physician, neurologist, pathologist, forensic expert, cold chain officer, member of Integrated Disease Surveillance Project (IDSP)& professional bodies such as IAP and IMA, representative (MOs) from local bodies such as municipal corporations and partner agencies such as WHO-NPSP and UNICEF (ex-officio members and may be invited when required).***

As per the national guidelines, state AEFI committee meeting should be held at least once a quarter. In case of any changes in membership of the committee, a new notification may be issued by the state. These new members may be nominated by SEPIO to attend the national causality assessment meeting for orientation on causality assessment processes for reported AEFI cases. The immunization programme manager is the member secretary of the state AEFI committee

Terms of reference for the State AEFI Committee

1. Review AEFI surveillance status of state (and districts)
   - AEFI reporting status and identification of silent districts
   - Ensure district AEFI committees meet every quarter or more frequently as needed and that they fulfil their responsibilities
   - Status of pending documents for reported AEFI cases
2. AEFI case investigation
   - Supporting and guiding District AEFI Committees in conducting case investigation
   - Field visit and inspection of vaccination sites, cold chain stores, etc.
   - Interviewing the AEFI case/relatives, treating doctors/staff and members of the district AEFI committee, if required, to help in coming to an informed causality assessment
3. Causality assessment of AEFI cases
   - Desk review of the CRF, PCIF, FCIF and supporting documents for causality assessment
   - Analysis of similar cases or clustering of cases in the state
   - Causality assessment of cases and sharing the results at national level.
4. Other activities
   - Support the spokesperson for media communication
   - Ensure minutes of the meeting are shared regularly with Joint Commissioner-Immunization Division and AEFI Secretariat within a fortnight of the meeting. Minutes may also be shared with districts to convey the key actionable points for strengthening AEFI surveillance activities.

Suggestive steps to conduct state AEFI committee meetings

A. Preparatory activities-

- Seeking due approval for conducting the meeting and a draft agenda– At least two weeks prior to the proposed date of meeting.
- Circulating the meeting notice with draft agenda **(Annexure B)**– to be shared with members of the State AEFI Committee members at least one week prior to the meeting.
- Preparing action taken report using the approved meeting minutes of last meeting
- Screening of cases for completion and preparation of case summaries may be supported by state AEFI technical collaborating center.
- Checklist for meeting
  - Agenda, approved minutes of last meeting, declaration and non-disclosure agreement formats (**Annexure C**), TA/DA claim forms – 15-20 copies
  - Attendance sheets
  - AEFI surveillance status report or presentation
  - Pending document status report
  - Blank CA formats (depending on number of cases to be assessed)
  - One set of photocopies of cases for Causality Assessment
  - Causality Assessment tool kit (suitcase)
  - Stationary (as required – pens, notepads, etc.)
  - Audio-visual equipment (projector, screen, mikes, etc.), if required

B. During the committee meeting

Update on AEFI surveillance status – Following are some of the key points related to surveillance that needs to be reviewed

- Action taken report of the SEPIO to discuss on actionable points of the last committee meeting.
- Status of silent districts (non-reporting districts), AEFI related trainings
- Discussion on Performance indicators related to AEFI surveillance and recommending actions to improve basic AEFI surveillance processes
- Operationalization of PHC/Block AEFI recording registers
- Discussion on frequency of District AEFI committees using district AEFI committee tracking tool (**Annexure D)** to ensure these meetings are being held regularly
- Discussion on case completion status, mismatch in reporting of AEFI cases especially death cases in HMIS and state/national line list, involvement of ADR monitoring center and private sector for reporting of cases

C. During the Causality Assessment process

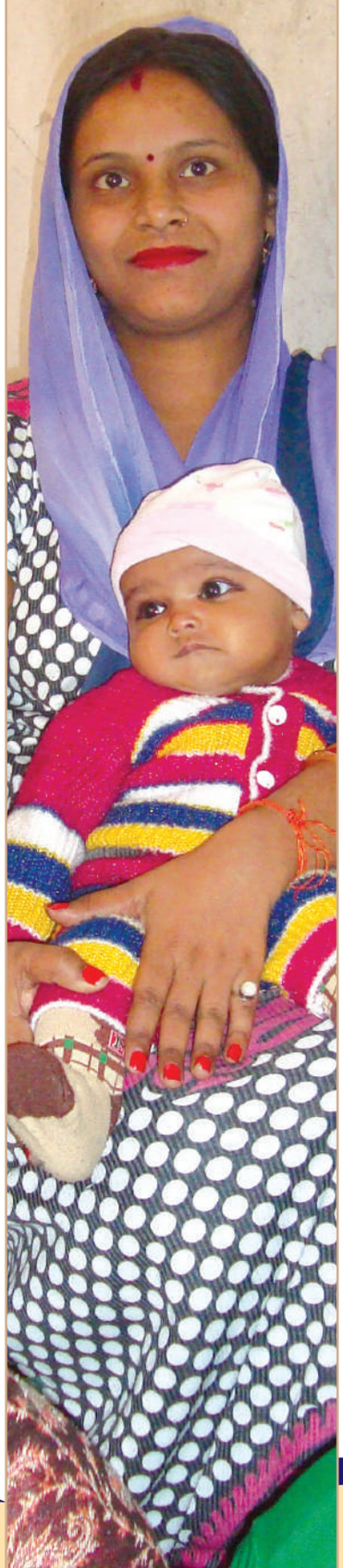
- Discussion on AEFI cases presented to the group of experts,
- Ascertaining the causality by consensus building,
- Filling up of causality assessment form
- Signature of experts (especially a pediatrician is mandatory) on the causality assessment form.

D. After the committee meeting-

- Document all the programmatic discussion in form of minutes of meeting and circulate it to the members after due approval from the chairperson.
- Cross check all the CA forms for completion and share the records with the Immunization Division (AEFI Secretariat) at SAFEVAC or aefiindia@gmail.com.

CHAPTER

5



MONITORING AND SUPERVISION OF AEFI SURVEILLANCE ACTIVITIES

The role of SEPIO includes monitoring and supervision of regular activities related to implementation of Adverse Event Following Immunization (AEFI) surveillance in the state.

Some of the key activities at the state level for monitoring and supervision are as follows-

- Analyze the state AEFI surveillance data and other analysis/feedback received from the national level.
- Coordinate with stakeholders which include- state AEFI technical collaborating centers, drug regulators, Adverse Drug Reaction Monitoring Centers (AMC), IAP, IMA, partner organizations.
- Track district AEFI committee meetings (DACM) using the DACM tracking tool
- Oversee the smooth implementation of SAFE-VAC in coordination with districts and national level. Reconcile the SAFE-VAC and the state level line list of reported AEFI cases every weekly or monthly basis.
- Ensure operationalization of AEFI recording registers in planning units/block PHCs.
- Monitor and implement continuous capacity building activities for District Immunization Officers (DIO), data entry operators, MOs, HWs and other frontline workers for AEFI surveillance activities.
- Ensure the implementation of Quality Management System for AEFI surveillance in districts and state.
- Conduct at least one state AEFI committee meeting every quarter.
- Follow up with districts for completion of AEFI records
- Share national AEFI committee meeting minutes along with the causality assessment reports with districts.

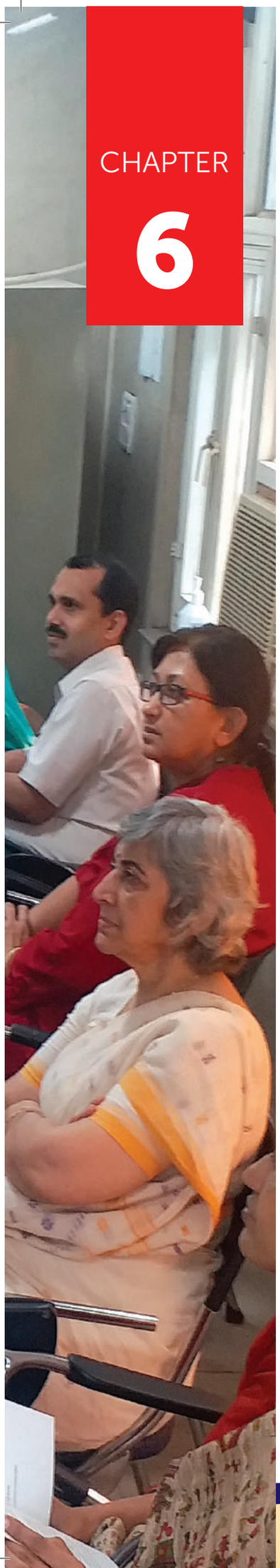
SEPIO may be supported by a medical officer/state level AEFI consultant/program assistant/ data entry operator to assist in above mentioned activities.

Funds related to AEFI surveillance activities (Annexure E)

MoHFW vide letter no. Z-16025/05/2012-Imm dated 1st Aug'16 communicated that expenditures related to following AEFI surveillance activities may be utilized from training head (C.3) of Part-C of immunization. Now the training head for Routine Immunization is changed to FMR 9.5.10 from which states may utilize the funds for AEFI surveillance activities such as:

- Holding State & District AEFI Committee meetings
- Carrying out investigations in the field by district and state AEFI committee members and to send samples to CDL for testing.
- State/District/Block level trainings under AEFI


BRIGHTON CASE
DEFINITIONS



CHAPTER

6

SUPPORT FROM NATIONAL AEFI SECRETARIAT

The National AEFI Secretariat at Immunization Technical Support Unit (ITSU) works closely with the Immunization division, MoHFW and the National AEFI Committee to support all activities related to AEFI surveillance in the country. Some of the important activities are:

- Coordinate with Immunization Division, NRA, CDSCO, CBHI, IEC Division, NCDC, IDSP, WHO - NPSP or other partner agencies for strengthening AEFI surveillance activities at national and state level.
- Liaise with the other vaccine safety stakeholders including DCGI and PvPI to enhance vaccine safety activities in the country.
- Support in regular conduct of National AEFI committee meetings (quarterly basis) and causality assessment meetings (monthly basis).
- Support the states and state AEFI committee to ensure continuous monitoring of AEFI surveillance activities such as follow up on timeliness and completeness of data reporting in surveillance, response and follow-up of serious AEFIs.
- Provide technical assistance to states/UTs on program monitoring and capacity building especially for case investigation and causality assessment process.

Support extended by Zonal AEFI senior consultants

Zonal AEFI senior consultants at National AEFI secretariat are representative of Immunization Division, MoHFW and collaborate with allocated states to strengthen AEFI surveillance activities. They support the states by –

- Providing regular feedback to states /districts on the quality of case investigation reports and records submitted for the reported AEFI cases and performance of AEFI surveillance programme.
- Follow-up with districts for pending documents, ensure preliminary screening followed by completion of documentation of reported cases from zone for quality causality assessment.
- Undertake field visits to states and districts for monitoring AEFI activities, coordinating special investigation of severe/serious AEFIs of special interest and provide feedback to the Immunization Division
- Providing support in identifying and coordinating with AEFI technical collaborating centres in states.
- Advocating and coordinating with professional associations (IAP, IMA, IAPSM, etc.) for participation of private sector in AEFI surveillance programme.
- Facilitating roll out of SAFE-VAC and QMS activities
- Facilitating capacity building activities for state AEFI committees (especially in causality assessment) and district immunization officers.
- Coordinating with proposed pharmacovigilance officers/associates at state and district levels and jointly review immunisation safety data at states.

Specific support to states

A. Performance indicator for AEFI surveillance processes

Immunization Division, MoHFW has initiated a system of sharing ranking of states based on their performance for AEFI surveillance activities in each quarter. Each state is expected to achieve a certain benchmark by conducting regular activities related to AEFI surveillance. Three core areas- AEFI reporting, case investigation and state level processes are further sub-divided into indicators and each of these indicators have been assigned a weighted average, and the compilation of all these scores leads to the overall score of the state.

1. AEFI Reporting Indicators-
   - Proportion of districts reporting AEFI case in a state
   - Percentage of AEFI cases actually reported against minimum expected in a year (GVAP criteria: At least 10 severe/ serious AEFI case is to be reported/1,00,000 surviving infant in a year)
2. AEFI Case investigation indicators
   - Proportion of AEFI cases with preliminary investigation document (CRF & PCIF) received at national level.
   - Timeliness for completing AEFI case investigations
3. State level processes-
   - No. of state AEFI committee meetings held
   - Proportion of eligible AEFI cases causally assessed by state AEFI committee

For example, if in a state good proportion of districts report AEFI case or the completed cases records of the reported cases are submitted to state and national level on time, the scores for reporting and investigation indicators will improve. Similarly, if a state conducts regular state AEFI committee meeting (at least once a quarter) and assess the causality of all eligible cases, the score improves. Thus, it is important for the state to have a consistent performance for all surveillance related processes in order to achieve the maximum score and rank in its category.

Moreover, this tool also provides an opportunity to the state to evaluate its own performance based on last quarter's performance. Immunization division also shares the recommended actionable points for the state program manager to focus on identified areas of concern.

B. AEFI dashboard in Immunization dashboard of ITSU

Based on direct reporting of AEFI cases by districts/states, a compiled analysis of AEFI surveillance and reporting status in the states is shared with them on a monthly basis. Some of the key elements indicated in the dashboard are-

- Percentage of districts in a state/UT reporting at least one serious/severe AEFI case.
- Percentage completeness of preliminary investigation by the states.
- Status of State AEFI committee meetings held

C. State specific presentations and AEFI line list

The AEFI Surveillance update along with line list of serious/severe AEFI cases reported by states are shared by zonal consultants with all the states on monthly basis. The surveillance update shares the progress made by the states in terms of maintaining sensitive surveillance along with the key action points for the gaps assessed at the national level. The line list helps in reconciling the state level data of reported AEFI cases with the national data and also helps the state programme manager to follow up on pending AEFI case investigation form (PCIF, FCIF, verbal autopsy) from the districts.

D. Information regarding rectification of mismatch between letters for AEFI data reported via HMIS & direct reporting (CRF)

Based on the comparative analysis of AEFI data especially for death cases reported in HMIS and through direct reporting (CRF) by the state, reminder letters are shared with all states and UTs to either correct the data entry error in HMIS or to submit any pending case records to the national level at aefiindia@gmail.com

E. Causality assessment results

Once the reported serious/severe AEFI cases are causally assessed and approved by the National AEFI committee, their information is shared with the states with the objective of further sharing it with the reporting district and using it as a reference for quality improvement of AEFI surveillance program.

F. Training support

Immunization Division supports in building capacity of the state level experts in the process of ascertaining causality assessment by inviting them to attend the national causality assessment meeting held every month at National AEFI technical collaborating centre (Lady Hardinge Medical College, New Delhi). Moreover, State EPI officers along with the chairpersons of the respective state AEFI committees are also invited to attend the National AEFI committee meeting, held every quarter, to participate in key policy discussions to strengthen AEFI surveillance in the country.


मध्यप्रदेश शासन द्वारा जनहित में जारी
AEFI FIELD
INVESTIGATION
SIMULATION
TRAINING

CHAPTER

7

ANNEXURES

A. Letter for AEFI registers to be placed at block/ Focal point/ Sector PHC level

L-11013/01/2012-Imm
Government of India
Ministry of Health and Family Welfare
(Immunization Division)

Dated: 30th December 2016
Nirman Bhawan, New Delhi

To,

Mission Director (NHM)
All States/UTs

Subject: Regarding AEFI registers to be placed at block/Focal point /Sector PHC level

Sir/Madam,

You may be aware that as per the National Adverse Event Following Immunization (AEFI) Surveillance Guidelines of 2015, each PHC/block PHC/CHC should maintain an AEFI register containing a line list of all minor, severe & serious AEFIs. The AEFI register should be updated on a weekly basis by ANMs. The medical officer will review the AEFI register and update the status of investigation of serious and severe AEFIs for the week. Based on this active case search of the register, if the facility is a Reporting Unit for VPD-H002, the nil reporting for serious and severe AEFIs will also be done and shared with the DIO. At the end of the month, the MO will also analyse the minor AEFIs to look for any pattern (clusters related to a sub centre area or particular batch, previously unnoticed new minor AEFI, etc.) and take action such as investigating the cluster as a severe/serious AEFI or train ANMs or improve monitoring, etc. and send a report to the DIO. Detailed SOPs with formats will be shared with the states very soon. The DIO will also compile reports, analyse and take necessary action at the district level and send a report to the state at the end of the month.

Therefore, you are requested to ensure that the AEFI registers (format attached) are printed and placed at all PHCs/block PHCswithin a month and operationalized. For any further information please contact Dr.Jyoti Joshi at Jyoti.joshi@phfi.org.

Encl: as above

Yours faithfully

Dr M K Aggarwal
Deputy Commissioner (UIP)

Copy to:

1. SEPIO, All States/UTs
2. Dr L Machado, Focal Person (AEFI), WHO – ICO
3. Dr Jyoti Joshi Jain, Dy. Director & Senior Advisor, AEFI Secretariat, ITSU
4. PPS to JS(RCH)
5. PPS to DC (Imm.)

B. Draft Agenda for the State AEFI committee meeting

Time	Discussion topic	Resource person
_: _ to _: _	Welcome Address & Introduction of participants As an initiative, members from select district AEFI committees, ADR (Adverse drug reaction) Monitoring Centre (PvPi), independent experts can be invited as special members for the state AEFI committee.	
_: _ to _: _	Discussion on action points for the last meeting A discussion on the meeting minutes and action points for the last meetings helps in monitoring the progress made in strengthening of AEFI surveillance in the state.	
_: _ to _: _	An update on AEFI surveillance status of districts/state- ■ ***Reporting trend***- No. of AEFI cases reported in the current year and also comparing it with last year corresponding period's data. ■ ***Timeliness & completeness***- Review the timeliness and completeness of AEFI cases reported and investigated. ■ ***Performance of silent districts***- Discussion on silent districts (not reported any AEFI case) and plan of action for these districts, ■ ***Functionality of district AEFI committee (DAC)***- Tracking the periodic meeting of DAC using a tracking tool. ■ ***Review of immunization data (HMIS mismatch for reported death cases vs direct reporting) based on the feedback received from national level*** ■ ***Update on AEFI surveillance training*** ■ ***Any other relevant points related to AEFI surveillance***	
_: _ to _: _	Causality Assessment process Case discussions followed by filling up of causality form using the WHO revised algorithm for causality assessment and signature of experts (at least one pediatrician)	
_: _ to _: _	Open Discussion and recording of proceedings in form of minutes of meeting (to be signed by the chair and shared with members and immunization division, MoHFW at national level)	
_: _ to _: _	Closing remarks	

C. Non-disclosure document for causality assessment meeting

DECLARATION OF INTEREST & CONFIDENTIALITY AGREEMENT FOR STATE AEFI COMMITTEE MEETING

Title of meeting: State AEFI committee meeting Date:

Declaration: Have you or your partner any financial or other interest in the subject-matter of the meeting or work in which you will be involved, which may be considered as constituting a real, potential or apparent conflict of interest?

Yes: ☐ **No::** ☐ **If yes, please give details in the box below.**

Type of interest, e.g. patent, shares, employment, association, payment (including details on any compound, work, etc.)	Name of commercial entity	Belongs to you, partner or unit?	Current interest? (or year ceased)

Is there anything else that could affect your objectivity or independence in the meeting or work, or the perception by others of your objectivity and independence?

_____

_____

I hereby declare that the disclosed information is correct and that no other situation of real, potential or apparent conflict of interest is known to me. I undertake to inform you of any change in these circumstances, including if an issue arises during the course of the meeting or work itself.

Please note that all proceedings of the state AEFI committee meeting shall be confidential and no member who is not authorized by the State AEFI Committee to speak on its behalf shall communicate externally about the discussion, decision and opinions expressed by the experts of the state AEFI committee, or by individual members during the course of this meeting, on a public or private forum. In signing below, I undertake to hold confidential what is shared and discussed within the state AEFI committee meeting.

_____ _____

Signature Date

_____ _____

Name Institution

D. Tracking tool for District AEFI committee meeting

Tracking tool for District AEFI committee meeting														
Name of the state			Financial Year-											
			Quarter-1 (Apr, May & June)			**Quarter-2** (July, Aug & Sept)			**Quarter-3** (Oct, Nov & Dec)			**Quarter-4** (Jan, Feb & Mar)		
S. No.	Name of the district	Date of updation of District AEFI committee membership	Date	Minutes received (Yes/No)	Reminder/ feedback sent (Yes/ No)	Date	Minutes received (Yes/No)	Reminder/ feedback sent (Yes/ No)	Date	Minutes received (Yes/No)	Reminder/ feedback sent (Yes/ No)	Date	Minutes received (Yes/No)	Reminder/ feedback sent (Yes/ No)
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E. Letter for financial guidelines related to activities under AEFI surveillance programt

Z-16025/05/2012-Imm
Government of India
Ministry of Health and Family Welfare
(Immunization Division)

Nirman Bhawan, New Delhi
Dated: 1st August 2016

To,

MD (NHM)
All states/UTs
Sub: Financial guidelines related to activities under AEFI surveillance programme.

Sir/Madam,

You may be aware that lot of initiatives have been taken to improve surveillance of Adverse Events Following Immunisation (AEFI) including establishment of National AEFI Committee, setting up AEFI Secretariat and National AEFI Collaborating Centres, trainings and capacity building of programme managers at state and district levels and of medical officers and health workers on AEFI surveillance. There has been an increase in numbers of AEFI cases reported as well as improvements in quality of investigations. Many State AEFI Committees have become active and are conducting regular meetings and some district AEFI committees are functional.

In various forums, State immunization officers raised the concerns on availability of funds for various activities on AEFI Surveillance programme, mainly for-

1. Holding State & District AEFI Committee meetings
2. Carrying out investigations in the field by district & state AEFI committee members and to send samples to CDL for testing.
3. State/District/Block level trainings under AEFI.

In this regard, it is suggested that the expenditure on the above noted activities may be under taken from training head (C.3) of Part-C of Immunization.

Yours faithfully,

Dr M K Aggarwal,
DC (UIP)

Copy to:

1. SEPIO, All States/UTs
2. Dr N K Arora, Chairperson, National AEFI Committee
3. Dr Jyoti Joshi Jain, Deputy Director (ITSU) & Senior Advisor - AEFI
4. PPS to JS (RCH)
5. PS to DC (Immunization)
6. Zonal AEFI Consultants, AEFI Secretariat

F. All AEFI related document are readily available at the following link-

S. No.	Forms and Guidelines	URL link
1	Case reporting format	http://www.itsu.org.in/?page_id=938
2	Preliminary case investigation form	
3	Final case investigation form	
4	Laboratory requisition form	
5	Revised Causality assessment form	
6	Format for Verbal Autopsy	
7	AEFI Surveillance and Response Operational Guidelines	
8	Causality Assessment of an Adverse Event Following Immunization (AEFI)- revised WHO classification	
9	Special Investigation protocol for Serious AEFIs	
10	Operational Guidelines initial management of anaphylaxis using injection adrenaline by ANMs	
11	QMS-AEFI guidelines	
12	Communication Guidelines for Building Vaccine Confidence around AEFI	http://www.itsu.org.in/?page_id=952
13	AEFI media communication proto-col	
14	Renuka (The Health Worker) train-ing film on AEFI	https://www.youtube.com/watch?v=x5eGVUbPmqk or http://www.itsu.org.in/?page_id=938
15	Training film of Health workers on Adrenaline administration in the management of anaphylaxis	https://www.youtube.com/watch?v=Xfgo-0LUsos or http://www.itsu.org.in/?page_id=938
16	NACM approved CA of AEFI cases	https://mohfw.gov.in/Organisation/Departments-of-Health-and-Family-Welfare/immunization/aefi-reports

ITSU
IMMUNIZATION
TECHNICAL SUPPORT UNIT
Ministry of Health & Family Welfare