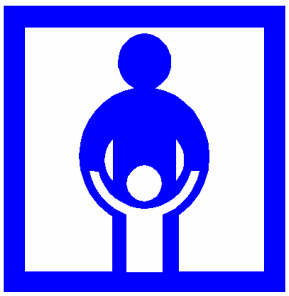

National Guideline for Surveillance of Adverse Events Following Immunization (AEFI)

Government of the Islamic Republic of Pakistan

Expanded Programme on Immunization

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PREFACE

By virtue of the immunization programme vaccine-preventable infectious diseases are declining day by day. However, international experience has shown that as vaccine-preventable diseases decline, people become increasingly concerned about the adverse events following immunization (AEFI). These adverse events are due to vaccine itself or programmatic error and some are at all not related to vaccination. Allegations regarding vaccine-related adverse events that are not rapidly and effectively dealt with can undermine confidence in a vaccine and the immunization programme and ultimately have negative consequences for immunization coverage and disease incidence.

Surveillance of AEFIs is an effective means of monitoring immunization safety and contributes to the credibility of the immunization programme. Through an effective AEFI surveillance system, cases of AEFI could be detected timely and appropriate and quick response to adverse events could be taken to lessen the negative impact on health of the individuals and maintain public confidence in the immunization programme.

This document provides a guideline on detection, reporting and investigating AEFIs, correcting and preventing programme errors and properly responding to parents/ community concerns following an AEFI.

I sincerely hope that managers at all levels and other concerned personnel will carefully read this document and follow the guideline herein. I am thankful to my colleagues at Federal EPI for their role in development of this guideline. I am also grateful to World Health Organization for their technical support in preparing and publishing this guideline. Finally I convey my sincere thanks to all who are engaged in providing immunization services to save the life of children from vaccine preventable diseases.

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ABBREVIATIONS AND ACRONYMS

AEFI	Adverse Event Following Immunization
AFP	Acute Flaccid Paralysis
BCG	Bacillus Calmette-Guerin
CNS	Central Nervous System
DT	Diphtheria-Tetanus
DPT	Diphtheria- Pertussis -Tetanus
DSC	District Surveillance Coordinator
DSV	District Superintendent Vaccination
EDO (H)	Executive District Officer (Health)
EPI	Expanded Programme on Immunization
HIV	Human Immune- Deficiency Virus
ILR	Ice-Lined Refrigerator
LHS	Lady Health Supervisor
LHW	Lady Health Worker
MO	Medical Officer
NGO	Non Government Organization
NRA	National Regularity Authority
OPV	Oral Polio Vaccine
SO	Surveillance Officer
TT	Tetanus Toxoid
UC	Union Council
VAPP	Vaccine Associated Paralytic Poliomyelitis
VPD	Vaccine-preventable disease
VVM	Vaccine Vial Monitor
WHO	World Health Organization

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Introduction

The goal of immunization is to protect children and women of childbearing age from vaccine-preventable diseases. Although modern vaccines are safe but no vaccine is entirely without risk. Some people experience events after immunization ranging from mild side effects to rare serious illnesses. In some cases these reactions are caused by the inherent property of vaccine; in others, they are caused by an error in transportation, storage, preparation and administration of vaccine; and in majority of cases, there is no relationship.

Whatever the cause, when an adverse event following an immunization upsets people to the extent that they refuse further immunizations for their children, the children are much more likely to get a vaccine-preventable disease, become seriously ill, disabled, and even die. To increase immunization acceptance and improve the quality of services, surveillance of AEFIs must become an integral part of national immunization programme.

EPI is one of the most important public health interventions in Pakistan. The program targets approximately 5.5 million children and over 6 million pregnant women every year with approximately 50 million injections for their vaccination. With addition of new vaccines in the programme the number of injections given annually is taking a sharp rise. As vaccine use increases 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 in AEFI surveillance activities. It provides information on the types of AEFI, detection, reporting and investigation of AEFI, corrective actions to be taken to prevent further occurrence of programme errors and how to evaluate an AEFI surveillance system. It also describes the communication strategy on immunization safety for the public and media.

AEFI Surveillance

An adverse event following immunization (AEFI) is defined as a medical incident that takes place after an immunization, causes concern, and is believed to be caused by immunization.

AEFI surveillance is an effective means of monitoring immunization safety and contributes to the credibility and quality of the national immunization programme.

Goals

The goal of AEFI surveillance is to:

a) Minimize the negative impact of AEFI on public health

b) Ensure the quality of vaccines used for immunization in the country

c) Ensure the quality of immunization services in the country

Objectives

The objective of AEFI surveillance is to:

i. Timely detect and report all AEFI
ii. Identify unusual high rates of AEFI with specific vaccine lots and brands
iii. Promptly address programmatic errors through implementation of corrective measures
iv. Ensure that coincidental events are not falsely blamed on immunization
v. Maintain confidence in the immunization programme by properly responding to concerns
vi. Estimates AEFI rates in the population compared with local and global data

Types of AEFI

AEFI can be 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 Events Following Immunization

Types of AEFI	Definition	Example
1. Vaccine Reaction	An event caused or precipitated by the vaccine when given correctly. This is due to the inherent properties of the vaccine.	Anaphylaxis
2. Programme Error	An event caused by an error in vaccine storage, transportation, preparation or administration.	Bacterial abscess due to un-sterile injection
3. Coincidental	An event that occurs after immunization but is not caused by the vaccine. This is due to a chance association.	Pneumonia after administration of Oral Polio Vaccine
4. Injection Reaction	Event from anxiety about, or pain from the injection itself rather than the vaccine.	Fainting spell after vaccination
5. Unknown	Event's cause cannot be determined.	Child dies within 24 hours of vaccination

VACCINE REACTION

Vaccine reactions can be classified into **common, minor reactions and rare, more serious reactions.** Table-2 and Table-3 provide a summary of frequency of common minor and rare serious reactions with an onset interval and a rate of occurrence.
Common, minor reactions are caused by immune system response of recipient to vaccine. Some of vaccine components can lead to reactions as well (e.g. aluminium adjuvants, stabilizers and preservatives).

Local reactions including pain, swelling and redness at injection site can be expected in about 10% of vaccination. This is even more common with Pentavalent injection. These reactions usually last a few days at the most and can be treated symptomatically with paracetamol. BCG causes a specific local reaction that starts as a papule after two or more weeks of vaccination and then becomes ulcerated leaving a scar. Measles vaccine may cause mild symptoms such as fever, rash and/or conjunctivitis, which are typically seen in a measles infection.

Mild fever, irritability, malaise and loss of appetite frequently occur with certain vaccines, which are usually self-limiting. However such symptoms are usually mild, but can be quite serious in severely immuno-compromised children.

It should be mentioned that *these minor reactions are common and usually expected, which don't need to be reported as AEFI***.**

Table-2: Summary of common minor vaccine reactions with management

Vaccine	Local reaction (pain, swelling, redness)	Fever	Irritability, malaise and non-specific symptoms
BCG	Common	Rare	Rare
Hepatitis B	Children up to 5%	1-6%	Rare
Measles	~10%	5-15%	5% rash
OPV	None	Less than 1%	Less than 1% *
TT	~10% ¥	~10%	~ 25%
Pentavalent†	Up to 50%	Up to 50%	Up to 60%
Pneumococcal conjugate vaccine	Up to 50%	~5%	Very common
Management	- Cold cloth at injection site - Paracetamol$^{\alpha}$	- Give extra fluids - Wear cool clothing - Tepid sponge or bath - Paracetamol	Symptomatic

* Diarrhoea, Headache, and/or muscle pains

¥ Rate of local reactions likely to increase with subsequent doses, up to 50 to 85%

† With whole cell pertusis vaccine. Acellular pertussis vaccines rate are lower.

α Paracetamol dose: up to 15 mg/kg every 4 hours, maximum of 4 doses in 24 hours

Serious vaccine reactions may occur in rare cases. Some of these do not lead to long-term problems (e.g. seizures, hypotonic hypo responsive episodes). Anaphylaxis, while potentially fatal, is treatable without leaving any long-term effects.

However, there are few reactions with long-term consequences (e.g. VAPP, BCG osteomyelitis etc.) Case definition and treatment of these serious vaccine reactions are in Appendix- 1.
Serious vaccine reactions included in the following table need to be reported as AEFI

Table-3: Summary of rare serious vaccine reactions, onset interval and rate

Vaccine	Reaction	Onset interval	Number of events per million doses
BCG	- Suppurative lymphadenitis - BCG osteitis/osteomyelitis - Disseminated BCG infection	2-6 months 1-12 months 1-12 months	100-1,000 1-700 2
Hepatitis-B	- Anaphylaxis	0-1 hour	1-2
Measles *	- Febrile seizures - Thrombocytopenia (low platelets) - Anaphylaxis	5-12 days 15-35 days 0-1hour	333 33 ~1
OPV	- Vaccine associated paralytic poliomyelitis (VAPP)	4-30 days	0.76-1.3 (1st dose) 0.17 (subsequent doses)
TT	- Brachial neuritis - Anaphylaxis - Sterile abscess	2-28 days 0-1hour 1-6 weeks	5-10 1-6 6-10
Pentavalent	- Persistent (>3hours) inconsolable screaming - Seizures ^ - Hypotonic hypo responsive episode (HHE) - Anaphylaxis/shock - Encephalopathy	0-24 hours 0-3 days 0-24 hours 0-1hour 0-3 days	1,000-60,000 570 570 20 0-1
Pneumococcal Vaccine	- Allergic reaction (dermatitis)		1 in 1000

* Approximately 85% of those receiving a second dose are already immune. Reactions do not occur if the child/woman is already immune. This is not the case for anaphylaxis, where this type of reaction is more likely on the second or subsequent doses.

^ Seizures are most likely febrile in origin, and rate depends on past history, family history and age, with much lower risk in children under the age of 4 months.

PROGRAMME ERROR

Programme errors are the most commonly reported adverse events. These occur as a result of inappropriate storage, transportation, reconstitution, preparation 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 programme errors and types of AEFI.

Table 4: Programme errors leading to adverse events

Programme Errors	Adverse Event
Non-sterile injection: ▪ Contaminated vaccine or diluents ▪ Use of reconstituted vaccine after 6 hours ▪ Improperly sterilized syringe or needle ▪ Reuse of disposable syringe or needle	Infection e.g. local suppuration at injection site, abscess, cellulitis, systemic infection, sepsis, toxic shock syndrome, transmission of blood borne virus (HIV, hepatitis-B or hepatitis-C)
Vaccine reconstituted incorrectly: ▪ Vaccine reconstituted with wrong diluents or inappropriate amount ▪ Drugs substituted for vaccine or diluent (e.g. muscle relaxant, insulin)	Local reaction or abscess Effects of drug
Vaccine injected in wrong route/site: ▪ Subcutaneous instead of intra-dermal for BCG ▪ Too superficial for toxoid vaccine (DPT, DT, TT) ▪ Administration in the buttocks.	Local reaction or injection site abscess Sciatic nerve damage
Vaccine transported/stored incorrectly	Increased local reaction from frozen vaccine (and ineffective vaccine)
Contraindications ignored: ▪ DPT given ignoring convulsion history with previous dose	More severe convulsion

COINCIDENTAL EVENTS

Children are usually given vaccines at an age when they are susceptible to many diseases. So when a medical event occurs after vaccination, it is usually believed that the event occurred due to vaccination. In fact this event is not linked with vaccination except in time so it is termed as coincidental. These events occur more frequently during mass immunization campaigns when large numbers of individuals are vaccinated in a short period of time.

INJECTION REACTION

Children or women might react out of fear or pain to an injection of any kind. This reaction is not related with vaccine itself. Examples of injection reactions include fainting, light-headedness, dizziness, tingling around the mouth and in the hands; occasionally breathe holding in younger children may lead to unconsciousness.

UNKNOWN

Some events may occur after vaccination where no cause can be determined. These will be classified as unknown AEFI.

Reporting AEFI

Followings are the reportable AEFIs:

i) Severe local reaction
ii) Injection site abscess
iii) BCG lymphadenitis
iv) High fever (more than 101^0 F) within 48 hours
v) Seizures within 14 days
vi) Encephalitis/encephalopathy within 14 days
vii) Loss of consciousness / shock-like state within 48 hours
viii) Anaphylaxis within 1 hour
ix) Toxic - shock syndrome
x) Acute flaccid paralysis (occurs extremely rare with OPV)
xi) Hospitalisation believed to be related to vaccination
xii) Death believed to be related to vaccination
xiii) Other severe or unusual health events that community thinks was caused by the vaccine

If the AEFI does not occur within the time frame specified, but there is a suspicion that the event may be related to vaccine, then these should also be reported. If the adverse event occurs outside of this time frame, the event is less likely to be due to vaccination. Case definitions for these and other vaccine reactions are reflected in Appendix-1.

AEFI REPORTING SYSTEM (WHEN, WHOM AND HOW TO REPORT)

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 individual in the community.

For AEFI, like other VPD surveillance, the District Surveillance Coordinator (DSC) or district epidemiologist would be the focal person. However, EDO (H) may designate any other competent official in his office for the purpose.

Table 5: List of Surveillance Focal Persons at different level

Locations	Surveillance Focal Person (SFP)
Overall responsibility in the district	EDO (Health)
EDO (Health) office	District Surveillance Coordinator (DSC)
Health Facilities	Facility In-charge
Union Council (UC)	Facility In-charge of the health facility in the respective UC

Community

Field workers (Vaccinator, LHS, LHW, NGO field worker) whoever detect or get information of an AEFI from the community should report to the Surveillance Focal Person (SFP) of their UC within 3 days using AEFI report form (Appendix-2). The SFP will send the report(s) to EDO (H) office along with VPD surveillance report on weekly basis.

Health Facility

Service providers in a health facility detecting AEFI should report to the facility in-charge within 24 hours using AEFI report form (Appendix-2). The health facility in-charge will submit these reports to the EDO (H) office by following Tuesday of every epidemiological week along with VPD surveillance report (Form B).

If the health facility is not a designated surveillance unit (e.g. dispensary, private clinic etc.) the facility in-charge would send the report(s) to the Surveillance Focal Person of that UC. SFP of the UC would in turn send those with his own report to the EDO (H) office.

District

The EDO (H) office will compile all AEFIs in AEFI district compilation form (Appendix-3) to submit to the Provincial EPI office. The district report should reach the provincial EPI office by the last working day of the same week.

In case of death, hospitalisation, cluster or any event causing significant parental/community concern the AEFI must be reported immediately to EDO (Health). Upon confirmation of the report about such event(s) the EDO (Health) should

immediately notify that to the Federal EPI through Provincial EPI office. The EDO (H) office would also notify an investigation team to investigate such AEFI at the earliest. Composition of the investigation team and their functions are described later in this guidebook.

Sometimes news of a report will come directly from the parents or the community. Such a report needs to be considered, and the reporter should be advised that it will be followed up. Follow-up would begin with the local health worker in validation of the case report. If there is a high level of community concern about an event, conducting an investigation is advisable.
During line listing if any cluster is identified which might be due to programme error EDO (H) will initiate investigation and take necessary corrective measures to prevent further occurrence of similar event.

Province

Province EPI office would designate one of its officers as AEFI surveillance focal person who would be preferably the provincial surveillance coordinator. He would be responsible for monitoring and follow-up of timeliness and completeness of weekly district reports, analyses of the report and give appropriate feedback to the district.

Provincial EPI office to compile reports received from districts and send the compiled report along with copy of the completed AEFI investigation forms (if any) to the Federal EPI Cell by next Tuesday.

Upon notification of any serious AEFI from any district, Provincial EPI office would immediately notify that to the Federal EPI and National Regulatory Authority (NRA) within 24 hours. When necessary, the provincial EPI office would provide or would request WHO to provide appropriate technical assistance to the districts for proper investigation of any serious reported AEFI e.g. death.

The Provincial EPI Cell should assist district in media handling for the AEFI when necessary. The provincial EPI office would also establish a Provincial AEFI Review Committee of which assistance might be sought for when required. The functions of the Provincial AEFI Review Committee are described in section 11.

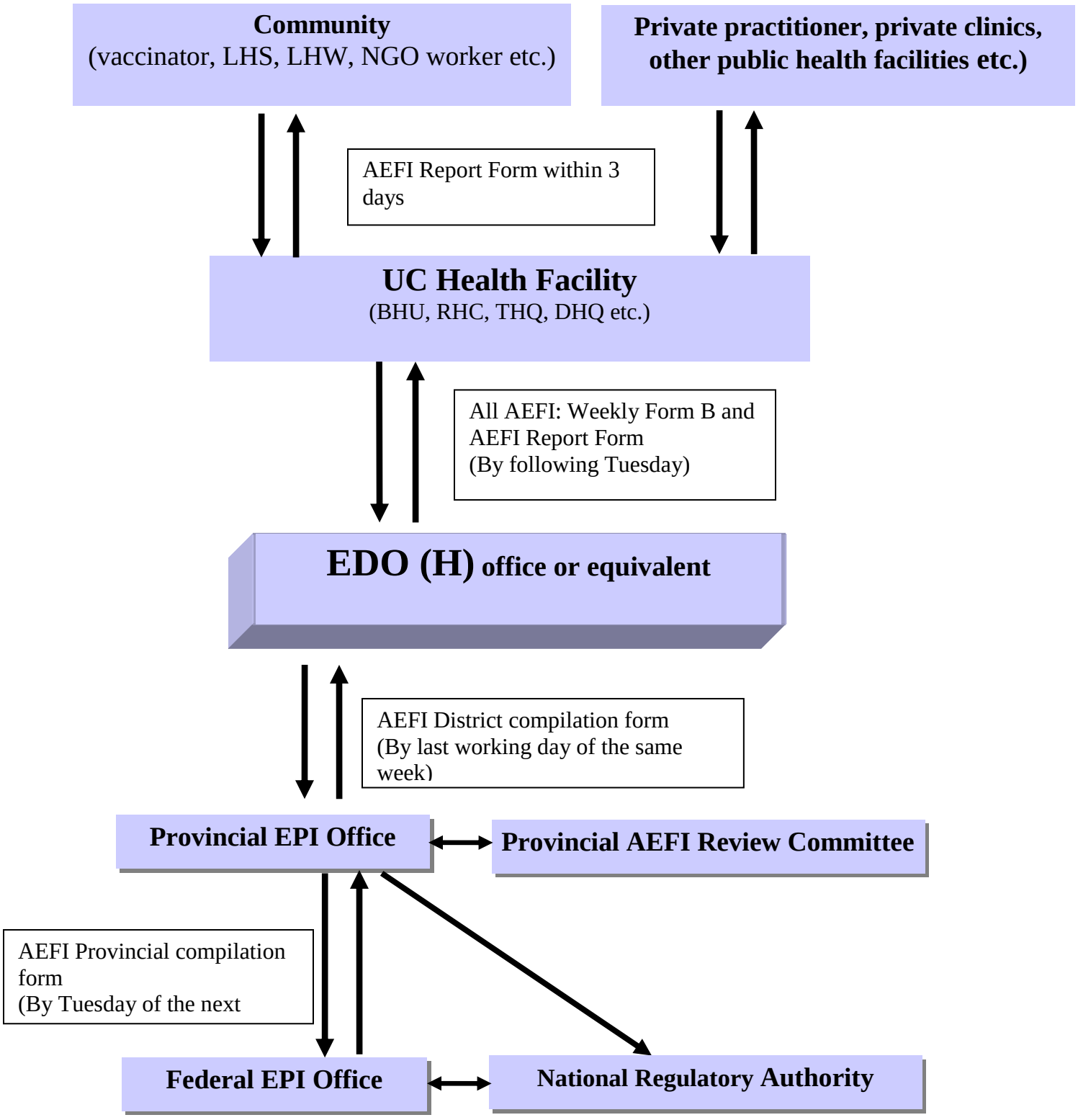
If any cluster is identified during compilation at provincial level then provincial EPI office will inform respective district to initiate an investigation.

Federal EPI

Federal EPI office would designate a focal person for AEFI Surveillance who would review and analyze all reported AEFI data submitted by the provincial EPI Cell and provide appropriate feedback. Federal EPI will compile AEFI reports on monthly basis and provide one copy to the National Regularity Authority (NRA).

In case of death, hospitalisation, cluster or significant parental/community concern, Federal EPI will immediately notify the NRA and would take necessary steps to provide appropriate technical assistance in coordination with partner agencies (e.g. WHO, UNICEF) to the district in investigating the case.

Flow Chart of AEFI Reporting



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 EDO (Health) 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

EDO (Health) should ensure that there is an ample supply of reporting and investigation forms in their institutions in order to facilitate timely reporting.

Investigation of AEFI

PURPOSE OF AN INVESTIGATION

The ultimate goal of an investigation is to determine whether the vaccine or immunization process is responsible for the reported adverse event(s) or to find another reason and correct it if possible and reassure the public. The purposes of investigating AEFI are:

i. To confirm diagnosis of a reported AEFI and determine the outcome
ii. To investigate link between the vaccine administered and the AEFI
iii. To determine contribution of the operational aspects of the programme to the reported AEFI
iv. To determine whether a reported event was isolated or part of a cluster
v. To determine cause of the AEFI so as to provide the best intervention/ medical care and take any further action deemed necessary
vi. To determine whether un-immunized persons are experiencing the same medical event(s)

If the cause is determined to be a programme 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.

WHAT TO BE INVESTIGATED

The following AEFIs must be investigated:

- Any death attributed to vaccine

- Any AEFI that lead to hospitalisation
- Any clusters of reportable AEFI
- Any AEFI causing significant parental or community concern

The above 4 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 AEFIs of same type, which has occurred in a Union Council or equivalent administrative area within a period of a week

OR

Two or more clients with same type of AEFI, vaccinated in the same vaccination centre, within a period of a week.

WHEN SHOULD BE INVESTIGATED

When an investigation is deemed necessary, it is important to initiate it immediately so that the cause could be determined quickly and additional cases prevented (where possible), in order to avoid compromising the programme as a result of ongoing community concern.

AEFIs those have resulted in death, hospitalisation, widespread community concern, or cluster, investigation procedure should start as soon as possible, ideally within 24 hours of notification.

WHO SHOULD INVESTIGATE

The EDO (H) will notify the AEFI investigation team with following members:

i. District Surveillance Coordinator and/or District EPI Focal Person
ii. Local Health Facility In-charge
iii. A consultant physician or surgeon or paediatrician (as applicable according to type of AEFI)
iv. District Superintendent Vaccination or Tehsil/Taluka Superintendent Vaccination
v. Local WHO Surveillance Officer
vi. Any other relevant person considered important

One member should be assigned as the investigation team leader. An individual with adequate experience for media handling should be designated as the spokes person in the EDO (H) office.

A representative from NRA should join the investigation team. Representatives from Provincial/Federal EPI office, experts from partner agencies may also join the investigation process.

HOW TO INVESTIGATE

For all AEFI investigation, the AEFI case investigation form (Appendix – 4) to be used. Beside the information required in the form any other important documents like copy of the medical record, vaccination card and photographs are to be attached with the report.

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/procedure to avoid such errors instead of putting blame or punish any individual. 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.
- Vaccinator, LHW, Other staff involved in vaccination: Vaccinator who gave vaccine during the suspected session should be interviewed. Other co-worker and supervisor of the vaccinator should also be asked about the vaccination practice problems in the past (if any).
- 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.

KEY DATA TO BE COLLECTED

A. Data for each patient

- demographic data about the patient which includes name, date of birth, age, sex, complete address
- history of present illness - symptoms and when it appeared and its duration, treatment, outcome, diagnosis
- history of past illness e.g. any reaction to previous doses, drug or other allergies, family history
- pre-existing disorders, current medications
- immunization history- vaccine, number of doses received, date and place of recent vaccination, site of administration (if possible, a copy of the vaccination card)

- laboratory results about blood, stool, or other samples, if appropriate and available
- full autopsy report with toxicological screening and histopathological analysis in case of death

B. Data about the vaccine(s) and diluents administered to the patient

- vaccine name
- lot number of vaccine and diluent
- expiry date of vaccine and diluent
- manufacturer of vaccine and diluent
- vaccine and diluent storage
- identify where the vaccine(s) were distributed

C. Programme related data

- common practices followed for
  - storage of vaccines and diluents (note if similar containers stored with vaccines and diluents which might cause confusion)
  - transportation
  - reconstitution
  - vaccination procedure
  - disposal of vaccine vials
- timing of EPI session
- availability of AD and disposable syringes
- training received by the vaccinator and supervisor

D. Data on other people of AEFI reporting area

- number of clients who received vaccination from the same lot or in the same vaccination session, or both, and number of them who fell ill and their symptoms. (Complete a separate AEFI case investigation form for each AEFI case)
- number of unvaccinated people who fell ill with similar symptoms

FORMULATING WORKING HYPOTHESIS

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

i. Programme related
   - vaccine transportation or storage error
   - reconstitution error
   - un-sterile practice
   - incorrect administration technique

ii. Vaccine Reaction

- known vaccine reaction
- vaccine manufacturer error

iii. Coincidental

iv. Injection reaction

v. Unknown

The working hypothesis may change during the course of investigation. The focus of investigation is to confirm the working hypothesis. No action should be taken based on the hypothesis, until it is confirmed with reasonable certainty.

COLLECT AND DISPATCH SPECIMEN

Once a working hypothesis is arrived at, 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.

NOTES ON SPECIMEN TAKING

A. From the patient

- blood, urine, CSF, swab from wound/abscess site as appropriate
- autopsy specimens (if death occurred) as above, plus tissue samples for toxicological screening (liver, brain, kidney and stomach content or section of stomach) and tissue samples for histopathological screening (brain with meninges, lung, adrenal glands as well as any other organ in which pathology is suspected)

It is difficult to generalize what specimens will be required in a given situation. It will depend much on symptoms and signs of the patient and clinical decision made by doctor in charge of the case.

B. The vaccine, diluents if applicable, in use at the vaccination centre

- if possible collect the actual opened vials of vaccine and diluents used to vaccinate the patient who suffered from AEFI
- collect some unopened vials of the same lot of vaccine and diluents from the same manufacturer from local EPI store as well as the district store

C. Syringes

- It will not be possible to locate the syringe by which the patient was vaccinated
- Collect a sample of unopened syringe

The vaccine and diluents may be tested for sterility and chemical composition, vaccine for adjuvant (e.g. aluminium content) and the syringes for sterility. Testing should be requested on a clear suspicion and not as routine, and never before the working hypothesis has been formulated.

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 in cold chain to the laboratory for toxicological screening and with formalin for histopathological analysis
- 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

INVESTIGATING AEFI CLUSTER

A cluster of similar adverse events is likely to arise from programme errors. If the event also occurred in un-immunized people, it may be coincidental. It is therefore important to identify if un-immunized people also developed similar symptoms around the same time.

Investigation of a cluster requires:

- Identifying all people in the area who have illness that meets the case definition
- Obtaining immunization histories (when, where and which vaccines were given)
- Identifying any common exposures among the cases

ASSESSING THE CAUSE OF AEFI

Until investigation is complete, a "working hypothesis" is all that can be formulated. Later it will be possible to analyse data, making a final diagnosis and identifying the cause. Causes of AEFI are classified in five ways: programme error, vaccine reaction, coincidental, injection reaction or unknown.

A. Programme error

Programme errors are the most likely causes of adverse events; therefore first step should be to examine data for evidence of any error in storage, handling, or administration of vaccines. Sometimes the diagnosis itself will tell that the cause is programme-related. For example, cases of toxic- shock syndrome after measles vaccination followed by sepsis have been found to be caused by programme errors. Attention will then be to find out what the particular error was so that corrective actions can be taken.
If the cause of an AEFI is not initially clear, evidence of the following errors may help in identification. Analysts should look for the errors listed below in every situation:

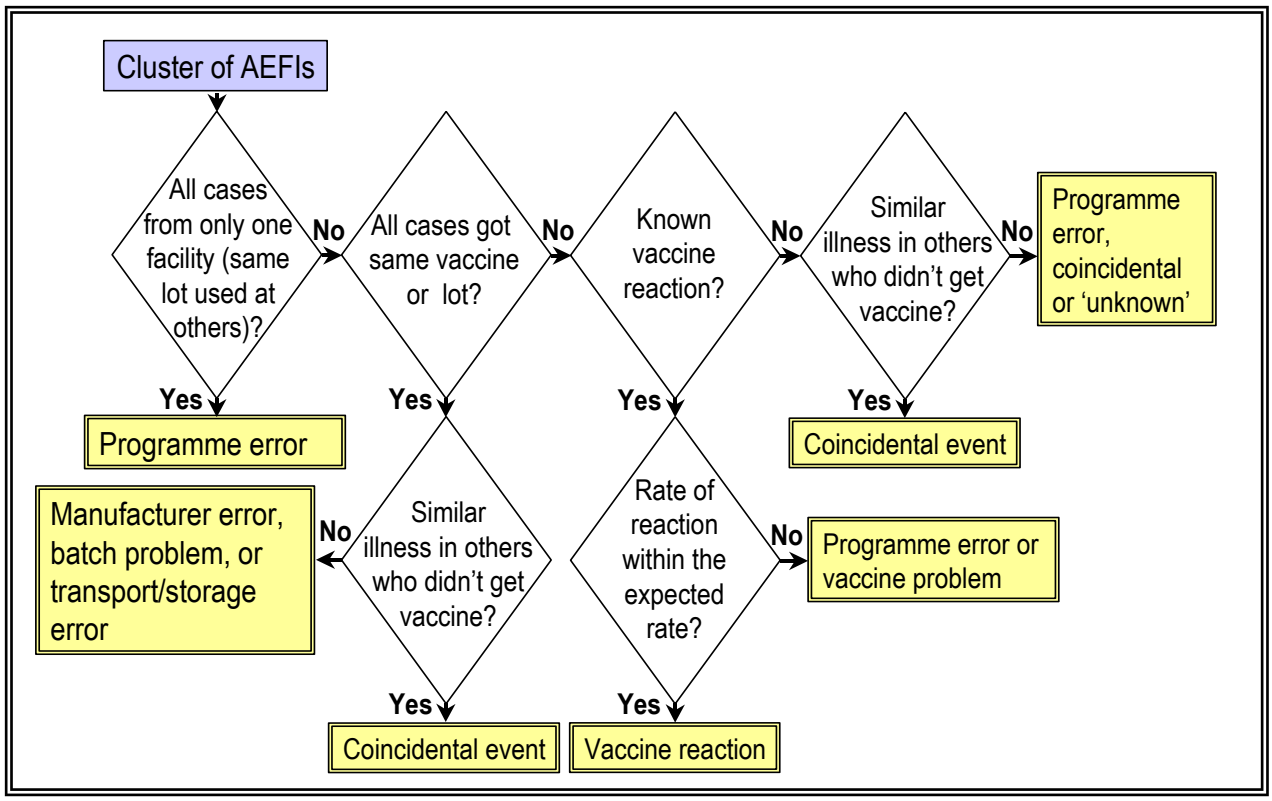
- Too much vaccine given in one dose
- Vaccine injected in wrong place or by wrong route
- Syringes are contaminated
- Vaccine or diluents contaminated

- Vaccine reconstituted with incorrect diluents (count remaining unopened vials of vaccine and check whether there is matching quantity of the diluents from the same manufacturer)
- Separate syringes not used for each vial of freeze dried vaccine for reconstitution
- Wrong amount of diluents used
- Drugs substituted for vaccine or diluents
- Vaccine and diluent stored incorrectly
- Vaccine or diluents was expired (check expiry date of same batch number)
- Contraindications ignored, e.g. when a child who has had a severe reaction after a previous dose of DPT is immunized with the same vaccine
- Reconstituted vaccines kept for more than 6 hours
- Vaccine not discarded at the end of an immunization session and used at a subsequent one

Identifying cause of a cluster

If all cases received vaccines from the same health worker/facility and there are no other cases, programme 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 is likely. If the event is a known vaccine reaction but occurring at an increased rate, a programme error or a vaccine problem are likely causes. Finally, if cases include people from the same area in the same age group who were not immunized, then the adverse event was probably coincidental.

Identifying Cause of AEFI Cluster



If programme error can be ruled out as the cause of AEFI under investigation, the analysts should look for evidence that it was vaccine reaction or coincidental.

B. Vaccine Reaction

Vaccine Reaction AEFI is caused by the reaction of a particular individual to a particular vaccine. Because this is a "personal" medical incident, it is highly unusual for more than one person to have a vaccine reaction to the same vaccine in the same session.

C. Coincidental

AEFIs are caused by something other than programme errors and individual reactions to vaccine. When the cause of an AEFI is coincidental, it means that the medical incidents would have occurred even if the individual had not been vaccinated. Coincidental events are unrelated to vaccinations or vaccines in any way except for the time that they occur.

The best evidence to support a conclusion that a medical incident is coincidental is that the same event has been diagnosed in people who have not been vaccinated.

D. Injection Reaction

The Injection reaction AEFIs are caused due to fear or anxiety of an injection.

E. Unknown

When the cause of an AEFI could not be determined then it is classified as unknown.

It must be recognized that despite proper investigation and analysis, sometimes no cause for an AEFI is found, or the cause may be determined to be unrelated, possibly related or probably related to immunization.

When deciding on what the cause of the adverse event was, the following points should be considered:

- Is this a known reaction to the vaccine?
- How frequent is the occurrence of this event (common/rare/not previously reported)?
- Are similar events known to occur with other diseases?
- Is event explainable by the biological properties of the vaccine?
- Did the event occur within a reasonable time frame from the vaccine administration?
- Has the patient had similar symptoms in the past? Did these occur after vaccination or independently of vaccination?
- Was the patient on any concomitant or preceding drug therapy?
- Did the patient have any concomitant or preceding medical condition, which could explain the event?

SUBMISSION OF THE AEFI INVESTIGATION REPORT

After completing investigation the AEFI investigation team will submit report to respective EDO (Health). The report includes filled in investigation form together with all medical records e.g. prescription, treatment sheet (if hospitalised), laboratory reports (if any), autopsy report (in case of death), vaccination card, photograph etc. EDO (Health) will send these reports to the provincial EPI office and they'll send a copy to the Federal EPI office within a week.

AEFI EXPERT REVIEW COMMITTEE

A Provincial AEFI Expert Review Committee to be formed. This committee will assess and classify serious AEFI reported to the surveillance programme. The committee will play a critical role in confirming the causality assessments of selected investigations and in determining causality when not established with confidence by the investigation team. This committee will also evaluate, analyze and make recommendations of actions to be taken, support EPI programme in encouraging AEFI reporting and advice EPI and National Regularity Authority (NRA) at times of crisis.

Taking Action

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

- Treatment: treatment is the first response to an AEFI
- Communication with patients / parents and other members of the community: rumours or public inquires must be responded to
- Reporting: timely reporting to appropriate level
- Corrective actions after completion of investigation

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

Table-5: Actions to be taken upon completion of the investigation

Vaccine Reaction	If a higher reaction rate than expected from a specific vaccine or lot then obtain information from the manufacturer and consult with WHO/UNICEF/NRA/AEFI Expert Review Committee to consider: ▪ Withdrawing that lot ▪ Changing manufacturing specifications or quality control ▪ Obtaining vaccine from a different manufacturer
Programme Error	Correcting cause of the error. This may mean one or more of the following: ▪ Change in logistics for supplying vaccine ▪ Change in procedures at the health facility ▪ Training of field workers ▪ Intensified supervision Whatever action is taken, it is important to review at a later date to check that the programme errors have been corrected.
Coincidental	Main task is communication to ensure that the community is persuaded that the link is just coincidental.
Injection Reaction	Assurance to the patients / parents
Unknown	Depending on the nature of the event, its extent and whether it is ongoing, a further investigation by an expert may be needed. However, it must be accepted that in some cases the relationship to immunization is not clear.

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 programme error, it is vital not to lay personal blame on anyone, but to focus on system-related problems that resulted in programme 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. The field workers need to be supported and provided with appropriate relevant information to respond directly to community concerns.

It is never appropriate to discontinue the immunization programme while awaiting the completion of investigation.

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 with taking the AEFI patient to nearest hospital
- Keep the parent/guardian routinely informed of the progress of the patient

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 programme 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)

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 (use Tables-2 and Table-3 to outline known risks of suspect vaccines)
- 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

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*

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.

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.

Evaluating AEFI Surveillance System

AEFI Surveillance System should be evaluated regularly to determine its effectiveness. The following indicators might be used to evaluate the surveillance system:

- timeliness, completeness, and accuracy of AEFI reporting
- timeliness and completeness of investigation
- appropriateness of actions taken to avoid further programme error
- increase in vaccination coverage

Analysis of AEFI Reports

The progress in AEFI surveillance can also be monitored by analysing the reports as follows:

- number of AEFI reports received annually from community and from facility
- number of AEFI by type
- number of AEFI by antigen
- classification of events by cause
- unusually severe AEFI

The EDO (Health) office will analyse the reports of all AEFIs on monthly basis and provide feedback to the vaccinator and facility in-charge of the respective UC. If there is any unusual high rate of AEFI he/she should inform the local facility in-charge of the respective UC to look into the matter and take appropriate action.

Provincial and Federal EPI will also analyse the reports of all AEFIs on monthly basis and provide feedback to the district and NRA.

Functions of Role Players

VACCINATOR / other Field Worker

- Recognise and report AEFI
- Refer patient to hospital, if possible accompany
- Reassure the parents/community
- Prevent AEFI due to programme error through strict compliance to proper vaccine handling and injection safety practices

Local facility in-charge and other supervisors

- Encourage and assist vaccinator, LHWs, LHS to report AEFI
- Ensure vaccinator has report forms
- Send weekly report to the EDO (Health) office
- Inform EDO (Health) immediately of deaths, hospitalisation, clusters, events causing significant community concern
- Do supportive supervision in order to prevent programmatic errors
- Support vaccinator to gain confidence of the community following an adverse event

EDO (Health)

- Compile all reports of AEFI and submit to Provincial EPI
- Notify serious AEFIs to Provincial EPI
- Monitor timely reporting of AEFI
- Notify investigation team and conduct investigation of serious AEFI
- Report results of investigation to provincial EPI
- Ensure appropriate case management

- Ensure enforcement of corrective action
- Communicate with media
- Encourage vaccinators to report AEFI
- Implement corrective action
- Provide feedback to field staff on results of investigation and corrective actions to be taken
- Monitor for clustering
- Inform Provincial EPI office immediately of deaths, hospitalisation, clusters of events, events causing significant community concern
- Reassure the parents/ community
- Handle the media appropriately

Medical Officer in Hospital

- Detect/recognise AEFI
- Report to facility in-charge within 24 hours
- Assist with diagnosis of AEFI
- Ensure appropriate case management
- Cooperate with the Investigation Team
- Inform facility in-charge immediately of deaths, hospitalisation, clusters, events causing significant community concern

WHO Surveillance Officer

- Encourage reporting of AEFI
- Facilitate timely reporting to appropriate authorities
- Assist in investigation (member of investigation team)
- Assist in managing the AEFI case
- Assist spokespersons to deal with media

Provincial EPI

- Facilitate training and awareness-building activities
- Encourage reporting of AEFI
- Collate all AEFI reports from districts and maintain a database
- Ensure adequate supply of AEFI forms at all levels
- Assist district in conducting investigation
- 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
- Communicate and collaborate with NRA and Federal EPI
- Respond to crisis
- Evaluate AEFI Surveillance System

Federal EPI

- Facilitate training and awareness-building activities
- Encourage reporting of AEFI
- Collate all AEFI reports nationally and maintain a database
- Ensure adequate supply of AEFI forms at all levels
- Assist district in conducting investigation
- Communicate findings of investigation of serious AEFIs with all stake holders including media
- Communicate and collaborate with NRA
- Respond to crisis
- Evaluate AEFI Surveillance System

AEFI Investigation Team

- Conduct AEFI case investigation
- Assess cause of AEFI investigated
- Assist with communication in case of crisis
- Recommend corrective action to be taken by appropriate authority

AEFI Expert Review Committee

- Assess and classify the unresolved cases of AEFI
- Advise EPI and NRA at times of crisis
- Assist investigation team as required
- Make recommendations of actions to be taken by EPI HQ and NRA

National Regularity Authority (NRA)

- Implement any regulatory action if necessary
- Participate in investigation of serious AEFI
- Implement recommendation by the AEFI Expert Review Committee

Appendix

CASE DEFINITIONS AND TREATMENTS FOR AEFI

Adverse event	Case definition	Treatment	Vaccines Involved
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.	OPV
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 **Mild allergic reactions do not need to be reported.**	Self-limiting Anti-histamines may be useful	All
Anaphylaxis	Severe immediate (within 1 hour) allergic reaction leading to circulatory failure with or without bronchospasm and/or laryngospasm/laryngeal oedema.	Adrenaline injection (See Appendix- 5)	All
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.	BCG
Encephalopathy	Acute onset of major illness characterized by any two of the following three conditions: ▪ seizures ▪ severe alteration in level of consciousness lasting for one day or more ▪ distinct change in behaviour lasting one day or more Needs to occur within 48 hours of DPT vaccine or from 7 to 12 days after measles vaccine, to be related to immunization.	No specific treatment available; supportive care.	Measles, DPT
Fever	The fever can be classified (based on rectal temperature) as: Mild fever: 100.4 ^{O}F to 102 ^{O}F (38 to 38.9^{o}C), High fever: 102 ^{O}F to 104.7 ^{O}F (39 to 40.4^{o}C) and Extreme fever (hyperpyrexia): 104.7 ^{O}F or higher ($\geq$40.5^{o}C)	Symptomatic; paracetamol.	All
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 younger than 10 years 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.	Mainly DPT, rarely others

Adverse event	Case definition	Treatment	Vaccines Involved
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.	All
Lymphadenitis (includes suppurative lymphadenitis)	Either at least one lymph node enlarged to >1.5 cm in size (one adult finger width) or a draining sinus over a lymph node. Almost exclusively caused by BCG and then occurring within 2 to 6 months after receipt of BCG vaccine, on the same side as inoculation (mostly axillary).	Heals spontaneously (over months) and best not to treat unless lesion is sticking to skin. If so, or already draining, surgical drainage and local instillation of anti-tuberculous drug. Systemic treatment with anti-tuberculous drugs is ineffective	BCG
Osteitis/ Osteomyelitis	Inflammation of the bone with isolation of *Mycobacterium bovis* BCG strain.	Should be treated with anti-tuberculous regimens including isoniazid and rifampicin.	BCG
Persistent inconsolable screaming	Inconsolable continuous crying lasting 3 hours or longer accompanied by high-pitched screaming.	Settles within a day or so; analgesics may help.	DPT,
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; paracetamol and cooling if febrile; rarely anticonvulsants.	All, especially DPT and Measles
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 programme error.	Critical to recognize and treat early. Urgent transfer to hospital for intravenous antibiotics and fluids.	All
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. **Local reactions of lesser intensity occur commonly and are trivial and do not need to be reported.**	Settles spontaneously within a few days to a week. Symptomatic treatment with analgesics. Antibiotics are inappropriate.	All
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 programme error.	Critical to recognize and treat early. Urgent transfer to hospital for intravenous antibiotics and fluids.	All

Expanded Programme on Immunization
AEFI Report Form

Name of case: _____ Sex: M F

Date of birth: _____Age: _____years _____months _____ weeks

Father/Husband's name: _____

Village: _____UC _____Teshsil/Taluka _____

District: _____ Province: _____

Clinical information

Major complaints (put tick as appropriate):

a) BCG Lymphadenitis	f) Convulsion
b) Severe Local Reaction	g) Unconsciousness
c) Injection site abscess	h) Respiratory Distress
d) Fever	i) Swelling of body or face
e) Rash	j) Others (Pls specify)_____

Is the case hospitalized: Yes No

If Yes, Name and address of the hospital

Information regarding vaccine and vaccination

Date of vaccination:

Name of vaccine(s) received on this day:

Name of manufacturer & Batch/Lot no. of vaccine(s):

Expiry date of vaccine(s):

Name and address of vaccination center:

Name & designation of person who vaccinated:

Submit this report to the local health facility in-charge within three days
In case of emergency, report to the local health facility in-charge immediately

Name and designation of the reporting person Date: ____/____/_____

Copy of all AEFI reports to be sent to the EDO (H) office along with weekly Form B by following Tuesday

EXPANDED PROGRAMME ON IMMUNIZATION

AEFI WEEKLY Compilation Form for District/Province

District: _____ Province: _____ Reporting Epidemiologic Week No: ____

Date from (Sunday) _____ to (Saturday) _____

(dd/mm/yy) *(dd/mm/yy)*

No. of reporting sites/unit:_____ No. reported:_____ No. reported on time:_____ No. of AEFI cases: _____ (If none, write "0")

Sl. #	Union Council	Tehsil/Taluka	Sex (M/F)	Date of birth/age	Date vaccine given	Date of AEFI onset	Suspected Vaccine	AEFI*	Hospita-lization (Yes/No)	Death (Yes/ No)

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

Prepared by: _____ _____ _____ _____ Submitted by: _____ _____ _____ _____

Name Designation Signature Date Name Designation Signature Date

Your weekly report, including "0" reporting, must reach Provincial EPI by the last working day of the week and Federal EPI by following Tuesday

Expanded Programme on Immunization
AEFI CASE INVESTIGATION FORM

An AEFI case investigation should be initiated within 24 hours of notification.

Investigation ID: PAK __ __/ __ __/ __ __/AEFI /__ __ __	**Date AEFI reported:**
	Date investigation started:

Demographic data of the patient:

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

Sex: ❑ Male ❑ Female

Name and cast of Father : _____

Address: House/Street No. _____ Village: _____ Union Council_____

Tehsil/Taluka/Town: _____ District: _____ Contact No:_____

Most Recent Immunization History:

Date and time of vaccination	Vaccine & dose number	Site of administration	Vaccination center	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 up this section by asking and observing practice):
Write yes or no where applicable, if yes specify

EPI store:

Temp inside ILR (ºC)	:
Temp of freezer (ºC)	:
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 ice-pack 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:				
Programme error	**Vaccine Reaction**	**Coincidental**	**Injection Reaction**	**Unknown**
❑ Non-sterile injection ❑ Vaccine prepared incorrectly ❑ Faulty administration technique/site ❑ Faulty vaccine transportation ❑ Faulty vaccine storage ❑ Other:	❑ Known vaccine reaction at expected rate ❑ Vaccine lot problem ❑ Others:	❑	❑	❑
Confidence about conclusion on main cause of AEFI:	certain	probable	possible	
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 EDO (Health) office or equivalent. Attach 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), photos etc. with the investigation form.
2) EDO (Health) or equivalent will send a copy of the investigation report with all attachments to the Provincial and Federal EPI office as soon as it is completed and not later then a week after completion of investigation.
3) In case of cluster, use separate investigation form for each 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.

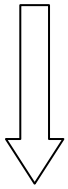
The vaccinators, paramedics and physicians should be adequately trained so that they are able to distinguish anaphylaxis from fainting, anxiety and breath-holding spells, which are common benign reactions.

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. face or mouth. Flushed, itching skin, nasal congestion, sneezing, tears Hoarseness, nausea, vomiting Swelling in the throat, difficulty in breathing, abdominal pain
Late, life-threatening symptoms	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

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 (BHU/RHC/THQ/DHQ/Tertiary 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.