UNIT-6

Adverse events following immunization

Learning objectives

- *Define AEFI and describe the types of AEFIs. List the responsibilities of MOs and other health service providers in managing AEFIs.*
- *Recognise and treat cases of anaphylaxis.*

Key Contents

Adverse events following immunization

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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, abnormal laboratory finding, symptom or disease.

Reported adverse events can either be true adverse events, i.e. actually a result of the vaccine or immunization process, or coincidental events that are not due to the vaccine or immunization process, but are temporally associated with immunization.

In 2015, revised classification relevant to cause-specific categorization of AEFIs has been introduced (Table 6.1).

Table 6.1. Cause-specific categorization of AEFIs

	Cause-specific type of AEFI	Definition
1	Vaccine product-related reaction	An AEFI that is caused or precipitated by a vaccine due to one or more of the inherent properties of the vaccine product
2	Vaccine quality defect-related reaction (Both 1 & 2 were earlier categorised in Vaccine Reaction)	An AEFI that is caused or precipitated by a vaccine that is due to one or more quality defects of the vaccine product, including its administration device as provided by the manufacturer
3	Immunization error-related reaction (formerly “programme error”)	An AEFI that is caused by inappropriate vaccine handling, prescribing or administration and thus by its nature is preventable
4	Immunization anxiety-related reaction (formerly “injection reaction”)	An AEFI arising from anxiety about the immunization
5	Coincidental event	An AEFI that is caused by something other than the vaccine product, immunization error or immunization anxiety

Vaccine reactions

There are two types of possible vaccine reactions. **First** - a vaccine product-related reaction; this is a reaction (an individual's response) to the inherent properties of the vaccine, even when the vaccine has been prepared, handled and administered correctly. **Second** - vaccine quality defect-related reaction; this is a defect in a vaccine that occurred during the manufacturing process. Due to introduction of improved good manufacturing practices (GMP), such defects are now extremely rare.

Vaccine reactions may be classified into common, minor reactions; severe reactions; or serious reactions. Most vaccine reactions are minor and settle on their own. More severe and serious reactions are very rare and in general do not result in long-term problems.

Common, minor vaccine reactions

A vaccine induces immunity by causing the recipient's immune system to react to the vaccine. Therefore, local reaction, fever and systemic symptoms can result as part of the immune response. In addition, some of the vaccine's components (e.g. aluminium adjuvant, stabilizers or preservatives) can lead to reactions. The proportion of reaction occurrences likely to be observed with the UIP vaccines are listed in Table 6.2.

Table 6.2. Common, minor vaccine reactions and treatment

Vaccine	Local adverse events (pain, swelling, redness)	Fever (> 38°C)	Irritability, malaise and systemic symptoms
BCG	90-95%	-	-
OPV	None	Less than 1%	Less than 1%
Hepatitis B	Adults: up to 15% Children: up to 5%	1-6%	-
Hib	5-15%	2-10%	-
Pertussis (DwPT)	up to 50%	up to 50%	up to 55%
Tetanus	~ 10%	~ 10%	~ 25%
Measles/MR/MMR	~10%	5-15%	5% (Rash)
JE live-attenuated	<1%	-	-

Local reactions include pain, swelling and/or redness at the injection site and can be expected in about 10% of vaccinees, except for those injected with DwPT (whole cell DPT), or tetanus 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.

Systemic reactions include fever and occur in about 10% or less of vaccinees, except for DwPT where the reactions are about half. Other common systemic reactions such as irritability, malaise, "off-colour" and loss of appetite can also occur after DwPT. For Live Attenuated Vaccines (LAV) such as measles/MR and OPV, the systemic reactions arise from vaccine virus infection. Measles/MR vaccine causes fever, rash and/or conjunctivitis, and affects 5–15% of vaccinees. It is very mild compared to "wild" measles.

Paracetamol, at a dose of up to 15mg/kg every 6–8 hours with a maximum of four doses in 24 hours is useful for the common minor reactions. It eases pain and reduces fever. However, it is important to advise not to overuse paracetamol as overdosing may harm the vaccinee. 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.

Serious and severe vaccine reactions

An AEFI will be considered serious if it results in death, requires hospitalization, results in persistent or significant disability/incapacity or a cluster (two or more cases) of AEFIs occur in a geographical area.

AEFIs that are not minor but do not result in death, hospitalization or disability are categorized as severe. Examples include non-hospitalized cases of seizures, hypotonic hyporesponsive episodes (HHEs), persistent screaming, anaphylaxis, severe local reaction, injection site abscesses, intussusception, etc. Table 6.3 details these rare vaccine reactions. Most of the rare and more serious vaccine reactions such as seizures, thrombocytopenia, HHEs and persistent inconsolable screaming do not lead to long-term problems. Anaphylaxis, while potentially fatal, is treatable without leaving any long-term effects. Although encephalopathy is included as a rare reaction to measles or DPT vaccine, it is not certain that these vaccines in fact cause encephalopathy.

Table 6.3. Rare vaccine reactions, onset interval and rates

Vaccine	Reaction	Onset interval	Rate/doses
BCG	Suppurative lymphadenitis BCG osteitis Disseminated BCG infection	2-6 months 1-12 months 1-12 months	1 to 10 /10,000 1 to 700/1,000,000 0.19 to 1.56/1,000,000
Oral poliomyelitis	VAPP†	4-30 days	2 to 4 /1,000,000†
Hepatitis B	Anaphylaxis	0-1 hour	1.1/1,000,000
Hib	None		

Pertussis (DwPT)/ Pentavalent vaccine	Persistent (>3 hours) inconsolable screaming	0-24 hours	<1 /100
	Seizures††	0-3 days	<1 /100
	Hypotonic, hypo responsive episode(HHE)	0-48 hours	1 to 2 /1000
	Anaphylaxis	0-1 hour	20/1,000,000
	Encephalopathy§	0-2 days	0 to 1 /1,000,000
Tetanus toxoid	Brachial neuritis	2-28 days	5 to 10 /1,000,000
	Anaphylaxis	0-1 hour	1 to 6 /1,000,000
Measles/MMR/ MR*	Febrile seizures	6-12 days	3 /1000
	Thrombocytopenia	15-35 days	3 /10,000
	Anaphylaxis	0-1 hour	~1 /1,000,000
	Encephalopathy §	6-12 days	< 1 /1,000,000
Rotavirus	Intussusception	3-14 days	1 to 2/100,000

Notes:

† VAPP Risk is higher following the first dose (1 in 750 000 compared to 1 in 5.1 million for subsequent doses), and for adults and immunocompromised.

†† Seizures are mostly febrile and the risk depends on age, with much lower risk in infants under the age of four months.

* Reactions (except anaphylaxis) do not occur if already immune (~90% of those receiving a second dose are immune): children over six years unlikely to have febrile seizures.

§ Although encephalopathy is included as a rare possible reaction to measles or DPT vaccines, it is not certain that these vaccines in fact cause encephalopathy. Hence, further scientific evaluation is necessary.

Though vaccines are very rarely contraindicated, it is important to check for contraindications to avoid serious reactions. For example, vaccines are contraindicated if there is a possibility of serious allergy to a vaccine or its components. Live vaccines should not be given to immune deficient children.

Advice on managing the common reactions should be given to parents, in addition to instructions to return if there are more serious symptoms. Such action will help to reassure parents about immunization and prepare them for common reactions.

It is recommended that facilities be available at all clinic settings to provide initial emergency care. All immunization providers need to have these skills and competence to manage anaphylaxis. Availability of adrenaline (within expiry date) and other basic items in the emergency tray (AEFI kit) is vital.

Administration of one dose of Intra Muscular (IM) adrenaline by ANM as first line management in the field - See annex on Page 294.

Immunization error-related reactions (formerly "programme error")

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 (Table 6.4); otherwise they may derail the benefits of the immunization programme.

An immunization error-related reaction may lead to a cluster of events associated with immunization. These clusters are usually associated with a particular provider, health facility, or even a single vial of vaccine that has been inappropriately prepared or contaminated. Immunization error-related reactions can also affect many vials. For example, freezing vaccine during transport may lead to an increase in local reactions.

Table 6.4. Immunization error-related reactions

Immunization error	Examples	Related reaction
Error in vaccine (and diluent) handling	Exposure to excess heat or cold (using hard frozen ice packs in RI) as a result of inappropriate transport, storage or handling of the vaccine (and its diluent) where applicable. 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. Failure to vaccinate as a result of loss of potency or non-viability of an attenuated product.
Error in vaccine prescribing or non-adherence to recommen-dations for use	Failure to adhere to a contraindication. Failure to adhere to vaccine indications or prescription (dose or schedule).	Anaphylaxis, disseminated infection with an attenuated live vaccine. Systemic and/or local reactions, neurological, muscular, vascular or bony injury due to incorrect injection site, equipment or technique.
Error in adminis-tration	Use of an incorrect diluent or injection of a product other than the intended vaccine. Incorrect sterile technique or inappropriate procedure with a multidose vial.	Failure to vaccinate due to incorrect diluent. Reaction due to the inherent properties of whatever was administered other than the intended vaccine or diluent. Infection at the site of injection/ beyond the site of injection.

With the introduction of AD syringes, infections due to non-sterile injections have reduced significantly. Such an infection could manifest as a local reaction (e.g. suppuration, abscess), systemic effect (e.g. sepsis or toxic shock syndrome), or blood borne-virus infection (e.g. HIV, Hep B or Hep C).

Use of reconstituted vaccine beyond the recommended period can lead to contamination of the vaccine (usually with bacterium *Staphylococcus aureus*). Within a few hours after administration, there may be local tenderness and tissue infiltration, vomiting, diarrhoea, cyanosis, high temperature leading to dehydration and death if not managed in time.

Inadequate shaking of the vaccine before use, superficial injection and use of frozen vaccine increases the risk of sterile abscesses which are rare (~1 per 100 000 doses) and local reactions from aluminium containing vaccines, especially DPT. Contamination of vaccine or injection equipment can also lead to a bacterial abscess. For BCG vaccine, injection abscess can arise from improper injection (subcutaneous rather than intradermal injection).

Immunization anxiety-related reactions (formerly “injection reactions”)

Immunization anxiety-related reactions are common in children over 5 years of age, resulting from fear or pain of injection rather than the vaccine. Vaccinated children or adults can react in anticipation to, and as a result of, an injection of any kind. This reaction is unrelated to the content of the vaccine.

These are common in mass vaccination campaigns. Examples include fainting, light-headedness, and dizziness, tingling around the mouth and in the hands. Younger children may react with vomiting, breath-holding, which in some cases can lead to a brief period of unconsciousness and convulsions.

Minimize overcrowding by proper planning of the immunization sessions to reduce waiting time. Prepare vaccine out of recipient’s view and ensure privacy during the procedure to prevent anxiety.

Coincidental events

Coincidental events have only a temporal association, i.e. event happening after immunization, and are not causally related.

Vaccines are normally scheduled early in life when infections and other illnesses are common, including manifestations of an underlying congenital or neurological condition. It is, therefore, possible to encounter many events, including deaths, to be falsely attributed to vaccine through chance association.

A coincidental event is more likely if the same or similar events also affected others in the same age group around the same time but who did not receive the suspect vaccine(s). There may also be evidence showing that the event is not related to immunization.

Immediate investigation is critical as a response to the community's concern about vaccine safety and to maintain public confidence in immunization.

Ensure appropriate follow-up communication with the affected group or community to avoid misunderstanding or negative rumours.

Responsibilities of health service providers in preventing, managing and reporting AEFIs

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 referral of any suspected cases
- Assist the team investigating the event
- Support in building community confidence.

Sub Centre level

ANM

- Follow best immunization practices. Prior to starting vaccination at the RI site, the ANM must note down (in vaccinator's logistics diary) the following particulars. This will help mitigate AEFIs at session site level:
    - 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 OVP)
    - In case of reconstituted vaccines, date and time of opening on the label.

- Ensure that vaccine vial septum has not been submerged in water or contaminated in any way.
- Provide a list of children vaccinated during the session to the AWW/ASHA and request them to be alert, follow up and report AEFIs (if any) to her and the concerned MO.
- Ensure reasons for dropouts are entered in the immunization card counterfoils.
- Treat minor/non-serious AEFIs (mild symptoms like fever, pain,etc.) symptomatically.
- For all other cases (serious/severe) provide immediate first aid and refer AEFI to MO(PHC) or to appropriate health facility for prompt treatment and report. Inform the MO(PHC) at the health centre immediately by the fastest means possible.
- Share details of all AEFIs (serious/severe and minor) with the MOIC in the weekly block level meeting. Ensure details of all serious/severe and minor cases are entered in the AEFI case register maintained at the block PHC (see Annexure 1 for suggested format for AEFI Case Register).
- Assist in investigation of AEFIs and take corrective action in response to the guidance from the MO (PHC).

Health supervisors (HSs)

- Supervise and provide hands-on training to the ANMs/vaccinators in the field. This includes provision of information on referral transport and concerned officials in case of crisis.
- Monitor the community for adverse events during supervisory visits to immunization sites or SCs. Also monitor and ensure follow-up of beneficiaries by HWs. Ensure reasons for dropouts are entered in the counterfoils.
- Encourage the HWs to report AEFIs. Serious/severe AEFIs should be notified immediately by the fastest means possible.
- Analyze the reported AEFIs in the SC monthly reports and keep track of HWs who have not reported any AEFI over a period of time.
- Assist the investigation team in conducting the investigation.

Block PHC/CHC/corporation/ward/urban health post

MO In-Charge

Detection of AEFIs

- Train staff in detecting, managing and reporting of AEFIs and differentiating between minor and serious/severe events. Encourage the staff to report AEFIs.
- During case visits, enquire about any recent outbreak of disease/illness or any death in the community which may or may not have been related to vaccination.

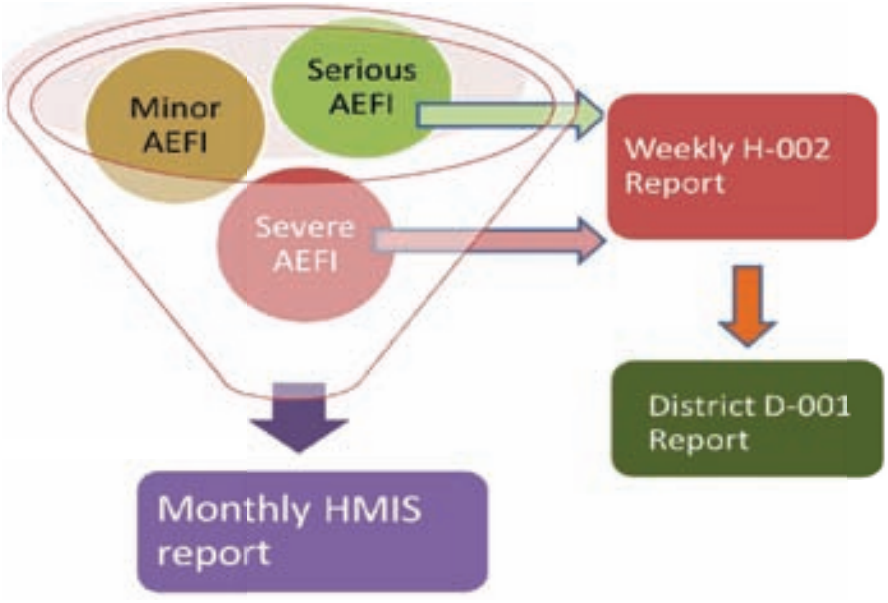
Management of AEFIs

- Ensure clinical case management of AEFIs and referral to the next level if required.
- Ensure availability of emergency drugs and medical equipment to deal with an adverse event. Regularly check the emergency kits (functional status of equipment and expiry of drugs)
- Ensure ANM is familiar with and that the anaphylaxis kit is certified every quarter.

Reporting of AEFIs (Fig. 6.1)

- Ensure timely notification of AEFIs from SC to PHC. Besides immediately informing all serious/severe AEFIs by telephone / in person, ensure that ANMs provide details of all AEFIs in their area on a weekly basis. A weekly NIL report from ANM gets submitted only after an effort has been made to look for these events in the children recently vaccinated.
- Detailed information of all serious, severe and minor AEFIs notified by HWs should be recorded in the block AEFI register.
- Ensure weekly submission of information of the number of serious/severe AEFI cases to the district in the VPD H-002 form. Assessment of Minor AEFI at the BLOCK PHC/PHC level - see page no 168.
- Conduct timely visits when cases are notified. Completely fill up Section A of CRF (Annexure 2) and submit the same to the DIO within 24 hours of case notification.
- Maintain quality (e.g. good clinical history, pre- and post-vaccination health status, community investigation, etc.) during interview and documentation.

Fig. 6.1. Reporting of AEFIs



- Ensure followup and collection of all relevant records including hospital records, laboratory records, other reports for all AEFI hospitalization cases which have been reported and investigated and submit the same to DIO.
- In AEFI death cases where postmortem has been conducted, track and collect postmortem, histo-pathological, toxicology and final cause of death reports and submit them to the DIO.
- Ensure adequate supervision and monitoring in the field.
- Communicate and share the results of investigation with HWs and the community wherever warranted.
- For any query from the media, refer the media person/s to the district authorities and abstain from giving any statements

(Please refer to the AEFI Surveillance and Response Operational Guidelines 2015 for further details and the activities to be conduced at district, state and national level)

The line list of serious, severe and minor AEFI should be maintained at the Block PHC/CHC in the block AEFI register. Number of serious and severe AEFI should be submitted to DIO as part of weekly reporting in the H002 form.

Recognition and treatment of anaphylaxis

Anaphylaxis is a very rare but severe and potentially fatal allergic reaction. Train HWs to distinguish anaphylaxis from fainting (vasovagal syncope), anxiety and breath-holding spells, which are common benign reactions (Table 6.5).

Table 6.5. Distinguish anaphylaxis from fainting (vasovagal reaction)

	Fainting	Anaphylaxis
Onset	Usually at the time or soon after the injection	Usually some delay, between 5 to 30 mins, after injection
Systemic		
Skin	Pale, sweaty, cold and clammy	Red, raised and itchy rash; swollen eyes, face, generalized rash
Respiratory	Normal to deep breaths	Noisy breathing from airways obstruction (wheeze or stridor)
Cardiovascular	Bradycardia, transient hypotension	Tachycardia, hypotension
Gastrointestinal	Nausea, vomiting	Abdominal cramps
Neurological	Transient loss of consciousness, relieved by supine posture	Loss of consciousness, not relieved by supine posture

Before immunization, check for contraindications to immunization by asking about known allergies and previous adverse reactions to vaccines.

Recognition of anaphylaxis

Signs and symptoms of anaphylaxis are given in Table 6.6. In general, the more severe the reaction, the more rapid is the onset. Most life-threatening reactions begin within 10 mins of immunization. **That is why it is advised that the beneficiary be kept under observation for at least 30 mins after the injection.**

Unconsciousness is rarely the sole manifestation of anaphylaxis – it only occurs as a late event in severe cases. A strong central pulse (e.g. carotid) is maintained during a faint, but not in anaphylaxis. Anaphylaxis usually involves multiple body systems. However, symptoms limited to only one body system (e.g. skin itching) can occur, leading to delay in diagnosis. Occasional reports have described reactions where symptoms recur 8 to 12 hours after onset of the original attack and prolonged attacks lasting up to 48 hours.

Table 6.6. Signs and symptoms of anaphylaxis

Clinical progression	Progression of signs and symptoms of anaphylaxis
Mild, early warning signs	Itching of the skin, rash and swelling around injection site. Dizziness, general feeling of warmth. Painless swellings in parts of the body e.g. face or mouth. Flushed, itching skin, nasal congestion, sneezing, tears. Hoarseness, nausea, vomiting Swelling in the throat, difficult breathing, abdominal pain.
Late, life-threatening symptoms	Wheezing, noisy and difficult breathing, collapse, low blood pressure, irregular weak pulse.

Treatment of anaphylaxis

Once the diagnosis is made, consider the patient as being in a potentially fatal condition, regardless of the severity of the current symptoms. Begin treatment immediately; and at the same time, make plans to transfer the patient immediately to the hospital (if not already in a hospital setting).

Role of adrenaline

Adrenaline (epinephrine) stimulates the heart, reverses the spasm in the lung passages and reduces edema and urticaria, thus countering the anaphylaxis. But this very potent agent can cause irregular heartbeat, heart failure, severe hypertension and tissue necrosis if used in inappropriate doses.

Every health facility should have health staff trained in treatment of anaphylaxis and should have rapid access to an emergency kit with adrenaline. They should be familiar with its dosage and administration. **The expiry date of the adrenaline should be written on the outside of the emergency kit and the whole kit should be checked three or four times a year**. Adrenaline that has a brown tinge must be discarded. Adrenaline has a short expiry life, so monitor the expiry date on a regular basis.

Steps in initial management

- If already unconscious, place the patient in the recovery position (pronate) and ensure that the airway is clear.
- Assess heart rate and respiratory rate (if the patient has a strong carotid pulse, he/she is probably not suffering from anaphylaxis).
- If appropriate, begin cardiopulmonary resuscitation (CPR).
- **Give adrenaline 1:1000 (See Table 6.7 for correct dose for age) by deep intramuscular injection into the opposite limb to that in which the vaccine was given.** Subcutaneous administration is acceptable in mild cases. Also, give an additional half dose around the injection site (deep intramuscular injection) to delay antigen absorption.

- If the patient is conscious after the adrenaline is given, place his/her head lower than the feet and keep the patient warm.
- Give Inj. Hydrocortisone IM or slow IV as per dosage chart below (Table 6.8).
- Give oxygen by facemask, if available.
- Call for professional assistance but **never leave the patient alone.** Call an ambulance (or arrange other means of transport, after the first injection of adrenaline, or sooner if there are sufficient people available to help you).
- If there is no improvement in the patient's condition within 10–20 mins of the first injection, repeat the dose of adrenaline up to a maximum of three doses in total. Recovery from anaphylactic shock is usually rapid after adrenaline.
- Record, or get someone to record, vital signs (pulse rate, respiratory rate and blood pressure), as well as time and exact dose of any medication given. **Make sure the medical and treatment details accompany the patient** when s/he is transferred.
- **Mark the immunization card clearly** so that the individual never gets a repeat dose of the offending vaccine. At a suitable moment, explain to parents or relatives the importance of avoiding the vaccine in future.
- Report the occurrence of anaphylaxis to the appropriate officer by phone followed by the reporting form.

Adrenaline dosage: 1:1000 adrenaline (epinephrine) at a dose of **0.01ml/kg up to a maximum of 0.5 ml injected intramuscularly** (or subcutaneously in very mild cases). If the weight of the patient is unknown an approximate guide is given in Table 6.7.

Table 6.7. Injection adrenaline (1:1000 solution) dosage chart IM

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	24G/ 25G	0.05	2
1-6		0.1	4
6-12		0.2	8
12-18		0.3	12
Adults		0.5	20

Table 6.8. Injection hydrocortisone (IM or slow IV): dosage chart

Age	Dosage
Less than 6 months	25 mg
6 months to 6 years	50 mg
6–12 years	100 mg
>12 years	200 mg

AEFI management centres

Each health facility staffed with a MO in the government as well as the private sector should be designated as an AEFI management centre. Each block should prepare a list of such centres dispersed geographically so that in the event of an AEFI, the beneficiary can be quickly managed. The RI microplan of each HW should include the name, address and phone number of the MO of the AEFI management centre. All the MOs of the designated AEFI management centres should be trained in standard AEFI management and reporting procedures. All AEFI management centres should be provided with AEFI treatment kits (Fig.6.2, Table 6.9) and standard AEFI reporting forms. Treatment protocol for anaphylaxis is given in Fig 6.3.

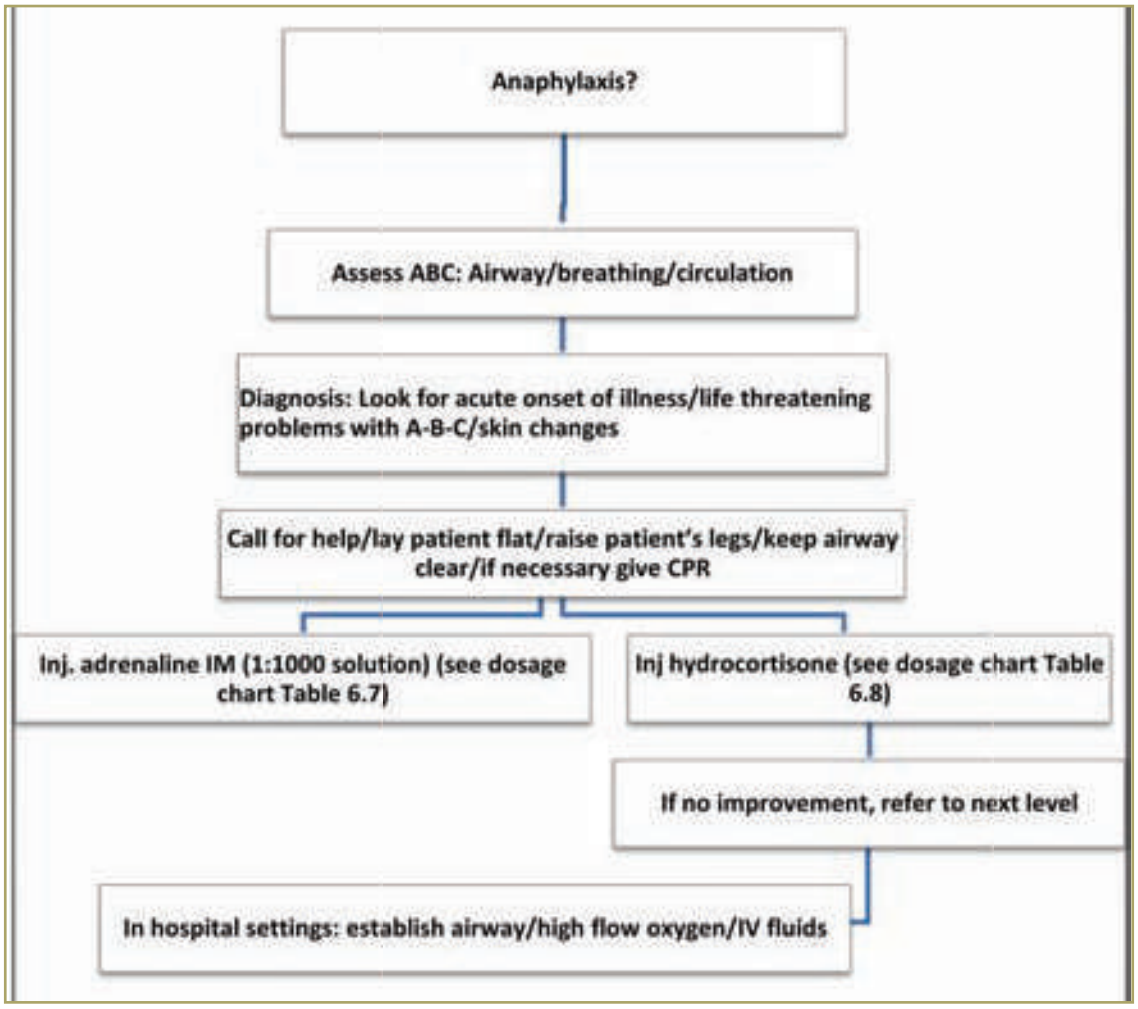
Fig. 6.2.Contents of AEFI kit

Table 6.9.Contents of an AEFI treatment kit

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

IV – intravenous

Fig. 6.3. Treatment protocol for anaphylaxis



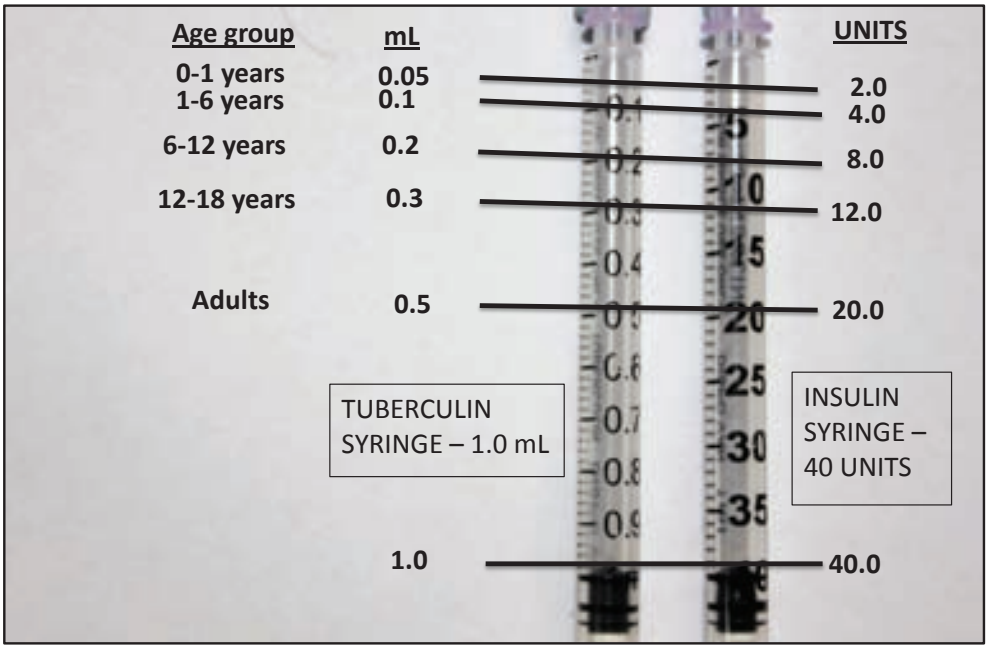
Anaphylaxis kit for ANM

1. Job aid for recognizing anaphylaxis; dose chart for adrenaline as per age
2. 1 ml ampoule of adrenaline (1:1000 aqueous solution) - 3 nos. (adrenaline ampoules may also labeled as epinephrine)
3. Tuberculin syringes (1ml) or insulin syringe (without fixed needle of 40 units)-3 nos.
4. 24G/25G needles (1 inch) - 3 Nos.
5. Swabs - 3 nos.
6. Updated contact information of DIO, Medical Officer(s) of PHC/CHC, referral centre and local ambulance services.
7. Adrenaline administration record slips.

Difference between AEFI kit and Anaphylaxis kit

	AEFI kit	Anaphylaxis kit
Location	**At health facilities with Medical Officer**	**Outreach session**
For use by	**Medical Officer**	**ANM**
Contents		
Equipment for intubation and resuscitation	Yes	No
Ringer lactate, normal saline, 5% dextrose, IV drip set, scalp vein sets(2)	Yes	No
Inj. Hydrocortisone and Tab. Hydrocortisone	Yes	No
Cotton wool	Yes	Yes
Inj. Adrenaline ampoules	Yes	Yes
24G/25G needles 1 inch length	Yes	Yes
Tuberculin syringes (1ml) or Insulin syringes (40 units, without fixed needles)	Yes	Yes

Fig. 6.4



Role of Medical Officer in Anaphylaxis management

Detection of AEFIs

- Encourage staff to insist on caregivers waiting for at least half hour following vaccination
- Train staff in suspecting, detecting and reporting of AEFIs
- Encourage staff to report AEFIs

Management of AEFI

- AEFI management centres in health facilities to be identified in microplans
- Ensure availability of emergency drugs and medical equipment to deal with an adverse event
- Regularly check to emergency tray (Functional status of equipment and expiry of drugs) and AEFI kits
- Provide apporpriate treatment to AEFI cases and refer if needed

Quarterly certification of ANM anaphylaxis kit by Medical Officer

- Medical officer will ensure availability of anaphylaxis kit with all ANMs at session sites/ sub centre during field visits.
- He will examine contents of the anaphylaxis kit at least once a quarter
- He will ensure injection adrenaline and other logistics do not have expiry dates within the next three months of the visit
- If the expiry date of any logistics is within three months of visit, this will be replaced during the next visit of the ANM to the PHC and signed by the Medical Officer in the following format which will be part of the kit

Name of subcenter:		**Name of ANM:**		**Name and contact number of MO**	
Date of Check-ing	**Contents**	**Expiry date of contents**	**Signature of MO**	**Action required (replace am-poule /syringe)**	**Action taken, signature of MO, date**
	1 ml ampoule of adrenaline (1:1000 aqueous solution)-3 Nos.				
	1 ml syringes-3 nos.				
	1 ml ampoule of adrenaline (1:1000 aqueous solution)-3 Nos.				
	1 ml syringes-3 nos.				
	1 ml ampoule of adrenaline (1:1000 aqueous solution)-3 Nos.				
	1 ml syringes-3 nos.				

Annexure 1 – Format for block AEFI register

Week No	Name of sub-centre	Name of vaccinee	Father's name	Age	Date of vaccination	Name of vaccines given	**Batch number of vaccines given**	AEFI noted (symptoms)	**Category (serious/ severe/ minor)**	Case seen by MOIC (Yes/ No)	Entered in case reporting form (Yes/No)

1. Kindly follow the AFP Surveillance Calendar to identify week no.
2. Information on serious and 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 Level and monthly cumulative data to be entered in HMIS report

Annexure 2 – AEFI Case Reporting Form

AEFI CASE REPORTING FORM (CRF)

AEFI reporting ID: IND (AEFI) /__ST_/DIS_/_YR _/_NUM_ (to be allotted by DIO)

Section A (To be submitted by MO within 24 hours of case notification to DIO)

State	**District**
Block/ward	**Village/urban area**

Name of reporting MO (person filling this form):	Today's date:
Posted at: Designation:	Time of preparing this form: a.m./p.m.
Contact phone number: email:	Date case visited and examined/interviewed: __ __/__ __/__ __ __ __
Notified by (name): Date notified to MO: __ __/__ __/__ __ __ __	Designation (please circle): health worker/government doctor/private practitioner/community/media/others (specify) _____ _____

Patient's name																				

Date of birth DD/MM/YYYY	**Age** (in months): _____ months	**Sex**	Male / Female

Mother's name																				
Father's name																				

Complete address of the case with landmarks *(street name, house number, village, block, tehsil, pin no., telephone no.)*

P	**i**	**n**	-							**P**	**h**	**o**	**n**	**e**	-											

Date of vaccination: __ __/__ __/__ __ __ __ Time of vaccination: __ __: __ __a.m./p.m.	Address of session site:
Session: Routine (including SIW)* **Campaign** (SIA)-IPPI/MR/JE/others (specify):_____ Other _____	**Place of vaccination:** govt health facility/outreach/private health facility/others ____

Names of vaccines received (write vaccine & diluent details in separate rows)	Dose no. (zero/first/second/etc. as applicable)	Name of manufacturer	Batch/lot No.	Expiry date	Date of opening of vial	Time of opening the vial (for reconstituted vaccine)	No. of OTHER beneficiaries who received vaccine from the SAME vial in this session

Date of first symptom	D	D	M	M	Y	Y	Y	Y	Time of first symptom	H	H	M	M	a.m.	p.m.
Hospitalization: No/yes – (Date)	D	D	M	M	Y	Y	Y	Y	Time of hospitalization	H	H	M	M	a.m.	p.m.

Name and address of hospital (if hospitalized):

*Special immunization week

Current status (encircle)	Death/still hospitalized/recovered & discharged with sequelae/recovered completely and discharged/left against medical advice (LAMA)/not hospitalized																	
If died, date of death	D	D	M	M	Y	Y	Y	Y	Time of death	H	H	M	M	a.m.		p.m		
Post mortem done? Yes/no/unknown If yes, then write date post mortem done	D	D	M	M	Y	Y	Y	Y	If not done, but planned, write date planned	H	H	M	M	Y	Y	Y	Y	

Describe AEFI (signs and symptoms):

Suspected adverse event(s) (tick at least one):

☐ Severe local reaction ☐ Seizures
- ○ *>3 days*
- ○ *beyond nearest joint*
- ○ *febrile*
- ○ *afebrile*

☐ Abscess ☐ Sepsis ☐ Encephalopathy ☐ Toxic shock syndrome ☐ Thrombocytopenia ☐ Anaphylaxis ☐ Intussusception

☐ Fever≥39 °C (102 °F) ☐ Hypotonic hyporesponsive episode (HHE) ☐ Acute flaccid paralysis ☐ Sudden unexplained death syndrome

☐ Death due to any reason other than above – specify……

☐ Hospitalization due to any reason other than above – specify…… ☐ Disability

☐ Cluster – is this case part of a cluster? Yes/no/unknown

If Yes, no of other cases in the cluster _____ (use separate form for each case in a cluster)

Signature and name of reporting medical officer:

Section B: District immunization office to complete and forward to state and national level within 24 hours of receiving the above information

Date case reporting form received at the district: __ __/__ __/__ __ __ __

Proposed date of preliminary investigation: __ __/__ __/__ __ __ __

Remarks:

DIO/district nodal person *(officer forwarding this report)*

Name …… Date……Designation……Mobile No……

Landline (with STD code)…… Fax No. ……

email id…… Complete office address (with Pin code)……

……

……Signature/seal

To be sent to: State Immunization Officer & Deputy Commissioner (UIP),
Immunization Division of Govt of India, MoHFW,
Nirman Bhawan, New Delhi – 110108.
Fax: 011-23062728 **email**: aefiindia@gmail.com

Date report received at state level – __ __/__ __/__ __ __ __

Remarks:

Section C: National level to complete

Date report received at national level – __ __/__ __/__ __ __ __

Remarks:

Annexure 3 – AEFI case definitions and treatment

Adverse event	Case definition	Treatment	Vaccines
Acute flaccid paralysis (AFP)	• Acute onset of flaccid paralysis within 4 to 30 days of receipt of OPV, or within 4 to 75 days after contact with a vaccine recipient • Neurological deficits remaining 60 days after onset • Death	No specific treatment available; supportive care	Oral polio vaccine (OPV)
Anaphylactic reaction (acute hypersensitivity reaction)	• Exaggerated acute allergic reaction occurring within 2 hours after immunization, characterized by one or more the following: • wheezing and shortness of breath due to bronchospasm • one or more skin manifestations, e.g. hives, facial oedema, or generalized oedema. Less severe allergic reactions do not need to be reported • laryngospasm, laryngeal oedema	Self-limiting; anti-histamines may be helpful	All
Anaphylaxis	• Severe and immediate allergic reaction (within 1 hour) leading to circulatory failure with or without bronchospasm and/or laryngospasm/laryngeal oedema	Adrenaline injection	All
Arthralgia	• Joint pain, usually including the small peripheral joints. Persistent if lasting longer than 10 days; transient if lasting up to 10 days	Self-limiting; analgesics	Rubella; MMR
Brachial neuritis	• Dysfunction of nerves supplying the arm/shoulder without any other involvement of the nervous system • A deep, steady, often severe aching pain in the shoulder and upper arm, followed in days or weeks by weakness and wasting in arm/shoulder muscles • Sensory loss may be present, but is less prominent. May present on the same or the opposite side to the injections and sometimes affects both arms	Symptomatic only; analgesics	Tetanus
Disseminated BCG infections	• Widespread infections occurring within 1 to 12 months after BCG vaccination and confirmed by isolation of mycobacterium bovis BCG strain. Usually in immunocompromised individuals	Should be treated with anti-tuberculous regimens including isoniazid and rifampicin	BCG

Encephalopathy	• Acute onset of major illness characterized by any two of the following three conditions: • Seizures • Severe alteration in level of consciousness lasting for one day or more • Distinct change in behaviour lasting 1 day or more • Needs to occur within 48 hours of DTP vaccine or from 7 to 12 days after measles or MMR vaccine to be related to immunization	No specific treatment available; supportive care	Measles, pertussis
Fever	• The fever can be classified (based on rectal temperature) as: • Mild: 100.4°F to 102°F (38 to 38.9°C), • High: >102°F to 104.7°F (39 to 40.4°C) and • Extreme: 104.8°F or higher (40.5°C or higher). • High/extreme fever should be reported.	Symptomatic; paracetamol	All
Hypotonic hyporesponsive episode (HHE) or shock-collapse	• Event of sudden onset occurring within 48 (usually less than 12 hours) of vaccination and lasting from 1 min to several hours, in children younger than 10 years of age. All of the following must be present: • Limpness (hypotonic) • Reduced responsiveness (hyporesponsive) • Pallor or cyanosis, or failure to observe/ recall	The episode is transient and self-limiting, and does not require specific treatment. It is not a contraindication to further doses of the vaccine	Mainly DTP, rarely others
Injection site abscess	• Fluctuant or draining fluid-filled lesion at the site of injection • If evidence of infection (purulent, inflammatory signs, fever, culture) then consider as bacterial if not consider as sterile abscess	Incise and drain; antibiotics if bacterial	All
Lymphadenitis (includes suppurative lymphadenitis)	• At least one lymph node enlarged to >1.5 cm in size (one adult finger width), or a draining sinus over a lymph node • Almost exclusively caused by BCG and occurring within 2 to 6 months after receipt of BCG vaccine, on the same side as inoculation (mostly axillary)	Heals spontaneously (over months) and best not to treat unless lesion is sticking to the skin. If so, or if already draining, surgical drainage and local instillation of anti-tuberculosis drug. Systemic treatment with anti-tuberculosis drugs is ineffective	BCG

Osteitis/ osteomyelitis	• Inflammation of the bone with isolation of mycobacterium bovis, BCG strain	Should be treated with anti-tuberculosis regimens including isoniazid and rifampicin	BCG
Persistent inconsolable screaming	• Inconsolable continuous crying lasting 3 hours or longer accompanied by high-pitched screaming	Settles within a day or so; analgesics may help	DTP, pertussis
Seizures	• Occurrence of generalized convulsions that are n**ot accompanied by focal neurological signs or symptoms. Febrile seizures if temperature elevated >10**0.4°F (rectal); afebrile seizures if temperature normal	Self-limiting; supportive care; paracetamol and cooling if febrile; rarely anticonvulsants	All, especially pertussis, measles
Sepsis	• Acute onset of severe generalized illness due to bacterial infection and confirmed (if possible) by positive blood culture. Needs to be reported as possible indicator of immunization error	Critical to recognize and treat early. Urgent transfer to hospital for parenteral antibiotics and fluids	All
Severe local reaction	• Redness and/or swelling centered at the site of injection and one or more of the following: • Swelling beyond the nearest joint • Pain, redness, and swelling of more than 3 days duration • Requires hospitalization • Local reactions of lesser intensity occur commonly; these are trivial and do not need to be reported	Settles spontaneously within a few days to a week. Symptomatic treatment with analgesics. Antibiotics are inappropriate	All
Thrombocy-topaenia	• Serum platelet count of less than 50 000/ml leading to bruising and/or bleeding	Usually mild and self-limiting; occasionally, may need steroid or platelets	MMR
Toxic shock syndrome (TSS)	• Abrupt onset of fever, vomiting and watery diarrhoea within a few hours of immunization. Often leading to death within 24 to 48 hours. Needs to be reported as possible indicator of immunization error.	Critical to recognize and treat early. Urgent transfer to hospital for parenteral antibiotics and fluids	All

Note: Brighton Collaboration has developed case definitions for many vaccines reactions that are available at www.brightoncollaboration.org.

For further details refer to the AEFI Surveillance and Response Operational Guidelines 2015.

Assessment of Minor AEFI at the BLOCK PHC/PHC level

(Format to be shared in the first week of every month to DIO)

To be filled by inchrge Block Medical officer

Month **Year:**

Name of the BLOCK PHC/PHC in charge: Phone Number:	Block Name: District:	Date:
Following table need to be filled up after reviewing block AEFI register of respective month. Tabulate the data for minor AEFIs listed in respective month.		

Name of PHC /SubCenter	Distribution of Minor AEFIs line listed in block AEFI register as per their clinical presentation							
	Fever <39 degree	Local Swelling	Localised Pain	Localised Redness	Irritability	Malaise	Systemic symptoms (ex. Fatigue etc)	Any other unusual MINOR events
Total								

Any Aggregation or Clustering (Tick on appropriate)	Possible reason	Action proposed
A) Antigenwise and Batch wise If antigenwise , does it exceed expected reaction rate. Refer Table No. 1 (Yes /No)		
B) Subcenterwise/Vaccinator wise		
C) Dose wise (First, Second, Booster Etc.)		
D) Any other (ex. Unusual minor event)		

Name of Incharge Medical officer- **Signature-**