Be Wise!
Get your child fully immunized

स्वास्थ्य एवं परिवार कल्याण मंत्रालय
MINISTRY OF HEALTH AND FAMILY WELFARE
सत्यमेव जयते

NATIONAL HEALTH MISSION
राष्ट्रीय स्वास्थ्य मिशन

A CONCISE GUIDE FOR PHC STAFF

AEFI ADVERSE EVENT FOLLOWING IMMUNIZATION

Reporting, Investigation and Management

2025

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आराधना पटनायक, भा.प्र.से.
अपर सचिव एवं मिशन निदेशक (रा.स्वा.मि.)
Aradhana Patnaik, IAS
Additional Secretary & Mission Director (NHM)

सत्यमेव जयते

आज़ादी का अमृत महोत्सव

भारत सरकार
स्वास्थ्य एवं परिवार कल्याण मंत्रालय
निर्माण भवन, नई दिल्ली-110011
Government of India
Ministry of Health & Family Welfare
Nirman Bhawan, New Delhi-110011

MESSAGE

India has made commendable progress in reducing mortality among children and mothers, with immunization playing a key role. Over the past decade, new vaccines such as the rotavirus vaccine, inactivated polio vaccine and pneumococcal vaccine have been introduced. We have also strengthened our capacity to indigenously produce vaccines required for the Universal Immunization Programme (UIP).

The immunization programme has seen major advancements through digital initiatives like eVIN for managing cold chain equipment and vaccine logistics and U-WIN, one of the largest electronic vaccination registries in the world. The reporting of Adverse Event Following Immunization (AEFI) has also been digitalized. Integration of UWIN with SAFEVAC (Surveillance and Action For Events following Vaccination) enables vaccinators to report even minor events from the field.

As part of the capacity building activities for further strengthening the AEFI surveillance programme, a concise guide on Adverse Event Following Immunization (AEFI) surveillance for the PHC staff (ANMs, their supervisors and medical officers) has been developed. This guide is based on the comprehensive Adverse Event Following Immunization (AEFI) Surveillance and Response Operational Guidelines of 2024.

I encourage all the healthcare workers, medical officers to effectively utilize this concise guideline to update their knowledge on prevention, management, and reporting of AEFIs, thus contributing to vaccine safety and sustain confidence of the community in vaccines.

Dated: 28th April, 2025

(Aradhana Patnaik)

Tel.: 011-23063618, 23061097 E-mail: asmd-mohfw@nic.in

Meera Srivastava, IRS
Joint Secretary

सत्यमेव जयते

आज़ादी का अमृत महोत्सव

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FOREWORD

The Universal Immunization Programme (UIP) is one of the largest in the world, ensuring protection of every child against 12 vaccine-preventable diseases. This is done by the ANMs with support of frontline workers such as ASHAs and Anganwadi workers, who work as a team to ensure full immunization.

One of the threats to full immunization coverage is vaccine hesitancy. A strong Adverse Event Following Immunization (AEFI) surveillance system in the country helps to recognize vaccine safety issues, prevent their recurrence and provides evidence in the safety of vaccines. Together with the drug regulatory authority, AEFI surveillance works towards ensuring the quality and safety of vaccines given in the country.

In recent years, several initiatives have been taken to strengthen the AEFI surveillance, including digitalization and improved management of adverse events following immunization at the session site.

It gives me immense pleasure to present this concise guide for the PHC staff on managing and reporting of Adverse Event Following Immunization (AEFI). The objective of this concise guide is to provide the details of recent changes, relevant information and tools related to AEFI surveillance required by the PHC staff in an easy to refer format.

I commend the efforts of the team members who have contributed to developing this valuable document.

(Meera Srivastava)

Tel : 011-23061842, 23061195 E-mail : jsrch-mohfw@gov.in

Dr. Pawan Kumar
MBBS, MD, DNB, MBA
Additional Commissioner, Incharge (MH & Immunization)

भारत सरकार
स्वास्थ्य एवं परिवार कल्याण मंत्रालय
निर्माण भवन, नई दिल्ली-110011
GOVERNMENT OF INDIA
MINISTRY OF HEALTH & FAMILY WELFARE
NIRMAN BHAWAN, NEW DELHI - 110011

PREFACE

The success of any national vaccination programme hinges not only on the implementation of the vaccination process but also on the robust monitoring of any potential adverse event following the immunization (AEFI). Identifying and addressing AEFIs promptly is essential to maintain the public confidence in immunization and helps to address vaccine hesitancy. The data generated through vaccine safety surveillance helps in ensuring that vaccines remain safe.

Adverse Events Following Immunization (AEFI) surveillance is a critical component of India's Universal Immunization Programme. It consists of implementation structures from national level to the PHC and Sub Centre levels and has oversight mechanisms in the form of district, state and national AEFI committees.

Staff at the PHC (ANMs, LHVs, Health Supervisors and Medical Officers) are aware of AEFI reporting processes. However, there is a need for regular trainings. Therefore, this concise document on AEFI surveillance processes, relevant primarily for PHC staff has been developed.

The first two chapters of the concise guide gives the basics of AEFI surveillance, the roles and responsibilities of different PHC staff with respect to AEFI surveillance and the types of AEFIs. Chapter three has details of how to report minor, severe and serious AEFIs through UWIN and in the AEFI registers by vaccinators. It also outlines the procedure for Medical Officers to accurately complete the Case Reporting Form (CRF) for serious and severe AEFIs, as well as their responsibilities in supporting investigation and follow-up actions. The fourth chapter details the management of minor AEFIs using syrup paracetamol and managing anaphylaxis at the session site (using anaphylaxis kits) and at the PHC (using AEFI kits). Chapter five covers the steps to be

Office : Room No. 522-A, Nirman Bhawan, New Delhi-110011
Tel : 011-23061288, E-mail : drpawan.kumar@gov.in, drpawan.mohfw@gmail.com

taken to implement the Quality Management System for AEFI surveillance at the PHC/Sub Centre session sites.

The annexure in the document includes a step-wise guide for vaccinators to report AEFIs in U-WIN, blank formats of the AEFI register, CRF and the QMS checklist for session sites at sub centers and PHCs.

I hope this concise guide will further enhance the capacity and capability of our PHC staff to respond to vaccine safety issues in the field practice.

I also sincerely appreciate the hard work of the team who contributed to the development of these concise guide.

(Dr Pawan Kumar)

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Abbreviations

AD	Auto-disable
AEFI	Adverse Event Following Immunization
AMC	Adverse Drug Reaction Monitoring Centre
ANM	Auxiliary Nurse Midwife
ASHA	Accredited Social Health Activist
AWW	Anganwadi Worker
BCG	Bacillus Calmette-Guerin
CHC	Community Health Center
CRF	Case reporting form
DH	District Hospital
DIO	District Immunization Officer
DPT	Diphtheria–Pertussis (whole-cell)–Tetanus vaccine
dT	Diphtheria-Tetanus Toxoid vaccine
FLW	Front-Line Workers
HBV/ Hep B	Hepatitis B Vaccine
HHE	Hypotonic Hypo-responsive episode
HMIS	Health Management Information system
HIV	Human Immunodeficiency Virus
HS	Health Supervisor
ICDS	Integrated Child Development Services
IM	Intramuscular
ITSR	Immunizaton Triggered Stress-Related Response
IV	Intravenous
JE	Japanese Encephalitis
MI	Mission Indradhanush
MO	Medical Officer
MO I / C	Medical officer In-charge
MPR	Monthly Progress Report
MR	Measles – Rubella vaccine
NQAS	National Quality Assurance Standard
OB	Observation
OPD	Out Patient Department
PHC	Primary Health Center
PI	Parent Interview
PIP	Programme Implementation Plan
QA	Quality Assurance
QMS	Quality Management System
RCH	Reproductive and Child Health

RMP	Registered Medical Practitioner
RR	Record Review
SAFE-VAC	Surveillance and Action for Events Following Vaccination
SDH	Sub-Divisional Hospital
SI	Staff Interview
SMS	Short Messaging Service
SOPs	Standard operation procedures
Td	Tetanus and adult diphtheria vaccine
TSS	Toxic Shock Syndrome
TT	Tetanus Toxoid
UIP	Universal Immunization Programme
U-WIN	Universal Immunization Programme Vaccine Intelligence Network
VHSNC	Village Health, Sanitation & Nutrition Committee
VVM	Vaccine Vial Monitor

1 Introduction

A robust Adverse Events Following Immunization (AEFI) surveillance system at the Primary Health Centre (PHC) level implemented by trained health and frontline staff is essential for identifying, reporting, investigating and managing AEFIs. This ensures that the vaccines administered through the immunization programme is safe and trust of the community in vaccines and the programme is maintained. It is important to note that PHC health staff should report all AEFIs following any vaccination and not just UIP vaccines. Therefore, AEFIs following anti rabies vaccines, tetanus toxoid injections, vaccinations administered in the private sector, yellow fever vaccinations, etc. should also be reported into the AEFI surveillance system.

This guidance document provides clear, step-by-step instructions for PHC level staff (medical officers, health supervisors, vaccinators, others) on conducting AEFI surveillance effectively. The objective is to enable staff at the PHC levels to strengthen AEFI reporting mechanisms, avoid preventable AEFIs, facilitate management of AEFIs at session sites/PHCs and at home and support investigations.

Adverse Events Following Immunization (AEFI)

Adverse event following immunization (AEFI) is defined as 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 unfavourable or unintended sign, symptom or disease.

- Reported adverse events can either be truly associated with vaccines or vaccination processes; or can be coincidental events that are not due to the vaccine or vaccination process but are temporally associated with vaccination.
- An adverse event may occur even when the vaccine has been prepared, handled and administered correctly. Any medical event which is adverse in nature and the onset of which has occurred following vaccination may be reported as an AEFI irrespective of whether this is related to vaccination or not.
- AEFIs may not necessarily be causally related to vaccine/vaccination. Therefore, adverse events generating parental, community or media concerns should also be reported as AEFIs.

The AEFI surveillance system at the PHC level operates as a passive reporting system. Any suspected adverse event following immunization reported to the PHC by health workers (ANM, ASHA or AWW) must be recorded and reported according to the National AEFI Surveillance and Response Operational Guidelines (2024).

Responsibilities of PHC Health Staff in AEFI Surveillance

Frontline Workers (FLWs)

- Regular follow up with beneficiaries to identify AEFIs after the vaccination session, using the beneficiaries' list provided by the ANM.
- Inform the adverse event immediately by telephone to concerned ANM, MO, etc.
- Assist in referral of any suspected cases.
- Support in building community confidence.

ANMs

- Follow safe immunization practices.
- Ensure an anaphylaxis kit with adrenaline within expiry date is available at the session site.
- Ensure four key messages are delivered after vaccination.
- Treat minor/non-serious AEFIs (mild symptoms like fever, pain, etc.) symptomatically.
- For all other cases (serious/severe) provide immediate first aid and refer the case to MO(PHC) or to the appropriate health facility for prompt treatment and report. Inform the MO(PHC) at the health center immediately by the fastest means possible.
- Report all minor AEFIs and all reported hospitalizations and deaths following vaccinations under UIP into UWIN-SAFEVAC and also record them in the AEFI register which is maintained at the PHC. A minimum of one AEFI (minor or serious/severe) should be reported by an ANM every month.
- AEFIs following any other vaccination (non-UIP) should be recorded in the AEFI register and reported to the DIO.
- Assist in investigation of AEFIs and take corrective action as recommended by the MO (PHC).

Health Supervisors (HS)

- Supervise and provide hands-on training to ANMs/vaccinators in the field.
- Oversee vaccination sessions to ensure adherence to safety protocols and identify any potential risks.
- Ensure proper vaccine storage and handling to minimize risks associated with improper immunization practices.
- Encourage health workers to report AEFIs directly into UWIN and record it in the AEFI register. Monitor that at least one AEFI (Minor or serious/severe) is reported by an ANM every month.
- Ensure that serious or severe events are immediately notified using the fastest available method.
- Support in AEFI investigations.

Medical Officer (MO)

A MO plays a key role in AEFI surveillance. Key activities are:

Management of AEFIs

- Ensure proper clinical management of AEFIs, including referral to a higher-level facility if necessary.
- Maintain the availability of emergency drugs and medical equipment to address adverse events, conducting regular checks on the expiry of drugs in AEFI kits.
- Ensure ANMs are well-trained in using the anaphylaxis kit and conduct quarterly certification of these kits.

Reporting AEFIs

- Facilitate prompt reporting of AEFIs following UIP vaccinations in UWIN and AEFI registers and non-UIP vaccines in the AEFI registers. Serious/severe AEFIs must be immediately communicated via phone or in person to the DIO.
- Display the poster at **Annexure A** with name and contact details of the MOIC and DIO at the doctors duty room and nursing station to remind staff to report serious/severe AEFIs.
- Ensure the availability of AEFI registers at the PHC. Ensure that each ANM reports at least one AEFI in a month. Verify the serious and severe AEFIs by visiting the beneficiary. Complete Section A of the CRF, and submit it to the DIO within 24 hours.
- Weekly and monthly review and assess AEFI entries in the AEFI registers to look for trends and issues.
- Encourage and motivate health workers and frontline workers to report AEFIs. Conduct training sessions for health workers, frontline workers (FLWs), and doctors on AEFI surveillance activities.

Investigating AEFIs

- Assist the DIO/ AEFI committee in investigating serious and severe AEFI cases.
- Facilitate the gathering of essential records and information, including detailed clinical and vaccination history, pre and post-vaccination health status, and findings from community investigations through interviews and documentation review.
- Ensure the retrieval of all relevant documents, such as hospital and laboratory records, and other reports for AEFI cases involving hospitalization. Submit these records to the DIO.

Implement QMS for AEFIs

Implement QMS for AEFIs at the PHC and Session sites as per the quality guidelines for AEFI surveillance.

Other activities

- Provide adequate supervision and monitoring in the field.
- Communicate and share investigation findings with health workers and the community, as appropriate.
- Direct any media queries to district authorities and refrain from making independent statements.
- In case of sudden or unexplained deaths, motivate relatives to agree for post-mortem.

2 Types of AEFIs

I. AEFIs by Severity of the Event

For the purpose of reporting, AEFIs can be minor, severe and serious. Most vaccine reactions are minor and settle on their own. Severe and serious reactions are rare.

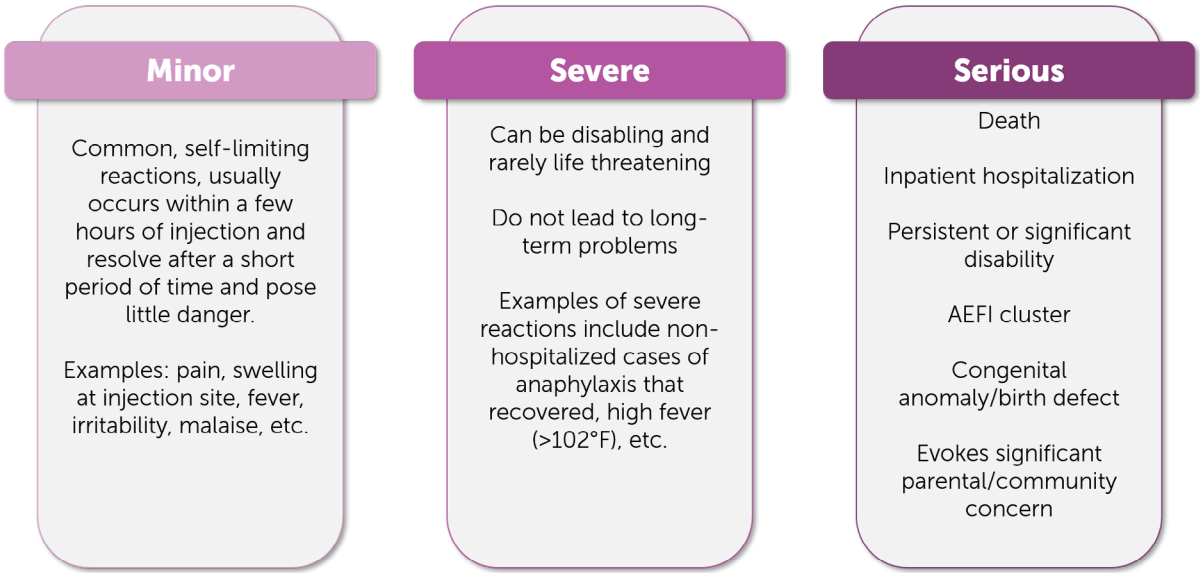


Figure 2.1: Minor, Serious and Severe Vaccine Reactions

Minor Vaccine Reactions

Minor reactions can be local and systemic. Local reactions are pain, swelling and/or redness at the injection site. Systemic reactions are low/moderate grade fever, malaise, body ache, nausea/vomiting, loss of appetite, etc. These last for two-three days and disappear on its own or can be managed with syrup paracetamol. It can be expected in about 10% of vaccine recipients, except for those vaccinated with pentavalent or DPT or tetanus-adult diphtheria (Td) boosters, where up to 50% can be affected. BCG causes a specific local reaction that starts as a papule (lump) two or more weeks after immunization, which becomes ulcerated and heals after several months, leaving a scar. Measles/MR vaccine causes fever, rash and/or conjunctivitis, and affects 5–15% of recipients. All AEFIs which are not minor are severe AEFIs.

Severe AEFI

Severe AEFIs are clinically more severe than minor AEFIs, but were not hospitalised or did not result in death. These can be disabling but most do not lead to long-term problems. Examples include cases of high-grade fever not requiring hospitalization, an episode of seizure which was not hospitalised, cases of hypotonic hyporesponsive episodes (HHEs) treated in casualty without admission, severe local reactions which are treated on OPD basis, injection site abscesses drained or treated without hospitalization, etc.

Serious AEFI

A very small proportion of severe AEFIs may be hospitalised, or result in death or in persistent or significant disability/incapacity. These are labelled as serious AEFIs. Congenital anomalies/ birth defects suspected to be following vaccination or adverse events occurring in clusters are also considered as serious AEFIs. Any adverse event which evokes community concern or reported in media is also considered as serious AEFI and should be reported and investigated.

Serious AEFI

Death, hospitalisation, clusters, disability, congenital anomaly/birth defect, media reports/community or parental concern

Cluster

Two or more cases of the same event occuring in a geographical area, related to a vaccine/vaccinator/cold chain point, etc.

II. Cause-Specific AEFIs

Following is the cause-specific categorization of serious/severe AEFIs:

Coincidental Events

- Coincidental events are events occurring after immunization and is not caused due to the vaccine or process of administration.
- These need to be immediately reported and investigated as a response is critical to the community's concern about vaccine safety and to maintain public confidence in immunization.

Vaccine Product-related Reaction

- This is a reaction (an individual body's response) to the inherent properties of the administered vaccine, even when the vaccine has been prepared, handled and administered correctly. Examples of common minor reactions are fever, pain etc and severe/serious reactions are allergic reaction, anaphylaxis etc.
- Such cases need to be reported and investigated to ensure that these events are occurring as expected and that there are no unusual increases or clustering related to a particular vaccine or batch or a group of recipients.

Immunization Error-related reactions

- An adverse event can occur as a result of inappropriate handling/ prescribing/ administration of a vaccine. It is very important to prevent, identify and rectify these errors. (Table 1).
- An immunization error-related reactions may be reported as a cluster of events associated with a particular provider, health facility/cold chain, or even a single vial of vaccine that has been inappropriately prepared or contaminated.
- Abscesses are common adverse events which are likely to be a result of programme errors. These should be reported and investigated and steps taken to reduce the possibility to minimise recurrence.
- Programme errors may impact the confidence of vaccine beneficiaries have in vaccines in the area and will require special advocacy and communication activities to get the immunization programme back on track.

Table 2.1: Immunization Error-related Reactions

Immunization Error	Related reaction	Preventive measures
Error in vaccine prescribing or non-adherence to recommendations for use of the vaccine		
• Failure to adhere to a contraindication • Failure to adhere to vaccine indication, dose or schedule.	• Disseminated infection with an attenuated live vaccine in an immune-compromised individual • Anaphylaxis in an individual with known allergy • Systemic and/or local reactions	• Administer the vaccine as specified in the National Immunization Schedule. • Use anaphylaxsis kit to provide initial management of suspected anaphylaxsis.
Non-sterile injection administration		
• Reuse of disposable syringe or needle leading to contamination of the vial, especially in multi-dose vials • Improperly sterilized syringe or needle • Contaminated vaccine or diluent • Reuse of reconstituted vaccine in subsequent sessions	• Local injection site reactions (e.g., abscess, swelling, cellulitis, induration) • Sepsis, toxic shock syndrome • Blood-borne transmission of disease, e.g., hepatitis B or C, HIV, • Death	• Wash hands with soap and running water for 40-60 seconds and dry before start of the session. • Before vaccination, inspect the area of injection. Avoid giving injections if the skin at the site of injection is compromised by any local infection such as a skin lesion, cut, or weeping dermatitis. • Always use Auto Disabled syringe for each injection and a new disposable syringe to reconstitute each vial of BCG, MR and JE. • Always pierce the rubber cap (septum) of the vial with a sterile needle. • Do not touch the needle or rubber cap (septum) of a vial with your finger. • If the injection site is dirty, clean it with a clean, dry swab.

Immunization Error	Related reaction	Preventive measures
Error in vaccine reconstitution or use of vaccine with abnormal physical condition		
• Reconstitution with incorrect diluent (drug substituted for vaccine or diluent) • Using vaccine with changed colour, turbidity, presence of foreign substances • Inadequate shaking of vaccine • Improper syringe filling	• Effect of wrong diluent (e.g., insulin, oxytocin, muscle relaxants) • Death • Local abscess • Increased local reaction (induration, pain) • Loss of vaccine potency	• Check if the vaccine vial has a usable Vaccine Vial Monitor (VVM), has readable manufacturing details, is within the expiry date, and has not crossed beyond 28 days from the date of first opening it (if under open vial policy) and date of opening is clearly written on the vial. • Ensure and check that the diluent supplied by the manufacturer for the respective vaccine is used at the vaccination sites and is within the expiry period. • Do not use any vaccine vial or diluent with visible contamination or breaches of integrity (e.g. cracks, leaks).
Error in vaccine handling		
• Exposure to excess heat or cold as a result of inappropriate transport, storage or handling of the vaccine (and its diluents where applicable) • Not maintaining cold chain at the session site or use beyond recommended time after reconstitution • Freezing of vaccine during transport • Use of a product after the expiry date	• Systemic or local reactions due to changes in the physical nature of the vaccine such as agglutination of aluminium-based excipients in freeze-sensitive vaccines. • Toxic shock syndrome • Loss of vaccine potency	• Follow product-specific recommendations for the use, storage, and handling of a vaccine. • Discard any needle that has touched any non-sterile surface. • Do not use any vaccine vial or diluent with visible contamination or breaches of integrity (e.g. cracks, leaks). • Do not use a needle or syringe if the package has been punctured, torn, or exposed to moisture, defaced, contaminated, etc.

Immunization Error	Related reaction	Preventive measures
Error in administration		
• Incorrect technique/ site of injection (BCG / DPT/dT/TT given subcutaneously, injection into buttocks in infants or medially on thighs or use of wrong needle)	• Local reaction or abscess • Traumatic neuritis • Neurologic, muscular, vascular or bony injury due to incorrect injection site, faulty equipment or technique, • Ineffective vaccine	• Follow product-specific recommendations for the use, storage, and handling of a vaccine. • Never leave a needle in the septum of the vial. • Fill the vaccine in the syringe just before injecting the beneficiary. Do not keep syringes prefilled. • Use separate and new syringe and needle for reconstitution of vaccine every time. Reuse of the same syringe/needle for reconstitution is strictly forbidden. Cut the hub of the used syringe with hub cutter immediately after use. • Anticipate sudden movement of the child.

Immunization Triggered Stress Response (earlier Immunization Anxiety-related reaction)

- It is a response to the stress some individuals may feel about getting an injection or results from pain of an injection. These are common in adults, adolescents and children over 5 years of age. They are unrelated to the content of the vaccine. These are common in mass vaccination campaigns.
- Clinical presentations include fainting, light-headedness, and dizziness, tingling around the mouth and in the hands. Younger children may have vomiting, breath-holding spells, which, in some cases can lead to a brief period of unconsciousness and convulsions.
- To minimize this anxiety response, it is advisable that the beneficiaries and caregivers are explained about the vaccine and its process before vaccination. If possible, the vaccinator should segregate potential recipients from those who received the vaccine.

Vaccine Quality Defect-related Reaction

This is a defect in a vaccine that occurred during the manufacturing process. Due to stringent control over the manufacturing process and independent testing of all batches of vaccines before they are released for use by health service providers, such quality defect reactions are very, very rare.

3 Reporting of Adverse Events Following Immunization (AEFI)

AEFI can be reported for any vaccine, regardless of:

- Whether it is part of the UIP schedule or not
- Administration in a government or private setting
- The beneficiary's age, whether a child or an adult

Notification

Notification of an adverse event is when a health staff (vaccinator or supervisor or doctor) is first informed of the event by a vaccine recipient or their caregiver.

Reporting

- Minor AEFIs are reported in UWIN and recorded in the AEFI register (for AEFIs following UIP vaccines) and only in AEFI register for other vaccines.
- Serious and severe AEFIs are also reported in UWIN and AEFI registers. They must also be reported immediately to the nearest Medical Officer, PHC/CHC or DIO using the quickest communication methods (e.g., phone, SMS, WhatsApp, email) to ensure timely action and response.
- Health workers or frontline workers should immediately inform the event (death or hospitalization) to the PHC Medical Officer, while private practitioners or doctors in hospitals or medical colleges should notify the DIO.
- The MO is responsible for filling a hard copy of the CRF and sharing it with the DIO within 24 hours of his getting to know about the AEFI.
- In large hospitals and medical colleges, the CRF should be completed with as much detail as possible and forwarded to the DIO through the hospital or medical college's AEFI Nodal Officer.
- The DIO will then submit the CRF to SAFE-VAC (a web-based application for recording and reporting of AEFI cases) as soon as possible.

REPORTING AEFIs IN U-WIN

- Vaccinators can report minor adverse events or deaths or hospitalization following a vaccination. The vaccination received should be recorded in U-WIN. The process of registering an adverse event in U-WIN by a vaccinator is explained in **Annexure B**.

AEFI Registers At Healthcare Facility / Planning Unit Level

ANMs/vaccinators at a block or planning unit should record all AEFIs (serious, severe and minor) informed to them on weekly basis in an AEFI register (see **Annexure C**) maintained at the centre. Medical Officer In-charge (MOIC) of the center should analyze the information regularly to look for any pattern or preventable programme errors and will submit the same to DIO of the district every month.

AEFI registers should also be maintained at all private and public healthcare facilities such as nursing homes, hospitals and medical colleges under the supervision of a nodal medical officer. Healthcare staff of the facility including vaccinators, nursing, para-medicals and doctors can enter AEFIs in this register.

The data related to minor and serious/severe AEFIs will be analysed for patterns leading to further investigations or actions such as more frequent monitoring of cold chain, vaccination sessions, trainings, etc. depending on the types of AEFIs reported and/or presence of clustering.

Monthly Progress Reports (MPR)

Health Management Information System (HMIS) is a monthly reporting system which collates data from all PHCs, CHCs, SDHs, DHs and medical colleges. This data is visible at both the district and state level. The numbers of minor, severe, serious and deaths reported following vaccination should be entered in the AEFI section.

Monthly Service Delivery Reporting format

HWC-Sub Centre (HWC-SC) FORMAT

Facility Code	Data Item	Numbers reported during the month (In-facility)	Numbers reported during the month (Outreach)
8.6	**Adverse Event Following Immunisation (AEFI)**		
8.6.1.	Number of cases of AEFI -Minor (eg.- fever, rash, pain etc)		
8.6.2.	Number of cases of AEFI - Severe (eg.- anaphylaxis, fever>102 degrees, not requiring hospitalization etc.)		
8.6.3.	Number of cases of AEFI - Serious (eg.- hospitalization, death, disability , cluster etc.)		
8.6.3.a	Out of Number of cases of AEFI - Serious , total number of AEFI deaths		

Please note that deaths (reported under 8.6.3a) will also be reported under 8.6.3.

Figure 3.1: HMIS Monthly Service Delivery Reporting Format

ANMs should enter "0" in the relevant row in the formats, if no AEFI has been reported. The numbers need to be entered separately for "In facility" and "Outreach" as may be the case. Please see Figure 3.1 for details.

As much as possible, the numbers recorded in HMIS should corroborate with the number of AEFIs entered in U-WIN and the AEFI register.

AEFI Case Reporting Form (CRF)

(only for serious/severe AEFIs)

The CRF captures basic minimal information pertaining to the following.

1. Reporter (Section A)
2. Patient (Section B)
3. Vaccine and diluent (Section C)
4. Event (Section D)
5. Decision making (Section E)

Purpose

- It provides basic information of the event for decision making at all levels and is therefore urgent.
- It should be carefully completed with as many details as possible, because investigation of the case is planned based on the information in the CRF.

Steps to fill Case Reporting Form (CRF) (see **Annexure D**)

1. A serious or severe AEFI cases can be reported using the CRF (in hard copy) from any health facility in the government or private sector. The reporting doctor / medical officer will enter information in "Section A", after receipt of information from any source including ANM, AWW, ASHA, ICDS, Health Supervisor, community mobiliser, private practitioners, clinicians in tertiary and secondary care hospitals and clinics, lay public, informal health practitioners such as RMPs, ADR Monitoring centres, media reports, etc.
2. The medical officer should examine the patient and complete sections B, C and D of the CRF and submit the CRF to the DIO within 24 hours of notification. In case of a reported unexplained death, the medical officer should make all efforts to ensure a post mortem is conducted at the earliest.
3. Within 24 hours of receipt of CRF, the DIO should review the CRF sent by the MO and
   a. provide district specific information in "section E".
   b. enter case details and generate Case ID in SAFE-VAC and write it on the hard copy of CRF.
   c. Upload the scanned copy of CRF and other available documents in SAFE-VAC. Contact aefiindia@gmail.com in case of problems in accessing SAFE-VAC.
   d. plan immediate investigation of the AEFI with the help of members of District AEFI Committee.

Planning for Investigations

1. The MO in consultation with the DIO should prepare a list of items relevant to that particular event that would assist the investigation team such as the relevant registers, ANM diaries, session tally sheets, indent records, used and unused vials, diluents and syringes.
2. The MO and DIO should ensure that such articles and items are preserved and are available at the time of filling up the case investigation form by the members of the investigative team from District level.
3. Copies of the completed CRF should be shared with the

- District AEFI committee
- Drug Inspector (who is also a part of the AEFI committee)
- Panel conducting the post mortem and the verbal autopsy in case of death. **Conducting a verbal autopsy in all death cases is mandatory.** This is to be done even if a post mortem has been conducted.

4 Managing Adverse Events Following Immunization (AEFI)

Health workers should ensure prompt management of AEFIs to prevent serious consequences and maintain caregivers' trust. At the session site, health worker or vaccinator should follow the guidelines as mentioned below:

- Ensure proper planning of immunization sessions to avoid overcrowding and reduce waiting times and minimize the occurrence of immunization stress-related responses.
- Anaphylaxis kit with inj. adrenaline within expiry date must be available at outreach session site.
- After vaccination, inform the recipient
  - (i) About the four key messages.
  - (ii) About possible minor events (mild to moderate fever, local pain, swelling at the injection site, or malaise, etc.) which may occur and advise age-appropriate dose of Syrup Paracetamol.
  - (iii) Visit the nearest health facility if minor events persist beyond 2-3 days or the severity of minor AEFIs increases and cannot be managed with paracetamol.
- Ensure that vaccine recipients stay back at the session site for 30 minutes after vaccination. Actively observe the recipient during this period for any adverse events.
- Inform Medical Officer immediately by telephone about serious/severe AEFIs.
- Call for an ambulance or arrange for transportation to the AEFI management center / higher health facility.

Managing Minor Adverse Events

Some common minor adverse events following immunization (AEFIs) are local reactions, pain at injection site and fever. High-grade fever following vaccination may precipitate febrile seizure in susceptible infants. The ANM should give age-appropriate dose of Paracetamol to all children who have got Pentavalent vaccine or DPT in case of fever or pain in injection site as follows (Table 4.1):

Table 4.1: Age Wise Doses of Paracetamol Syrup (125 MG/5 ML)

Age group	Dose	How often (in 24 hours)
6 weeks - 6 months	2.5 ml	SOS or 4-6 hourly vaccination#
6-24 months	5 ml	
2-4 years	7.5 ml	
4-6 years	10 ml	

* Paracetamol is not recommended in children weighing <2kg

Maximum four doses in 24 hours with gap of atleast four hours between two doses

Care givers should be informed and encouraged to practice non-pharmacological methods like breastfeeding before, during and after immunization for relieving pain and crying. Other methods like sponging, skin to skin contact and keeping with mother are also helpful in reducing pain, fever and crying after immunization. A feverish child can be cooled with a tepid sponge or bath, and by wearing cool clothing. Extra fluids need to be given to feverish children. For a local reaction, a cold cloth applied to the site may ease the pain. Refer the child to the hospital, if a child develops fever indicated by:

- An axillary temperature of 38 °C or 100.4 °F or higher
- Or feels hot to touch

1. Dispense one bottle of 60 ml syrup paracetamol 125 mg/5 ml after every dose of pentavalent and DPT.
2. Use the dosage chart to choose volume of single dose of paracetamol required to be given as per age group.
3. Show the mark on the cap till which the syrup has to be filled to the caregiver and instruct to:
   - » Administer age-appropriate dose of syrup paracetamol ONLY WHEN THERE IS FEVER.
   - » Not administer more than four doses a day.
   - » USE only the cap supplied with the paracetamol syrup bottle to measure and administer syrup paracetamol to the child.
   - » Shake the bottle for 10 seconds before use.
   - » Refer the child to a doctor if the fever is >38 °C (100.4 °F)

For more information, please refer to "***Guidelines on use of syrup paracetamol following vaccinations***" of the Ministry of Health and Family Welfare, Govt. of India.

Initial Management of Anaphylaxis

Remember: Giving one dose of adrenaline to any suspected case of anaphylaxis intramuscularly is completely safe even if it actually turns out NOT to be a case of anaphylaxis later.

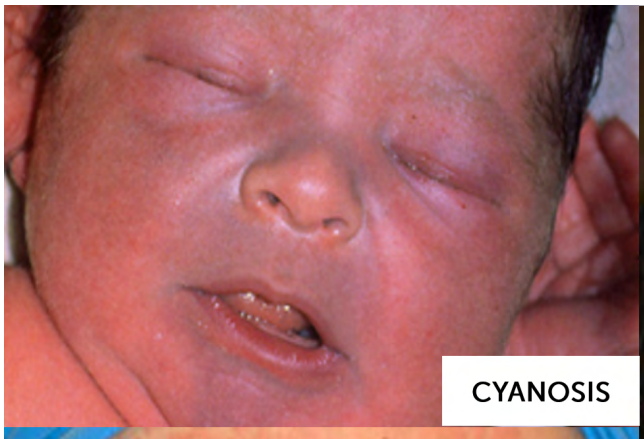
A. Suspecting a Case of Anaphylaxis

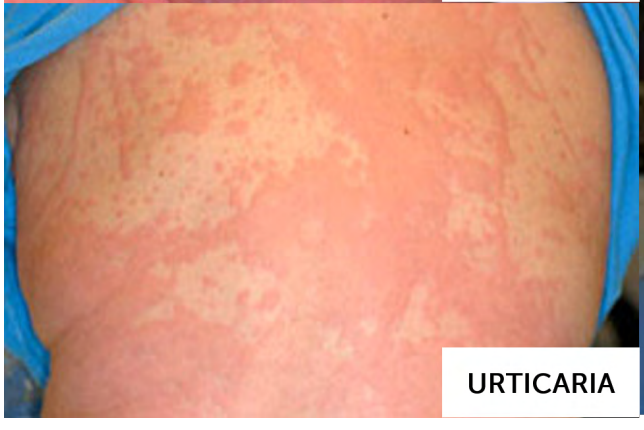
A case of anaphylaxis is suspected* if there is early onset (within few minutes to 6 hours of vaccination) and rapid progression of signs and symptoms with involvement of at least one sign/symptom from at least two of the three systems given in Table 4.2.

Table 4.2: Symptoms of Anaphylaxis

System	Sign and Symptom
Respiratory	• Swelling in tongue, lip, throat, uvula or larynx • Difficulty in breathing • Stridor (Harsh vibrating sounds during breathing) • Wheezing (breath with whistling or rattling sound in the chest) • Cyanosis (bluish discoloration of arms and legs, tongue, ears, lips etc.) • Grunting (noisy breathing)
Cardiovascular	• Decreased level /loss of consciousness (fainting, dizziness) • Low blood pressure (measured hypotension) • Tachycardia (increased heart rate, palpitation)
Dermatological or mucosal	• Generalized urticaria (raised red skin lesion, rash with itching) • Generalized erythema (redness of skin) • Local or generalized Angioedema- itchy/ painful swelling of subcutaneous tissues such as upper eyelids, lips, tongue, face etc. • Generalized pruritus (itching) with skin rash
Others	• Anxiety, diarrhea, abdominal cramps, nausea, vomiting and sneezing or rhinorrhea.

*Many of the initial signs and symptoms are similar in both mild allergic reactions and severe allergic reactions / anaphylaxis. ANM may administer a single dose of adrenaline injection at the first sign or symptom suggestive of allergy or anaphylaxis.


CYANOSIS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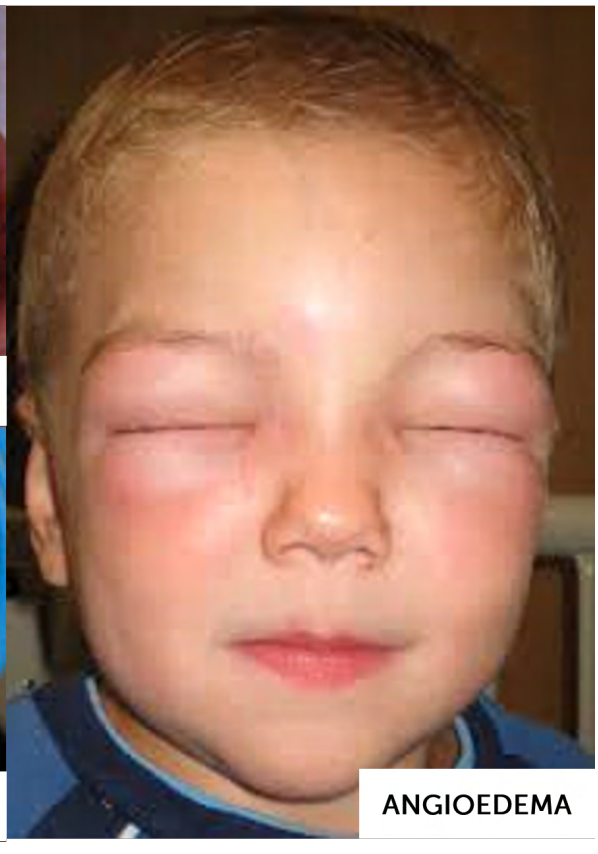
ANGIOEDEMA

B. Steps to Manage a Case of Suspected Anaphylaxis

1. Do not panic; reassure patient/parents and care givers.
2. Conscious patient should be kept in a supine position with lower limbs raised higher than head. The unconscious patient should be kept in left lateral position.
3. Immediately administer one dose of injection adrenaline by deep intramuscular route.

Figure 4.2: Contents of Anaphylaxis Kit

C. Steps for Administration of Injection Adrenaline by ANM

1. From the anaphylaxis kit, take one ampoule of adrenaline (1:1000) and check name, dilution and expiry date on label.
2. Take a 1 ml tuberculin / 40 units insulin syringe and a 24G/25G one-inch-long needle and use the chart given in Table 4.3 to choose and load the required dose of adrenaline as per age and type of syringe supplied (Figure 4.3).

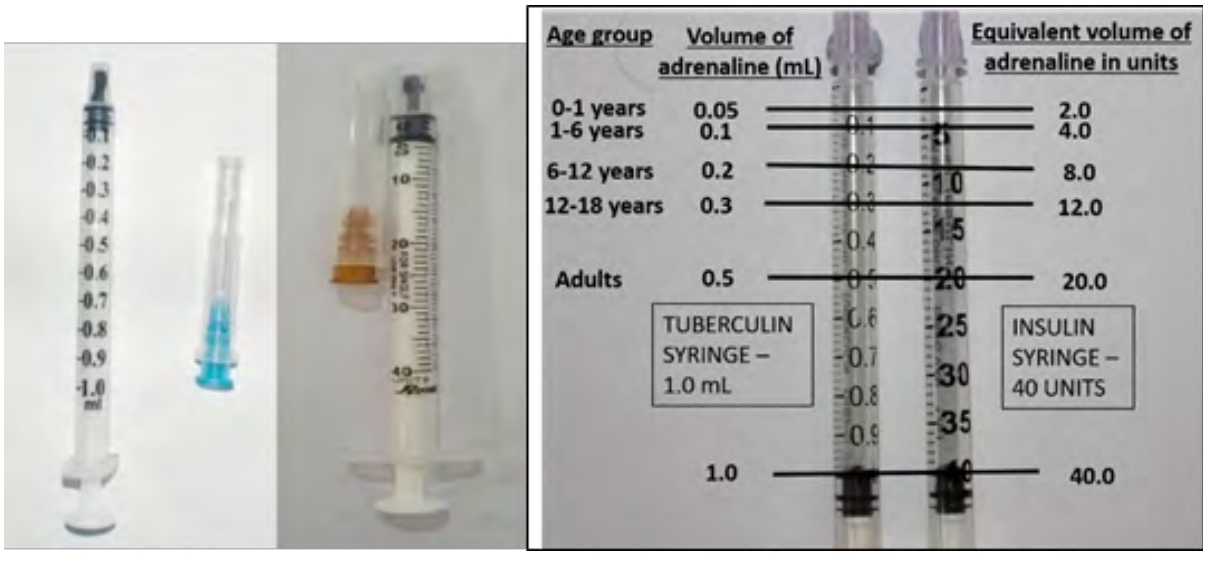

Figure 4.3: Tuberculin and Insulin Syringes with Detachable Needles

Table 4.3: Age-wise Dosage of Adrenaline when using Tuberculin & Insulin Syringe

Age group	Dose in mL (tuberculin syringe)#	Equivalent volume in insulin syringe#
0-1 year	0.05	2
1-6 years	0.1	4
6-12 years	0.2	8
12-18 years	0.3	12
Adults	0.5	20

Based on type of syringe available (tuberculin/insulin), choose relevant volume of adrenaline for administration

3. Use swab to clean the middle 1/3rd of anterolateral aspect of the thigh of the opposite limb to that in which vaccine was given.
4. Give deep intramuscular injection at 90 degrees angle to skin in middle 1/3rd of anterolateral aspect of thigh.

D. Transportation, Informing MO and Documentation

1. Immediately arrange for an ambulance to transport the patient to the nearest health facility well equipped to manage anaphylaxis / health facility (PHC/CHC/DH/Civil Hospital).
2. As the patient is being transported to health facility, inform medical officer about the case with necessary details (name, age, date, time, site, route and dose of adrenaline administered) for further management at the health facility well equipped to manage anaphylaxis and for follow up.
3. Record the anaphylaxis reaction in the immunization card in block letters
4. The case details should also be recorded in the AEFI register at the PHC

Once a quarter, the Medical Officer of the PHC should verify and certify that the injection adrenaline in the Anaphylaxis kit with each vaccinator will not expire within the next three months. If the expiry date is within the next three months, the injections should be replaced with fresh ones with longer expiry dates.

AEFI Management Kit

The AEFI management kit should be available at the PHC (or any other health facility) with a doctor. The health facility should be designated as an AEFI management centre and the details mentioned in the routine immunization or campaign microplans. Once an AEFI is referred to the management centre, the doctor should be able to diagnose the adverse event and immediately start treatment. All MOs of the designated AEFI management centres should be trained in standard AEFI management and reporting procedures.

Figure 4.5: Contents of an AEFI Management Kit

Table 4.4: Contents of an AEFI Management Kit

1. Injection adrenalin (1:1000) solution – 3 ampoules
2. Injection hydrocortisone (100 mg) – 3 vial
3. Disposable syringe - Tuberculin syringes (1mL) OR insulin syringe of 40 units (without fixed needle) - 3 Nos
4. Disposable syringe (5 ml)
5. 24/25G IM needle – 3 sets
6. Scalp vein sets or intravenous cannula set – 2 sets
7. Tab paracetamol (500 mg) – 10 tabs
8. Intravenous (IV) fluids (Ringer lactate/ normal saline): 2 units in plastic bottle
9. IV fluids (5% dextrose): 2 units in plastic bottle
10. IV drip set: 2 sets
11. Vial cutter
12. Cotton wool, adhesive tape – 1 each
13. AEFI Case Reporting Form (CRF)
14. Label showing date of inspection, expiry date of Inj. adrenaline and shortest expiry date of any of the components
15. Drug dosage tables for Inj. adrenaline and hydrocortisone
16. In hospital settings, oxygen support and airway intubation facility should be available

The AEFI management kit is different from the anaphylaxis kit and should not be confused. The key difference is that the anaphylaxis kit is for use of the vaccinator at the session site for early management of suspected anaphylaxis, whereas the AEFI management kit is for use by a medical officer at the AEFI management centre (PHC/CHC, etc.). Other differences are mentioned in Table 4.5.

Table 4.5: Difference Between an Anaphylaxis Kit & an AEFI Management Kit

Anaphylaxsis Kit	AEFI Kit
At immunization site	At health facility well equipped to manage anaphylaxsis (PHC/CHC/district hospital, etc.)
For use by ANM/Health worker/vaccinator	For use by medical officer
Contains adrenaline, tuberculin/insulin syringes, 24/25G one-inch needles, swabs, guidelines/job aid with dose calculation	In addition to contents of Anaphylaxsis kit, contains intubation and resuscitation equipment, hydrocortisone (injection and tablet), ringer lactate, normal saline, 5% dextrose, IV drip set, scalp vein sets

5 Quality Management System (QMS) for AEFI

Implementing a Quality Management System (QMS) for AEFI surveillance aims to:

- Improve efficiency, quality, and safety
- Standardize processes across all levels
- Ensures transparency and defines roles clearly
- Strengthen accountability in implementation
- Enhance immunization safety for all vaccine recipients

QMS will be implemented simultaneously at all subcentres and PHC session sites. There is no need to wait for the subcentre to be completed before starting at the PHC. For example, if a PHC has 4 subcentres and sessions are held at 4 subcentres and 1 at PHC, QMS must be implemented at all the five sites at the same time.

A systematic step-by-step process, including internal, peer, and external assessments of all levels, will be followed to achieve National certification.

- Internal Assessments: Conducted at all levels every three months to identify gaps and develop action plans for improvement.
- Peer Assessments: Conducted at all levels based on internal assessment scores to ensure readiness for external evaluation.
- External Certification: States meeting the criteria during peer assessments can apply for national certification.

A PHC/session site checklist (at **Annexure E**) is used to conduct assessments in PHCs and session sites located in sub centres and PHCs. A feedback survey of vaccine beneficiaries is also conducted. Scores are given for each checkpoint in the checklist. After the assessment, a gap analysis is done and a gap action plan is prepared. This is implemented so that in the next assessment, there is an improvement of scores following the closure of the gap. Eligibility for peer and external assessment is based on specific criteria based on the scoring and the proportion of session sites under the PHC or districts achieving the minimum score.

Budget for all QMS activities (training, preparing SOPs and other quality documents, internal, peer and external assessment, etc.) is available under RCH-4/S.No. 32-Immunization/SRRE of the PIP.

At the PHC level, medical officer in consultation with Quality Assurance (QA) cell and DIO will be responsible for the implementation of activities. Key activities include:

- Familiarising Health staff with the checklist and details of the SOPs. To ensure that ANMs and their supervisors are aware of the contents of the checklist, its utility during assessments, the structure of the gap action plan and details of the SOPs.
- Checking the processes described in the SOPs, modifying them if needed to align them with the actual/expected practice before sharing and implementing the SOPs.
- Conducting the internal assessment of all sub-centre/PHC session sites.
- After every assessment (internal and peer), preparing a gap analysis and action plan of PHC and sub centre session sites.
- Sharing internal assessment checklists and gap action plans to the district.
- Sharing the gap action plan and other related information with the sub centre ANM and support implementation of the action plan.

The indicators for AEFI Surveillance at sub-district level are mentioned in **Annexure F**.

**Refer to "National Quality Assurance System for AEFI Surveillance (2016)" and "Implementing guidebook of Quality Management System for AEFI surveillance in states and districts" for more details.

Annexures

Annexure A: Poster on Reporting Serious/Severe AEFIs

MAINTAINING PUBLIC CONFIDENCE IN VACCINATION PROGRAMME

Ministry of Health & Family Welfare
Government of India

Report Adverse Events Following Immunization (AEFI)

An AEFI is any hospitalization, death, events occurring in clusters* (two or more cases of the same adverse event related in time, place or vaccine administered), disability or congenital anomaly following vaccination.

Reporting an adverse event following immunization does not mean that the vaccine has caused the event. Reported adverse events following immunization are investigated and assessed to know the cause.

Notify the following cases, if these are reported to have occurred following vaccination:

- Anaphylactoid reaction (acute hypersensitivity reaction)
- Anaphylaxis
- Allergic Reaction
- Persistent (more than 3 hours) inconsolable screaming
- Toxic Shock Syndrome (TSS)
- Severe local reaction
- Hypotonic Hypo-responsive Episode (HHE)
- Fever >102˚F (>38.9˚C)
- Seizures, including febrile seizures
- Encephalopathy
- Acute flaccid paralysis
- Brachial neuritis
- Intussusception
- Thrombocytopenia
- Disseminated BCG infection
- Lymphadenitis
- Osteitis /Osteomyelitis
- Sepsis
- Injection site abscess (bacterial/sterile)
- Guillain-Barré Syndrome

Any other severe and unusual events, suspected by doctors, healthcare professionals or public, to be related to immunization may also be reported as an AEFI.

For any queries related to reporting AEFIs, please contact the following:

Medical Officer/Facility Nodal Officer:	Mobile No.:	Email:
District Immunization Officer:	Mobile No.:	Email:

Annexure B: Process of Reporting an AEFI in U-WIN by Vaccinator

Vaccinator (ANM/others) will **login into U-WIN** using user ID and password (vaccinators' module).

To report an AEFI, click "**Report AEFI**" in the menu located on the extreme left.

The "Report AEFI" page will be displayed. Click on drop down menu in "**Search by**" in "Report AEFI" page.

A **list of options of identity proofs** (mobile/Aadhar/reference ID, etc.) against which the beneficiary was registered in U-WIN will be displayed in the drop-down menu. Select the correct option and enter the identity number in "**Search Members**" field and click on "Search". All beneficiaries registered with the particular ID will be displayed. From the list, **locate the name of the beneficiary** who has suffered an adverse event which is being reported. Click "Report AEFI" button against that name.

All dates when vaccinations were received by the chosen beneficiary will be listed with separate "Report AEFI" buttons against each date of vaccination. Identify the **date of vaccination** before the date of onset of the symptoms of the adverse event and click on "Report AEFI" against this date of vaccination.

A list of vaccines received on the selected date of vaccination will be visible which cannot be changed (pre-filled). Scroll down to locate "**Details of Notifier**" section. Fill the name, mobile number, place of posting and select the "Designation" of the person informing the adverse event to the vaccinator from the drop-down menu.

The "**Details of the session site**" are pre-filled and cannot be changed by the vaccinator. Fill "**Time of vaccination**" in hh:mm format and select 'Routine Immunization Session', 'Campaign (MI, Pulse Polio, MR, JE...)' or 'Other' from the drop-down menu in "**Vaccination done in**".

A page displaying a list of adverse events (signs/symptoms/diagnosis) will be displayed. The vaccinator will click on the relevant boxes before the signs/symptoms/diagnosis in the given list of adverse events. Select "**Any other**" if the signs/symptoms/diagnosis is not available in the given list and give details in the field.

Fill the **date** (in DD/MM/YYYY format) and **time of first symptom** (in hh:mm format), and click on option (Yes or No) against "**whether hospitalized**". If the beneficiary is hospitalized, then enter date of hospitalization (in DD/MM/YYYY format).

Select "Yes" in the drop-down menu below the question "**Whether death**" to report a death following vaccination. If 'Yes' is selected under "**Death**", then enter "**Date of death**" in DD/MM/YYYY format.

For non-death (hospitalized or non-hospitalized) cases, select "No". As appropriate, select one of the following options - 'Recovered completely', 'Recovered with sequalae', 'Still under treatment or unknown' - from the drop-down list under "Current status of patient". Select

"Yes" in drop down menu under "**Is this case part of a cluster**" if this case is part of a cluster. Otherwise, select "No".

Once the form is completely filled, click the "**Submit**" button. After submission of case, in place of the 'Report AEFI' button, an **AEFI ID** will be displayed next to the date of vaccination of reported adverse event. Now for this date of vaccination, no other adverse event can be reported. This AEFI ID will be also be linked to the Reference ID of the beneficiary in UWIN and will be visible in the dashboard linelist of the District Immunization Officer.

AEFI REGISTER

(to be kept at PHC/cold chain point/sector or block PHC/facility conducting vaccination) (to be filled by ANMs once a week)

Date of entry	Name of Facility / Centre	Name of the patient	Mother's / Father's / Husband's name (with mobile no.)	Date of birth / age	Sex	Date & time of vaccination	Name of vaccines given	Manufacturer name with batch number of vaccines given	Date and time of onset of symptom(s)	AEFI sign / symptom / diagnosis	Type of AEFI (minor / severe / serious)	Reporting of serious / severe case using CRF (if yes – mention date / otherwise mention No)	AEFI Case ID (Epid Number, only for serious / severe cases)	Final AEFI causality classification (as informed by State)

Please note-

- All AEFI recorded in this register during the month are to be entered in HMIS report at the end of the month.
- Medical Officer in-charge to verify the weekly AEFI (minor, severe and serious) entries and sign.
- If no AEFI (minor, severe and serious) is recorded in a week, then the Medical Officer in-charge should certify for 'No case reported' and sign.

Annexure C: AEFI Register

Assessment of AEFIs recorded at the Planning unit level

(Format to be shared in the first week of every month to DIO)
To be filled by MO in charge

Month **Year:**

Name of the BLOCK PHC/CHC/Facility along with MO in charge: Phone Number:	Block Name: District:	Date:
Following table need to be filled up after reviewing AEFI register of respective month. Tabulate the data for all (minor/severe/serious) AEFIs listed in respective month.		

Name of Planning unit /Facility/ Centre	Minor AEFI			Serious/Severe AEFI				Any other (specify)
	Fever < 39^0 C	Injection site reaction (pain/redness and swelling)	Irritability, malaise, fatigue, loss of appetite	Fever >39^0 C	Allergic reaction	Abscess	Seizures	
Total								

Any Aggregation or Clustering (Tick as appropriate)	Possible reason	Action proposed
A) Antigen wise and Batch wise - If antigen wise, does it exceed expected reaction rate. Refer Table No. 1 (Yes /No)		
B) Sub-centre wise/Vaccinator wise		
C) Any other (e.g. unusual event)		

Name of in-charge Medical officer: **Signature with date:**

Annexure D: Case Reporting Form (CRF)

CASE REPORTING FORM (CRF)

To be filled by doctor and sent to District Immunization Officer within 24 hours *Mandatory Field

AEFI Case ID: IND (AEFI) / ST / DST / YR / NUM (from SAFE-VAC, for all vaccines except COVID-19 vaccines)

AEFI Case ID: IND (CO-AEFI) / ST / DST / YR / NUM (from Co-WIN - SAFE-VAC, for COVID-19 vaccines)

Section A: Reporter and notifier details

Name of doctor reporting / filling this form*: Contact phone number*: E mail*: Place of present posting*: Designation*: Address of present posting:	Reporting Date: __ __ / __ __ / __ __ __ __ (date when this form is prepared) Date case visited and examined / interviewed: __ __ / __ __ / __ __ __ __ (date when the case visited or interviewed)
Notified by (Name)*: Date notified: __ __ / __ __ / __ __ __ __ (date when the case informed to reporting doctor)	Designation of notifier (please circle): ASHA / AWW / Health worker / Government doctor / Private practitioner or hospital / Parent / Community / Media / Others Specify: _____
Address of session site*: Village or Urban area: Block Name: District: State:	Place of Vaccination*: Govt Health Facility / Outreach / Private Health Facility / Others (specify): _____ Source of vaccine: Government supply / Privately purchased / Others (specify): _____
Date of Vaccination*: __ __ / __ __ / __ __ __ __ Time of Vaccination: __ __ : __ __ AM/PM	Vaccination in*: Routine Immunization / Campaign (MI, Pulse Polio, MR, JE, COVID 19) / Others (specify):_____ Type of Session Site: Fixed / outreach / mobile / school / others (specify):_____

Section B : Patient details

Patient Name*																			

Date of Birth * DD/MM/YYYY	Age: _____ years ___ Months ___ days	Sex*	Male / Female

Mother's Name																			
Spouse / Father / Guardian's name*																			

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

P	I	N	-							P	H	O	N	E*	-											

For women in reproductive age group:

1. Status of pregnancy at the time of vaccination: Yes / No / Don't know
2. If Yes, duration of pregnancy at the time of vaccination: 1-3 months / 4-6 months / 7-9 months
3. Lactating at the time of vaccination: Yes / No / Don't know

Section C : Details of vaccine(s) and diluent(s) administered to the AEFI case during this session (to be filled by MO incharge or DIO of area where vaccination took place)

Name of vaccines administered to this case (write vaccine & diluent details in separate rows)*	Dose no. (birth / zero / 1st / 2nd / 3rd / booster 1 / booster 2 / campaign)*	Name of Manufacturer / Brand Name*	Batch / Lot No.*	Mfg. date	Expiry date	Date & Time of vaccine reconstitution / opening vaccine vial	No. of OTHER beneficiaries who received vaccine from SAME vial in this session

Section D : Details of adverse event(s)

1. Type of Adverse Event: Serious / Severe
2. If serious AEFI specify: Death / Hospitalization / Cluster / Persistent or significant disability / Congenital anomaly or birth defect / Media, community or parental concern

If this is a part of a cluster*: Yes / No / Unknown

If yes number of other cases in the cluster _____ Cluster ID (as generated by SAFE-VAC):

Adverse event(s) - clinical* (TICK AS MANY AS APPLICABLE):

☐ Severe local reaction	☐ Fever	☐ Seizures	☐ Injection site abscess
☐ Sepsis	☐ Encephalopathy	☐ Toxic shock syndrome	☐ Thrombocytopenia
☐ Allergic reaction	☐ Anaphylaxis	☐ Intussusception	☐ Lymphadenitis
☐ Acute Flaccid Paralysis	☐ Hypotonic Hypo-responsive Episode (HHE)	☐ Unexplained Death	☐ Anxiety reaction

Additional for COVID vaccine

☐ Joint pain / swelling of recent onset	☐ Painful single limb swelling	☐ Chest pain / fainting / palpitation
☐ Recent ECG / Echo / angiography changes	☐ Breathlessness / difficulty in breathing / worsening of existing respiratory problem	
☐ Altered sensorium / Loss of consciousness	☐ Acute disseminated encephalomyelitis	☐ Guillain-Barre syndrome
☐ Meningoencephalitis	☐ Mono-neuropathy / Poly-neuropathy	☐ Rashes
☐ Loss of taste / smell	☐ Acute liver injury / Acute Liver Failure	☐ Chilblain-like lesions /vasculitis
☐ Acute kidney injury / Acute Renal Failure / Hematuria / Oliguria / Edema of legs / Hypertension		☐ Lymphadenopathy
☐ Coagulation / bleeding disorder (Thromboembolism, Hemorrhage)		
☐ Worsening of existing disease (Cardiac / Respiratory / Liver / Kidney / Diabetes etc.)		☐ Others (specify).....

Pregnancy related events

☐ Maternal death ☐ Fetal loss (abortion) ☐ Premature delivery ☐ Still birth ☐ Neonatal mortality ☐ Congenital anomaly in newborn

Date & Time of first symptom*: DD / MM / YYYY at ___:___AM/ PM	Hospitalization (In-patient admission)*: Yes / No
Name and address of hospital:	
Date & Time of hospitalization*: DD / MM / YYYY at ___:___AM / PM	Hospital Reg. No. (OPD/Admission/Bed Head Ticket):
If hospitalized, outcome*: Discharged / Still Hospitalized / Left Against Medical Advice (LAMA) / Absconded / Referred / Death / Brought dead	
Current status of patient*: Recovered completely / recovered with sequalae / still under treatment / death / unknown	
Date & Time of Death*: DD / MM / YYYY (if died) at ___:___AM / PM Place of death: Home / Hospital / On the way to hospital / Others	Post mortem done: Yes / No / Unknown Date of Post mortem: DD / MM / YYYY
Describe AEFI (sequence of events, signs and symptoms after vaccination) *:	

Signature and name of Reporting Medical Officer:

Section E: Decision making details

District Immunization Officer to complete and submit in **SAFE-VAC / Co-WIN SAFE-VAC (for COVID-19 vaccines)** within 24 hours of receiving the above information. SAFE-VAC: https://safevac.mohfw.gov.in; Co-WIN - SAFE-VAC: https://www.cowin.gov.in

Date report received at District level: __ __ / __ __ / __ __ __ __

Date investigation planned: __ __ / __ __ / __ __ __ __

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

Name ..... Designation..... Mobile No*: .....

Email id*: ..... Signature..... Date/ Seal: .....

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

.....

For any support or help, write to: aefiindia@gmail.com; safevac.chi@gmail.com

Annexure E: QMS Checklist of PHC/ Session Site

National Quality Assurance Standards for AEFI Surveillance Programme			
Checklist for Immunization Sites			
Assessment Summary			
Name of the Immunization sites:			Date of Assessment:
Names of Assessors:			Names of Assesses:
Type of Assessment:			Action plan Submission Date:
Immunization Sites Score Card			
Area of Concern wise Score			**Total Score**
A	**Notification & Reporting**		
B	**Investigation**		
D	**Operational Management**		
E	**Communication**		
F	**Convergence**		
H	**Quality Management System**		
Major Gaps Observed			
1			
2			
3			
4			
5			
Strengths / Good Practices			
1			
2			
3			
4			
5			
Recommendations/ Opportunities for Improvement			
1			
2			
3			
4			
5			
Signature of Assessor (s):			
Date :			

Ref.no	Area of Concern	Score Received	Maximum Score	Percentage
A	Notification & Reporting			
B	Investigation			
D	Operational Management			
E	Communication			
F	Convergence			
H	Quality Management System			
Total Score				

National Quality Assurance Standards for AEFI Surveillance Programme

Checklist for Immunization Sites

Reference No.	Measurable Element	Compliance	Assessment Method	Means of Verification	Remarks
Area of Concern - A Notification and Reporting					
Standard A1	**The primary responsibility for notifying AEFI cases is defined and communicated at each level**				
ME A1.1	Vaccinator is aware of categories of AEFI		SI/PI	Ask staff to enumerate categories & whether he/ she can differentiate between minor & severe/ serious AEFI	
ME A1.2	Person responsible for notifying the AEFI is identified		SI/RR	Ask staff regarding the responsibility for notifying the AEFI	
ME A1.3	Person responsible for reporting the AEFI is identified		SI/RR	Ask staff regarding the responsibility for reporting the AEFI	
ME A1.4	Identified person is aware of the categories of AEFI to be notified		RR/SI	Ask staff to enumerate	
ME A1.5	Reporting authority and route is communicated		RR/SI	Ask staff to whom are the cases reported and how	

Standard A2	**There is an established procedure for routine reporting of AEFI cases**				
ME A2.1	Weekly reporting of AEFI cases is ensured by ANM/ Nodal person for reporting AEFI		RR	In case no AEFI case is reported during the week, a nil report is submitted	
ME A2.2	AEFI register is maintained at the block Primary Health Centre		RR	Verify whether the register is available	
ME A2.3	Weekly report of all serious / severe cases is submitted to District Immunization Officer		RR	Verify weekly reports of AEFI cases	
ME A2.4	AEFI cases are reported in HMIS on monthly basis		RR/SI	Verify HMIS reports for previous months	
Standard A3	**There is an established procedure for immediate reporting of serious/severe AEFI cases**				
ME A3.1	The service provider is aware of the AEFI events required to be immediately notified and reported		SI	Ask staff which AEFIs need to be reported immediately	
ME A3.2	List of severe / serious AEFI with case definition are available with service provider		SI/RR	Verify availability of case definition list	
ME A3.3	AEFI case reporting format is available with the designated medical officer		RR	Check availability of printed CRF format	
ME A3.4	Route and timelines of reporting of CRF are communicated		SI	Ask staff whom to report AEFI cases and how	
ME A3.5	Duly filled CRF is reported by medical officer to DIO within 24 hours of notification		RR/SI	Check timeliness of reporting of serious AEFI cases. If no case has been reported, ask the MO if he is aware of the timeline for sending CRF to DIO.	
Standard A5	**There is an established procedure to ensure recording and reporting of AEFI cases from the private sector**				
ME A5.1	Key private facilities providing immunization services are identified		RR	Verify whether the list of private facilities exists in the facility/level	
ME A5.2	Private service providers have been effectively communicated the reporting channel and procedures with contact details		RR/SI	Verify with private service providers and also if documentation is available (letters, meeting minutes, etc.)	
ME A5.3	Primary and secondary care hospitals are involved in reporting of AEFI cases		SI	Verify number of cases reported	

Area of Concern - B Investigation					
Standard B2	**Preliminary investigation of cases is done as per guidelines**				
ME B2.1	Reporting Medical Officer prepares the list of evidences which will be required for investigation in consultation with DIO		SI/RR	Relevant registers, ANM diaries, session tally sheets, indent records, used and unused vial, diluents, syringes etc. Ask MO/DIO for itemsto be included in the list of evidence.	
Area of Concern – D Operational Management					
Standard D3	**Roles and responsibilities of stakeholders at different administrative levels are defined and effectively communicated**				
ME D3.1	Front line worker is aware of her role and responsibilities for AEFI surveillance Programme		SI	Ask ANM, ASHA and AWW if they are aware of what to do if there is an AEFI	
ME D3.2	Health Supervisor is aware of his/ her role and responsibility for AEFI surveillance Programme		SI	Ask the Health Supervisor regarding his/her role and responsibility in the AEFI surveillance Programme. Verify with the current AEFI guideline	
ME D3.3	Medical Officer is aware of his/ her role and responsibility for AEFI surveillance Programme		SI	Ask MO and verify with the current AEFI guideline	
Standard D4	**There are established procedures for training and capacity building of personnel involved in AEFI Surveillance**				
ME D4.1	AEFI guidelines are available with key stake holders at all levels		RR/SI	Verify availability of copies of the AEFI guidelines with committee members at all levels: BMO, DIO, SEPIO, others.	
ME D4.2	Training and skill needs assessment has been done for AEFI surveillance Programme at all levels		RR/SI	Verify whether the TNA report exists	
ME D4.4	Training has been provided to stakeholders as per schedule		RR	Verify training records	

Standard D5	**Immunization sites are prepared for preventing and treating any adverse event following immunization**				
ME D5.1	Parents are counselled for informing about any untoward event of concern following vaccination		OB	Observe interaction at session site and interview parents/ caregivers	
ME D5.2	Antipyretic drugs are provided wherever required		OB, PI	Observe session site and interview parents/caregivers	
ME D5.3	Beneficiaries are observed for 30 minutes after immunization		OB, PI	Observe session site and interview parents/caregivers	
ME D5.4	Emergency drug tray is available at the site of immunization		OB/RR/SI	Verify the emergency tray with the updated available list as per recommendation	
ME D5.5	Protocols and Instructions regarding preventing, identifying, managing AEFI are displayed at the immunization sites		OB	Verify whether the materials are displayed at the session site	
ME D5.6	Vaccinator is aware of what to do in case of any immediate serious reaction/anaphylaxis		SI	Ask the vaccinator what steps to take in case of a serious reaction/ anaphylaxis	
ME D5.7	Vaccinator is aware of how to prevent immunization error related reactions		SI	Ask the vaccinator how to prevent immunization error related reactions from occurring	
Area of Concern – E Communication					
Standard E1	**There are established procedures for regular communication to build and maintain confidence in the Universal Immunization Programme in the community**				
ME E1.1	Key personnel for community engagement have been identified and authorized		SI	List of designated staff	
ME E1.2	Vaccinators and extension workers deliver the four key messages to parents after each vaccination		OB	Observe ANM and ask parents/caregivers the four key messages	
ME E1.3	Vaccinators and extension workers communicate the benefits of RI at VHND sessions		OB	Observe sessions and interactions	
ME E1.4	Advocacy with community Influencers for giving key messages on benefits of immunization		OB/SI/PI	Meeting with VHSNC members, District Medical DMEIO and block panchayat raj members	

Standard E5	**There are established procedures for capacity building of key personnel responsible for communication at each level of administration**				
ME E5.5	Capacity building for social mobilization and advocacy is undertaken for community engagement		SI/PI	Verify by interacting with volunteers, chosen advocates and community	
Area of Concern – F Convergence					
Standard F5	**There are established procedures for coordination with civil administration and law enforcement agencies**				
ME F5.3	There is an established procedure for seeking help of civil administration in case of crisis		RR	Ask for meeting minutes or SOPs or directives or evidences of previous events in which help was sought from civil administration or police	
Area of Concern - H Quality Management System					
Standard H1	**Quality policy and objectives are defined and disseminated**				
ME H1.2	Quality policy for AEFI surveillance Programme is defined		OB/RR/SI	Check quality policy is displayed & staff is aware of quality policy	
ME H1.3	Quality objective for AEFI surveillance is defined		OB/RR/SI	Check quality objectives are displayed. Also check staff is aware of quality objectives	
ME H1.4	Progress in achieving quality objectives is monitored periodically		RR	Check quality objectives are reviewed at periodic intervals	
Standard H2	**Standard Operating Procedures are defined, documented and established at each level**				
ME H2.1	Standard operating procedures for key processes are prepared, approved & updated		RR	Covers following areas: notification & reporting, investigation, causality assessment, operation management, communication, convergence, monitoring & feedback & QMS. Check current version of SOP is available	
ME H2.2	Standard operating procedures are available at point of use		RR/SI	Check relevant part of SOP is available with its process owner	
ME H2.3	Standard operating procedure adequately describe processes & procedures		OB/RR/SI	Check work instructions are displayed	
ME H2.4	Staff is trained & aware of procedures written in SOPs		RR/SI	Verify with the training records and staff interview	

ME H3.1	Periodic internal assessments are conducted at various levels at defined intervals		RR	Check whether internal assessment plan & schedule is prepared, internal assessors are identified & trained, records of internal assessment are maintained & person identified to coordinate activities.	
ME H3.2	Non compliances are enumerated & recorded adequately		RR	Check records are maintained	
ME H3.3	Action plans are made on gaps found during assessment process		RR	Check action plan is reviewed periodically	
ME H3.4	Corrective actions are taken to address the issues, observed in the assessment		RR	Check system is in place to ensure that corrective actions are taken timely	
Standard H4	**Continual Quality Improvement is practiced at each level of AEFI surveillance Programme**				
ME H4.2	Action plans are prepared for the low performing areas in stakeholder survey		RR	Check records are available & maintained	
ME H4.3	Internal quality assurance Programme for its key processes are in place		RR	Check availability & use of checklist for investigations, causality assessment, communication, monitoring & feedback etc.	
Standard H5	**There is an established procedure to identify and mitigate risks in relation to AEFI Programme**				
ME H5.1	Risk management framework is in place for AEFI surveillance Programme		RR	Check availability of risk management framework with commitment to manage risk. Also check availability of plans, relationships, accountabilities, resources, processes and activities to manage all types of risks	

ME H5.2	Risks & opportunities for improvement in all critical processes are identified, analysed & prioritized		RR/SI	Check whether risks and opportunities are clearly defined including what is acceptable & what is unacceptable, how to eliminate, avoid & mitigate specific risks	
ME H5.3	There is a system in place to take actions to eliminate, avoid & mitigate the risks		RR	Verify risk register	
ME H5.4	There is a system in place to check effectiveness of the actions taken.		RR	Verify risk register	

Annexure F: Indicators for AEFI Surveillance

At Sub-District Level - to be assessed by MOI/C			
Reporting Indicator	**Formula**	**Review Frequency**	**Data Review Benchmark (proportion of times indicator has been reviewed)**
Number of AEFI cases reported	Number of AEFI cases reported	Data to be assessed on quarterly basis	>75%
Proportion of sub centre immunization sites scoring at least 70% in internal assessment (QMS indicator for PHC/ Immunization Site)	No. of sub centre immunization sites scoring at least 70% in internal assessment / Total number of subcentre immunization sites in the PHC area	Data to be assessed on quarterly basis	50% of the sub centre score at least 70% in internal assessment

List of Contributors

The development of this concise guide on AEFI surveillance processes for PHC staff was carried out under the guidance of Ms. Aradhana Patnaik, Additional Secretary & Mission Director (NHM) and Ms. Meera Srivastava, Joint Secretary (RCH), MoHFW, Government of India.

Dr. Pawan Kumar, Additional Commissioner (Immunization), provided the overall guidance and special inputs during the development of this concise guide.

The following from the AEFI Secretariat contributed to the development of this concise guide:

1. Dr. Deepak Polpakara, Senior Team Lead – AEFI, ITSU
2. Dr. Rajat Ranjan, Senior Programme Manager – AEFI, ITSU
3. Dr. Preeti Kharb, Programme Lead – Pharmacovigilance, ITSU
4. Dr. Priyanka Sachdeva, Zonal AEFI Senior Consultant, MOHFW
5. Dr. Farishta H D Singh, Senior Programme Officer, ITSU
6. Dr. Sneha Kumari, Consultant (Program Officer- Quality Assurance AEFI), ITSU

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This document was designed by Ms. Aakanksha Sharma, Graphic Designer, ITSU.