Guideline for AEFI Surveillance
(Third Edition)

Expanded Programme on Immunization
Directorate General of Health Services
Mohakhali, Dhaka- 1212

স্বাস্থ্য ও পরিবার কল্যাণ মন্ত্রণালয়

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PREFACE

Expanded Programme on Immunization (EPI) is one of the greatest public health success stories of Bangladesh. The goal of immunization programme is to protect the individual and the public from vaccine-preventable diseases. Vaccines used in national immunization programme are procured through UNICEF from WHO pre-qualified list of vaccines. These vaccines are very safe and effective. Nevertheless, no vaccine is perfectly safe and adverse events may occur. Reported adverse events can be either true adverse events- i.e. resulting from the vaccine or immunization process – or coincidental events that are not due to vaccine or immunization process but are temporally associated with immunization.

The major goal of AEFI surveillance is early detection and analysis of adverse events and appropriate and quick response in order to decrease the negative impact on health of individuals and immunization programme. An effective AEFI surveillance will maintain the confidence of the community and health staff in the immunization programme by appropriate and timely responses to their concerns about immunization safety.

This is the third edition of the guideline with updated information based on the WHO global manual on AEFI Surveillance. This document provides a guideline on AEFI detection, reporting, investigation, causality assessment and the new classification of cause-specific AEFI, necessary actions and effective communication with parents, community and media following an AEFI.

I would like to express my thankful gratitude to World Health Organization, Bangladesh for their overall technical support in updating and publishing the third edition of the guideline. I also acknowledge with sincere gratitude to my colleagues at EPI and partners including UNICEF who contributed in the development of the third edition of the guideline. Finally I convey my heartfelt thanks to all who are engaged in providing immunization services to protect our children and mother.

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ABBREVIATIONS AND ACRONYMS

AEFI	Adverse Event Following Immunization
AFP	Acute Flaccid Paralysis
AHI	Assistant Health Inspector
AHO	Assistant Health Officer
BCG	Bacillus Calmette-Guerin
CC	City Corporation
CHO	Chief Health Officer
CIOMS	Council for International Organizations of Medical Sciences
CNS	Central Nervous System
CS	Civil Surgeon
CSF	Cerebro Spinal Fluid
DGDA	Directorate General of Drug Administration
DGHS	Directorate General of Health Services
DMCH&IO	District Maternal Child Health and Immunization Officer
DaPT	Diphtheria- Pertussis (acellular)- Tetanus
DPT	Diphtheria- Pertussis- Tetanus
DwPT	Diphtheria- Pertussis (whole cell)-Tetanus
DSFP	Disease Surveillance Focal Person
DT	Diphtheria-Tetanus
EPI	Expanded Programme on Immunization
FPI	Family Planning Inspector
FW	Field Worker
FWA	Family Welfare Assistant
GMP	Good Manufacturing Practices
HA	Health Assistant
HHE	Hypotonic Hypo Responsive Episode
HI	Health Inspector
HIV	Human Immune- Deficiency Virus
HO	Health Officer
HPV	Human Papilloma Virus
HQ	Head Quarter
HSO	Hospital Surveillance Officer

HSV	Herpes Simplex Virus
ILR	Ice-Lined Refrigerator
IMR	Infant Mortality Rate
LSO	Local Surveillance Officer
MMO	Municipal Medical Officer
MMR	Measles-Mumps-Rubella Vaccine
MO	Medical Officer
MO-CS	Medical Officer- Civil Surgeon's Office
MO-DC	Medical Officer Disease Control
MR	Measles-Rubella Vaccine
MT-EPI	Medical Technologist-EPI
NCL	National Control Laboratory
NGO	Non Government Organization
NRA	National Regularity Authority
OPD	Out Patient Department
OPV	Oral Polio Vaccine
PCR	Polymerase Chain Reaction
PCV	Pneumococcal Conjiugate Vaccine
PPSV	Pneumococcal Polysaccharide Vaccine
PVV	Pentavalent (DTP-HepB-Hib) Vaccine
SIDS	Sudden Infant Death Syndrome
SMO	Surveillance Medical Officer
TSS	Toxic Shock Syndrome
TT	Tetanus Toxoid
UHC	Upazila Health Complex
UH&FPO	Upazila Health and Family Planning Officer
UNICEF	United Nations Children's Fund
USC	Union Sub Centre
VAPP	Vaccine Associated Paralytic Poliomyelitis
VPD	Vaccine-preventable Disease
VVM	Vaccine Vial Monitor
WHO	World Health Organization
ZMO	Zonal Medical Officer

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GLOSSARY

Adverse event following immunization (AEFI)	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.
Causal association	A cause-and-effect relationship between a causative (risk) factor and an outcome. Causally associated events are also temporally associated (i.e. they occur after vaccine administration), but events which are temporally associated may not necessarily be causally associated.
Causality assessment	In the context of AEFI surveillance, causality assessment is a systematic review of data about AEFI case(s) in order to determine the likelihood of a causal association between the event and the vaccine(s) received.
Cluster	Two or more cases of the same or similar events related in time, geography (place), and/or vaccine administered. AEFI clusters are usually associated with a particular supplier/ provider, health facility, and/or a vial of vaccine or a batch of vaccines.
Coincidental events	An AEFI that is caused by something other than the vaccine product, immunization error or immunization anxiety.
Immunization safety	The process of ensuring the safety of all aspects of immunization, including vaccine quality, adverse events surveillance, vaccine storage and handling, vaccine administration, disposal of sharps and management of waste.
Immunization safety surveillance	A system for ensuring immunization safety through detecting, reporting, investigating and responding to AEFI.
Non-serious AEFI	An event that is not "serious" and does not pose a potential risk to the health of the recipient. Non-serious AEFI should also be carefully monitored because they may signal a potentially larger problem with the vaccine or immunization, or may have an impact on the acceptability of immunization in general.
Serious AEFI	An event that results in death, is life-threatening, requires in-patient hospitalization or prolongation of existing hospitalization, results in persistent or significant disability/incapacity, or is a congenital anomaly/birth defect. Any medical event that requires intervention to prevent one of the outcomes above may also be considered as serious.

Signal (safety signal)	Information (from one or multiple sources) which suggests a new and potentially causal association, or a new aspect of a known association, between an intervention and an adverse event or set of related adverse events, that is judged to be of sufficient likelihood to justify verificatory action.
Surveillance	The continuing, systematic collection of data that are analyzed and disseminated to enable decision-making and action to protect the health of populations.
Trigger event	A medical incident following immunization that stimulates a response (usually a case investigation).
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, whether the active component or one of the other components of the vaccine (e.g. adjuvant, preservative or stabilizer).
Vaccine quality defect-related 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.
Vaccine reaction	An event caused or precipitated by the active component or one of the other components of the vaccine. It may also relate to a vaccine quality defect.

1. Introduction

Immunization is one of the most effective public health interventions to protect the individual and the public from vaccine preventable diseases (VPDs) and has saved millions of lives. Modern vaccines are safe and they effectively protect individuals and public. However, vaccines as other medicinal products are not free from occasional adverse reactions.

Adverse Event Following Immunization (AEFI) range from mild to rare serious events. Vaccines rarely cause serious adverse reactions, and common reactions are minor and self-limited. In majority of serious cases these are merely coincidental and have no relationship with vaccines. In others, they are caused by an error in transportation, storage, preparation and administration of vaccine. In most AEFI, there is no causal relationship between the vaccine and the adverse event.

Irrespective of the cause, when AEFI occur, people become suspicious of vaccines and even refuse further immunization for their children, making them susceptible to VPDs which are more disabling and life-threatening. To increase immunization acceptance and improve the quality of services surveillance of AEFI must become an integral part of national immunization programme.

EPI is one of the greatest public health success stories of Bangladesh. Fully vaccination coverage increased from 2% in 1985 to 82 % in 2013, and EPI has prevented an estimated 2 million deaths from 1987-2000, and continues to prevent approximately 200,000 deaths each year. As vaccine use increases VPDs become less visible, therefore more public attention will be given to AEFI and reports on adverse events following immunization (AEFI) also increases which may have a negative impact on the national immunization programme. An effective AEFI surveillance system, therefore, helps to preserve public confidence in immunization programme.

The purpose of this field guide is to help managers and public health field staff in AEFI surveillance activities. It provides information on the types of AEFI, detection, reporting investigation and causality assessment of AEFI, corrective actions to be taken to prevent further occurrence of programme errors and how to monitor and evaluate an AEFI surveillance system. It also describes the communication strategy on immunization safety for the public and media and role and responsibilities of each category of health staff involve in the EPI service delivery.

2. Adverse Event Following Immunization (AEFI)

What is an AEFI?

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

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

Types of AEFI

In 2012, the Council for International Organizations of Medical Sciences (CIOMS) and WHO revised the existing classification relevant to cause-specific categorization of AEFI and a new classification has been introduced.

AEFI is classified into 5 types, depending on the suspected cause of the reaction. These are described and defined in Table-1.

Table 1. Classification of Adverse Event Following Immunization

Types 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**	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**	An AEFI that is caused by inappropriate vaccine handling, prescribing or administration.
4. **Immunization anxiety - related 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.

2.1. Vaccine reactions

Based specifically on (i) cause and the (ii) seriousness and frequency, vaccine reactions may be grouped into two broad categories:

(i) Cause specific vaccine reactions:
- (a) vaccine product-related reaction and
- (b) vaccine quality defect-related reactions

(ii) Vaccine reactions by seriousness and frequency:
- (a) common- minor reactions
- (b) rare-serious reactions

2.1.1 Cause specific vaccine reactions

Vaccine product-related reaction is a reaction in an individual's response to the inherent properties of the vaccine, even when the vaccine has been prepared, handled and administered correctly. These are caused by immune response of recipient to vaccine. Some of vaccine components can also lead to reactions as well (e.g. aluminium adjuvants, stabilizers and preservatives)

Vaccine quality defect-related reaction is the defect in a vaccine that occurred during manufacturing process. Such a defect may have an impact on an individual's response and thus increase the risk of adverse vaccine reactions. Insufficient inactivation of wild type vaccine agent (e.g Wild polio virus) during the manufacturing process or contamination introduced during manufacturing process could cause the vaccine quality defect-related reactions. In early years of immunization programmes, a few major incidences of vaccine quality defect- related reactions were reported. However, since the introduction of Good Manufacturing Practices (GMP) manufacturing defects are now very rare. Since, vaccine manufacturers have being following GMP, and national regulatory authorities (NRA) have been strengthened, potential risk of such quality defects are now very low and extremely rare.

2.1.2 Vaccine reactions by seriousness and frequency

Vaccine reactions can be classified into **common, minor reactions and rare, more serious reactions.** Most vaccine reactions are minor and subside on their own. Serious reactions are very rare and, in general, do not result in death or long-term disability.

Table 2. Frequency of Occurrence of Reported Adverse Reactions

Frequency category	Frequency in rate	Frequency in %
Very Common	≥ 1/10	≥ 10%
Common (Frequent)	≥ 1/100 and < 1/10	≥ 1% and < 10%
Uncommon (Infrequent)	≥ 1/1,000 and < 1/100	≥ 0.1% and < 1%
Rare	≥ 1/10,000 and <1/1,000	≥ 0.01% and < 0.1%
Very rare	≥ 1/10,000	≥ 0.01%

2.1.2.1 Common, minor reactions

These are caused by immune system response of recipient to vaccine. Some of vaccine's components (e.g. adjuvants, stabilizers and preservatives) can lead to reactions as well. The proportion of reaction occurrences likely to be observed with the most commonly used vaccines are listed in Annex-1.

The occurrence of local reactions such as pain, swelling and/or redness at the injection site varies by the type of antigen. For example, whole cell DPT has reported these local reactions very commonly (>10%), whereas for a cellular DPT it is only a common reaction with a frequency of 1-10%. 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. Keloid (thickened scar tissue) from the BCG lesion is more common among Asian and African populations.

The occurrence of systemic reactions also varies by the type of antigen. Fever is a very common (>10%) systemic reaction reported for most antigens. Other common systemic reactions (e.g. irritability, malaise, loss of appetite) can also occur after many antigens and DwPT has more reports of these systemic reactions than DaPT. For live attenuated vaccines such as measles/MR/ MMR and OPV, the systemic reactions arise from vaccine virus infection. Measles vaccine causes fever, rash and/or conjunctivitis, but it is very mild compared to "wild" measles. However, for severely immunocompromised individuals, it can be severe, even fatal. Vaccine reactions for rubella vaccine (joint pains and swollen lymph nodes) are uncommon and affect less than 1% of children. Rubella vaccine causes symptoms very common in adults, with 15% suffering from joint pains. Systemic reactions from OPV are uncommon and affect less than 1% of vaccinees with diarrhoea, headache and/or muscle pain.

2.1.2.2 Rare, serious vaccine reactions

"Serious" and "severe" are often used as interchangeable terms but they are different. An AEFI will be considered "serious" if it results in death, is life-threatening, requires in-patient hospitalization or prolongation of existing hospitalization, results in persistent or significant disability/incapacity, is a congenital anomaly/birth defect, or requires intervention to prevent permanent impairment or damage. "Severe" is used to describe the intensity of a specific event (as in mild, moderate or severe). The event itself, however, may be of relatively minor medical significance. For example, fever is a common and relatively minor medical event but, according to its severity, it may be graded as mild fever or moderate fever. Anaphylaxis, on the other hand, is always a serious event and life-threatening.

Serious vaccine reactions may occur in rare cases. Most of these do not lead to long-term effects (e.g. seizures, thrombocytopenia, hypotonic hypo responsive episodes). 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.

However, there are few reactions with long-term consequences (e.g. VAPP, BCG osteomyelitis etc.) Case definition and treatment of the serious vaccine reactions are in Annex- 2.

Serious AEFI

An AEFI will be considered serious, if it results in death, is life-threatening, requires in-patient hospitalization or prolongation of existing hospitalization, results in persistent or significant disability/incapacity, or is a congenital anomaly/birth defect.

Any medical event that requires intervention to prevent one of the outcomes above may also be considered as serious.

Non-serious AEFI

An event that is not "serious" and does not pose a potential risk to the health of the recipient. Non-serious AEFI should also be carefully monitored because they may signal a potentially larger problem with the vaccine or immunization, or may have an impact on the acceptability of immunization in general.

Signal (safety signal)

Information (from one or multiple sources) which suggests a new and potentially causal association, or a new aspect of a known association, between an intervention and an adverse event or set of related adverse events, that is judged to be of sufficient likelihood to justify verificatory action.

2.1.3 Prevention and treatment of vaccine reactions

Vaccines are very rarely contraindicated. However, 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.

Advice on managing the common, minor reactions should be given to parents, in addition to instructions to seek proper medical care if there are more serious symptoms. Early medical care by a qualified clinician will minimize any unwanted outcome and ensure early recovery and may also save lives. Such action will help to reassure parents about immunization and prepare them for common and rare serious reactions.

Table 3. Management of Common Minor Reactions

	Local reaction (pain, swelling, redness)	Fever	Irritability, malaise and non-specific symptoms
Management	- Cold cloth at injection site - Paracetamol*	- Give extra fluids - Wear light cool clothing - Tepid sponge or bath - Paracetamol*	Symptomatic

* Paracetamol dose: up to 15 mg/kg/dose every 6 -8 hours, maximum of 4 doses in 24 hours

2.2 Immunization error-related reactions

Immunization error-related reactions are preventable. These occur as a result of inappropriate handling, prescribing and administration of vaccines. It is extremely important that these AEFIs are reported and addressed for early correction. Table-4 provides a list of some immunization errors and types of AEFI.

An immunization error-related reaction may lead to a cluster of events associated with immunization. These clusters are usually associated with a particular provider, or 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 4. Immunization Error-related Reactions

Immunization Errors		Related Reactions
Error in vaccine handling	Exposure to excess heat or cold as a result of inappropriate transport, storage or handling of the vaccine (and its diluents where applicable)	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
	Use of a product after the expiry date	Failure to protect as a result of loss of potency
Error in vaccine prescribing or non-adherence to recommendations for use	Failure to adhere to a contraindication	Anaphylaxis, disseminated infection with a live attenuated virus
	Failure to adhere to vaccine indications or prescription (dose or schedule)	Systemic and/or local reactions, neurological, muscular, vascular or bony injury due to incorrect injection site, equipment or technique
Error in administration	Use of an incorrect diluent or injection of a product other than the intended vaccine	Failure to vaccination due to incorrect diluent, reaction due to inherent properties of whatever was administered other than the intended vaccine or diluent
	Incorrect sterile technique or inappropriate procedure with a multidose vial	Infection at/beyond the site of injection

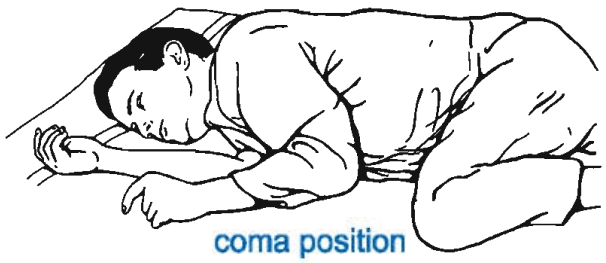
Sterile abscesses are rare (~1 per 100,000 doses) local reactions from aluminium-containing vaccines, especially DPT. Inadequate shaking of the vaccine before use, superficial injection and use of frozen vaccine increase the risk of sterile abscesses and local reactions. Contamination of vaccine or injection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

Ignoring contraindications can lead to serious vaccine reactions and is considered an immunization error.

2.3 Immunization anxiety-related reactions

Individuals and groups can become stressed and may react in anticipation to, and as a result of, any kind of injection. This reaction is unrelated to the content of the vaccine. Fainting (vasovagal syncope or syncope) is relatively common, particularly in children over five years of age and among adolescents.

Fainting does not require any clinical management beyond placing the patient in a recumbent position. Some children who faint may have a syncopal hypoxic convulsion. This is a short-lived generalized tonic-clonic seizure. The management is to keep the child lying down and secure the airway by placing the child in the "coma" position. The seizure will end spontaneously but, if prolonged or focal, further investigations may be required.


coma position

The likelihood of fainting should be anticipated when immunizing older children. It can be reduced by minimizing stress among those awaiting injection, through short waiting time, comfortable room temperatures, preparation of the vaccine outside the recipient's line of vision, and privacy during the procedure.

Hyperventilation as a result of anxiety about the immunization leads to specific symptoms such as light-headedness, dizziness, tingling around the mouth and in the hands. This is also common in mass vaccination campaigns.

Younger children tend to react differently, with vomiting a common symptom of anxiety. Breath-holding may also occur and can result in a brief period of unconsciousness during which breathing resumes. Young children may also scream or run away to avoid the injection.

These reactions are not related to the vaccine, but to the injection process. Some individuals may have needle-phobia, aggravating such reactions. In group immunization, mass hysteria is possible, especially if a vaccinee is seen to faint or have some other reaction such as itching, weakness of limbs and so on. Sometimes these cases may even require hospitalization and can cause public concern. Clear explanations about the immunization and a calm, confident delivery will decrease the level of anxiety about the injections and thus reduce the likelihood of an occurrence.

2.4 Coincidental events

An event may occur coincidentally with immunization and sometimes be falsely attributed to the vaccine. In other words, a chance temporal association (i.e. an event happening after immunization) is falsely considered to be caused by immunization. Such temporal associations are inevitable given the large number of vaccine doses administered, especially in a mass immunization campaign.

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

For instance, incidence of sudden infant death syndrome (SIDS or "cot death") peaks around the age of early childhood immunization. Consequently, many SIDS cases will occur in children who have recently been immunized. However, several well designed studies have shown that the association of SIDS and immunization is coincidental and not causal.

Coincidental adverse events may be predictable. The number of events to be expected depends upon the size of the population and the incidence of disease or death in the community. Knowledge of these background rates of disease and deaths, particularly age-specific disease incidence rates, allows estimation of the expected numbers of coincidental events.

A similar calculation is shown in Table-5 for the number of deaths of infants (aged under one year) in selected countries temporally associated with routine DPT or pentavalent vaccine (PVV) immunization. There will be many coincidental deaths in the day, week and month after immunization which are only temporally related to immunization. The actual number of coincidental deaths depends on the population size, infant mortality rate, number of immunization episodes and immunization coverage.

In general, coincidental events which are clearly unrelated may still require investigation because certain serious events may be blamed on the vaccine by parents, public or media due to the close temporal association with immunization, especially if the child was previously healthy. Such cases need to be investigated in order to allay public fear and maintain credibility. Responding to public concerns about immunization safety is important in maintaining confidence in the immunization programme. Availability of information on background rates of reported coincidental events may be helpful in the investigation of an AEFI.

Table 5. Estimated Number of Coincidental Infant Deaths that could be Temporally Linked to Immunization (e.g. with DPT/PVV) in the Month, Week and Day after Immunization in Selected Countries

Country	IMR	Number of births per year	Estimated number of infants death in			Estimated number of PVV/DPT immunizations in		
			a month	a week	a day	a month	a week	a day
Bangladesh	43	3,478,236	12,464	2,876	410	816,357	188,390	26,839
Bhutan	42	15,000	53	12	2	3233	746	106
Canada	5	388,000	162	37	5	86,864	20,045	2,856
China	13	16,364,000	17,728	4,091	583	3,634,035	838,624	119,475
Indonesia	25	4,331,000	9,023	2,082	297	950,113	219,257	31,237
Iran	21	1,255,000	2,196	507	72	276,445	63,795	9,089
Mexico	13	2,195,000	2,378	549	78	487,455	112,490	16,026
Sudan	57	1,477,000	7,016	1,619	231	313,382	72,319	10,303
United Kingdom	4	761,000	254	59	8	170,540	39,355	5,607

If the same or similar events affect others in the same age group around the same time but those others did not receive the suspect vaccine(s), then a coincidental event is more likely. There may also be evidence showing that the event is not related to immunization.

3. AEFI surveillance

Surveillance of AEFI, i.e. systematic collection of data on events following immunization, provides valuable information to help plan and take necessary actions in order to sustain public confidence and ensure smooth functioning of the immunization programme. Hence, AEFI surveillance becomes an integral part of national immunization programme.

Goals

The goal of AEFI surveillance is to:

1. Ensure the quality and safety of immunization services in the country
2. Ensure the quality and safety of vaccines used for immunization in the country
3. Minimize the negative impact of AEFI on public health

Objectives

The objectives of AEFI surveillance are to:

1. Timely detect and report all AEFI
2. Timely and properly investigation of serious and unexpected/unusual AEFIs
3. Identify unusual high rates of AEFI with specific vaccine lots and brands
4. Promptly address programmatic errors through implementation of corrective measures
5. Ensure that coincidental events are not falsely blamed on immunization
6. Identify events which may indicate a previously unknown and potential vaccine reaction (i.e. a signal)
7. Maintain confidence in the immunization programme by properly responding to concerns

Key elements of an effective AEFI surveillance system include:

1. Rapid notification of the basic information
2. Timely and effective evaluation of information received
3. Timely and effective response/action, ensuring appropriate outcome of response/ action
4. Evaluation of the activities of involving officers and train and re-train when it is justified
5. Defining responsibility and avoid duplication of efforts
6. Effective communication with all relevant stake holders

4. Reporting AEFI

Case detection is the first important step in AEFI surveillance. The primary reporter (i.e. the one who first reports an AEFI) may be a field worker, clinic or hospital staff, a volunteer or any other person who detects the AEFI.

4.1 Which events should be reported?

All AEFI that was notified by the parent or guardian or reported by the health care provider to the health care system needs to be reported (in a standard AEFI reporting form- Annex 3) .Any AEFI that is of concern to parents or health-care workers should be reported. In particular, health workers must report:

- serious AEFI
- signals and events associated with a newly introduced vaccine
- AEFI that may have been caused by an immunization error
- significant events of unexplained cause occurring within 30 days after vaccination
- events causing significant parental or community concern.

It should be mentioned that minor reactions such as pain, mild swelling, mild redness at the injection site and mild fever are common and usually expected, which don't need to be reported as AEFI.

Table 6. List of Examples of Reportable AEFI

AEFI	Time onset following immunization
• Acute flaccid paralysis for OPV recipient • Acute flaccid paralysis for contact of OPV recipient	• 4-30 days following immunization • 4-75 days following immunization
Anaphylaxis (after any vaccine)	Within 48 hours of immunization
Brachial neuritis (after tetanus-containing vaccine)	2-28 days following immunization
Disseminated BCG infection after BCG vaccine	Between 1 and 12 months
Encephalopathy • after measles/MMR vaccine • after DPTvaccine	• 6-12 days following immunization • 0-2 days following immunization
Hypotonic hyporesponsive episode (HHE) after DPT/PVV vaccine	Median time is 3-4 hours after immunization, but ranges from immediate to 48 hours. However, it can occur even after 48 hours
Injection site abscess (bacterial/sterile) after any injectable vaccine	Not specific. However, commonly within first 14 days of immunization
Intussusception (after rotavirus vaccines)	Commonly within 21 days, risk increased after the first 7 days and usually first dose
• Lymphadenitis after BCG vaccine • Osteitis/osteomyelitis after BCG vaccine	Between 1 and 12 months
Persistent (more than 3 hours) inconsolable screaming after DPT/PVV vaccine	Common immediately and up to 48 hours of immunization. However, it can occur even after 48 hours
Sepsis (after any injectable vaccine)	Within 7 days following immunization
Seizures, including febrile seizures • after measles/MMR • after DPT/PVV	• 6-12 days following immunization • 0-2 days following immunization
Severe local reaction (after any injectable vaccine)	Within 7 days following immunization
Thrombocytopaenia (after measles/MMR)	Median time is 12 -25 days after immunization, but the range is 1-83 days
Toxic shock syndrome (TSS) (after any injectable vaccine)	Commonly within 72 hours following immunization
Death Hospitalization Disability Any other severe and unusual events that are attributed to immunization by health workers or the public	No time limit, but in general those within 30 days following any immunization

4.2 AEFI Reporting system

AEFI surveillance will be carried out in both facilities and community. Facility based AEFI surveillance refers to collection of data from designated facilities. Community based AEFI surveillance refers to collection of data from community by the field health staff and other individuals.

When, Whom and How to report:

Information on AEFI are reported from following sources:

- Community: All health care workers in EPI session or during house visits may detect AEFI cases. They need to report the cases within 24 hours using AEFI report form (Annex-3).
- Health Facility: All designated health facilities will report AEFI cases from Indoor and Outdoor (OPD) services. In OPD it is the responsibility of treating Medical Officer (MO) to report AEFI. In high workload setting, MO/OPD may refer the case to EPI Unit for reporting within 24 hours using AEFI report form (Annex-3).
- NGO clinics providing immunization services will report to respective UH&FPO, Municipal Medical Officer (MMO) or Chief Health Officer (CHO). AEFI reporting form should be made available to these clinics.

Disease Surveillance Focal Person (DSFP)

For AEFI, like other VPD surveillance, the Disease Surveillance Focal Persons (DSFP) are Civil Surgeon for district, CHO for City Corporation, UH&FPO for Upazila and MMO for municipality. If MMO post is lying vacant then for upazila municipality respective UH&FPO and for district municipality UH&FPO-Sadar will act as DSFP.

Local Surveillance Officer (LSO)

Like other VPD surveillance the Local Surveillance Medical Officer (LSO) will also assist DSFP in carrying out his/her responsibilities in AEFI reporting and investigation.

Table 7. List of DSFP and LSO

Locations	DSFP	LSO
District	Civil Surgeon	MO-CS
City Corporation	Chief Health Officer	HO/AHO/ZMO
Upazila	UH&FPO	MO-DC
Municipality with Medical Officer	Municipal Medical Officer	MMO
Municipality where MMO post is vacant	Respective UH&FPO (UH&FPO-Sadar for district municipality)	MO-DC of respective UHC

Hospital Surveillance Officer (HSO)

Like other VPD surveillance the Hospital Surveillance Officer (HSO) will also assist the DSFP in carrying out his/her AEFI surveillance responsibilities in the facility/hospitals.

4.2.1 AEFI reporting system for rural areas

Community

Field workers (HA/FWA/NGO field worker) who detect or get information of an AEFI from the community/EPI session should report to their supervisor (AHI / FPI / HI / NGO Supervisor) and send the filled AEFI report form (Annex- 3) to UH&FPO within 24 hours via porter. The supervisor will ensure reporting of the case to UHC.

Health facility

i. UHC

Service providers of UHC (including OPD) detecting AEFI should report to respective HSO within 24 hours using AEFI report form (Annex-3). The HSO will submit these reports to UH&FPO of the concerned Upazila at the end of every epidemiological week.

The UH&FPO will report all AEFIs (from both community and UHC including zero report to Civil Surgeon using AEFI weekly line-listing form (Annex-4). The report should reach to CS office by the following Tuesday. Local Surveillance Officer (LSO) will help UH&FPO in preparing the weekly line list.

ii. Other health facility

Service providers of designated surveillance site (other than UHC) detecting AEFI should report to respective HSO within 24 hours using AEFI report form (Annex-3). The HSO will report to Civil Surgeon of all AEFIs detected in the facility including zero report using AEFI weekly line listing form (Annex-4). The report should reach the CS Office by the following Tuesday. At the same time HSO should give a copy of the line list to respective UH&FPO for information. UH&FPO will not include these reports in his/her weekly line listing form to avoid duplication.

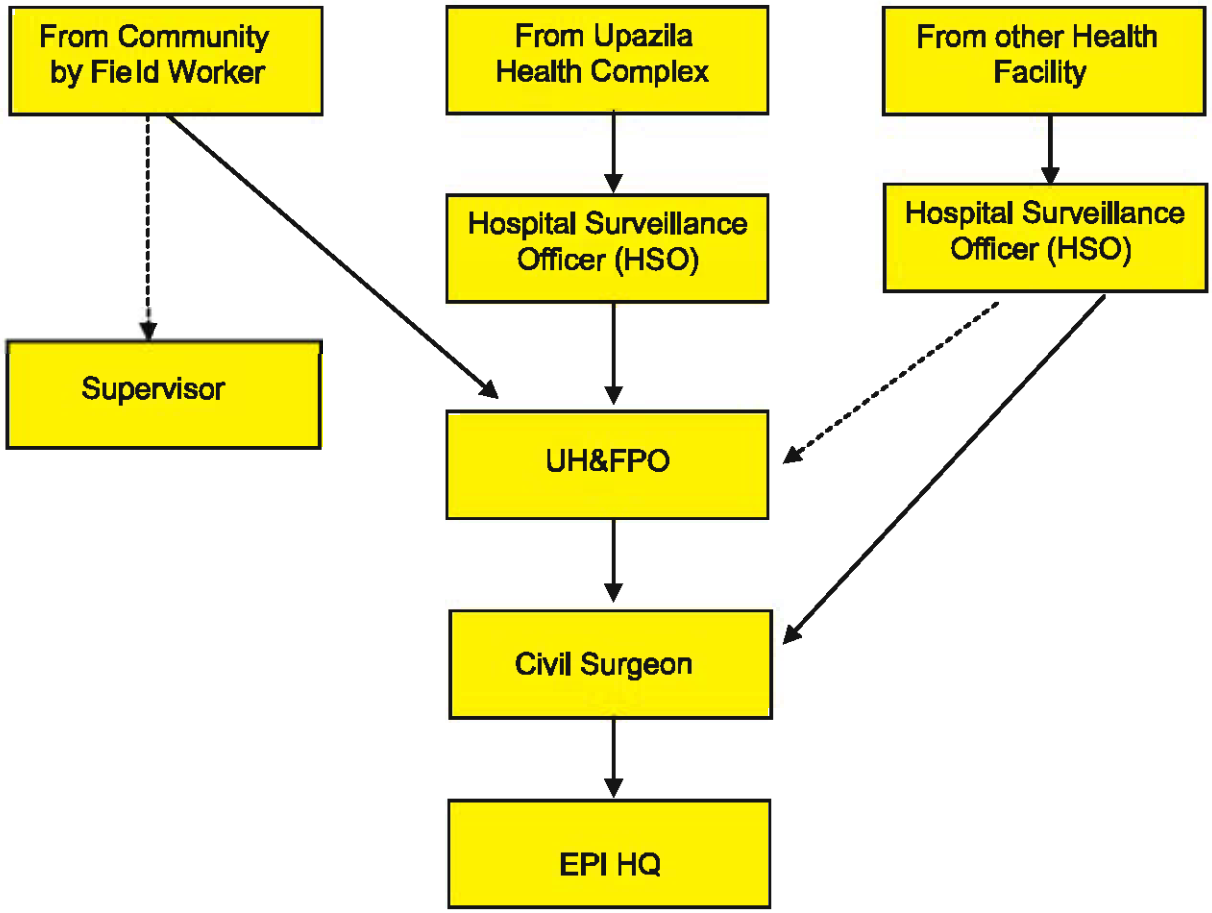
The Civil Surgeon will submit all AEFIs reported in each epidemiological week in the AEFI district compilation form (Annex-5) to EPI HQ. Local Surveillance Officer (LSO) will help Civil Surgeon in compiling the reports. The report should reach EPI HQ by the following Tuesday.

Immediate reporting

In case of death, hospitalisation, cluster or any event causing significant parental /community concern the AEFI must be reported immediately by telephone to UH&FPO. Once UH&FPO is notified of the above events he will immediately notify to EPI HQ through Civil Surgeon and will initiate an investigation. If these events occur in a facility other than UHC,

respective HSO will immediately notify to CS (over telephone) who will initiate an investigation and notify to EPI HQ. Within 24 hours of detection of such cases, the AEFI report form (Annex-3) should be completed and sent to respective UH&FPO. During line listing if any cluster is identified UH&FPO will initiate investigation and take necessary actions to prevent further occurrence of similar event. If such cluster is identified during compilation at district level then Civil Surgeon will inform respective UH&FPO to initiate an investigation. All individual cases of a cluster should be documented in an AEFI report form (Annex-3).

Figure 1. Flow Chart of AEFI Reporting for Rural Areas



4.2.2 AEFI reporting system for urban areas

A. Municipality

Community

Field workers of municipalities including NGOs, who detect or get information of an AEFI from the community/EPI session should report to their supervisor and send the filled AEFI report form (Annex- 3) to MMO within 24 hours via porter. The supervisor will ensure reporting of the case to Municipality. If MMO position is lying vacant, reports should be addressed to respective UH&FPO (UH&FPO-Sadar in case of district municipality).

The MMO/UH&FPO will report to Civil Surgeon of all AEFIs of the municipality including zero report using AEFI weekly line-listing form (Annex-4). The report should reach to the CS office by the following Tuesday.

Health facility

Service providers of health facility detecting AEFI should report to their respective HSO within 24 hours using AEFI report form (Annex-3). The HSO will report to Civil Surgeon of all AEFIs detected in the facility including zero report using AEFI weekly line-listing form (Annex-4). The report should reach to Civil Surgeon Office by the following Tuesday.

At the same time HSO should give a copy of the line list to respective MMO or UH&FPO (if MMO post is lying vacant) for information. MMO/UH&FPO will not include these reports in his/her weekly line listing form to avoid duplication.

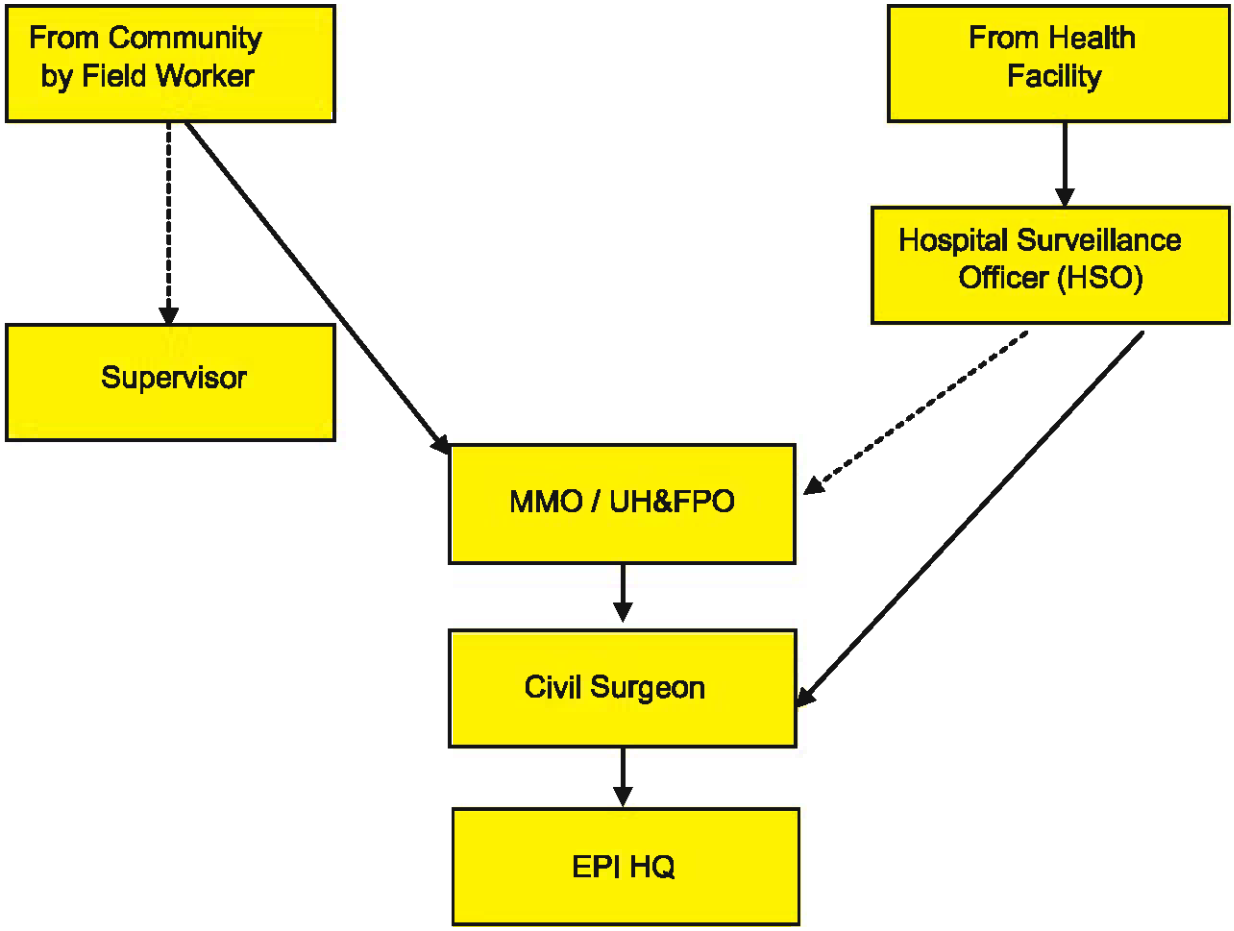
The Civil Surgeon will submit all AEFIs reported in each epidemiological week in AEFI district compilation form (Annex-5) to EPI HQ. The report should reach EPI HQ by the following Tuesday.

Immediate reporting

In case of death, hospitalisation, cluster or any event causing significant parental /community concern the AEFI must be reported immediately to MMO/UH&FPO by telephone. Once MMO/UH&FPO is notified of the above events he will immediately notify to EPI HQ through Civil Surgeon and will initiate investigation. If these events occur in a facility, respective HSO will immediately notify to CS who will initiate an investigation and notify to EPI HQ. Within 24 hours of detection of such cases, the AEFI report form (Annex-3) should be completed and sent to respective MMO/UH&FPO.

During line listing if any cluster is identified MMO will inform respective UH&FPO and vice versa. The MMO/UH&FPO will initiate investigation and take necessary actions to prevent further occurrence of similar event. If such cluster is identified during compilation at district level then Civil Surgeon will inform respective MMO / UH&FPO to initiate an investigation.

Figure 2. Flow Chart of AEFI Reporting for Municipality



B. City Corporation

Community

Field workers of City Corporation including NGOs, who detect or get information of an AEFI from the community/EPI session should report to their supervisor and send the filled AEFI report form (Annex- 3) to AHO/ZMO within 24 hours via porter where zone exist otherwise directly to CHO. The supervisor will ensure reporting of the case to City Corporation.

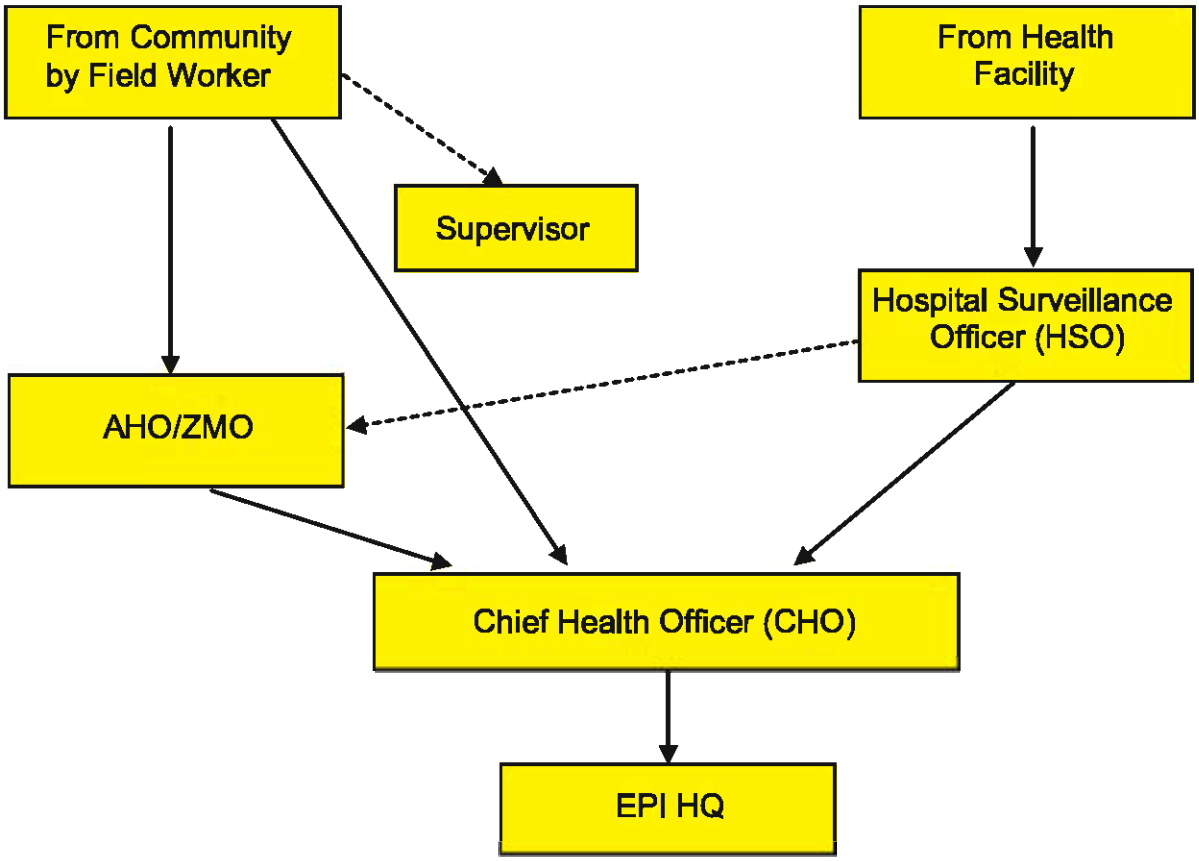
The zonal in-charge (AHO/ZMO) reports all AEFIs of an epidemiological week including zero reporting to CHO using AEFI weekly line-listing form (Annex-4). The reports should reach to CHO by the following Tuesday.

Health facility

Service providers of health facility detecting AEFI should report to their respective HSO within 24 hours using AEFI report form (Annex-3). The HSO will report to CHO of all AEFI detected in the epidemiological week including zero report by using AEFI weekly line listing form (Annex-4). The report should reach to CHO by the following Tuesday. At the same time HSO should give a copy of the line list to respective AHO/ZMO for information. AHO/ZMO will not include these reports in his/her weekly line listing form to avoid duplication.

The CHO will submit all AEFIs reported in each epidemiological week to EPI HQ in AEFI compilation form (Annex-5). The report should reach EPI HQ by the following Tuesday.

Figure 3. Flow Chart of AEFI Reporting for City Corporation



Immediate reporting

In case of death, hospitalisation, cluster or AEFI causing significant parental/ community concern AEFI must be reported immediately to AHO /ZMO. Once notified of the above events, AHO/ZMO must immediately notify to EPI HQ through CHO and will initiate an investigation. In case of facility, respective HSO will immediately notify to CHO who will initiate an investigation and will notify to EPI HQ. Within 24 hours of detection of such cases, the AEFI report form (Annex-3) should be completed and sent to respective AHO/ZMO/CHO.

During line listing if any cluster is identified which might be due to programme error AHO/ZMO will initiate investigation and take necessary corrective measures. During compilation at city corporation level if such cluster is identified, CHO will inform respective AHO/ZMO to initiate an investigation.

4.2.3 EPI HQ

EPI HQ will compile and analyze AEFI reports on monthly basis and provide one copy to National Regularity Authority (NRA). In case of death, hospitalisation, cluster or significant parental/community concern, EPI HQ will communicate with local health authority and assist in responding to the AEFI. EPI HQ may seek assistance from the National AEFI Expert Review Committee whenever needed. It is the responsibility of EPI/HQ to provide feedback to the District, City Corporation, Municipality and Upazila health authorities regularly. This may be done through regular EPI surveillance bulletin, reviews and verbal communications.

4.3 Encouraging reporting

The support of field staff is crucial for the success of any surveillance programme. Field workers are encouraged to report adverse events without fear of penalty. The aim is to improve the health care system or provide further training and not to blame individuals.

In order to encourage reporting the manager (e.g. UH&FPO, HSO, MMO, HO/ MO/AHO/ ZMO) is responsible to carry out the following activities:

- Train staff on AEFI and its reporting
- Increase awareness of health staff on importance of reporting
- Give positive feedback and appreciation for reporting. It is essential that health workers be given feedback about the results of investigations and any actions taken as a result of the report

The type of feed back that is given and the manner in which it is given depends on the audience. Managers should ensure that there is an ample supply of reporting and investigation forms in their institutions in order to facilitate timely reporting.

5. Investigation of AEFI

5.1 Why AEFI reports should be investigated ?

The ultimate goal of a case investigation is to find the cause of an AEFI and to implement follow-up actions. Investigation should identify any immunization error-related or vaccine product-related reactions because these are preventable. If coincidental events are recognized, proving them will be important to maintain public confidence in the immunization programme.

The purposes of investigating an AEFI case are the following:

- To identify the details of vaccine(s) administered and to determine the timing between administration of the vaccine and the onset of the event
- To confirm the reported diagnosis or establish a diagnosis
- To document the outcome of the reported adverse event

- To identify the cause of the AEFI
- To determine whether a reported event is a single incident or one of a cluster and, if it is part of a cluster, where the suspected immunizations were given and what vaccines were used
- To examine the operational aspects of the programme and to prevent immunization-related errors
- To determine whether similar events are occurring in individuals who have not received the same vaccine

If the cause is determined to be an immunization error, problem should be corrected quickly. If an AEFI is found to be coincidental, then the community can be reassured about the safety of the vaccine and the immunization programme. The act of investigating AEFI increases the confidence of the community in the health care system and the immunization programme in particular.

5.2 Which AEFI reports should be investigated ?

Not all AEFI reports need investigation. The following AEFIs must be investigated:

- serious AEFI (as defined by WHO)
- belongs to a cluster of AEFI
- is a previously unrecognized event associated with an existing or newly introduced vaccine
- involves an increased number or rates of known cause
- is a suspected immunization error
- causes significant parental/guardian or public concern

The above 6 types of events are called trigger events because they stimulate or trigger a response, such as investigation and corrective actions.

Cluster of AEFI

A cluster is defined as two or more cases of the same or similar events, related in time, geography (place), and/or vaccine administered. AEFI clusters are usually associated with a particular supplier/provider, health facility, and/or a vial of vaccine or a batch of vaccine.

For e.g. two or more cases of abscess occurring following one immunization session in a village; repeated abscess cases following immunization by the same vaccinator.

5.3 When to investigated AEFI ?

AEFIs investigation procedure should start as soon as possible, ideally within 24 hours of notification.

5.4 Who should investigate AEFI ?

UH&FPO /MMO/HO/MO/AHO/ZMO will initiate investigation and notify to the CS / CHO. In city corporations where zone does not exist, CHO will initiate the investigation. The CS/CHO will conduct the investigation procedure by formed and approved team within 24 hours of notification.

5.4.1 Rural areas

A team comprising of the following members will investigate AEFI in rural areas:

i. Civil Surgeon or a medical officer assigned by Civil Surgeon
ii. UH&FPO (concerned Upazila)
iii. Medical Officer designated as LSO
iv. Paediatrician
v. District EPI Supervisor
vi. Surveillance Medical Officer (WHO)
vii. District MCH & Immunization Officer (where available)

UH&FPO will initiate investigation and notify to the CS. Subsequently CS will form an investigation team with the above members. He can also include any other medical professional in the team depending on the nature of AEFI.

5.4.2 Urban areas

Municipalities

A team comprising of the following members will investigate AEFI in municipality:

i. Civil Surgeon or a medical officer assigned by Civil Surgeon
ii. MMO / UH&FPO
iii. Medical Officer designated as LSO
iv. Paediatrician
v. Vaccinator Supervisor
vi. Surveillance Medical Officer (WHO)
vii. District MCH & Immunization Officer (where available)

MMO will initiate investigation and notify to CS. Subsequently CS will form an investigation team with the above members. He can also include any other medical professional in the team depending on the nature of AEFI. If MMO position is lying vacant then respective UH&FPO will initiate investigation.

City Corporation

A team comprising of the following members will investigate AEFI in City Corporation:

i. Chief Health Officer or a doctor assigned by CHO
ii. Zonal Medical Officer/ Assistant Health Officer (ZMO/AHO)
iii. Paediatrician
iv. EPI supervisor of city corporation
v. Surveillance Medical Officer

AHO/ZMO will initiate investigation and notify to Chief Health Officer (CHO). Subsequently CHO will form an investigation team with the above members. He can also include any other medical professional in the team depending on the nature of AEFI. In the city corporation where zone does not exist, CHO will initiate the investigation.

Special Note: In case of deaths, it is strongly recommended that experts opinion on the cause of death to be received.

5.5 How to investigate AEFI ?

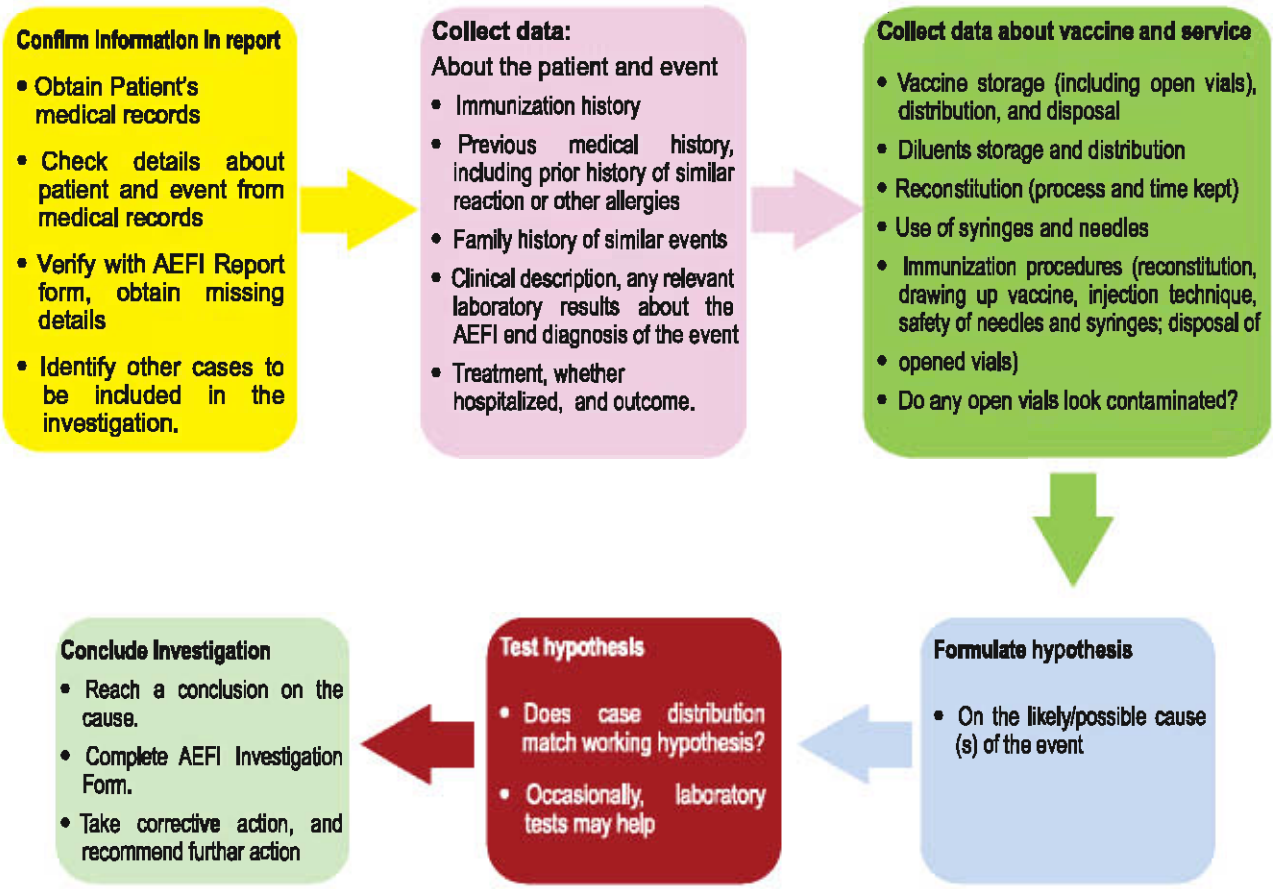
It is essential to investigate adverse events completely and without any delay. The investigator should search for system problems rather than finding individuals to blame. While an individual may have been at fault, it is more effective to concentrate on changing the system/procedures to avoid such errors than to blame or punish any individuals. Such an approach is essential to ensure that AEFI reports are encouraged. During investigation the investigators will gather information from the following persons:

- AEFI Patients: Patient should be examined and all available medical records should be reviewed.
- Clinicians who have treated the patient
- Field workers / vaccinators / supervisors / MT-EPI: Field workers vaccinators who gave vaccine during the suspected session should be interviewed. Supervisors of that field worker and MT-EPI should also be asked about the vaccination practice problems in the past (if any). Need to check and collect information on the cold chain, logistics and vaccine storage at all levels.
- Besides interview, it is important to observe a session of the same health worker because it might reveal the cause, since bad practice may be repeated.
- Community members: Investigators should talk to parents and others who were present during the suspected vaccination session about what they might have seen. Those who received vaccine on the same session should also be interviewed if necessary.

5.5.1 Steps in an AEFI investigation

The following figure describes the steps of AEFI investigation.

Figure 4. Steps of AEFI Investigation



After collecting sufficient information a working hypothesis should be formulated as to what was the probable cause of the AEFI. For example:

i. Immunization error - related reaction
   - vaccine transportation or storage error
   - reconstitution error
   - un-sterile practice
   - incorrect administration technique
   - any other

ii. Vaccine reaction (product related or quality defect related)
   - known vaccine reaction
   - vaccine manufacturer error

iii. Coincidental

iv. Immunization anxiety related reaction

The working hypothesis may be a simple statement linking the suspected cause with the reported AEFI. For instance, an abscess following immunization may initially be investigated with the following hypothesis: "An abscess following immunization due to incorrect technique". The working hypothesis may change during the course of the investigation. In this example, additional information may reveal that there are similar cases from more than one clinic and therefore the working hypothesis could be modified as "Abscess following immunization due to cold chain failure in vaccine storage". The focus of the investigation should be to seek to confirm the working hypothesis.

No action should be taken based on the hypothesis, until it is confirmed with reasonable certainty. It is the responsibility of investigation team to form, test and confirm /discard the working hypothesis in a scientific manner.

Note: It is not recommended all members of the investigation team to visit to the field as it may cause unnecessary concern by the public. Field investigation is the responsibility of UH&FPO or MMO or AHO/ZMO or CHO (where there is no zone). `

5.6 Collect and dispatch specimen

Once a working hypothesis is formulated, it should be apparent whether specimens are required to confirm or rule out the suspected cause. Only appropriate specimens necessary for investigation should be collected, and a clear explanation should be sent to the laboratory of why they were taken and what information is required. It is recommended investigation team to contact the laboratory and get advice on specimen collection, transport etc., well before the specimen collection and dispatch.

5.6.1 Notes on specimen taking

It is difficult to generalize what specimens will be required in a given situation. It will much depend on symptoms and signs and clinical diagnosis. A good communication among clinician, laboratory and investigation team is important to make a good decision on what specimens to be collected and where to be sent for investigation. Testing of vaccines and diluents should be requested on a clear suspicion and not as routine and never before the working hypothesis has been formulated.

Table 8. Laboratory Testing to Investigate AEFI by Working Hypothesis

Working Hypothesis	Specimens to send	Laboratory Test
Vaccine transportation or storage error	Vaccine vial	Visual test for clarity, presence of foreign matter, turbulence, discoloration or flocculation (examine under magnification)
Reconstitution error	Vaccine vial and/or diluents	Chemical composition analysis for abnormal components (e.g. suspect medicine used instead of vaccine or diluent), or microbiological culture for bacterial contamination
Non-sterile injection	Needle, syringe , vaccine vial and diluents	Sterility, if an infectious cause is suspected
Vaccine problem	Vaccine vial	Chemical composition analysis: preservatives, adjuvant level, etc. (e.g. aluminium content) or biological tests for foreign substances or toxins if abnormal toxicity is suspected

The collection and storage of specimens following serious AEFI (e.g. deaths, anaphylaxis, toxic shock syndrome) is important. Therefore, as soon as information is received about a suspected AEFI, the hospital staffs are advised to collect all relevant samples such as blood, urine, cerebrospinal fluid (CSF), vomitus, faeces, sputum, swabs etc. If there is a delay in transport to the laboratory, samples should be stored in a refrigerator at the recommended temperature, depending the type of sample and the facilities available.

Table 9. Guide to Human Specimen Samples Collection Following Selected AEFI

Hypothesis	Specimen	Reason	Specimen collection
Suspected bacterial sepsis due to contaminated vial, needle contamin ation, coincidental	Whole blood	Bacterial culture	Blood 8-10 ml in each of 2 blood culture bottles.
	CSF	Differential cell count, biochemistry, bacterial and viral culture, PCR (HSV1/2, enterovirus, other)	Sterile container Viral culture media
Suspected viraemia due to vaccine virus or coincidental disease	Serum	IgM and IgG antibodies for viral pathogens	Clotted blood 5 -10 ml
	CSF	Differential cell count, biochemistry, bacterial and viral culture, PCR (HSV1/2, enterovirus, other)	Sterile container Viral culture media
	Skin vesicle	Viral culture	Sterile container Viral culture media
Suspected anaphylaxis	Serum	Mast cell tryptase	Clotted blood 5-10 ml
		Specific IgE	Clotted blood 5 -10 ml
Suspected toxin or drug injection/ingestion, either programme error or coincidental	Urine	Drug screen	Sterile container 1 ml
	Blood	Chemistry when indicated, liver enzymes, glucose, electrolytes	Clotted blood or in Li Heparin 5-10 ml
Suspected VAPP or coincidental encepha litis	Stool	Enterovirus and viral culture	Sterile container

5.6.2 Notes on dispatch specimen

- All specimens (whether of human origin, vaccines, diluents or syringes) should be labelled and sealed in containers or plastics bags
- Specimens should be transported on ice to the laboratory for toxicological screening and with formalin or any other medium for histo-pathological analysis as instructed by laboratory
- Attach in a separate envelop a copy of the case investigation form to help laboratory perform the correct tests as well as the request form by appropriate authority to perform tests

Again, it is recommended investigation team to contact the laboratory and get advice on specimen collection, transport etc., well before the specimen collection and dispatch.

5.7 Investigating AEFI clusters

A cluster of AEFI is defined as two or more cases of the same adverse event related in time, place or vaccine administration. Apart from checking on these three factors, the investigator should look for AEFI occurring in similar age groups and populations with genetic predisposition or disease.

Cluster investigation begins by establishing a case definition for the AEFI and related circumstances and by identifying all cases that meet the case definition. The investigation should promptly characterize all known cases and search similar ones (Figure-5).

Cluster identification (i.e. cases with common characteristics) is done by gathering details (who, when and where) of vaccines administered. This can be achieved by collecting and recording

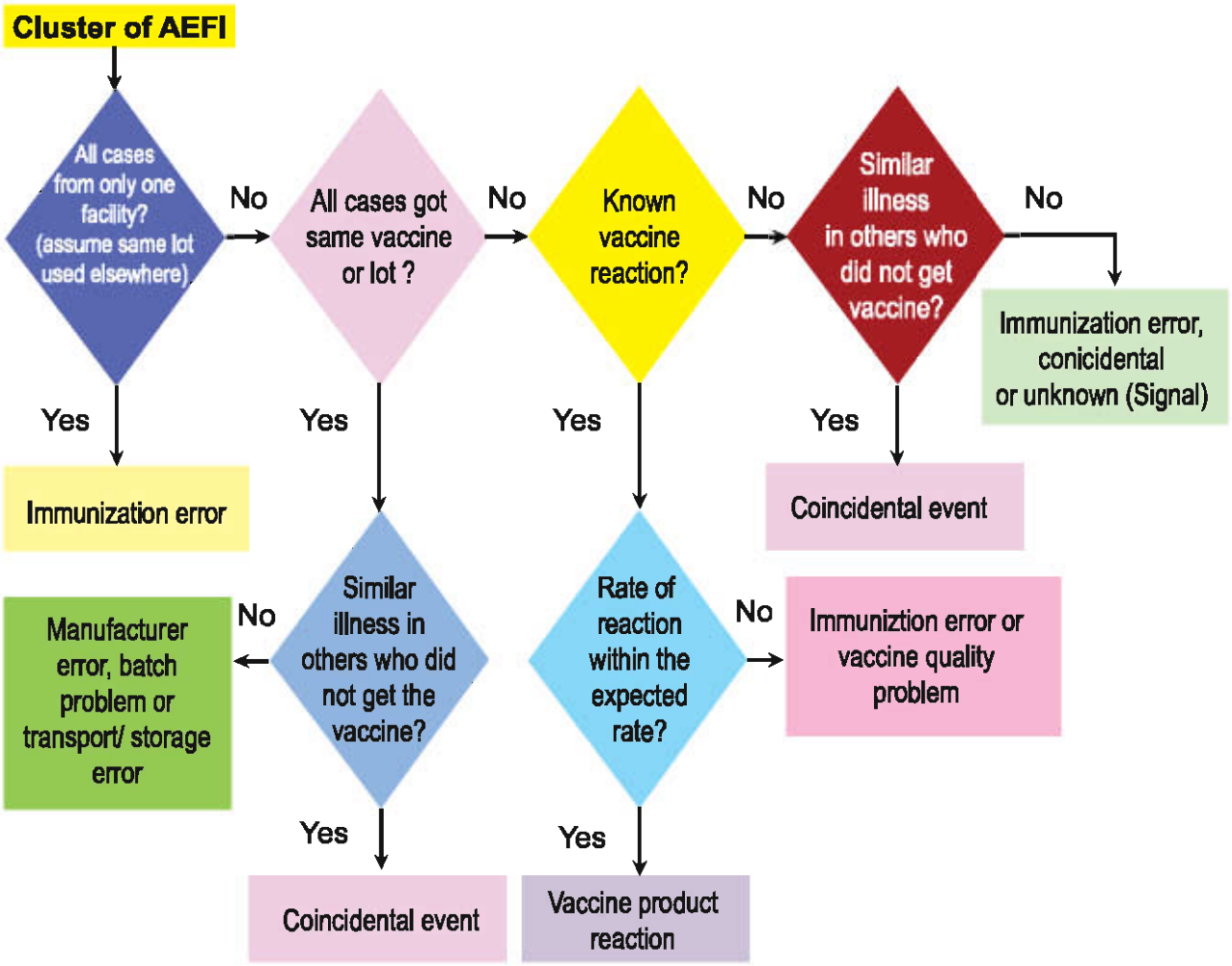
- detailed data on each patient
- programme-related data (storage and handling etc.)
- immunization practices and the relevant health workers' practices

Common exposures among the cases can be identified by reviewing:

- all data on vaccine(s) used (name, lot number etc.)
- data on other people in the area (also non-exposed)
- any potentially coincident factors in the community

When an AEFI cluster has been identified, the cause-specific definitions provide a framework for investigation and causality assessment. Usually, the key considerations will be to investigate the possibility of a vaccine quality defect or an immunization error-related AEFI.

Figure 5. Identifying the Causes of an AEFI Cluster



If all cases received vaccines from the same health worker/facility and there are no other cases, an immunization error is likely. If all cases received the same vaccine or lot, and there are no similar cases in the community, a problem with the vaccine or the respective lot is likely. If the event is a known vaccine reaction but is found to occur at an increased rate, an immunization error or a vaccine problem are likely causes. Finally, if cases in the unvaccinated population are occurring at about the same rate/proportion as among the vaccinated from the same area in the same age group, the adverse event was probably coincidental (Table-10).

Table 10. Cause-specific Cluster Characteristics

Cause-specific AEFI	Cluster characteristics
Vaccine reaction (product-related or quality defect-related)	If all cases received the same vaccine or lot, and there are no similar cases in the community If an increased frequency of events is reported from multiple settings
Immunization error-related	If all cases received vaccines from the same health worker/facility and there are no other cases
Coincidental	If cases include people from the same area in the same age group who were not immunized
Immunization anxiety-related reaction	Clusters of fainting after immunization are well-recognized as anxiety-related reactions during immunization programmes targeting adolescent girls

5.8 Investigation of deaths

A field investigation of a death following immunization has to be conducted without delay, as the death can cause significant community concern. All administrative levels, including the national immunization programme, should be notified of the death.

An autopsy is preferred and is recommended following all deaths suspected to be caused by vaccine or immunization. However, the decision to conduct the autopsy should be taken within the context of religious, cultural and the legal framework of the country.

If an autopsy is not possible, a verbal autopsy can be carried out in accordance with established guidelines and protocols. WHO protocols for verbal autopsy standards are a useful reference.

5.9 Submission of the AEFI investigation report

After completing investigation the AEFI investigation team will submit the report to respective UH&FPO/MMO/AHO/ZMO. For City Corporation where zone does not exists, the investigation team will submit the report to respective CHO. The report includes filled in AEFI case investigation form (Annex-6) together with all medical records e.g. prescription, treatment sheet (if hospitalised), laboratory reports (if any), autopsy report (in case of death) etc. A copy of the AEFI report form should be attached with the investigation report. UH&FPO/MMO/ AHO/ZMO will send these reports to respective CS/CHO who will send a copy of all these to EPI HQ within a week.

6. Causality assessment of AEFI

Causality assessment is the systematic evaluation of the information obtained about an AEFI to determine the likelihood that the event might have been caused by the vaccine(s) received. Causality assessment does not necessarily establish whether or not a definite relationship exists, but generally ascertains a degree of association between the reported adverse events and the vaccine/vaccination. Nevertheless, causality assessment is a critical part of AEFI monitoring and enhances confidence in the national immunization programme. Causality assessment is done by the National AEFI Expert Review Committee.

6.1 Case selection for AEFI causality assessment

Not all AEFI investigated need to be subject to a formal causality assessment. In some cases, it becomes immediately clear that symptoms began before the vaccination. It is generally recommended that causality assessment should be done for the following:

- serious AEFI events which are life-threatening or leading to death, hospitalization, significant disability or congenital anomaly, where it is important to evaluate whether a vaccine could have been responsible for the event
- clusters of events above an expected rate or level of severity, where it is important to establish whether the number of cases related to vaccination is truly elevated and thus action needs to be taken
- signals generated as a result of an unusual individual case or a cluster of cases that then will warrant further analysis or investigation

Other AEFI may also be subject to a causality assessment if there is a need to assess them in more detail given their potential need for a detailed investigation or follow-up, as outlined below:

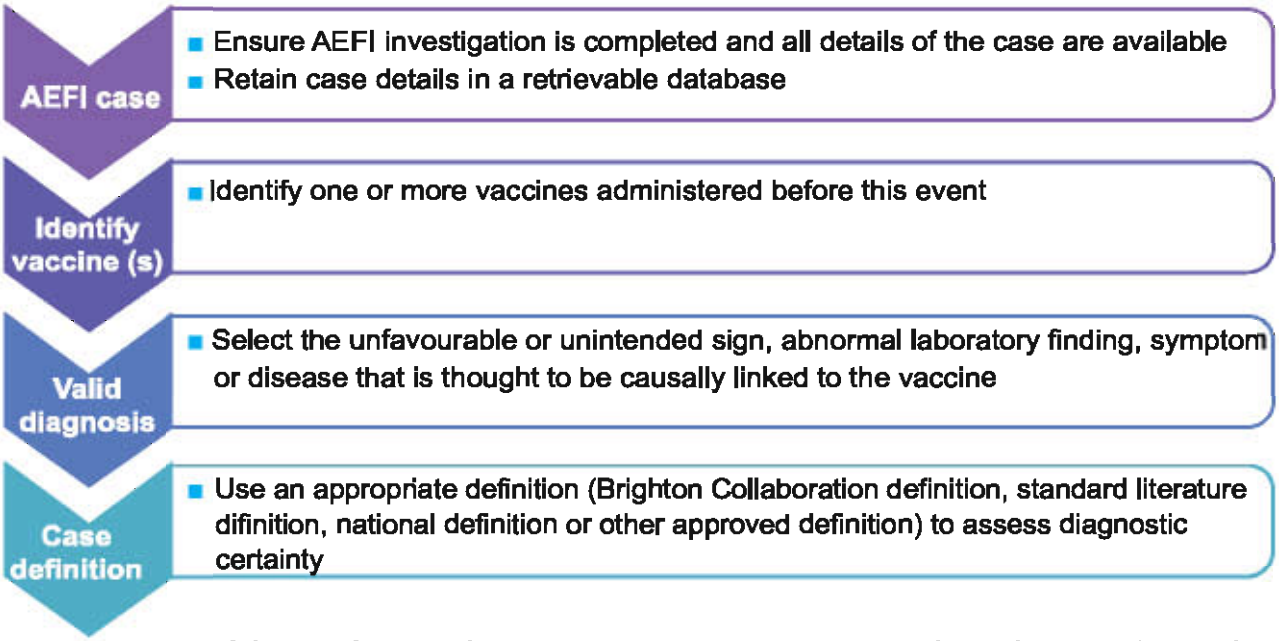
- AEFI that may have been caused by immunization error (e.g. bacterial abscess, severe local reaction, high fever or sepsis, BCG lymphadenitis, toxic shock syndrome)
- significant events of unexplained cause occurring within 30 days after a vaccination (and not listed in the product label)
- events that are causing significant parental or community concern and where a formal case assessment can provide a detailed, more reassuring explanation to the parents and/or community (e.g. HHE, febrile seizures)

6.2 Steps in causality assessment

There are four steps in causality assessment:

Step 1: Eligibility : to determine if the AEFI case satisfies the minimum criteria for causality assessment as outlined below in Figure 6.

Figure 6. Causality Assessment : Eligibility



At the successful completion of this stage, the reviewers should define the "causality question" (Figure-7).

Figure 7. Causality Question

Create your question on causality here:

Has the _____vaccine/vaccination caused _____?

(the event for review in step 2)

Step 2. Checklist : to systematically review the relevant and available information to address possible causal aspects of the AEFI .

The checklist contains elements to guide the assessor or committee of reviewers to collate the evidence for case review (Table-11). It is designed to assemble information on patient-immunization-AEFI relationships in the following key areas:

1. Is there evidence for other causes?
2. Is there a known association with the vaccine/vaccination in the medical literature? If so, did the event under assessment occur within an appropriate time window and, if so, was it associated with the vaccine product, an immunization error or immunization-related anxiety?
3. Is there any strong evidence against a causal association?
4. Other qualifying factors for classification (e.g. background rate of the event, present and past health condition, potential risk factors, medication, biological plausibility, etc.).

Table 11. The Causality Assessment Checklist

I. Is there strong evidence for other cause?

- Does a clinical examination, or laboratory tests on the patient, confirm another cause?

II. Is there a known causal association with the vaccine or vaccination?

Vaccine product(s)

- Is there evidence in the literature that this vaccine(s) may cause the reported event even if administered correctly?
- Did a specific test demonstrate the causal role of the vaccine or any of the ingredients?

Immunization error

- Was there an error prescribing or non-adherence to recommendations for use of the vaccine?
- Was the vaccine (or any of its ingredients) administered unsterile?
- Was the vaccine's physical condition abnormal at the time of administration?
- Was there an error in vaccine constitution/preparation by the vaccinator?
- Was there an error in vaccine handling?
- Was the vaccine administered incorrectly?

Immunization anxiety

- Could the event have been caused by anxiety about the immunization?

II. (time).If "yes" to any question in II:

- Was the event within the time window of increased risk, after vaccine administration?

III. Is there strong evidence against a causal association?

- Is there strong evidence against a causal association?

IV. Other qualifying factors for classification

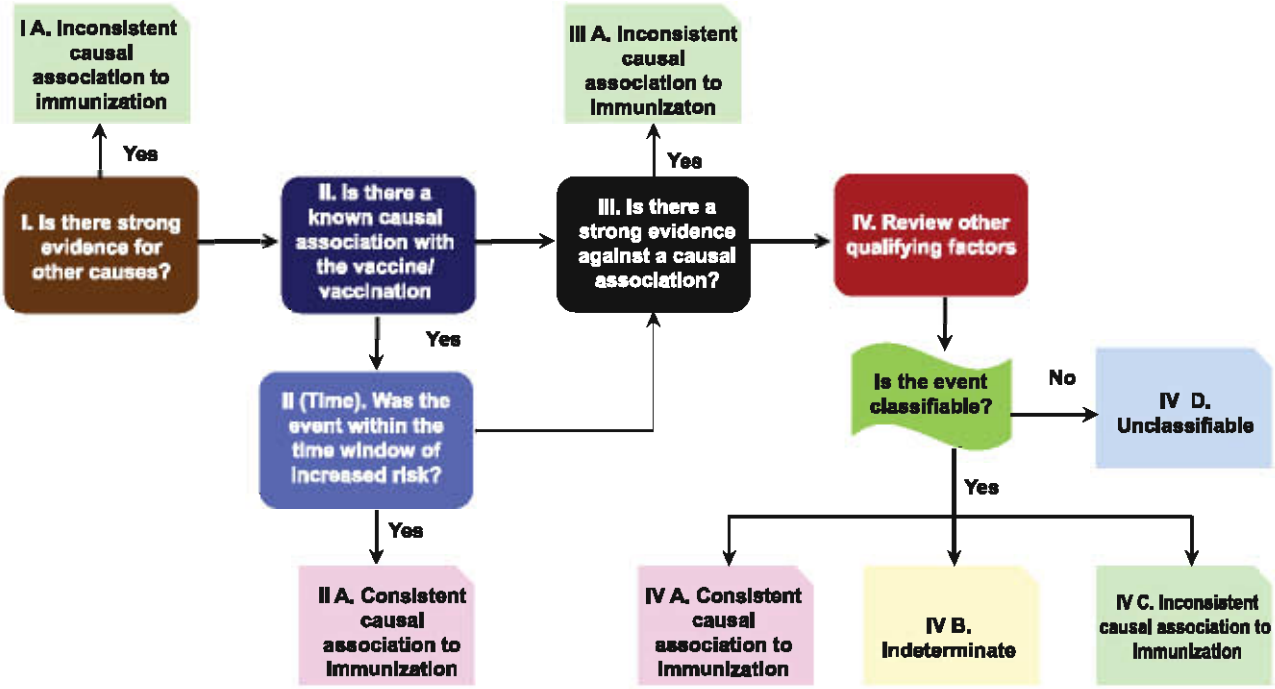
- Could the event occur independently of vaccination (background rate)?
- Could the event be a manifestation of another health condition?
- Did a comparable event occur after a previous dosc of a similar vaccine?
- Was the exposure to a potential risk factor or toxin prior to the event?
- Was there the acute illness prior to the event?
- Did the event occur in the past independently of vaccination?
- Was the patient taking any medication prior to vaccination?

Source: Causality assessment of adverse event following immunization (AEFI): user manual for the revised WHO classification. Geneva: World Health Organization; 2013.(See Annex 5 for the standard template of the checklist.)

Step 3. Algorithm: to obtain direction as to the causality with the information gathered in the checklist.

The algorithm (Figure 8) follows the key questions and related answers on the checklist. A stepwise approach using the algorithm helps determine if the AEFI could be consistent, or inconsistent, with an association to immunization, or is indeterminate or unclassifiable.

Figure 8. Causality Assessment: Algorithm



Step 4. Classification: to categorize the AEFI's association to the vaccine/vaccination on the basis of the direction determined in the algorithm.

The final classification is based on there being available adequate information for the case, as mentioned above. After working through the algorithm, a case can be classified as follows:

(A) Consistent causal association to immunization

A1: vaccine product-related reaction, or
A2: vaccine quality defect-related reaction, or
A3: immunization error-related reaction, or
A4: immunization anxiety-related reaction

(B) Indeterminate

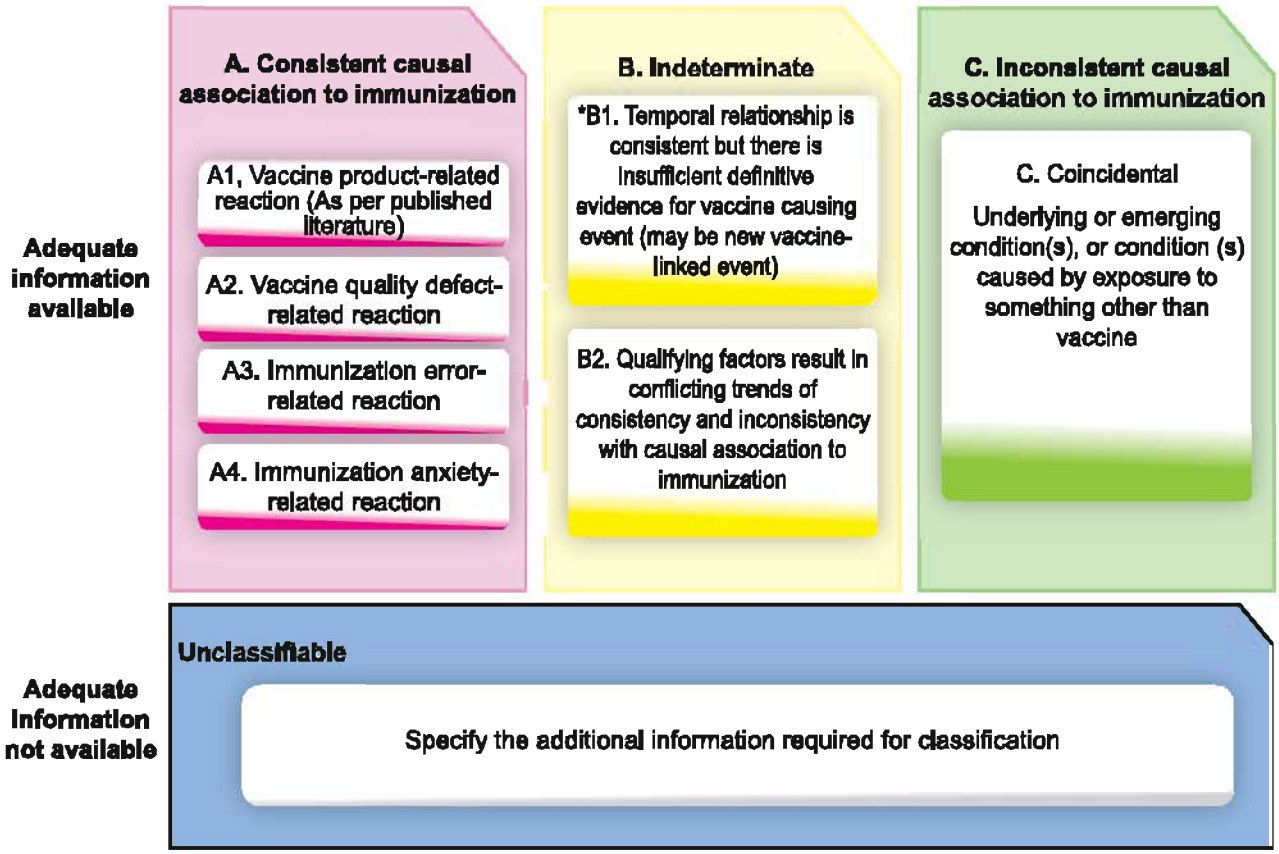
B1. The temporal relationship is consistent but there is insufficient definitive evidence for the vaccine causing the event. It may be a new vaccine-linked event. This is a potential signal and needs to be considered for further investigation.

B2. Reviewing factors result in conflicting trends of consistency and inconsistency with a causal association to immunization.

(C) Inconsistent causal association to immunization (coincidental)

This could be due to underlying or emerging condition(s) caused by exposure to something other than the vaccine. A case without adequate information for a conclusion on causality is "unclassifiable" and requires additional information for further review. The available information on unclassifiable cases should be placed in a repository or electronic database which should be reviewed periodically to see if additional information is available for classification and to perform analysis for identifying signals.

Figure 9. Causality Assessment Classification



*B1: Potential Signal and may be considered for investigation

The final classification (Step 4) is critical as it provides direction to follow-up actions. It is important to note that the final classification of a given AEFI may change as knowledge and information are updated.

When AEFI occur as clusters, it is important to consider each case separately and do an independent causality assessment and classification for each case in the cluster.

7. AEFI Expert Review Committee

There is a national AEFI Expert Review Committee consisting of Paediatrician, Virologist, Pharmacologist, Pathologist, Epidemiologist,Immunologist, and representatives from Directorate General of Drug Administration, EPI, UNICEF and WHO. The TOR of the national AEFI Expert Review Committee is as follows.

- The committee will play an advisory role in confirming the causality assessment of selected investigations and in determining causality when not established with confidence by the investigation team.
- Review the investigation reports of serious AEFI, assess and classify the unresolved cases of AEFI.
- The committee will provide technical advice on strengthening the AEFI surveillance system by reviewing AEFI Surveillance Data.
- The committee will monitor reported AEFI data for potential signals of previously unrecognized vaccine-related adverse events and make recommendations for further investigation.
- The committee will advise EPI/HQ, NRA/NCL at times of crisis/ emergency and assist the AEFI investigation team if needed.

The committee will meet quarterly and as and when needed. The chair of the committee can co-opt members for causality assessment if needed.

8. Necessary action following AEFI

To keep credibility of immunization program high, following actions need to be taken following an AEFI:

- Treatment: treatment is the first response to an AEFI
- Reporting: timely reporting to appropriate level
- Communication: with patients / parents and other members of the community
- Communication: with media (if necessary, by authorised persons only)
- Ensuring continuation of the Programme: It is never appropriate to discontinue the immunization programme while awaiting the completion of investigation. However, corrective actions after completion of investigation are essential.

The following table provides a summary of actions that are usually taken when different types of AEFI occur:

Table 12. Actions to be taken upon Completion of the Investigation/ Causality Assessment

Type of AEFI	Follow-up action
Vaccine-related Reaction	If there is a higher reaction rate than expected from a specific vaccine or lot, obtain information from the manufacturer and consult with the WHO regional office to consider: • withdrawing that lot • investigating with the manufacturer • obtaining vaccine from a different manufacturer
Immunization error-related reaction	Correct the cause of the error. This may mean one or more of the following: • changing logistics for supplying the vaccine • changing procedures at the health facility • training of health workers • intensifying supervision Whatever action is taken, it is important to review at a later date to check that the immunization error-related events have been corrected.
Immunization anxiety- related reaction	Assurance to the patients / parents andhealth (field) staff.
Coincidental	The main objective is to present the evidence showing that there is no indication that the AEFI is a vaccine-related or immunization-error related reaction and, that the most likely explanation is a temporal association between the event and vaccine/vaccination. This communication can be challenging when there is widespread belief that the event was caused by immunization.

8.1 Treatment

Treatment must be the first response to an AEFI. Mild symptoms such as mild fever, pain are likely to be of short duration and can be managed by assuring and educating parents during immunization. Field staff should refer serious AEFIs to nearby hospital/clinic for treatment.

8.2 Reporting

For detail information of timely reporting to appropriate level is described in section 4.

8.3 Communication with parents and health care providers

It is crucial that any actions taken as a result of an AEFI are communicated to appropriate individuals in appropriate manner. Parents and the concerned immunization staff need to

be kept informed about the results of investigation and what actions are going to be taken. In addition the wider community and perhaps the entire country may need to be informed of the results of investigation and corrective action taken. It is important that not only the risks of immunization are communicated in such situations but the benefits of immunization as well.

When communicating about AEFI, remember that trust is a key component of exchange of information at every level, and overconfidence about risk estimates that are later shown to be incorrect contributes to a breakdown of trust. Admit uncertainty, investigate fully, and keep the community informed. Avoid making a premature statement about the cause of the event before investigation is complete. If the cause is identified as a immunization error, it is vital not to lay personal blame on anyone, but to focus on system-related problems that resulted in immunization error(s) and steps being taken to correct the problem.

In communicating with the community, it is useful to develop links with community leaders and field workers so that information can be rapidly disseminated.

Below are a few key points to consider when communicating with parents during or after an AEFI has occurred.

- Listen sympathetically to parents and their concerns
- Reassure and support the parent or patient but do not make false promises
- Assist the parent/caregiver to take the AEFI patient to UHC/other hospital/clinic
- Keep the parent/guardian routinely informed of the progress of the patient

The field workers need to be supported and provided with appropriate information to respond directly to community concerns.

8.4 Communication with media

The mass media (newspaper, radio and television) play an important role in public's perception of vaccination and can have a positive or negative influence. The support of mass media for vaccination depends to a large extent on communication skills of the health authority. Statements and press conferences are useful tools to communicate with media when an adverse event occurs.

Media are most interested in stories that will attract attention and boost their sales/audience. One technique is to dramatise and personalise events, including events which are either unrelated to immunization (coincidental) or a localised immunization error without wider implications. In addition, media tend to report on numbers of events, ignoring the context of the small rate of occurrence. If given inappropriate information, media can present the health service or officials responsible for immunization as being uncaring, impersonal, incompetent, or even dangerous.

Media can also be a helpful partner in communicating public health messages such as reminding public of the importance of immunization and the risks of the diseases. Building a personal relation with key health reporters will help them to understand the public health perspective.

The guiding principle for dealing with media must be honesty and building up trust. The effectiveness of our communication is largely determined by whether the audiences perceive us to be trustworthy and believable. Trust and credibility are difficult to achieve; if lost, they are even more difficult to regain. It is vital to prepare before any media contact with:

- key messages
- answers for likely and awkward questions
- identifying which issues not to respond to (e.g. blaming an individual or speculating on the cause before investigation is complete)

Preparing key messages

Messages need to be as simple as possible. Use simple words and short sentences. The key messages should be kept to a minimum and are likely to include some of these facts:

- benefit of immunization in preventing disease is well proven
- it is very risky not to immunize (risk of disease and complications)
- vaccine-preventable diseases caused millions of death and/or disability before introduction of vaccines, and that situation would return without continued use of vaccines
- vaccines do cause reactions, but these are rarely serious and hardly ever cause long-term problems
- immunization safety is of paramount importance, and any suspicion of a problem is investigated (advantage of well established AEFI Surveillance System)
- the AEFI is currently being investigated, but is likely to be coincidental/due to a local problem (depending on type of event), and the immunization programme must continue to keep the population safe from disease
- action is being taken

Preparing a press statement

All the information to be conveyed in a media conference should be prepared in advance and included in a press statement/press release. An effective press statement/ press release must specifically answer the six Ws and should include a one-page (400-500 words maximum) account written in short sentences outlining:

- a complete account of the event, framed in its context (e.g. an isolated event or a cluster of AEFI, or a coincidental event)
- no technical jargon
- an outline of actions taken or planned (such as the AEFI investigation)
- a description of the possible cause of the event

- an assurance that corrective action will be taken, and what steps have already been taken
- reference to any relevant publication or website for further information
- the sender's name and spokesperson's details
- quotes from key officials, after seeking their permission (the quotes must be positive and carry the key messages)
- repetition of the key message

It is essential to present information to the media in a way that will generate a sense of credibility and confidence by being:

- honest - never lie; if you do not know, say so, but promise to find out (e.g. "We don't know at this time, but we have taken steps to answer that question"); note that a lie or cover-up can become a bigger news story than the initial event
- caring - create a strong, compassionate, competent image of yourself and the service
- clear - avoid jargon; use simple phrases and give examples to clarify meaning
- serious - jokes can be disastrous and the subject is rarely amusing anyway
- aware of body language - it is of critical importance in perceptions
- responsible - don't be defensive, but accept responsibility appropriate to your position and avoid blaming someone else (e.g. "We will see if there is any truth in the report")
- responsive - hold a daily press conference if that is what is needed to meet the needs of the pubic and media; regular contact helps build a trusting relationship with media
- positive - reframe the situation in positive terms; use terms such as vaccine safety (which has a positive connotation) rather than adverse event

Facing hostile interviewer

When facing a hostile interviewer, prepare the following techniques:

- **block** - respond to a negative question with a positive answer (e.g. when asked, "How many children have died from immunization?", answer: "Immunization saves lives. Since our immunization programme began X children have been immunized, and of them Y% might have died from one of these diseases. That is the context in which we must consider the tragic, but thankfully rare adverse events which follow immunization."
- **bridge** - having answered a difficult question, move quickly to something linked but positive
- **correct what is wrong** - immediately correct information from the interviewer that is wrong. Be assertive, not aggressive and state the facts simply, factually and in a friendly way
- **stay cool** - no matter how bad it gets, don't get angry or defensive; stay friendly, polite and warm
- **be assertive** - means stating what you want to say in a clear way without getting aggressive; take time to think about the response and don't be rushed or forced

Bridge Technique

Question: Does vaccination cause abscesses?

Answer: (Face the element of truth) We know that vaccination can rarely cause abscesses. (here comes the first bridge….) That is why we train staff to avoid them by using sterile Auto Disable (AD) syringe for every child. (Now comes the second bridge) We also purchase only the highest quality vaccines approved by WHO and UNICEF. So we can assure parents/clients that we are providing quality immunization services.

8.4.1 Who should be the spokesperson

Media usually appreciate an honest, polite, accurate and authoritative person who can provide them with information they need. Designating the spokesperson(s) to communicate with media limits the possibility of conflicting messages coming from different sources.

The following persons will be the spokesperson at different levels:

- UH&FPO at Upazila and Upazila Municipality
- Civil Surgeon at District and District Municipality
- Chief Health Officer at City Corporation
- Focal person at EPI at National level

8.5 Crisis management

A crisis is a situation in which a real or potential loss of confidence in the vaccine or in the immunization programme is triggered by information about an AEFI. Crises can often be avoided through foresight, care and training. If managed properly, the investigation and management of a vaccine safety situation will boost public confidence and acceptance and ultimately strengthen the immunization programme.

How to manage a crisis?

- Anticipate. Do not wait until a crisis occurs. Prepare for the unavoidable situation. Develop a good relationship with the media. Good public awareness and understanding of the immunization programme is necessary.
- Train staff at all levels to respond adequately. Develop confidence in responding to the public and the media (particularly the local media) properly and correctly.
- Confirm all facts and prepare (see steps for a press conference or press release) before making any public comments.
- Prepare a plan to react to a crisis when it occurs. This has to be done in advance, identifying responsible persons to handle the crisis and preparing all supporting documents and information.

9. Analysis of AEFI data

Analysis of data is required to measure the impact of vaccines used in the immunization programme and to disseminate findings to advise programme managers, the NRA and other stakeholders, including manufacturers.The progress in AEFI surveillance need to be monitored by analysing the AEFI data monthly /quarterly /annually as follows:

- Number of AEFI reports received from community and from facility
- Number of AEFI by different levels (by divisions, districts, upazilas, wards etc.,)
- Number of AEFI by type (i.e. number of deaths, number of abscess, etc.)
  - Number of AEFI by type and level (number of deaths by districts, number of abscess by upazilas etc.)
- Number of AEFI by antigen
  - Total number of AEFI by antigen (total AEFI for pentavalent, total AEFI for Measles etc.)
  - Each Type of AEFI by antigen (number of deaths following pentavalent, number of abscess by pentavalent etc.)
- Classification of AEFI by cause (number of vaccine product-related reactions, number of immunization error, number of coincidences etc.)
  - Classification of AEFI by cause and Level (number of vaccine product-related reactions by district, number of immunization errors by upazila etc.)
- Assessing number of AEFI's rate: The number of vaccine product-related reactions will naturally increase with increased vaccine use, so it is essential to calculate antigen (vaccine)-specific adverse reaction reporting rates.

Eg., Incidence of Abscess per 100,000 doses of pentavalent vaccine

How to calculate this?

Incidence of abscess for penta in upazila 'Y"

$$= \frac{\text{Number of abscess reported following penta vaccine in upazila 'Y'}}{\text{Total number of penta vaccine given in upazila'Y' during a given time period}} \times 100{,}000$$

9.1 Who should analyse the data

Data analysis could be carried out at different levels of the AEFI surveillance system: the programme implementation level, the subnational level (districts) and the national level. The extent and purposes of analysis will vary at each level. Analysis of data at the service provider level is very important for identifying immunization errors and ensuring that corrective action is carried out in a timely manner. Data analysis at higher levels with larger denominators is important to identify rare vaccine safety events and also detect signals.

At the service delivery level

UH&FPO/MMO/AHO/ZMO will analyse the AEFI data on monthly basis and provide report to CS/CHO. LSO will assist UHFPO in analysing the AEFI data.

At the district /city corporation level

The CS/CHO will analyse the reports of all AEFIs on monthly basis and provide report to EPI- HQ. If there is any unusual high rate of AEFI he/she should inform respective UH&FPO/MMO/AHO/ZMO to look into the matter and take appropriate action. LSO will assist CS/CHO in analysing the AEFIs.

At the central level

EPI HQ will also analyse the reports of all AEFIs on monthly/quarterly basis and provide feedback to CS/CHO, NRA, NCL and other partner agencies (WHO, UNICEF etc.)

10. Monitoring and evaluation of AEFI surveillance system

AEFI surveillance system should be cautiously monitored and also evaluated regularly. The purpose is to identify gaps and rectify them in order to strengthen the immunization safety surveillance system in the country. The evaluation should be based on performance, quality and responses:

A. To monitor the **performance** of the AEFI surveillance system:

i. AEFI reporting rate per 100,000 population
ii. AEFI reporting rate per 100,000 < 1 population
iii. AEFI reporting rate per 100,000 administered doses of vaccines
iv. Percentage of serious AEFI cases versus total AEFI reports
v. Number of facilities submitting "zero reports"

B. To monitor the **quality** of AEFI reporting:

i. Timeliness of reporting
ii. Completeness of AEFI reports

C. To monitor the **response** to serious AEFI:

i. Timeliness of case investigation (% of serious AEFI case investigation initiated within 24 hours of notification)

11. Functions of role players

HA / FWA / Vaccinator

- Detect and report AEFI timely
- Refer patient to hospital, if possible accompany
- A good communication: reassure the parents/community
- Prevent AEFI due to programme error through strict compliance to proper and safe vaccine handling and injection safety practices

AHI / FPI / HI

- Encourage and assist HA/FWA to report AEFI timely
- Ensure HA/FWA has report forms
- Ensure completeness and accuracy of report forms send by HA/FWA/ Vaccinator
- Inform UH&FPO of AEFI reported by HA/FWA
- Do supportive supervision in order to prevent programmatic errors
- Support HA/FWA to gain confidence of the community following an adverse event
- Supportive communication with public

UH&FPO / MMO /HO/ MO/ AHO / ZMO

- Ensure appropriate case management of an AEFI
- Encourage HA/FWA/Vaccinators to report AEFI
- Maintain weekly line list and timely report to CS /CHO
- Analyse AEFI data and provide feed back to field staff
- Initiate investigation if needed and support the investigation team
- Report results of investigation to CS/CHO and EPI HQ
- Implement corrective action
- Provide feedback to field staff on results of investigation and corrective actions to be taken
- Monitor for clustering
- Inform Civil Surgeon/ CHO immediately of deaths, hospitalisation, clusters of events, events causing significant community concern
- Provide AEFI update information to field staff
- Staff motivation in AEFI surveillance
- Reassure the parents/ community
- Handle the media appropriately

Medical Officer in Hospital

- Detect AEFI and report to HSO within 24 hours
- Assist with diagnosis of AEFI
- Ensure appropriate case management
- Cooperate with the Investigation Team
- Inform HSO immediately of deaths and hospitalisation

Local Surveillance Medical Officer (LSO)

- Assist UH&FPO/MMO in preparing AEFI weekly line list
- Assist CHO /CS in compiling the weekly reports
- Assist DSFP in analyse AEFI data
- Report AEFI to SMO/DMCH&IO/Zonal Health Officer of UNICEF where further investigation is warranted

- Assist in investigating AEFIs (member of investigation team)
- Assist spokespersons to deal with media

Hospital Surveillance Officer (HSO)

- Assist UH&FPO/ MMO/ CHO /CS in AEFI surveillance
- Encourage reporting within the facility
- Timely report to CS/CHO
- Report AEFI to SMO/DMCH&IO/ Zonal Health Officer of UNICEF where further investigation is warranted
- Inform CS/CHO immediately of deaths and hospitalisation following immunization
- Assist spokespersons to deal with media

SMO (WHO) / Zonal Health Officer (UNICEF) / DMCHIO (GAVI)

- Encourage reporting of AEFI
- Facilitate timely reporting to appropriate authorities
- Facilitate data analysis
- Assist in investigation
- Assist in managing the AEFI case
- Assist spokespersons to deal with media

EPI Divisional Coordinator (WHO)

- Monitor and evaluate AEFI surveillance with SMO
- Support SMO to facilitate AEFI surveillance activities including AEFI investigation
- Coordination with CS and CHO

Civil Surgeon / Chief Health Officer

- Ensure a functioning AEFI surveillance system in the district
- Compile all reports of AEFI and timely submit to EPI HQ
- Notify serious AEFIs to EPI HQ
- Monitor timely reporting of AEFI
- Facilitate investigation of serious AEFI
- Ensure appropriate case management
- Ensure enforcement of corrective action
- Analysis of AEFI data and feed back to Health facilities including UHC/Municipalities
- AEFI Surveillance review with UH&FPO
- Monitoring and Evaluation of AEFI surveillance in the district
- Communicate with media

EPI Head Quarter

- Ensure a functioning national AEFI surveillance system in the country
- Encourage reporting of AEFI
- Collate all AEFI reports nationally, maintain a database and regular feed back
- Ensure adequate supply of AEFI forms and other logistics at all levels
- Identify clusters of AEFI at national level
- Initiate investigation if clusters are detected at national level or any AEFI with national EPI programme concern
- Provide facilities to conduct proper investigation at district level
- Communicate findings of investigation of serious AEFIs with all stake holders including media
- Support activities of AEFI Expert Review Committee
- Facilitate implementation of the recommendations of AEFI Expert Review Committee
- Facilitate training and awareness building activities among staff
- Assure public awareness on immunization safety
- Communicate and collaborate with NRA (DGDA), NCL and partner agencies (WHO, UNICEF)
- Respond to crisis
- Monitoring and Evaluation of AEFI Surveillance System

AEFI investigation team

- Conduct AEFI case investigation and causality assessment
- Prepare AEFI investigation report with findings and conclusions
- Assist with communication in case of crisis
- Recommend corrective action to be taken by appropriate authority

National Regularity Authority (NRA)

- Ensure participation of a member in AEFI Expert Review Committee
- Inform EPI HQ of any AEFI reported directly to NRA via the Adverse Drug Reaction Reporting System
- Implement any regulatory action if necessary
- Participate in investigation of serious AEFI
- Implement recommendation by the AEFI Expert Review Committee

Annex-1

Frequency of Vaccine Adverse Reactions of Commonly Used Vaccines

BCG Vaccine Summary

Vaccine Adverse Reactions	Frequency category
Injection site reaction (Papule, mild ulceration or scar)	Very common
Suppurative lymphadenitis	Uncommon to Rare
BCG osteitis	Uncommon to Very rare
Disseminated BCG disease or systemic BCG-itis	Very Rare
Immune Reconstitution Inflammatory Syndrome (IRIS)	Very Rare

Hepatitis B Vaccines Summary

Vaccine Adverse Reactions	Frequency category
Fever	Common
Headache	Common
Injection site pain	Common to very common
Injection site redness	Common
Injection site swelling	Common
Anaphylaxis	Very rare

DTP Vaccines Summary

Vaccine Adverse Reactions	Frequency category
Whole Cell Pertussis Vaccines	
Fever 100.1°F - 102°F	Very common
Injection site redness	Very common
Swelling	Very common
Pain (Severe-Moderate)	Very common
Fussiness (Severe-Moderate)	Very common
Drowsiness	Very common
Anorexia	Very common
Vomiting	Common
Persistent screaming	Uncommon to Rare
HHE	Very rare
Seizures	Very rare
Encephalopathy	Very rare
Anaphylaxis	
Acellular Pertussis vaccines	
Fever 100.1°F - 101°F	Very common
Fever 100.1°F - 102°F	Common
Injection site redness	Common to very common
Injection site swelling	Common to very common
Pain (Severe-Moderate)	Uncommon to common
Fussiness (Severe-Moderate)	Common to very common
Drowsiness	Very common
Anorexia	Very common
Vomiting	Very common
Persistent screaming	Uncommon
HHE	Rare
Seizures	Very rare

Human Papiloma Vaccines (HPV) Summary

Vaccine Adverse Reactions	Frequency category
Bivalent HPV Vaccine	
Fever	Common
Headache	Very common
Injection site pain	Very common
Redness	Very common
Swelling	Very common
Rash	Uncommon
Arthralgia	Very common
Myalgia	Very common
Fatigua	Very common
Gastrointestinal disorders	Very common
Quadrivalent HPV Vaccine	
Fever 100.1°F - 101°F	Very common
Fever 100.1°F - 102°F	Very common
Injection site redness	Common
Injection site swelling	Common
Pain (Severe-Moderate)	Common
Fussiness (Severe-Moderate)	Common
Drowsiness	Common
Anorexia	Common
Vomiting	Common
Persistent screaming	Common
HHE	Very common
Seizures	Very rare

Tetanus Vaccines Summary

Vaccine Adverse Reactions	Frequency category
Brachial nauritis	Very rare
Anaphylaxis	Very rare

Hib Vaccines Summary

Vaccine Adverse Reactions	Frequency category
Fever	Common
Injection site reaction	Very common

Polio Vaccines Summary

Vaccine Adverse Reactions	Frequency category
Whole Cell Pertussis Vaccines	
■ VAPP	
– Recipient VAPP	Very rare
– Total VAPP	Very rare
Inactivated Polio Vaccine (IPV)	
■ Injection site erythema	Uncommon to common
■ Injection site induration	Common to very common
■ Injection site tenderness	Very common

Measles Vaccines Summary

Vaccine Adverse Reactions	Frequency category
■ Fever	Common to very common
■ Rash	Common
■ Injection site reaction	Very common
■ Febrile seizures	Rare
■ Encephalomyelitis	Very rare
■ Thrombocytopenia	Very rare
■ Anaphylaxis	Very rare

Pneumococcal Vaccines Summary

Vaccine Adverse Reactions	Frequency category
Unconjugated Vaccine (PPSV)	
■ Fever > 39°C	Uncommon
■ Injection site reaction	Very common
Conjugated Vaccine (PCV)	
■ Fever > 39°C	Uncommon
■ Injection site reaction	Very common

Rubella Vaccines Summary

Vaccine Adverse Reactions	Frequency category
■ Fever	Common
■ Injection site reaction	Very common
■ Acute Arthralgia (adults)	Very common
■ Acute Arthritis (adults)	Very common

Varicella Vaccines Summary

Vaccine Adverse Reactions	Frequency category
■ Febrile seizures	Rare
■ Fever > 39°C	Very Common
■ Injection site reaction	Common to very common
■ Site rash (local/generalized)	Common

Mumps Vaccines Summary

Vaccine Adverse Reactions	Frequency category
■ Injection site reaction	Very common
■ Parotid swelling	Common
■ Aseptic meningitis	Very common

Rotavirus Vaccines Summary

Vaccine Adverse Reactions	Frequency category
■ Intussusception	Very rare

Yellow Fever Vaccines Summary

Vaccine Adverse Reactions	Frequency category
■ Vaccine-associated viscerotropic disease	Very rare

Source: WHO Fact sheets www/who.int/vaccines safety/initiative/tools/vaccinfosheets

Key		
Very common	> 1/10	> 10%
Common	> 1/100 and < 1/10	> 1% and < 10%
Uncommon	> 1/1,000 and < 1/100	> 0.1% and < 1 %
Rare	> 1/10,000 and < 1/1,000	> 0.01% and < 0.1%
Very rare	< 1/10,000	< 0.01%

Case Definitions and Treatments for AEFI

Adverse event	Case definition	Treatment
Acute flaccid paralysis (Vaccine associated paralytic poliomyelitis)	Acute onset of flaccid paralysis within 4 to 30 days of receipt of oral poliovirus vaccine (OPV), or within 4 to 75 days after contact with a vaccine recipient and neurological deficits remaining 60 days after onset, or death.	No specific treatment available; supportive care.
Anaphylactoid reaction (acute hypersensitivity reaction)	Exaggerated acute allergic reaction, occurring within 2 hours after immunization, characterized by one or more of the following: ▪ Wheezing and shortness of breath due to bronchospasm ▪ Laryngospasm/laryngeal oedema ▪ One or more skin manifestations, e.g. hives, facial oedema, or generalized oedema	Self-limiting Anti-histamines may be useful
Anaphylaxis	Severe immediate (within 48 hours) allergic reaction leading to circulatory failure with or without bronchospasm and/or laryngospasm/laryngeal oedema.	Adrenaline injection (See Annex-7)
Disseminated BCG infections	Widespread infection occurring within 1 to 12 months after BCG vaccination and confirmed by isolation of *Mycobacterium bovis* BCG strain. Usually in immunocompromised individuals.	Should be treated with anti-tuberculous regimens including isoniazid and rifampicin.
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 one day or more Needs to occur within 48 hours of DPT vaccine or from 6 to 12 days after measles vaccine, to be related to immunization.	No specific treatment available; supportive care.
Fever	The fever can be classified (based on rectal temperature) as: Mild fever: 100.1 ^{O}F to 101 ^{O}F High fever: 102 ^{O}F to 104.7 ^{O}F and Extreme fever (hyperpyrexia): 104.7 ^{O}F or higher	Symptomatic; paracetamol.
Hypotonic hypo responsive episode (HHE or shock-collapse)	Event of sudden onset occurring within 48 (usually less than 12) hours of vaccination and lasting from one minute to several hours, in Children yenger then 10 yrears of age. All of the following must be present: ▪ limpness (hypotonic) ▪ reduced responsiveness (hypo responsive) 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.

Adverse event	Case definition	Treatment
Injection site abscess	Fluctuant or draining fluid-filled lesion at the site of injection. Bacterial if evidence of infection (e.g. purulent, inflammatory signs, fever, culture), Sterile abscess if no evidence of bacterial Infection on culture. Sterile abscesses are usually due to the inherent properties of the vaccine.	Incise and drain; antibiotics if bacterial.
Lymphadenitis (includes suppurative lymphadenitis)	Either at least one lymph nodeenlarged to >1.5 cm in size (one adult finger width) or a draining sinus over a lymph node. Almost exclusively caused by BCG and then occurring within 1 to 12 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 skin. If so, or already draining, surgical drainage and local instillation of anti-tuberculous drug. Systemic treatment with anti-tuberculous drugs is ineffective
Osteitis/ Osteomyelitis	Inflammation of the bone with isolation of *Mycobacterium bovis* BCG strain.	Should be treatedwith anti-tuberculous regimens including isoniazid and rifampicin.
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.
Seizures	Occurrence of generalized convulsions that are not accompanied by focal neurological signs or symptoms. Febrile seizures: if temperature elevated >100.4 ^{O}F (rectal) Afebrile seizures: if temperature is normal	Self-limiting; supportive care; especially paracetamol and cooling if febrile; rarely anticonvulsants.
Sepsis	Acute onset of severe generalized illness due to bacterial infection and confirmed by positive blood culture (if possible). Needs to be reported as possible indicator of immunization error.	Critical to recognize and treat early. Urgent transfer to hospital for intravenous antibiotics and fluids.
Severe local reaction	Redness and/or swelling centred 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 hospitalisation.	Settles spontaneously within a few days to a week. Symptomatic treatment with analgesics. Antibiotics are inappropriate.
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 intravenous antibiotics andfluids.

Annex-3

Form-1

টিকাদান পরবর্তী বিরূপ প্রতিক্রিয়ার (AEFI) রিপোর্ট ফর্ম

শিশু/ মহিলার নাম: _____ ছেলে /মেয়ে(শিশুর ক্ষেত্রে) _____

জন্ম তারিখ: _____/_____/_____ (দিন / মাস / বছর) অথবা বয়স: _____

মাতার নাম: _____ পিতার নাম: _____

স্বামীর নাম (মহিলার ক্ষেত্রে) : _____ অবিভাবকের ফোন নং: _____

ঠিকানা: বাড়ি/জিআর নং_____ মহল্লা/গ্রাম_____ওয়ার্ড _____ ইউনিয়ন _____

উপজেলা/পৌরসভা/জোন:_____ জেলা/ সিটি করপোরেশন: _____

বিরূপ প্রতিক্রিয়ার ধরণ (√ চিহ্ন দিন):

১. ☐ টিকার স্থানে ফোঁড়া (abscess)
২. ☐ খুব জ্বর (১০১° ফা. এর বেশি)
৩. ☐ ইনজেকশনের জায়গায় মারাত্মক প্রতিক্রিয়া
৪. ☐ লালচে দানা/ফুসকুরি (rash)
৫. ☐ খিঁচুনি (convulsion)
৬. ☐ বিসিজি লিম্ফ এডেনাইটিস [গলা (Cervical) এবং/ অথবা বগলের (Axillary) গ্রন্থি ফুলে যাওয়া ও ব্যথা]
৭. ☐ অজ্ঞান হয়ে যাওয়া (unconsciousness)
৮. ☐ সাময়িক ভাবে মূর্ছা যাওয়া (Fainting)
৯. ☐ অন্যান্য (নির্দিষ্ট করে লিখুন) _____

প্রযোজ্য ক্ষেত্রে (√ চিহ্ন দিন/ লিখুন):

☐ হাসপাতালে ভর্তি : তারিখ _____ ☐ মৃত্যু: তারিখ _____

টিকাদান সংক্রান্ত তথ্য :

কোন টিকা দেয়ার পর বিরূপ প্রতিক্রিয়া শুরু হয়েছে বলে ধারণা করা হচ্ছে (√ চিহ্ন দিন/ লিখুন):

☐ বিসিজি ☐ পেন্টাভ্যালেন্ট ☐ ওপিভি ☐ পিসিভি ☐ এম আর ☐ হাম ২য় ডোজ ☐ টিটি ☐ অন্যান্য _____

টিকা গ্রহণের তারিখ: _____/_____/_____ (দিন / মাস / বছর)

প্রতিক্রিয়া শুরু হবার তারিখ: _____/_____/_____ (দিন / মাস / বছর)

টিকাদান কেন্দ্রের নাম : _____ মহল্লা/গ্রাম_____

ওয়ার্ড _____ ইউনিয়ন _____ উপজেলা/পৌরসভা/জোন:_____

জেলা/ সিটি করপোরেশন:_____

কোথা থেকে রিপোর্ট করা হয়েছে (√ চিহ্ন দিন):☐ মাঠ পর্যায় (Community) ☐ হাসপাতাল (Hospital)

রিপোর্টকারীর নাম: _____ স্বাক্ষর: _____

পদবী ও সংস্থা :_____ তারিখ: _____

(Translation of AEFI Report Form)

AEFI Report Form

Name of the Child/Women : ..... Male/female (for child).....

Date of Birth: ….. ..... ……(dd/mm/yy) or Age: ……Years

Name of Mother:……..Name of Father: .....

Name of Husband (if applicable): .....Gaurdian's phone no.....

Address: House/ GR No. .....……Mahalla/ Village:.....…...Ward.....….....…

Union.....….Upazila/Municipality/Zone.....District/CC.....…….....…..

Type of AEFI (√ mark)

1. ____Abscess at the injection site	6. ____BCG Lymphadenitis
2. ____High Temperature > 101° F	7. _____Unconsciousness
3. _____ Severe local reaction	8._____ Fainting
4._____ rash	9. _____Others (specify) _____
5. ____Convulsion	

Put √ mark where applicable and write date

☐ Hospitalized; date---------- ☐ Death: date ----------

Immunization Information:

Suspected vaccine for occurring AEFI (√ mark/write) BCG / Pentavalent / OPV / PCV / MR / Measles 2nd dose / TT / other (specify).....
Date of vaccine received:.....……(dd/mm/yy)
Date of onset of AEFI: .....…….....(dd/mm/yy)
Name and address of vaccination centre: ……..……..

AEFI is reported from: ☐ Community ☐ Health Facility

Name of Reporter:.....…Signature .....

Designation & Organization :.....Date.....

EXPANDED PROGRAMME ON IMMUNIZATION

AEFI Weekly Line Listing Form for Hospital/Upazila/Municipality/Zone

Annex-4

Form-2

Name of Facility: _____ Upazila/Municipality/Zone: _____ District/City Corporation: _____

Reporting Epidemiologic Week No: _____ Date from (Sunday) _____ *(dd/mm/yy)* to (Saturday)_____ *(dd/mm/yy)* No. of AEFI cases (if none, write "0"): ☐

Sl. #	Patient's Name	Father's and Mother's name / Husband name (if applicable)	Village/Mohalla Union/ Ward	Upazila/ Municipality/ Zone	District/CC	Sex (M/F)	Date of birth/age	Type of AEFI*	Date vaccine given	Date of AEFI onset	Suspected vaccine	Hospital Admission (Yes/ No)	Death (Yes/ No)	Case reported from (C/H)**

* Write any of the following: abscess, severe local reaction, rash, BCG lymphadenitis, encephalitis/encephalopathy, loss of consciousness, fainting, anaphylaxis, high fever, convulsion, , toxic shock syndrome, AFP and other (describe)

** If the case is reported from community write "C" and if the case is reported from Hospital write "H"

Prepared by: _____ *Name* _____ *Designation* _____ *Signature and Date*

Verified by Locel Surveillance Officer (LSO) : _____ *Name* _____ *Designation* _____ *Signature and Date*

Submitted by: _____ *Name* _____ *Designation* _____ *Signature and Date*

Your weekly report, including "0" reporting, must reach Civil Surgeon office or CHO office by the following Tuesday.

Annex-5

Form-3

EXPANDED PROGRAMME ON IMMUNIZATION

AEFI Weekly Compilation Form for District/ City Corporation

District/CC: _____ Reporting Epidemiologic Week No: ____ Date from (Sunday) _____ *(dd/mm/yy)* to (Saturday) _____ *(dd/mm/yy)*

No. of reporting sites: _____ No. reported: _____ No. reported in time: _____ No. of AEFI cases ((If none, write "0") : [ ]

Sl. #	Patient's Name	Father's and Mother's name / Husband name (if applicable)	Village/Mohalla Union/Ward	Upazila/ Municipality/ Zone	Sex (M/F)	Date of birth/age	Type of AEFI*	Date vaccine given	Date of AEFI onset	Suspected vaccine	Hospital Admission (Yes/No)	Death (Yes/ No)	Case reported from (C/ H)**

* Write any of the following: abscess, severe local reaction, rash, BCG lymphadenitis, encephalitis/encephalopathy, loss of consciousness, fainting, anaphylaxis, high fever, convulsion, toxic- shock syndrome, AFP and other (describe)

** If the case is reported from community write "C" and if the case is reported from hospital write "H"

Prepared by: _____ _____ _____ Verified by Local Surveillance Officer (LSO): _____ _____ _____

Name *Designation* *Signature and Date* *Name* *Designation* *Signature and Date*

Submitted by: _____ _____ _____

Name *Designation* *Signature and Date*

Your weekly report, including "0" reporting, must reach Surveillance Unit, EPI HQ, EPI Bhaban, Mohakhali, Dhaka, by the following Tuesday

Annex-6

AEFI CASE INVESTIGATION FORM

An AEFI case investigation should be initiated within 24 hours of notification.
This form to be completed by the AEFI Investigation Team

Investigation ID: BAN AEFI __ ___ __ ___	Date AEFI reported:
	Date investigation started:

Demographic data of the patient:

Name of the child/woman: _____ Date of Birth/Age: _____

Sex: ❑ Male ❑ Female

Name of Mother/Father/Husband: _____

Address: House/GR No. _____Para/Village: _____ Mahalla/Rural Ward: _____

Union/Urban Ward _____ Upazila/Mun/Zone: _____ District/CC: _____

Most Recent Immunization history:

Date and time of vaccination	Vaccine & dose number	Site of administration	Vaccination centre	Vaccinated by

Information about the vaccines and diluents administered to the patient:

Vaccines	Manufacturer	Lot no./batch no.	Expiry Date
Diluents			

Suspected vaccine which caused AEFI:

Describe the adverse event in detail:

H/O present illness:

Date of onset of AEFI: _____ Time of onset of AEFI: _____

Date of hospitalization: _____ Time of hospitalization: _____

Date of death: _____ Time of death: _____

Examination Findings:

Pulse	:	/min	Temp	:	°F
BP	:	mm of Hg	Heart Rate	:	/min
Resp. Rate	:	/min	Lungs (wheeze, creps, ronchi)	:	
Skin change	:		Size of skin lesion	:	cm
Cyanosis	:		Pupil (reaction to light)	:	
Kernig's sign	:		Neck stiffness	:	
Level of Consciousness	:		Lymph Node	:	
Jerks	:				
Cranial nerve abnormality	:				

Other Abnormal Signs (if any):

Treatment:

Provisional Diagnosis:

Outcome:

Additional information about the patient: (write yes or no, if yes specify)

Past H/O similar event	:
Reaction after previous vaccination	:
H/O allergy	:
Pre-existing illness/ disorder	:
Current medication (for other than AEFI)	:
H/O hospitalization in last 30 days with cause	:
Recent H/O trauma with date, time, site and mode	:
Family history of any disease or allergy	:

Community investigation:

No. of cases immunized with suspected vaccine in same session	:
No. of cases of same adverse events found in immunized children/women	:
No. of cases of same adverse events found in non-immunized population	:

EPI Management Practice (fill upthis section by asking and observing practice):
Write yes or no where applicable, if yes specify

EPI store :

Temp inside ILR (°C)	:
Temp of freezer (°C)	:
Correct procedure of storing vaccines, diluents and syringes followed	:
Any other object (other than EPI vaccines and diluents) in the ILR or freezer	:
Partially used reconstituted vaccines in the ILR	:
Unusable vaccines (expired, no label, VVM stage 3 & 4, frozen) in the ILR	:
Unusable diluents (expired, manufacturer not matched, cracked, dirty ampoule) in the store	:

Transportation:

Type of vaccine carrier used	:
Vaccine carrier packed properly	:
Vaccine carrier sent to the EPI site on the same day of vaccination	:
Vaccine carrier returned from the EPI site on the same day of vaccination	:
Conditioned icep-ack used	:

Reconstitution:

Correct procedure followed	:
Correct amount of diluent used	:
Used separate syringe for each vial	:
Matching diluent used	:

Injection technique:

Correct dose and route	:
Non-touch technique followed	:
Vial shaked before each injection	:
Contraindication assessed	:
How many AEFI reported from vaccination sites of the same worker in the last 30 days?	:
Training on EPI received by the vaccinator: (specify the last training including date)	:

Laboratory investigation(s) conducted?: Yes☐ No☐ If yes, mention the tests (attach copy of the reports)

Assessment:

Conclusion about cause of AEFI: tick categories, rank if more than one cause:				
Immunization error	**Vaccine product - related reaction**	**Vaccine quality defect - related reaction**	**Immunization anxiety - related reaction**	**Coincidental**
❑ Non-sterile injection ❑ Vaccine prepared incorrectly ❑ Faulty administration technique/site ❑ Faulty vaccine transportation ❑ Faulty vaccine storage ❑ Other:	❑	❑	❑	❑
Reason(s) for conclusion:				

Corrective Actions:

Recommendations:

Additional Notes (attach additional paper):

Investigation Team Details:

1. Name: _____ Designation: _____ Signature: _____
2. Name: _____ Designation: _____ Signature: _____
3. Name: _____ Designation: _____ Signature: _____
4. Name: _____ Designation: _____ Signature: _____
5. Name: _____ Designation: _____ Signature: _____
6. Name: _____ Designation: _____ Signature: _____
7. Name: _____ Designation: _____ Signature: _____

Date Investigation Completed: ____/____/_____

Notes:

1) Investigation team will submit the filled in AEFI investigation form to UH&FPO/ MMO/AHO/ZMO. Attach copy of all medical records e.g. prescription, treatment sheet (if patient is hospitalised), laboratory investigation reports (if any), death certificate & autopsy report (in case of death, if any) etc. with the investigation form. Copy of the AEFI report form should also be attached with the investigation report.
2) UH&FPO/MMO/AHO/ZMO will send a copy of the investigation report with all attachment to Civil Surgeon/CHO as soon as it is completed and not later then a week after completion of investigation.
3) CS/CHO will send a copy of the investigation form with all attachment to EPI-HQ within a week.
4) In case of cluster, use separate investigation form for each of the case.

Recognition and Management of Anaphylaxis

Anaphylaxis is a very rare, unexpected, and occasionally fatal allergic reaction. When anaphylaxis does occur, the patient must be diagnosed properly, treated and managed urgently by trained staff and transferred to a hospital setting (if not already in a hospital setting).

There is a high risk that health workers who lack training will misdiagnose faints (vasovagal syncope) and dizziness following immunization for the onset of anaphylaxis. Most episodes of feeling ill or faint, or actual fainting that occur immediately after immunization are not due to the onset of anaphylaxis. Administration of adrenaline in faints is not only contraindicated, it is very dangerous.

The vaccinators, paramedics and physicians should be adequately trained so that they are able to distinguish anaphylaxis from fainting, anxiety and breath-holding spells, which are common benign reactions.

During fainting, the individual suddenly becomes pale, loses consciousness and collapses to the ground. Fainting is sometimes accompanied by brief clonic seizure activity (i.e., rhythmic jerking of the limbs), but this requires no specific treatment or investigation. Fainting is relatively common after immunization of adults and adolescents, but very rare in young children. It is managed by simply placing the patient in a recumbent position. Recovery of consciousness occurs within a minute or two, but patients may take some more time to recover fully.

An anxiety spell can lead to pale, fearful appearance and symptoms of hyperventilation (light-headed, dizziness, tingling in the hands and around the mouth). Breath holding occurs in young children and will lead to facial flushing and cyanosis. It can end in unconsciousness, during which breathing resumes.

Recognition of Anaphylaxis

Anaphylaxis is a severe reaction of rapid onset (usually 5-30 minutes after the injection) characterized by circulatory collapse. The early signs of anaphylaxis are generalized erythema and urticaria with upper and/or lower respiratory tract obstruction. In more severe cases, limpness, pallor, loss of consciousness and hypotension become evident in addition. Vaccinators should be able to recognize the signs and symptoms of anaphylaxis in the box below.

Clinical Progression	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 swelling in part of the body e.g. faces or mouth. Flushed, itching skin, nasal congestion, sneezing, tears
↓	Hoarseness, nausea, vomiting
Late, life-threatening symptoms	Swelling in the throat, difficulty in breathing, abdominal pain wheezing, noisy, difficult breathing, collapse, low blood pressure, irregular weak pulse

In general, the more severe the reaction, the more rapid the onset. Most life-threatening reactions begin within 10 minutes of immunization. Keep the recipient under observation for at least 30 minutes after 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.

Distinguishing Anaphylaxis From a Faint (Vasovagal Reaction)

	Faint	Anaphylaxis
Onset	Usually at the time or soon after injection	Usually some delay between 5-30 minutes after injection
System		
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 LOC, good response once prone	LOC, little response once prone

LOC= loss of consciousness

Conditions that may be Mistaken for Anaphylaxis Post Immunization

Diagnosis	Onset: symptoms and signs
Vasovagal event	Symptoms are usually immediate (< 5minutes) and commence during the injection process. No skin rash, bradycardia not tachycardia, no respiratory involvement, spontaneous resolution when prone.
Hypotonic hyporesponsive episode	Onset 2-6 hours post-immunization, sudden pallor, hypotonia and unresponsiveness, usually in an infant. No skin rash, respiratory or cardiovascular compromise
Seizure	Onset usually at least 6-8 hours post-vaccinationwith a killed vaccine. Sudden unresponsivenessusually with tonic-clonic movement, usually febrile,no cardiovascular compromise, no respiratorycompromise unless apnea or aspiration.
Aspiration of oral vaccine (e.g.OPV or rotaviral vaccine)	Immediate respiratory symptoms (cough, gagging,stridor or wheeze) during administration, usually ininfant. No skin rash or cardiovascular compromise.
Somatic conversion symptoms	Immediate or delayed respiratory symptoms, syncope, neurological symptoms without objective respiratory or neurological signs.
Severe coincidental diseases	Usually due to coincidental – unrecognized congenital heart disease or occult infections. May have respiratory or cardiovascular compromise but there are usually symptoms, signs or investigations to indicate alternate cause
Immunization-error related	Immediate toxic drug reaction with symptoms and signs due to drug toxicity. Reported with immunization errors related which has resulted from inadvertent administration of a muscle relaxant or insulin.

Case management of anaphylaxis:

Once the diagnosis is made, consider the patient as being in a potentially fatal condition, regardless of severity of the current symptoms.

Vaccinators will not be allowed to give adrenaline. They will transfer the case to the nearest health facility (USC/H&FWC/UHC/District Hospital) immediately (if not already in a hospital setting).

Role of Adrenaline:

Adrenaline (epinephrine) stimulates the heart and reverses spasm in the lung passages, and reduces oedema 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.

Steps in management:

- Lay the patient flat on back and make him/her relaxed
- Keep the airway clear
- Keep the legs raised a little more than the head
- Start an I/V drip immediately
- Measure the breathing, observe the pulse and heart beat
- If breathing stops, start mouth-to-mouth respiration immediately

If heart stops beating:

- Cardio-pulmonary resuscitation - push forcefully 72 times per minutes above the 5th rib on left chest of the patient with base of your palm and start mouth-to-mouth respiration with every 4th push; if possible, use Aumbubag
- Mix 1 ampoule injection Adrenaline 1:1,000 into 9 ml normal saline or distilled water and give intramuscularly up to a maximum of 500 microgram (5 ml) according to the age group (guideline below) at a dose of 0.1ml/kg body weight:
  - 1 year (10kg) give 1 ml
  - 3 years (15kg) give 1.5 ml
  - 5 years (20kg) give 2 ml
  - 8 years (25kg) give 2.5 ml
  - >8 years (>25kg) give 3 ml
- Give injection hydrocortisone I/V:
  - 100 mg for <1 year child
  - 200 mg for 1 to <3 years child
  - 300 mg for 3 to <7 years child
  - 400 mg for 7 to <9 years child
  - 500 mg for 9 years and above

Check the blood pressure: if systolic pressure is less than 80 mm of Hg, follow these steps:

- Injection Adrenaline 1:1000 (mix 1 ampoule Inj. Adrenaline with 9 ml normal saline) give 0.1 ml per kg body weight I/V
- Repeat same process in every 10-20 minutes interval until the patient fully recovers
- Give normal saline or Ringer's Lactate solution 20 ml/kg body weight I/V drip till the patient's pulse can be felt
- Report the occurrence immediately to appropriate authority over telephone and later by reporting form.

World Health Organization
Country Office for Bangladesh

unicef