सत्यमेव जयते

Ministry of Health & Family Welfare
Government of India

NATIONAL HEALTH MISSION
राष्ट्रीय स्वास्थ्य मिशन

DEMONSTRATION OF MODEL AEFI SURVEILLANCE PROCESSES IN SELECT DISTRICTS, INDIA

NATIONAL AEFI SECRETARIAT
IMMUNIZATION TECHNICAL SUPPORT UNIT, MoHFW
2020

ACKNOWLEDGMENT

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CONTENTS

ABBREVIATIONS

AEFI - Adverse Event(s) Following Immunization
AFP - Acute Flaccid Paralysis
AMC - Adverse Drug Reaction (ADR) Monitoring Centre
ANM - Auxiliary Nurse Midwife
ASHA - Accredited Social Health Activist
AWW - Anganwadi Worker
CHC - Community Health Centre
CIOMS - Council for International Organizations of Medical Sciences
CMO - Chief Medical Officer
CRF - Case Reporting Form
DACM - District AEFI committee meeting
DH - District Hospital
DIO - District Immunization Officer
EPI - Expanded Programme for Immunization
FLW - Front Line Worker
GVAP - Global Vaccine Action Plan
HMIS - Health Management Information System
IAP - Indian Academy of Pediatrics
IEC - Information education and communication
IMA - Indian Medical Association
IMI - Intensified Mission Indradhanush
IPC - Inter Personal Communication
ITSU - Immunization Technical Support Unit
MO - Medical Officer
MoHFW - Ministry of Health and Family Welfare
NHSRC - National Health Systems Resource Centre
NPSP - National Public Health Surveillance Project
PHC - Primary Health Centre
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 of Immunization Officer
STFI - State Task Force for Immunization
UIP - Universal Immunization Programme
UNDP - United Nations Development Programme
UNICEF - United Nations Children's Fund
VPD - Vaccine Preventable Disease
WHO - World Health Organization

CHAPTER **1**

INTRODUCTION

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 annual cohort of eligible beneficiaries in the world i.e. 26 million children and 29 million pregnant women who are to be vaccinated as per schedule through 10 million[1] immunization sessions being conducted by trained health workers across the country.

Although modern vaccines are safe, no vaccine is entirely without risk. Adverse events or reactions may occur occasionally following immunization. Adverse events following immunization (AEFI) are usually mild but may be life-threatening on rare occasions. However, most of the serious events reported after immunization are coincidental and, in many cases, no causal relationship between the vaccine and the reported event has been identified.

'Immunization safety' refers to a wide spectrum of activities which ranges from vaccine manufacturing, regulation, safety & quality, safe injections and also the surveillance for adverse events following immunization[2]. The objective of AEFI surveillance is to systematically collect data on events following immunization and help in providing valuable information required to take necessary actions for prevention of AEFI caused due to programme errors and sustain community's confidence in vaccines safety. It is also important to detect rare, late onset, unexpected and population-specific adverse events that cannot be detected in the pre-licensure vaccine trials due to the limited numbers usually enrolled in the trials, the time-frame of follow-up, or in different populations or age groups[3].

The national guidelines currently in place for AEFI surveillance are in line with the revised WHO/ Council for International Organizations of Medical Sciences (CIOMS) guidelines circulated in 2012-13. These guidelines are aimed at providing information to health-care providers and programme managers at national, state, district, block and primary health centre (PHC) levels for establishing a sensitive AEFI surveillance system. They also guide the health workforce in improving the efficiency of surveillance activities for AEFI, maintaining the quality of immunization services at the national and state levels and ensuring immunization safety of all recipients of vaccines.

1.1 AEFI surveillance in India

In India, the AEFI surveillance programme was launched in 1986 but the reporting of suspected AEFI cases was minimal. In 2005, the first operational guidelines for AEFI surveillance was developed and shared by Immunization Division, MOHFW. Subsequently a series of steps were taken to improve and strengthen AEFI surveillance in the country. These are as follows: -

- **Establishing AEFI committees** – In 2008, the national AEFI committee was established and meetings were held once or twice a year. The objective of the committee was to advise national

1 Operational Guidelines, Strengthening Immunization Systems to Reach Every Child, IMI 2.0, 2019

2 Global manual on surveillance of Adverse Event Following Immunization, 2014

3 Joshi et al., "Vaccine Safety and Surveillance for Adverse Events Following Immunization (AEFI) in India.", 2017

programme managers to strengthen vaccine safety in the country by recommending key policy decisions and providing technical advice. The process of setting up state and district AEFI committees with specific terms of reference of the committee and roles and responsibilities of members was also initiated.

- **Periodic revision of the National AEFI guidelines**- The national AEFI guidelines is revised every five years to keep it updated and in sync with latest developments in the field of vaccine safety.
- **Establishment of national AEFI secretariat**- Recognising the need to have dedicated human resources to support the National AEFI Committee and the Immunization Division, MoHFW, to make informed recommendations related to improving AEFI surveillance and implement them, an AEFI secretariat was established at Immunization Technical Support Unit (ITSU) in 2012.
- **Collaborations with medical colleges and research institutions** – In order to provide scientific inputs to the AEFI surveillance system and vaccine safety and to support in causality assessments of reported cases, collaborations with medical colleges were encouraged. A National AEFI Technical Collaborating Centre was established at LHMC, New Delhi. Similar state AEFI technical collaborating centres were established in different states, such as AIIMS, Patna and Bhopal for Bihar and Madhya Pradesh respectively.
- Other initiatives
  - Partnership and data sharing with drug regulators and pharmacovigilance partners and WHO-NPSP at national, state and district levels
  - Hiring of Zonal AEFI Consultants through NHSRC to support states
  - Involvement of WHO-NPSP and other partners for support in the field
  - Roll out of web-based portal, Surveillance and Action for Events Following Vaccination (SAFEVAC) for reporting of AEFI cases:
  - Implementation of Quality Management System (QMS) for AEFI surveillance
  - Sharing of feedback and recommendations for improvement with stakeholders, etc.

As a result, there has been a steady increase in the sensitivity to report suspected serious and severe AEFI cases. As depicted in Figure 2, there has been a consistent improvement in reporting of AEFI cases. More than 2500 serious/severe AEFI cases were reported in 2018. In addition to the cases reported due to the ongoing MR campaign, there was an increase in reporting of non-campaign AEFI cases too. This was a result of increased ownership of the programme by the states and districts, regular feedback and support from the national level, regular sensitization of field staff using different opportunities such as new vaccine introductions, campaigns and Mission Indradhanush.

Some of the key activities/ milestones discussed above are indicated in the figure below:

Figure 1: AEFI Surveillance milestones

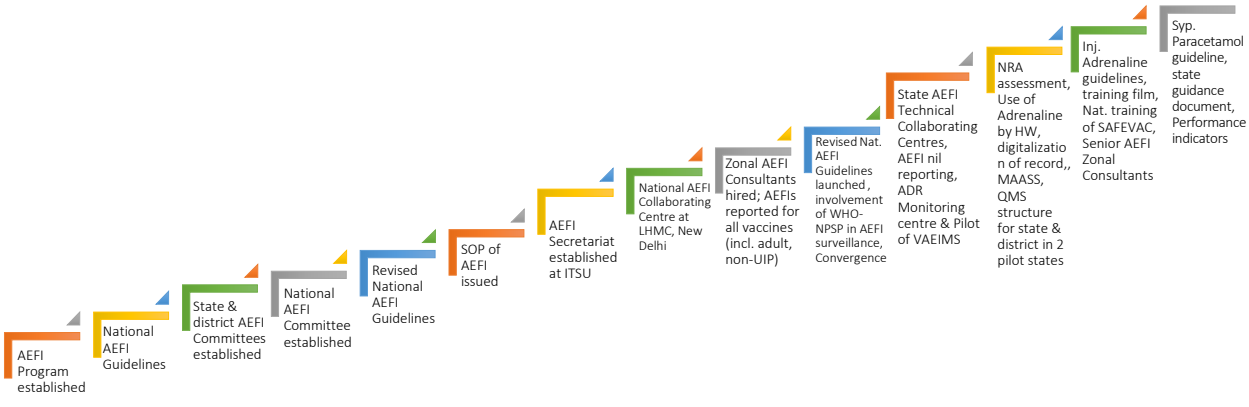
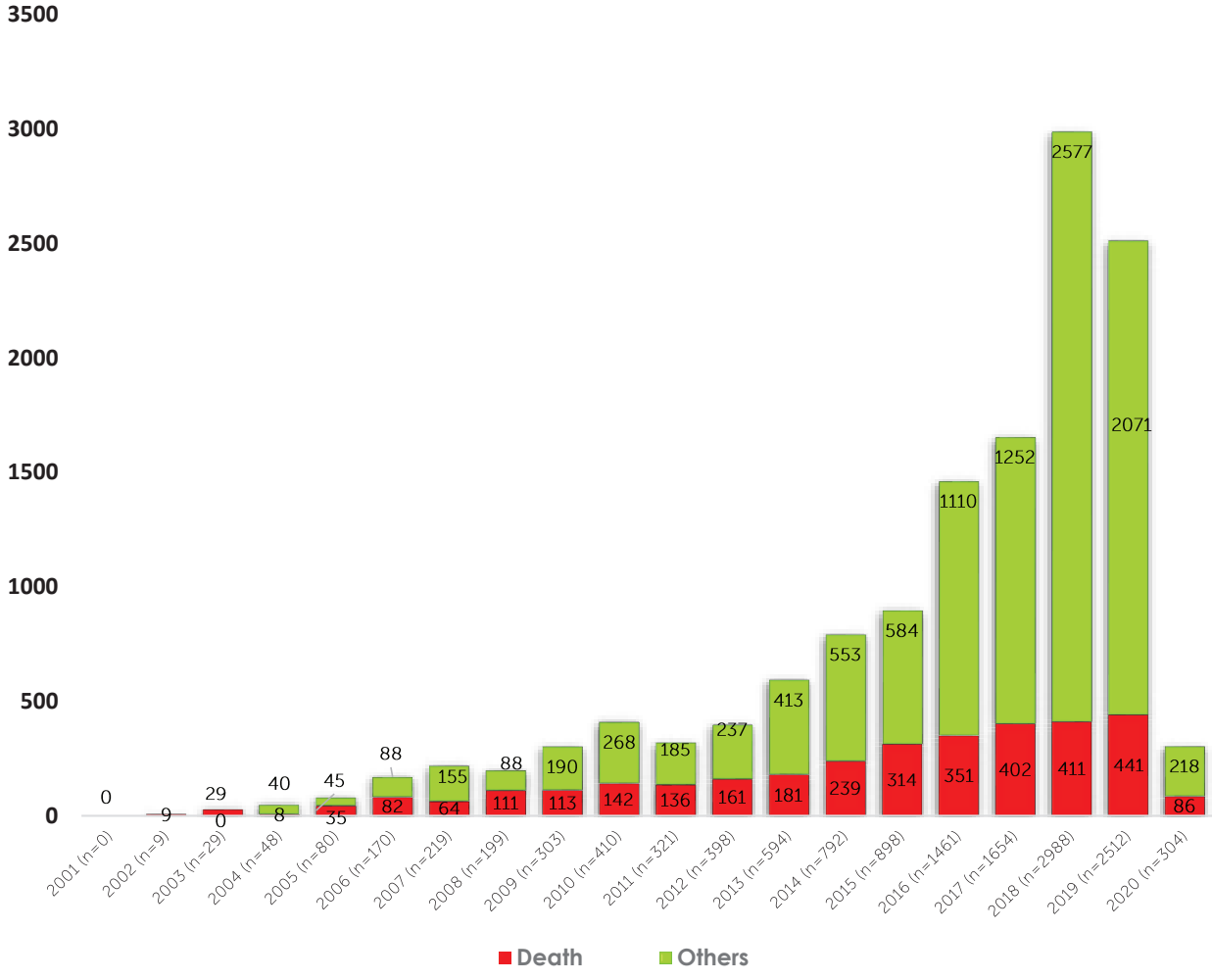


Figure 2: Reporting trend of serious/severe AEFI cases in India



Source: National AEFI secretariat data till 31st March'2020

CHAPTER 2

SCOPE OF THE PROBLEM

Although there has been improvement in the number of AEFI cases over the years, about 30-40 % districts fail to report even a single serious/severe AEFI case a year. The AEFI surveillance data shows that out of 716 districts in India, 211 districts have been silent in both 2018 and 2019. Given the birth cohort in most districts, it is highly unlikely that even a single serious / severe has AEFI not occurred in a district.

It is a known fact that in field situations, health workers, medical officers (MO) and district officials have different priorities at different times. AEFIs may not be reported due to poor awareness, lack of information on what and how to report an AEFI, fear of reporting AEFIs (as acceptance of a mistake, increase in workload – having to investigate, etc.), lack of resources, poor networking with medical colleges/private and public sector clinicians and many other reasons.

In 2018, zonal AEFI senior consultants were tasked with identifying causes why some districts in a state with high birth cohort/populations were not reporting AEFIs. They were asked to visit some of the silent districts, interview stakeholders and find the cause of non-reporting. During visits to some of these districts, some interventions were also done by them and a positive effect was found following the visits.

Keeping this experience in mind, it was proposed to identify a minimum set of activities (as per national AEFI guidelines) which if well executed at the district level, should lead to reporting of AEFIs in silent districts. The set of activities had to be in line with the current AEFI surveillance guidelines, which recommended the following activities related to AEFI surveillance in districts:

- Training and sensitization of MOs and health workers on AEFI surveillance
- Orientation of district AEFI committees and regular meetings
- Monitoring of implementation of PHC AEFI registers
- Networking and sensitization of doctors in public and private hospitals for reporting AEFIs to DIO
- Monitoring and support from state immunization programme managers

In view of the requirement a pilot project (Demonstration of Model AEFI surveillance processes) was conducted with due approval from Immunization Division, MoHFW to implement AEFI surveillance processes and activities in a district in an ideal manner.

2.1 Objective

The objectives of the project were: -

- To demonstrate a set of ideal AEFI surveillance processes in silent districts and its impact
- To recommend a set of minimum activities with tools to ensure reporting of AEFIs in a district

2.2 Methodology

Two states namely Bihar and Odisha were selected for implementation as recommended by the MoHFW. The details of activities planned to be conducted in these select states/districts are mentioned below: -

Details of activities (map)

Selection of intervention districts

All districts in Bihar and Odisha were ranked based on the following criteria:

- Districts which had not reported any AEFI case (silent) for the last three years
- Number of cases expected to be reported by the district in a year as per GVAP indicator (10 cases per 100000 surviving infants) [4]
- Availability of a medical college, preferably with an Adverse drug reaction Monitoring Centres (AMCs) of the Pharmacovigilance Programme of India, in the district or catering to the district.

Three-four lowest ranked districts were chosen and State EPI Officers chose districts from these shortlisted districts. Based on the above-mentioned criteria the following districts were selected for intervention-

Figure 3: State map of Odisha with selected district (Bhadrak)

State	District
Odisha	Bhadrak

Figure 4: State map of Bihar with selected districts (Arwal & Rohtas)

State	District	District
Bihar	Arwal	Rohtas

Baseline data collection

During the first visit to the selected districts, extensive interaction was done with key stakeholders to understand their perspective about status of AEFI surveillance. Visits were made to select planning units to interact with MOs, supervisors, ANMs, ASHAs and AWWs. Representatives from partner organizations (UNICEF and WHO) also supported by sharing their experience in strengthening routine immunization (RI) service delivery in the district.

Some of the key parameters which were utilized to understand the demographic and health profile of the selected district is documented in the table below: -

4 World Health Organization. Global vaccine action plan. Secretariat annual report 2016; 2016. Available from: http://www.who.int/immunization/global_vaccine_action_plan/gvap_secretariat_report_2016.pdf?ua=1>

Table no 1: District profile with relation to human resource and RI service delivery (source- district data)

Parameter/activity/indicator	Bihar		Odisha
	Arwal	Rohtas	Bhadrak
District population	7,84,136	35,33,853	16,10,885
Annual birth cohort	19,536	81,273	29,961
Immunization coverage (HMIS) FY 18-19	80%	77%	89%
Number of planning units	6 (including 1 DH)	19 (including 1 DH and 2 SDH)	9 (including 1 DH)
Number of sub centres	64	258	178
Medical college	No	NMCH, Jawahar	No
Number of MOs	38	122	65
Number of ANMs	107	383	194
Number of ASHAs	711	2435	1379
Number of AWWs	574	2436	2435
District AEFI committee constituted	Yes	Yes	Yes
Last training on AEFI done in the district	January, 2019	December, 2018	January, 2018

AEFI surveillance activities planned at state, district and sub-district levels

Since it was not possible to visit three interventional districts to conduct all activities by the AEFI Secretariat or Senior AEFI Zonal Consultant, it was decided that some activities will be conducted by the national facilitators, remaining activities would be conducted by the district and monitoring would be ensured by the state.

State level activities

- Discussion with State EPI Officer regarding the demonstration district, finalisation of intervention district and informing the silent district regarding the pilot.
- State approves utilization/reallocation of district immunization budget to conduct trainings at district and sub-district levels, translation & printing of job aids for HWs and MOs, etc.
- State actively follows up implementation of activities by the district and feedback.

District level activities

- **Meetings**
  - DIO and CMO
    - Sensitization regarding AEFI surveillance, discuss status of AEFI surveillance in the district, listing stakeholders, causes for non-reporting, planning of interventions
    - Ensure availability of updated media response template for crisis.
  - District AEFI committee members
    - Review membership, orientation on immunization and AEFI surveillance processes and their roles.
  - Immunization partners
- **Advocacy**
  - regular conduction of meetings of the district AEFI committee (at least once a quarter) to review the status of AEFI surveillance

- discussion on status of AEFI surveillance in district task force meeting so as to ensure adequate support from key stakeholders (district administration, drug controller, etc) during crisis.

❖ Training

» Medical officer in charges and paediatricians of planning units (PHC, CHC, SDH, DH and medical college) using specially developed training package on reporting of suspected serious/severe AEFI cases.

» District level data entry operator on AEFI surveillance reporting and documentation including entries in SAFE-vac portal

❖ Liaison with stakeholders

» Medical colleges, public and private health institutions

- Internal AEFI notification system in medical colleges
- Sensitization of staff nurse and immunization service providers on AEFI surveillance
- Paediatric, emergency/casualty, community medicine and general medicine departments
- Adverse Drug Reaction Monitoring centre (ADR-MC)

Sub-district level activities-

❖ Training

» Other MOs, health workers (ANMs, health supervisors, CCH)

- Identify and record/report suspected AEFI cases.
- Record all AEFIs in AEFI register

» Monitor availability

- AEFI management kits
- Anaphylaxis kits

» ASHA and AWW

- Identify, inform (notify) suspected AEFI cases to ANMs/supervisors/MO.

Designing the targeted interventional strategy-

Based on the baseline assessment and information gathered from the initial state and district visits, interventions were planned and prioritised against what was initially planned. The interventions were designed to provide initial support to the districts to initiate AEFI surveillance processes in an ideal manner. Two separate training packages for MOs and health workers which were developed to conduct trainings in an organised manner are as follows:

❖ **Medical officers** – covering basic concepts of AEFI surveillance, recording & reporting of AEFI cases, review of Block/PHC AEFI registers, exercise on filling up of the Case Reporting Form (CRF), management of AEFI cases, Inter Personal Communication (IPC), etc. through presentations, training videos, hands on exercise, case scenario discussions, etc. (Annexure A- Agenda)

❖ **Health workers**- dedicated training module (Training module on AEFI surveillance for ANMs/ health workers') covered identification, informing (notifying), recording and reporting suspected AEFI cases. (Annexure B– training module)

CHAPTER 3

IMPLEMENTATION AND RESULT

The key activities which were initiated and completed in different districts/urban areas are detailed below:

State level activities

» Meeting with the state officials (state EPI Officer and RI consultant) to finalize the district for implementation of model AEFI surveillance processes. (Bihar-May'19 and Odisha-June'19)

» Finalization of key milestones and issuing of necessary directions from state to district to facilitate and support the implementation of model AEFI surveillance activities (Bihar-June'19 and Odisha- Dec'19)

District level activities
(Bihar- May'19 and Odisha -Dec'19)

❖ Interaction with key stakeholders i.e. Chief District Medical and Public Health Officers, District Immunization officer, representative from partner organization to understand the bottleneck for reporting of serious/severe AEFI cases and discuss the potential implementation strategies which could be implemented to strengthen AEFI surveillance in the district.

❖ Collected baseline data to plan for capacity building of the nodal MO (medical officer in-charge of planning units, sector MO, paediatrician specialist of district hospital/CHC) and other district level functionaries such as members of the district AEFI committee, ADPHO (FW), RVCCM, DVLM, ICA and CCT.

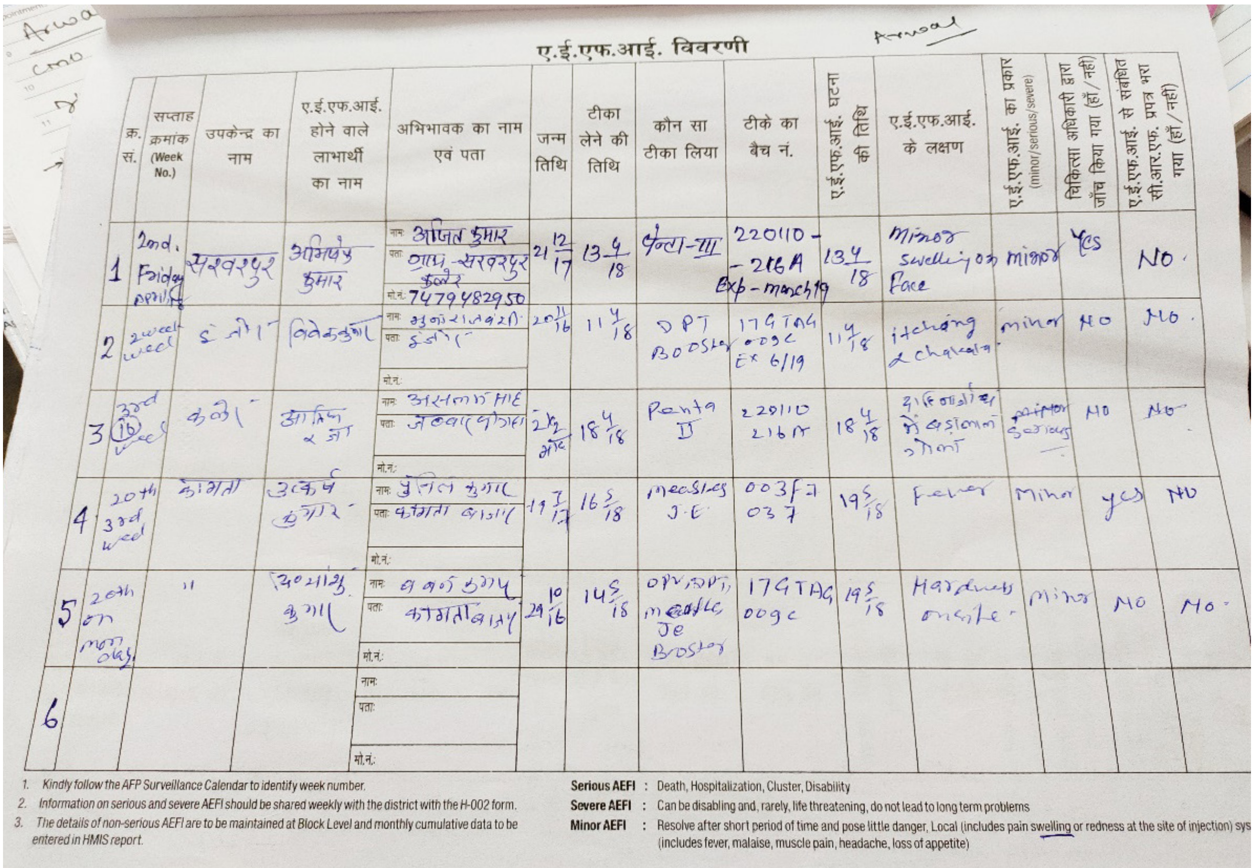
Interaction with the MO-PHC, ANM, ASHA and AWW on AEFI surveillance – District Arwal, Bihar

❖ Reviewed the membership of the district AEFI committee and the minutes of its meeting, presentation of the District Task Force meeting on Immunization (DTFI) and the availability of updated media response template for use during crisis.

Sub-district activities

Bihar	Odisha
Interacted with the health staff (MO and ANM, ASHA and AWW) of Khurta block (Arwal) and Sasaram block (Rohtas) to understand barriers for reporting of AEFI and reviewed the availability and use of AEFI recording register and content of AEFI management kit and anaphylaxis kit	Conducted a half day training of the MO using custom made set of presentation to focus on their role and responsibilities in improving the sensitivity of AEFI surveillance in respective planning units
Discussed with representatives of the partner organization (WHO, UNICEF, CORE and UNDP) to formulate strategies to improve AEFI surveillance in the district	Facilitated training of front-line health worker staff (ANM, ASHA and AWW) of Bhandaripokhri PHC using training module developed for re-sensitization of health workers on key aspects of AEFI surveillance.
Supported the DIO in liaising with key functionaries (Dean, Registrar and Head of departments of Paed., Medicine, Pharmacology) of Narayan Medical College and Hospital, Rohtas to support in improving the sensitivity of AEFI surveillance in the district through the Adverse Drug Reaction monitoring centre (under Pharmacovigilance Programme of India, Indian Pharmacopeia Commission) established in the medical college.	Reviewed the availability and use of AEFI recording register and content of AEFI management kit and anaphylaxis kit

Sample picture of PHC AEFI register available at planning unit in District Rohtas, Bihar



ए.ई.एफ.आई. विवरणी

क्र. सं.	सप्ताह क्रमांक (Week No.)	उपकेन्द्र का नाम	ए.ई.एफ.आई. होने वाले लाभार्थी का नाम	अभिभावक का नाम एवं पता	जन्म तिथि	टीका लेने की तिथि	कौन सा टीका लिया	टीके का बैच नं.	ए.ई.एफ.आई. घटना की तिथि	ए.ई.एफ.आई. के लक्षण	ए.ई.एफ.आई. का प्रकार (minor/serious/severe)	चिकित्सा अधिकारी द्वारा जाँच किया गया (हाँ/नहीं)	ए.ई.एफ.आई. से संबंधित सी.आर.एफ. प्रपत्र भरा गया (हाँ/नहीं)
1	2nd. Friday April	सरवरपुर	अभिषेक कुमार	नाम: अजित कुमार पता: ग्राम-सरवरपुर [illegible] मो.नं.: 7479482950	21/12/17	13/4/18	पेन्टा-III	220110-216A Exp-march19	13/4/18	Minor swelling on Face	minor	Yes	No.
2	2 week	[illegible]	विवेक कुमार	नाम: [illegible] पता: [illegible] मो.नं.:	20/11/16	11/4/18	DPT Booster	17GTAG 009C Ex 6/19	11/4/18	itching & [illegible]	minor	NO	NO.
3	3rd (16) week	[illegible]	आसिफ रजा	नाम: [illegible] पता: [illegible] मो.नं.:	2½ month	18/4/18	Penta II	220110 216A	18/4/18	[illegible]	~~minor~~ serious	NO	No
4	20th 33rd week	[illegible]	उत्कर्ष कुमार	नाम: सुनिल कुमार पता: [illegible] मो.नं.:	19/7/17	16/5/18	measles J.E	003F21 037	19/5/18	Fever	Minor	yes	NO
5	20th on monday	"	[illegible] कुमार	नाम: [illegible] पता: [illegible] मो.नं.:	29/10/16	14/5/18	OPV, DPT, measles JE Booster	17GTAG 009C	19/5/18	Hardness onsite	Minor	NO	NO.
6				नाम: पता: मो.नं.:									

1. Kindly follow the AFP Surveillance Calendar to identify week number.
2. Information on serious and severe AEFI should be shared weekly with the district with the H-002 form.
3. The details of non-serious AEFI are to be maintained at Block Level and monthly cumulative data to be entered in HMIS report.

Serious AEFI : Death, Hospitalization, Cluster, Disability
Severe AEFI : Can be disabling and, rarely, life threatening, do not lead to long term problems
Minor AEFI : Resolve after short period of time and pose little danger, Local (includes pain swelling or redness at the site of injection) sys (includes fever, malaise, muscle pain, headache, loss of appetite)

District level training of trainers for medical officers, facilitated by National AEFI secretariat, and supported by State RI consultant, DIO and representative from WHO, district Bhadrak, Odisha

District level training of trainers for medical officers, facilitated by National AEFI secretariat, and supported by State RI consultant, DIO and representative from WHO, district Bhadrak, Odisha

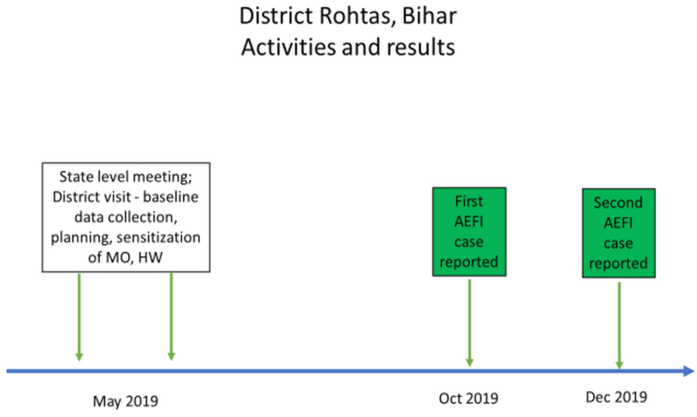
Demonstration of Model AEFI Surveillance Processes in Select Districts, India

3.1 Results

❖ **Reporting of cases from silent districts-** Following our visit and interaction with the key stakeholders at state, district and sub-district level the details of AEFI cases reported from these districts are mentioned below-

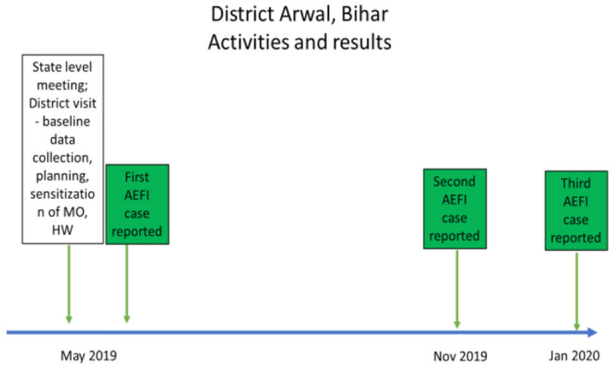
» District- Rohtas-Bihar - Period for intervention-(May'19-Oct'19)

- Two serious AEFI cases were reported by the district, one each in Oct and Dec'2019. One was notified by an ASHA (FLW) the other by a MO.

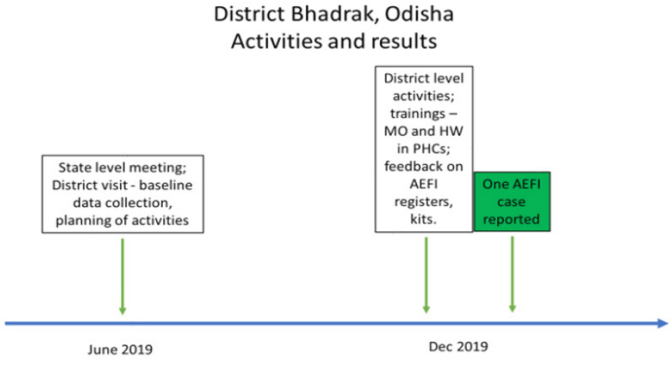


» District- Arwal -Bihar - Period for intervention-(May'19-Oct'19)

- Three serious AEFI cases were reported by the district in May and November'19 and Jan'2020 respectively. Of these, two were notified by health workers and one by a MO.



a. **District- Bhadrak -Odisha - Period for intervention-(June'19-Dec'19)**
One severe AEFI case was reported by and FLW in Dec'19.



Limitations

As per the design of the intervention, national support was provided for the baseline, planning, conducting sensitization meetings and trainings at district level after which it was expected that the district will take over the regular activities and the state will monitor and support these activities on a monthly basis, with minimal intervention from the national level. Constant follow-up was done and feedback given to districts and states for monitoring and conducting further activities like trainings and holding of district AEFI committee meetings, etc. These activities could not be conducted due to the following reasons:

- Engagement of SEPIOs and DIOs in other priority programmes such as Intensified Mission Indradhanush 2.0 (December 2019-March 2020), Japanese Encephalitis campaign (Bihar)
- Lack of dedicated resource person at state level to follow up and support districts (state level AEFI consultant/RI consultant) for further AEFI activities
- Frequent change in leadership/supporting staff at state levels
- Non availability of dates in districts for conducting trainings and meetings for AEFI surveillance activities as per plan

CHAPTER 4

DISCUSSION AND KEY LEARNINGS

While there was initial enthusiasm in the districts and states for the activities to strengthen AEFI surveillance, there were delays in getting necessary approvals for the district to conduct trainings and provide necessary logistic supply. Furthermore, there were inordinate delays in getting dates for conducting trainings of batches of medical officers and health workers (Arwal and Rohtas) due to various reasons including holidays/festivals, engagement of state/district functionaries in other immunization related activities (IMI, JE campaign etc.). The position of the consultant supporting the SEPIO for AEFI related activities fell vacant.

In Bhadrak district, while the initial batches of trainings were conducted, there was no follow up for completion of trainings of all the medical officers and health workers. Despite reminders and follow-up emails from the national level, district AEFI committee meetings were not held in addition to other activities as planned.

Despite the non-completion of all activities to demonstrate ideal processes, there were some immediate results in terms of cases being reported from these silent districts. During this process, district level training packages consisting of agenda, pre and post-test, presentations, exercises and handouts/job aids were developed and used in the districts.

In a similar exercise between Oct 2018 and Dec 2019, Senior AEFI Zonal Consultants undertook the following activities during one-two day visits to silent districts in south India (refer to Annexure 9) to improve reporting of AEFI cases:

- Sensitize DIOs and visit private medical institutions (HOD Paediatrics and staff of vaccination clinic) with DIO to build linkages for reporting of AEFI cases.
- Liaising with nodal officers of ADR monitoring centres of Pharmacovigilance Programme of India (PvPI) in medical colleges whose catchment area included population of silent districts for reporting of AEFIs.
- Use rotavirus vaccine introduction trainings to re-orient health workers and medical officers for recording of minor, severe and serious AEFI cases in AEFI registers at the planning units.

State EPI Officer was requested to invite DIOs of silent districts to state AEFI committee meetings to explain why cases are not being reported and to describe steps taken to improve AEFI reporting. As a result of these visits, these silent districts started reporting AEFI cases. (see Annexure 9 for details).

Recommended key activities:

Based on the activities and impact in the demonstration districts and the experience of the zonal consultants in silent districts of south India, the following set of minimum key activities can be listed. These activities can be categorised as follows:-

- State level interventions
- District level interventions
- Sub-district level interventions

State level interventions-

- Invite DIOs/Urban nodal officers of non-reporting districts/urban areas to state AEFI committee meetings to explain the reasons for non-reporting and what actions are being taken to initiate reporting of AEFIs.
- A medical officer or consultant at state level may be designated to support the SEPIO for follow up of AEFI case records, monitoring conduction and quality of quarterly district AEFI committee meetings and implementing AEFI activities at state level (coordinate with IMA, IAP, state drug controller, programme managers of Integrated Disease Surveillance Project (IDSP) for support in improving AEFI surveillance in districts).
- SEPIO can seek support from immunization partners (WHO, UNICEF, UNDP, etc.) with presence at the district level for increased sensitivity for reporting of AEFI cases, conducting AEFI committee meetings, trainings of MO and HW, supporting in case investigations and follow-up for pending AEFI case documents.
- AEFI surveillance update should be shared by SEPIO during state level immunization review meetings and State Task Force for Immunization (STFI) meetings focusing on silent districts.
- State communication plan should include specific activities to identify and manage AEFI related crisis.

State AEFI consultants have been sanctioned for 14 states (Uttar Pradesh, Madhya Pradesh, Rajasthan, Bihar, Chhattisgarh, Jharkhand, Maharashtra, Gujarat, West Bengal, Andhra Pradesh, Telangana, Karnataka, Tamil Nadu/Kerala, Odisha) by MOHFW in state PIPs.

District level interventions

- DIO should ensure membership of the committee is updated and meetings are held at least once a quarter during which the status of AEFI surveillance is reviewed and recommendations are given to improve surveillance.
- DIO should give an update on AEFI surveillance in District Task Force on Immunization (DTFI) meetings to sensitize key stakeholders such as District Magistrate/collector, Chief Medical Officer (CMO) and representative of other line departments such as ICDS and PRI, district level representatives of IMA, IAP, etc., to support in efforts to improve reporting of AEFI cases.
- DIO will monitor whether AEFI registers are in place in all block/PHCs and every week minor, serious and severe AEFI cases are being recorded by health workers.
- DIO to ensure trainings and orientations of all medical officers and health workers in all government health facilities with the support of immunization partners (WHO-SMO, UNICEF), sensitization paediatricians of district hospital/CHC, and private practitioners for reporting of AEFI cases. Training material for MOs and HWs is available on http://www.itsu.org.in/?page_id=938 and a training module for the health workers is attached as annexure.
- DIO should engage with faculty of medical colleges and nodal officer of the Adverse Drug Reactions (ADR) Monitoring Centres of the Pharmacovigilance Programme of India in the medical college (if functional) to sensitize them for reporting of serious/severe AEFI cases.
- DIO should regularly review data of SAFEVAC and HMIS and analyse AEFIs reported from all planning units and share specific feedback in monthly review meetings.
- District communication plan should include specific activities to identify and manage AEFI related crisis.

Sub-district interventions-

- Medical officer in charge should sensitize all the health workers (ANMs, Health supervisors, CCH, ASHA and AWW) on the important aspects related to AEFI surveillance by using the training material developed by AEFI secretariat. The job aid for the ANM may be translated in local language.
- MO should ensure that AEFI register is available at the planning unit and it being used by the health worker to enter details of all minor, severe and serious AEFI cases. These registers should be reviewed by the medical officer on weekly basis, so that no potential serious/severe AEFI cases is missed from reporting.
- MO should periodically review the availability of drugs in the AEFI management kit and should also certify the contents of the anaphylaxis kit (available with the ANM) in order to ensure that none of the constituent of the kit is nearing expiry date.
- Job aid on AEFI surveillance (recording and reporting) may be displayed at the planning unit.

ANNEXURES

Annexure 1: Agenda for training of MO

Time	Topic	Methodology (and material)	Resource Person / Facilitator
15 minutes	Introduction and pre-test	Round of introduction, Administration of pre-test; handout-1	DIO
25 minutes	Training objectives; basic concepts of AEFI surveillance	Brainstorming, lecture, discussion (presentation)	AEFI Secretariat
25 minutes	Recording & reporting of AEFI; Block/PHC AEFI registers	Lecture, discussion and exercise (presentation, hand out)	AEFI Secretariat
15 minutes	Case reporting format	Lecture, discussion and exercise (handout)	AEFI Secretariat
15 minutes	Management of AEFI Cases and Case scenario exercise	Lecture, discussion (presentation)	AEFI Secretariat
25 minutes	Inter Personal Communication and Role of MO in AEFI	Renuka, The Health Worker – A film on AEFI (film) & Training film of Health workers on Adrenaline administration in the management of anaphylaxis	AEFI Secretariat
10 minutes	Post-test	Administration of post-test; handout-3, discussion on correct answers	AEFI Secretariat
5 minutes	Closing remarks and questions		DIO

CONTENTS

Chapter -1: Introduction

The training module on AEFI surveillance for ANM/health workers is a **two-hour module** which can be used to re-orient health workers (ANM/ Multi-Purpose Worker and supervisory staff of the health department) on the basics of AEFI surveillance (identification, recording and reporting of minor, serious and severe AEFIs) and management and prevention of common AEFIs.

This module can be used for conducting standalone trainings for AEFIs or as a short (two-hour) re-orientation session within a larger training workshop e.g. when an immunization campaign is being conducted or when a new vaccine is being introduced, etc. This module will help the trainer (DIO or nodal medical officer) to conduct training for a batch of 30-40 participants over 2 hours duration at block or planning unit level.

The overall objective of this training module is to enable the participants to:

- Differentiate between minor, serious and severe AEFIs
- Describe the processes for recording of AEFIs in session tally sheets, AEFI registers
- Understands when, how and whom to report serious and severe AEFI case
- List the steps for monthly reporting of AEFIs in HMIS
- Use the job aid on AEFI
- Enumerate preventable AEFIs and steps to prevent them
- Use anaphylaxis kit to manage suspected anaphylaxis case

The training will involve administration of pre- and post-test questionnaire, lectures and discussion sessions, exercises, watching video films and use of job aid. The module has a draft agenda, a questionnaire which can be used for both pre- and post-tests with answers and an analysis format, practice exercises and job-aid in the form of handouts, as well as links to training videos. The questionnaires, exercises, job aid should be translated into local language and photocopied for distribution during the training to participants as handouts.

Before initiating the training-

Read the module – Facilitators are encouraged to read the module in order to familiarise themselves with the content. It elaborates on topics such as basics of AEFI surveillance, reporting and recording of AEFIs, prevention and management of preventable AEFIs including management of suspected anaphylaxis cases.

Sessions wise topic discussion -

- ***Start with a round of introduction-*** A quick round of introductions followed by sharing the objective of the training (listed above) with the participants (kindly refer to Annexure A for the draft agenda, this may be modified as per need).
- ***Ensure availability and use of training material (preferably translated in vernacular language)***- Adequate copies of pre and post-test (attached as Annexure B) should be obtained before the start of training session. Participants should be instructed to write name of the district, venue, date and encircle "pre-", as the pre-test is being administered. Allow 10 minutes to fill in the responses. After completion, use the answer keys (Annexure C) and the scoring table to analyse responses for each of the participant.
- ***Session on Basics of AEFI surveillance*** -Start the first session on *basics of AEFI surveillance, reporting and recording of AEFIs* by distributing the job aid on AEFI surveillance to the participants**.** **Brainstorm** on the opinion of participants regarding vaccine safety by asking the following

questions: Are vaccines safe? Does anyone have any experience of an AEFI? Participants tend to answer that vaccines are always safe. Explain to them that this is not so and adverse events can occur co-incidentally or if vaccines are incorrectly stored, transported, handled or administered. Some AEFIs occur even if vaccines are correctly stored, handled and administered and these are expected due to the inherent properties of the vaccine (vaccine product related reactions). Ask for examples of coincidental cases, cases due to immunization errors and vaccine-product related reactions. Ask the participants to read the first point in the Job Aid and reiterate that AEFIs need to be reported even if it is known not to be caused due to vaccination, which means that even co-incidental cases need to be reported.

- Ask participants which AEFIs are treated with paracetamol. If they give examples of minor local and systemic reactions, point out that these are minor AEFIs. Ask which are the events which are considered serious. If the responses are in the form of diagnosis such as seizures, etc., tell them that for reporting, in place of diagnosis, the severity of the event is considered. Ask them to read the contents of the box in the job aid. Ensure that participants can clearly differentiate between minor and serious and severe AEFIs.
- ***Exercise on use of recording format***- Ask the participants where they will record AEFIs occurring during the session. In some states, session site details may be shared in letter or handwritten report forms. In such states, ask participants where and how they record these AEFIs occurring during the sessions.
- ***Use of job aid for health worker*** - Share handouts of Annexure D & E– Job aid and the format of AEFI register. Ask participants to refer to the job aid and list the AEFIs which need to be recorded in the register. Reiterate that minor AEFIs (fevers, pain and swelling, etc.) informed to them by caregivers on mobile also need to be entered in the registers once a week. Serious and severe AEFIs are also recorded along with minor AEFIs once a week, but reporting to MO in charge should be immediate.
- ***Exercise on filling up of AEFI recording register*** - Ask the participants to read out loud the columns of the blank AEFI register (Annexure E) and tell from where they will get the information to fill each column. Ask them to look at the data in the filled example of an AEFI register and ask them in which rows critical information (vaccine batch details in four rows) is missing and from where they will get the information. Also ask them if they can see clustering of any AEFIs (such as two abscesses in HSC1) or if any AEFI which should have been reported in CRF and investigated has not been investigated (fever >102, severe).
- Share Annexure F which is the Monthly HMIS Format and ask them to point out the section for reporting of AEFIs (Section 6.6) and use the information in the filled up AEFI register to fill rows 9.6.1, 9.6.2 and 9.6.3 in the format. Clarify doubts and confusion of participants regarding this.

❖ ***Discussion on examples of AEFI cases*** - Read out examples of AEFIs from Annexure G and ask the participants to answer for each example whether this AEFI will be recorded in AEFI register, under which row it will be reported in the HMIS monthly report (abscess, death or others) and whether the MO has to be informed immediately about this case. Ask why and clarify and correct, if needed. Reiterate that all AEFIs (including minor) need to be recorded in AEFI registers, abscesses will be recorded under 6.6.1, deaths under 6.6.2 and all remaining under 6.6.3.

- ***Session on prevention and management of AEFIs***- Participants should be briefed about the potential AEFIs which can occur due to incorrect storage, handling and administration of vaccines. Annexure H contains the complete list of suspected AEFIs with its causes and measures for its prevention. Also, ask the participants about what should be done if they come to know of a preventable AEFI (refer for treatment, report and record).

❖ ***Discussion on anaphylaxis and its management*** -Trainings for use of adrenaline to manage suspected cases of anaphylaxis using an anaphylaxis kit has already been completed in most

states. Each vaccinator should carry an anaphylaxis kit for all the sessions. Ask the participants to take out their anaphylaxis kits and ask them the common signs and symptoms which will make them suspect anaphylaxis. Ask some of the participants to use the dosing chart to choose the dose as per age by calling out ages from each age group. Ask each one of them to read out the expiry date of one adrenaline ampoule from their kits loudly. Ask the participants, what will happen if they administer one dose of adrenaline to a case which is not an anaphylaxis case. Tell them that it will not harm the patient.

❖ ***Use of training videos***- Ensure internet connection and audio-visual equipment is available beforehand to show the films. If CDs of the Anaphylaxis film and the AEFI film are not available, use the following links to show the film to the participants:

Link for Renuka, the health worker film	http://www.itsu.org.in/?page_id=938
Link for use of inj. Adrenaline for initial management of anaphylaxis film	http://www.itsu.org.in/?page_id=938

» Show them the animated anaphylaxis film. Reiterate that if there is redness of skin, swelling of face, tongue and mouth, vomiting, difficulty in breathing or loss of consciousness, etc., immediately suspect anaphylaxis and administer a dose of adrenaline. Administering one dose in a non-anaphylaxis case is safe. Refer the patient immediately to nearest health facility for further treatment.

» Following this, show the AEFI film – Renuka, the health worker. Point out how the ANM called the MO for help and reported the AEFI immediately. Also underline the fact that the ANM showed concern regarding the health of the child and continued to be polite and helpful despite negative attitude of the community.

❖ ***Post-test and open discussion*** - Before administering the post test, ask if the participants have any doubts. Ask the participants to circle "post-test" and mark the correct answer with a tick. Enter the marks in the scoring sheet. Discuss the correct answers before closing the session with concluding remarks. Thank the participants for their involvement.

After the training, analyse the scoring sheet to see where improvements can be made and stress on those areas in the subsequent trainings.

Chapter 2: Basics of AEFI Surveillance

Immunization is important to protect infants from vaccine-preventable diseases (VPDs). Although vaccines are safe, there exists a risk for adverse events to occur following vaccinations. Adverse events following immunization (AEFI) are usually mild but may on rare occasions be life-threatening. As per the trends of AEFI cases reported in the country, most of the cases are coincidental in nature as there is no causal relationship between the vaccine and the reported event.

AEFI surveillance refers to the systematic collection of data on events following immunization and is important for sustaining public confidence in vaccine safety. It will also help to distinguish a co-incidental event from a true vaccine-related event.

More the AEFIs reported, investigated and causality assessment conducted in a timely manner, more will be the confidence that any safety issue related to use of vaccines can be detected timely and appropriate action taken for prevention and recurrence. All health-care providers including ANM/health workers should be aware of the types of AEFI which are to be identified, recorded and investigated as per the national AEFI guideline, 2015.

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 unfavorable or unintended sign, abnormal laboratory finding, symptom or disease. Most adverse events are coincidental i.e. unrelated to vaccine or vaccination process but have to be reported as the symptoms or signs have occurred after vaccination

Need for AEFI surveillance system

- To ensure vaccine safety and build vaccine confidence in the community
- To investigate known coincidental events causing concern to parents/community and prevent false blame,
- To recognise, correct and prevent immunization programme errors (improper storage, handling, administration of vaccines) and take corrective action
- To capture rare, serious AEFI undetectable during clinical trials

Types of AEFI

On the basis of vaccine reactions, AEFI may be classified into three types -

- Minor
- Severe
- Serious

Minor AEFI

- These are AEFI which are self-limiting with or without treatment.
- Low-grade fever, pain, swelling, redness at the injection site, irritability, malaise, etc. which are self- limiting or relieved with symptomatic treatment.

Actions – Manage the case symptomatically, reassure parents and refer if required

Severe AEFI

- High-grade fever, seizures, persistent (more than 3 hours) inconsolable cry, etc. and other minor AEFI which persist beyond two-three days.
- Severe AEFI are those which require hospitalisation but could not be hospitalised due to some reason.
- For example- An allergic reaction which was relieved by administering Adrenaline injection can also be considered as severe AEFI
- *Action – Manage the case and refer to nearest health facility, report immediately to MO of PHC*

Serious AEFI

- Death
- Hospitalization
- Disability
- Cluster (two or more cases of the same adverse event related in time, place or vaccine administered)
- Significant parental /community/media concern
- Action – Manage the case and refer to nearest health facility, report immediately to MO of PHC

What to report

All types of AEFI cases such as minor, severe and serious are to be identified by the health worker and recorded in AEFI recording register at PHC/CHC during weekly block level meeting. This register is to be periodically reviewed and signed by the medical officer-in-charge so as to identify any potential clustering of minor AEFI in a particular area or sub-centre.

When to report

All serious/severe AEFI are to be immediately notified by health worker/front line worker to the medical officer of the nearest AEFI management centre (any government PHC/CHC/DH) and/or to the DIO by the quickest means of communication (telephone, messenger, etc.). Examples of events which require prompt reporting and investigation are-

- Serious AEFI (death, hospitalization, cluster, disability, significant parental/community concern)
- AEFI associated with a newly-introduced vaccine
- AEFI that may have been caused by immunization error-related reaction
- Significant events of unexplained cause occurring within 30 days after vaccination
- Events causing significant parental or community concern

All notified severe/serious AEFI cases should be reported using a case reporting form (CRF) and submitted to the DIO within 24 hours of notification.

How to record AEFI cases

Hands-on exercise for the recording of AEFI cases in –

a. PHC AEFI recording register (Annexure E)
b. Monthly progress sheet (Annexure F)

Chapter 3: Prevention and management of avoidable AEFI – roles and responsibilities

At Community level- *Anganwadi and ASHA/volunteers/frontline workers*

- 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 the referral of any suspected cases

At the session site level- *ANM*

- Enquire for any contraindications for the use of a vaccine in the beneficiary to avoid serious reactions. Example- vaccines are contraindicated if there is a possibility of a serious allergy to a vaccine or its components. Live vaccines should not be given to immune-deficient children
- Maintain standard immunization practices, note down the following details manufacturer's name, expiry date, batch number, VVM status (for new and partially used vaccines), date on the label of partially used vaccine (in case of Open vial policy), date and time on the label (in case of reconstituted vaccines)
- Ensure that vaccine vial septum has not been submerged in water or contaminated in any way
- Use Measles-Rubella, BCG and JE vaccine within 4 hours of reconstitution.
- Never carry and use reconstituted vaccine from one session site to another
- Ask the beneficiaries to wait for half an hour after vaccination to observe for any AEFI
- Advice the parents on managing common, minor reactions such as fever, injection site pain and swelling pain and to seek proper medical care if there are more serious symptoms.

For the health supervisor-

- Supervise and provide hands-on training to the ANMs/vaccinators during RI monitoring.

Anaphylaxis and its management-

Anaphylaxis is an extreme and severe allergic reaction, that is potentially life-threatening. Initial signs of anaphylaxis may be similar to allergic reactions. If anaphylaxis is suspected, immediately administer age-appropriate dose of adrenaline deep intramuscular and transport the patient to the nearest health facility. In case this is not anaphylaxis, a single dose of adrenaline will not cause any harm. If this is a case of anaphylaxis, then one dose can save the patient.

Dose chart for Injection Adrenaline (1:1000 solution)

Age group in years	One-inch needle gauge	Dosage (in mL) using 1 mL tuberculin syringe	Dosage (in units) using 40 units insulin syringe
0-1	24 G/ 25 G	0.05	2
1-6		0.1	4
6-12		0.2	8
12-18		0.3	12
Adults		0.5	20

Summary for management of a suspected case of anaphylaxis

Summary for management of a suspected case of anaphylaxis	
After immunization let the parents or guardians wait for 30 minutes. Suspect* Anaphylaxis in a case with following symptoms and signs.	
Step 1: Assess Case	**Early onset (within few minutes to 6 hours) & rapid progression of >= 1signs & symptoms of any of the two systems (Respiratory, cardiovascular and dermatological / mucosal)** **Respiratory:** ❖ Swelling of tongue, lip, throat, uvula, larynx ❖ Difficulty in breathing ❖ Stridor (harsh vibrating sounds during breathing) ❖ Wheezing (breathing 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
Step 2: Administer one dose of adrenaline deep IM	**Management of anaphylaxis** ❖ **Reassure** patient, parents/ relatives ❖ **Immediately administer** one dose of injection Adrenaline by deep IM route ❖ **Seek help to immediately arrange for ambulance** to transport the patient to the nearest health facility (PHC/CHC/District Hospital/Civil Hospital) ❖ **Do not leave the patient alone** ❖ If patient is **conscious**, he/she should be kept in **supine position with lower limbs raised** higher than head ❖ If patient is **unconscious**, he/she should be kept in **left lateral position**
Step 3: Refer immediately	**Refer to higher center** ❖ Call for ambulance ❖ **Inform MO** about the case before arriving at the health facility for timely management

Annexure A: AEFI Surveillance Workshop for Health workers

Date: **Venue:**

Session	Time	Topic	Methodology (and material)	Resource person/ Facilitator
1	10 minutes	Introduction to training session, objectives, agenda		Medical officer (in charge)
2	10 minutes	Pre-test	Pre-test questionnaire	AEFI Secretariat
3	25 minutes	Basics of AEFI surveillance: Need for reporting AEFI cases, definition, types of AEFIs for reporting, recording and reporting AEFIs. Session tally sheet (exercise) AEFI recording register (exercise) Monthly progress sheet Using Job Aid	Brainstorming, lecture and discussion; exercises on session tally sheet, AEFI register, monthly progress report (HMIS); job aid	AEFI Secretariat/ Medical officer
4	15 minutes	Examples / Scenarios	Discussion	AEFI Secretariat/ Medical officer
5	20 minutes	Prevention and management of common AEFI Prevention of avoidable Adverse event following immunization – roles and responsibilities Anaphylaxis- Identification and its management	Brainstorming, lecture, discussion	AEFI Secretariat/ Medical officer
6	25 minutes	Training films- Renuka, The Health Worker Anaphylaxis training video	Audio-visual aid	AEFI secretariat
7	10 minutes	Post-test	Post-test questionnaire	
8	5 minutes	Closing remarks and questions		Medical officer (in charge)

Annexure B : Pré-test / Post-test Questionnaire

District :	Venue :	Date :
Name of participant :	Pre or Post (encircle)	

Q1. Adverse Events following immunization are-

- ❖ Unfavorable or unintended sign
- ❖ Abnormal lab findings
- ❖ Symptom or disease
- ❖ All of the above

Q2. Severe AEFI is

- ❖ Another term for serious AEFI
- ❖ Minor AEFI with a higher degree of severity but not hospitalized
- ❖ Serious AEFI which have not been hospitalized due to some reason
- ❖ Both b and c
- ❖ None of the above

Q3. **Serious AEFI which should be immediately notified to the Medical Officer are any adverse event following vaccination resulting:**

- ❖ Death
- ❖ Hospitalization
- ❖ Disability
- ❖ Cluster
- ❖ Parental/community concern
- ❖ All of the above

Q4. **For how long the vaccinee should be observed following immunization?**

- ❖ 30 minutes
- ❖ 60 minutes
- ❖ 10 minutes
- ❖ No need to observe

Q5. **The following AEFI should be entered in the PHC AEFI recording register:**

- ❖ Minor
- ❖ Severe
- ❖ Serious
- ❖ All of the above

Q6. What will you do in case of redness at injection site which starts spreading rapidly with in few minutes following immunization throughout the body?

- ❖ Give symptomatic treatment and refer the child to Medical Officer in charge
- ❖ Refer to MO in charge
- ❖ Reassure the mother or care giver
- ❖ Leave as such and send home
- ❖ a, b and c

Annexure C : Answer key: Q1 (d), Q2 (d), Q3 (f), Q4 (a), Q5 (d), Q6 (d)

AEFI training on AEFI surveillance

District : Venue : Date :

Analysis of pre- and post-test scores

S. no.	Name of participants	Pre-test scores (Mark a Tick (√) for a correct response) for each of six questions						Total score (pre-test)	Pre-test scores (Mark a Tick (√) for a correct response) for each of six questions						Total score (post-test)	Difference in score (Post-test vs Pre-test)	
		1	2	3	4	5	6		1	2	3	4	5	6			
1																	
2																	
3																	
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	Totals																

Annexure D: JOB AID - Adverse Events Following Immunisation (AEFI)

टीकाकरण के बाद होने प्रतिकूल प्रभाव (एईएफआई)

- टीकाकरण के बाद की कोई भी चिकित्सीय घटना जिसका संबंध टीकाकरण से हो सकता है या नहीं भी हो सकता है।
- एईएफआई को मामूली, गंभीर और अत्यधिक गंभीर प्रकारों में वर्गीकृत किया जा सकता है.

मामूली गंभीर और अत्यधिक गंभीर एईएफआई

मामूली एईएफआई–

- इन्जेक्शन स्थल पर दर्द, सूजन, लालिमा जैसे प्रभाव।
- सामान्य लक्षण जैसे कि हल्का बुखार, चिड़चिड़ापन, अस्वस्थता इत्यादि।
- उपचार के बिना भी दो–तीन दिनों में ठीक हो जाए।
- साधारण दवा जैसे पैरोसिटामॉल से ठीक हो जाए।

क्या करें– पैरोसिटामॉल से उपचार करें, तथा माता–पिता को आश्वत करें और यदि आवश्यक हो तो उच्च चिकित्सा केन्द्र पर इलाज हेतु भेजें। सभी एईएफआई को प्रत्येक सप्ताह एईएफआई रजिस्टर में दर्ज करें।

गंभीर एईएफआई–

- मामूली एईएफआई जो दो–तीन दिनों में ठीक ना हो या उसकी गंभीरता बढ़ती जाए–टीकाकरण स्थान के निकटतम जोड़ों में सूजन/दर्द ; तीन दिनों से अधिक रहने वाला हल्का बुखार और पैरोसिटामॉल देने के बाद में लक्षणों में कोई सुधार ना हो।
- ऐसे मामले जिसमें आमतौर पर बच्चे को अस्पताल में भर्ती करना चाहिए लेकिन किसी कारणवश नहीं कर पाए जैसे कि दौरे पड़ना, एलर्जिक प्रतिक्रियाएं/ संदिग्ध एनाफिलैक्सिस (Anaphylaxis) मामलें जिसमें इन्जेक्शन एड्रेनालीन (Adrenaline) दिया हो इत्यादि।
- तेज बुखार, दौरे, 3 घंटे से अधिक बच्चे का लगातार रोना, ओपीडी में उपचारित एलर्जिक प्रतिक्रिया आदि।

क्या करें–इस तरह के रोगी को तुरंत निकटतम स्वास्थ्य केन्द्र पर भेजने का प्रबंध करें और प्राथमिक स्वास्थ्य केन्द्र के चिकित्साधिकारी को तुरंत सूचना दें तथा एईएफआई रजिस्टर में केस की जानकारी अवश्य दर्ज करें।

अत्यधिक गंभीर एईएफआई–निम्न में से कोई भी एक परिस्थिति–

- मृत्यु
- अस्पताल में भर्ती
- विकलांगता
- क्लस्टर (समय, स्थान या टीका से संबंधित एक ही प्रतिकूल प्रभाव या घटना के दो या दो से अधिक मामले।
- अभिभावकों/समुदाय/मीडिया में अत्यधिक चिंता उत्पन्न होना।

क्या करें–इस तरह के रोगी को तुरंत निकटतम स्वास्थ्य केन्द्र पर भेजने का प्रबंध करें और प्राथमिक स्वास्थ्य केन्द्र के चिकित्साधिकारी को तुरंत सूचना दें तथा एईएफआई रजिस्टर में केस की जानकारी अवश्य दर्ज करें।

याद रखें गंभीर और अत्यधिक गंभीर एईएफआई केस की जानकारी तुरंत अपने संबंधित चिकित्साधिकारी को दें।

चिकित्साधिकारी का नाम मोबाइल नं:

महत्वपूर्ण बिंदु:–

1. सभी आवश्यक सावधानियों व सुरक्षा उपायों के बावजूद भी एईएफआई हो सकता है।
2. सभी एईएफआई को अवश्य रिर्पोट करें भले ही आपको मालूम हो कि इसका टीकाकरण से कोई संबंध नहीं है।
3. टीकाकरण के पश्चात चार महत्वूपर्ण संदेश अवश्य दें और टीकाकरण के दौरान सुरक्षित इंन्जेक्शन हेतु सभी प्रचलित प्रणालियों का पालन करें।
4. आशा को टीकाकरण आच्छादित बच्चों की सूची अवश्य दें तथा उनसे अनुरोध करें कि वे टीका प्राप्त कर चुके लाभार्थियों के साथ सम्पर्क में रहें और किसी भी तरह के प्रतिकूल प्रभाव की जानकारी तुरंत चिकित्साधिकारी को अवश्य दें।
5. एईएफआई की जॉच में चिकित्साधिकारी को सहयोग दें और उनके द्वारा दिये गये दिशा–निर्देशों का पालन करें।

Annexure E: AEFI recording register

Block/Planning unit AEFI recording register											
Week no.	Name of the Sub Centre	Name of the vaccinee	Father's Name	Age	Date of vaccination	Name of vaccines given	Batch no. of vaccines given	AEFI noted (symptoms)	Category (serious/ Severe/Minor)	Case seen by MO i/c (yes/no)	Entered in case reporting form (Yes/no)

1. Kindly follow the AFP Surveillance calendar to identify week no.
2. Information on serious & severe AEFI should be shared weekly with the district along with the H-002 form
3. The details of Minor AEFI are to be maintained at Block /Planning unit level & monthly cumulative data to be entered in HMIS report

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 days	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 days	14-03-2018	BCG, Hep B, OPV	BCG 037G5041 Hep B 3421A91 OPV S-151	Abscess	severe	Yes	Yes

Annexure F: State specific monthly progress report form

स्वास्थ्य एवं परिवार कल्याण मंत्रालय
निगरानी एवं मूल्यांकन प्रभाग

प्राथमिक स्वास्थ्य केन्द्र का मासिक एचएमआईएस रिपोर्टिंग प्रपत्र

इस प्रपत्र में संबंधित प्राथमिक स्वास्थ्य केन्द्र संस्था/ क्षेत्र अंतर्गत माह में दी गई सेवाओं व प्रकरणों को ही रिपोर्ट किया जाना है जिन सेवाओं/प्रकरणों को अन्य संस्था द्वारा रिपोर्ट कर दिया गया है रिपोर्ट न किया जावे

राज्य का नाम– मध्यप्रदेश	जिला का नाम–	माह–
संस्था का नाम–	विकासखंड–	वर्ष–
संस्था का प्रकार– शासकीय/ अशासकीय	ग्रामीण/शहरी एनआईएन–	

रिपोर्टिंग अवधि– वर्तमान माह की 26 से आगामी माह की 25 तारीख तक

Sl. No.	Data Item (नीति आयोग एवं भारत सरकार द्वारा जिन डाटा एलीमेंट को रैंकिंग में प्रयोग किया जा रहा है उन्हे {# Ranking} के साथ अन्डरलाईन किया गया है)	माह में उपलब्धि	वर्तमान वित्तीय वर्ष में प्रतिवेदित माह तक
9.6	Adverse Event Following Immunisation (AEFI) एईएफआई		
9.6.1	Number of cases of AEFI - Abscess	टीकाकरण प्रतिकूल प्रभाव– फोडा	
9.6.2	Number of cases of AEFI - Death	टीकाकरण का प्रतिकूल प्रभाव– मृत्यु (पुष्टि उपरांत रिपोर्ट करें)	
9.6.3	Number of cases of AEFI - Others	टीकाकरण प्रतिकूल प्रभाव– अन्य (फोडा एवं मृत्यु के अतिरिक्त)	

ANNEXURE G: Examples of AEFI and its recording/reporting

1. Low grade fever following immunization. Parents convinced that fever will occur under normal circumstances. They call ANM asking if they can give PCM to the child.
   AEFI register, HMIS under "others"

2. Fever with pain and some swelling in a child after immunization. Subsided within a day with Paracetamol.
   AEFI register, HMIS under "others"

3. Fever with seizures following immunization. Child hospitalised.
   AEFI register, HMIS under "others", inform MO

4. High grade fever following immunization. Parents panic and insist on hospitalization for treatment.
   AEFI register, HMIS under "others", inform MO

5. Child died within 3 hours of receiving the vaccination. The treating physician knows that the child had suffered from Pneumonia and died due to pneumonia. It was only a coincidence that the child died the same day of vaccination.
   AEFI register, HMIS under "death", inform MO

6. Local pain and induration in a child vaccinated at an outreach site.
   AEFI register, HMIS under "others"

7. A case of abscess in a child given DPT. No other cases reported from any other part of the block or district.
   AEFI register, HMIS under "abscess"

8. Three cases of abscess in children after DPT in same sub-centre area over a period of two weeks.
   AEFI register, HMIS under "abscess", inform MO

9. Three children received Hep B vaccine orally instead of OPV. All are safe and do not suffer from any side effects. There is a lot of community concern leading to media coverage.
   AEFI register, HMIS under "others", inform MO

10. Foot drop after DPT booster gluteal injection in a six-year-old child.
    AEFI register, HMIS under "others", inform MO

11. An adult dies within half an hour of receiving a rabies vaccination.
    AEFI register, HMIS under "death", inform MO

Annexure H: Immunization error related reactions

An adverse event can occur as a result of inappropriate handling, prescribing or administration of a vaccine. It is very important to identify and correct these errors, as they are preventable.

Adverse event	Cause	Prevention
Non-sterile injections		
Abscess	Contact of needle with unsterile surface e.g. finger, swab, table, etc. or use of contaminated vaccine or diluent or administering vaccine over clothes or without cleaning evidently dirty skin surface.	Do not touch needle with finger during vaccination or clean needle using swab before vaccination or use needle which has touched any unsterile surface.
Toxic shock syndrome	Use of reconstituted vaccines beyond the stipulated 4 hours or reuse of reconstituted vaccines in subsequent sessions or reuse of reconstitution needles and syringes	Discard all reconstituted vaccines after four hours. Do NOT use reconstituted vaccines in subsequent sessions even if maintained in cold chain. Always use fresh needle and syringe for reconstitution of each vaccine vial.
Blood-borne infections (Hep B, HIV, Hep C, etc.)	Reuse of disposable syringes and needles	Dispose off used needles and syringes as per guidelines to prevent reuse.
Incorrect site/route of injection		
Sciatic nerve damage, foot drop	Injection in gluteal region	Do not vaccinate in gluteal region.
Local reaction, abscess	BCG or T-series vaccines given sub-cutaneously	Ensure correct route of vaccination.
Incorrect vaccine storage or transportation		
Sterile abscess	Administration of frozen and thawed freeze-sensitive vaccine	Ensure freeze sensitive vaccines are not frozen. Avoid use of freeze-sensitive vaccines which have floccules.
Reconstitution error/incorrect vaccine preparation		
Reactions due to another drug used in place of diluent/vaccine	Use of another drug in place of diluent/vaccine	Before vaccination or reconstitution, read label of vaccine vial or diluent ampoules. Write vaccine and diluent batch details in tally sheet. Ensure no drug other than vaccines and diluents are stored in ILRs / DFs.

Annexure 3: Impact of activities conducted in silent districts by zonal consultant in southern India

Silent district (state)	Month of intervention	Outcome (no. of cases reported following intervention)
Idukki, Kerala	Oct'18	11 AEFI cases reported in 2019
Wayanad, Kerala	Oct'18	14 AEFI cases reported in 2019
Chamrajnagar, Karnataka	Feb'19	4 cases in 2019, 10 cases in 2020
West Godavari, Andhra Pradesh	Feb'19	3 cases reported in 2019
Kurnool, Andhra Pradesh	Feb'19	3 cases reported in 2019
Thiruvananthapuram, Kerala	Mar'19	10 cases reported in 2019
Guntur, Andhra Pradesh	May'19	1 case reported in 2019
Karur, Krishnagiri, Nilgiris, Tirupur of Tamil Nadu	May'19	7 cases reported in 2019-20
Kollam, Karnataka	Aug'19	13 cases reported in 2019
Tumkuru, Karnataka	Aug'19	6 cases reported in 2019
Coimbatore, Tamil Nadu	Sept'19	2 cases reported in 2019
Raichur, Karnataka	Nov'19	1 case reported in 2019

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Ministry of Health & Family Welfare

IMMUNIZATION DIVISION
MINISTRY OF HEALTH & FAMILY WELFARE
GOVERNMENT OF INDIA