MINISTRY OF HEALTH

REPUBLIC OF UGANDA

NATIONAL AEFI SURVEILLANCE GUIDELINES UGANDA

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World Health Organization

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Forward

Vaccines are administered as a preventive measure to large numbers of healthy individuals particularly children and are among the safest of pharmaceuticals. However no immunization can be declared to be entirely without risk and in rare instances, some people experience Adverse Events Following Immunization (AEFI).

Conducting vaccine pharmacovigilance activities requires continuous improvements in order to adjust the sensitivity of surveillance systems and the quality of the response to vaccine safety alerts. Uganda is one of the 12 countries that participates in the Global network for Post-Marketing surveillance of vaccines since 2008. This network aims at adopting standardized tools and methods for the collection of accurate and complete safety data essential for a subsequent evaluation and strengthening technical capacities to analyse safety data, to detect safety signal and address potential public health issues related to vaccine safety concerns.

These national guidelines of AEFI will serve as a general reference tool to enable districts establish an effective spontaneous reporting system of all AEFIs from district to national level; investigate all AEFIs when identified as a potential public health risk and minimize the negative impact of AEFI on public health. They provide a set of procedures to follow when an AEFI is detected from treatment to risk communication. These guidelines have been revised from the previous edition integrated with vaccine preventable disease surveillance guidelines to incorporate more information related to vaccine pharmacovigilance activities as Uganda plans to introduce several new vaccines into its routine immunization program. These guidelines should be adapted to reflect public health intervention and used to be able to:

- Define an Adverse Event Following immunization
- Prevent an AEFI
- Detect and report AEFI
- Investigate an AEFI
- Determine the causes of an AEFI
- Analyze data of AEFI surveillance and implement corrective actions.

Remember AEFI surveillance system is part of an Integrated Disease Surveillance and Response system**. Use this tool at all times as a reference document.**

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Contents

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 unfavourable or unintended sign, abnormal laboratory finding, symptom or disease.
Causal association	A cause-and-effect relationship between a causative factor and a disease with no other factors intervening in the process.
Cluster	Two or more cases of the same or similar event related in time, geography and/or vaccine administered. National programme managers may decide upon a more precise definition.
Coincidental adverse events	An AEFI that is caused by something other than the vaccine product, immunization error or immunization anxiety
Injection safety	The public health practices and policies dealing with various aspects of the use of injections (including adequate supply, administration and waste disposal) so that the risk of transmission of bloodborne pathogens is minimized. All injections, irrespective of their purpose, are covered by this term (see definition of safe injection practices).
Immunization safety	The public health practices and policies dealing with the various aspects of the correct administration of vaccines, focusing on minimizing the risk of transmission of disease with the injection and maximizing the effectiveness of the vaccine. The term encompasses the spectrum of events from proper manufacture to correct administration. *The term usually includes both injection safety (programmatic errors compromising injection safety) and vaccine safety (faults in the vaccine itself compromising vaccine safety).*
Immunization safety surveillance	A system for ensuring immunization safety through detecting, reporting, investigating and responding to AEFIs.
Minor AEFI	An event that is not 'serious' and has no potential risk to the health of recipient
Pharmacovigilance	The science and activities relating to the detection, assessment, understanding and prevention of adverse effects or any other drug-related problems.
Safe injection practice	Those public health practices and policies which ensure that the process of injection carries the minimum of risk, regardless of the reason for the injection or the product injected. *This is the preferred generic term for this subject.*

Serious AEFI	An AEFI which 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 or is a medically important event that may jeopardize the patient or may require intervention to prevent one of the above outcomes.
Surveillance	The continuous and systematic collection of data that is analysed 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	Biological substance that is administered to individuals to elicit immunity (protection) against a specific disease.
Vaccine pharmacovigilance	The science and activities relating to the detection, assessment, understanding and communication of AEFIs and other vaccine- or immunization-related issues and to the prevention of untoward effects of the vaccine or immunization.
Vaccine reaction	An event caused or precipitated by the active component or one of the other components of the vaccine (e.g. adjuvant, preservative or stabilizer). This is due to inherent properties of the vaccine.
Vaccination failure	Vaccination failure is based on clinical endpoints or immunological criteria, where correlates or surrogate markers for disease protection exist. Vaccination failure can be due to vaccine failure (primary – when immune response is inadequate or secondary when the immune response wanes) or failure to vaccinate, i.e. that an indicated vaccine was not administered appropriately for any reason

ABBREVIATIONS

AEFI	Adverse Event Following Immunization
BCG	Bacillus Calmette-Guerin - vaccine for tuberculosis (TB)
CIOMS	Council for International Organizations of Medical Sciences
DT	Diphtheria-tetanus vaccine
DTaP	Diphtheria-tetanus-pertussis (acellular) vaccine
DTwP	Diphtheria-tetanus-pertussis (whole-cell) vaccine
EPI	Expanded Programme on Immunization
GVSI	Global Vaccine Safety Initiative
Hib	*Haemophilus influenzae* type b vaccine
IDSR	Integrated Disease Surveillance and Response
IPV	Injectable polio vaccine
MMR	Measles-mumps-rubella vaccine
MR	Measles-rubella vaccine
NDA	National Drug Authority
NRA	National Regulatory Authority
OPV	Oral polio vaccine
PMS	Post Marketing Surveillance
PvV	Pentavalent (DTP-HepB-Hib) vaccine
Td	Adult tetanus-diphtheria vaccine
UNEPI	Uganda National Expanded Program on Immunization
VAPP	Vaccine associated paralytic poliomyelitis
VPD	Vaccine Preventable disease
WHO	World Health Organization

1. INTRODUCTION

Vaccines are administered as a preventive measure to large numbers of healthy individuals, particularly children and are among the safest of pharmaceuticals. Uganda National Expanded Program on Immunization (UNEPI) uses vaccines that have been proven over many years to be very safe and effective. However, no immunization can be declared to be entirely without risk and in rare instances, some people experience Adverse Events Following Immunization (AEFI). These range from mild hypersensitivity to serious (but rare) adverse events. In addition to the vaccines themselves, the process of vaccination is a potential source of adverse events if immunization procedures and recommendations are not strictly adhered to. Despite rare potential medical events, the benefits of immunization against diseases far outweigh the risks of adverse events following immunization.

The Council for International Organizations of Medical Sciences (CIOMS) / WHO working group on vaccine pharmacovigilance (2012) defined AEFI as "any untoward medical occurrence which follows immunization and which does not necessarily have a causal relationship with the usage of the vaccine. The adverse event may be any unfavourable or unintended sign, abnormal laboratory finding, symptom or disease".

Vaccine pharmacovigilance is the science and activities relating to the detection, assessment, understanding and communication of adverse events following immunization and other vaccine or immunization-related issues and to the prevention of untoward effects of the vaccine or immunization.

Surveillance of AEFIs forms an integral part of Vaccine Pharmacovigilance system within the umbrella of Integrated Disease Surveillance and Response (IDSR). The purpose of surveillance for AEFIs is to improve the quality of immunization and to ensure that any such event is handled in a way that is acceptable to the patient, the parents, vaccinator and the community.

AEFI surveillance monitors immunization safety, detects and responds to adverse events following immunization, corrects unsafe immunization practices, reduces the negative impact of the event on health and contributes to the quality of immunization activities.

Immunization safety has a wide spectrum ranging from vaccine manufacturing and regulation, vaccine safety and quality, safe injections and waste disposal and AEFI surveillance. Since Uganda procures prequalified vaccines, the issues of vaccine manufacturing, safety and quality control are handled by WHO prequalification systems in place. Uganda procures vaccines through the UN system. The Government of Uganda (GOU), through the National Medical Stores (NMS), provides funds to UNICEF country office that procures vaccines from WHO pre-qualified suppliers. Similarly GAVI supported vaccines are also procured through UNICEF as per procedure of the existing government arrangement. All this is governed by an MOU signed annually between GOU and UNICEF. NMS is responsible for distribution of vaccines to all district vaccine stores. District vaccine stores distribute vaccines to the operational levels.

The Epidemiology Surveillance Division in the Department of National Disease Control is the focal point for coordination of the IDSR activities in the MOH. The IDSR/ HMIS committee is responsible for reviewing and monitoring the implementation of the IDSR strategy; the committee is constituted by the relevant technical programs within the Ministry of Health, other relevant government sectors and Partner Agencies with clear roles of each technical program.

The EPI program (UNEPI) is responsible for setting up and maintaining an EPI surveillance system for AFP, measles, neonatal tetanus, Adverse Events Following Immunization (AEFI) to ensure that the targets for control/ elimination/ eradication certifications are met. The program is responsible for setting up and maintaining a system to ensure that case based investigation is done for all reported cases of AFP, measles, and maternal and neonatal tetanus. In addition, the program is responsible for establishing a disease surveillance system for new and underutilized vaccines. Working with other line MoH programs, UNEPI is responsible for coordinating annual central, and regional review meetings; and district quarterly surveillance review meetings with the District Surveillance Focal Persons (DSFP), HMIS FP, and HSD Surveillance Focal Persons. This forum is used for reviewing IDSR performance, EPI surveillance, capacity building and charting a way forward for improving IDSR and EPI surveillance. Coordination of EPI/IDSR regional supervisors in close collaboration with ESD is done by UNEPI. Regular updates to the IDSR/ HMIS committee during each meeting on the performance of case-based surveillance system for AFP, measles, neonatal tetanus and new /under utilized vaccines is provided by the program.

All health facilities in the National health system collect, analyze, use and transmit data on all the diseases on the National Priority list including data on curative and preventive services. This data is transmitted through the system from the village health team level up to the National level using the following two complementary reporting systems: the Health Management Information System (HMIS) and the weekly reporting system. Under the Integrated disease surveillance and response strategy which the country has been implementing since 2000, all the programs have their surveillance data needs integrated into the two reporting systems so as to make the best use of the available resources.

The National Pharmacovigilance Center in Uganda is involved in the detection, assessment and prevention of adverse drug reactions in humans by monitoring effects, assessing risks and benefits, providing information and monitoring the impact of any action taken. Post-Marketing Surveillance (PMS) is the practice of monitoring the performance of a drug or a vaccine after it has been released into the market.

Though PMS is done initially by the manufacturers, AEFI surveillance needs to be sustained by the health care providers at all levels particularly after a new vaccine is introduced into the immunization program. HPV demonstration vaccination projects was conducted in 2008 and 2009 in two Districts of Ibanda and Nakasongola . The target population was in-school girls and out of school girls.Two different vaccine delivery strategies were identified from the results of formative research, which suggested that schools could be a viable venue to reach the target age group. This was followed by the bridging phase to guide the government to make decisions about HPV vaccine introduction in the country. In this period additional lessons were learnt through using a mix of methods in delivering the HPV vaccinations to the target population in the two districts, thereby referred to as "hybrid vaccine delivery strategy". MSD (Merck Company), one of the HPV vaccine manufactures conditionally donated free HPV vaccines for 12 districts in Uganda for two years (2012-2013), after which the government of Uganda has decided to continue HPV vaccinations in the country by 2014 using GAVI support.

Safe injections and waste disposal are managed at the immunization session site by the service provider as per the guideline laid down in Uganda[1] .

This document is intended to help surveillance officers, all health workers particularly those involved in immunization activities and immunization safety experts to be able to

[1] Ministry of Health National Policy on Injection safety and health care waste management, July 2004

- Define an Adverse Events Following Immunization
- Prevent AEFIs
- Detect and report AEFI
- Investigate AEFI
- Determine the causes of an AEFI
- Analyze data of AEFI surveillance and investigation and
- Implement corrective actions

2. BASIC CONCEPTS OF AEFI SURVEILLANCE

Vaccines have tremendous impact on the health of populations and the control of disease. More people than ever before are being reached with immunization. It has led to global eradication of smallpox as well as the eradication of poliomyelitis and elimination of measles in many regions of the world. Rarely vaccines cause adverse events. Table 1 outlines the side effects after immunizations with DTP and measles vaccines compared with the serious effects suffered from the diseases they prevent.

Table 1 **Incidence of complications of pertussis and measles disease and adverse events following their respective immunization**

Complications	**Pertussis**		**Measles**	
	Pertussis disease*	DTP immunization**	Measles disease	Measles immunization
Encephalitis	90 – 4,000	0.2	50 – 400	0.1
Convulsions	600 – 8,000	0.3 – 90	500 – 1,000	0.02 – 190
Death	100 – 4,000	0.2	10 – 10,000	0.002 – 0.3

*per 100,000 cases
** per 100,000 injections
Source: Global Programme for Vaccination and Immunization. *Surveillance of adverse events following immunization*. (WHO/EPI/TRAM/93.02REV.1). Geneva: WHO, 1997

AEFI surveillance monitors immunization safety, detects and responds to adverse events following immunization, corrects unsafe immunization practices, reduces the negative impact of the adverse event on health and contributes to the quality and confidence in immunization programs.

2.1 Goals and objectives of AEFI surveillance

The Global Vaccine Safety Blueprint of the WHO, March 2012 outlined the need to strengthen vaccine safety monitoring at all levels in countries and the need to strengthen the ability of countries to evaluate vaccine safety signals. In line with this, the health program in Uganda encourages

- the establishment of an effective spontaneous reporting system of all AEFIs from the district to the national level
- the investigation of all AEFIs when identified as a potential public health risk
- Minimize the negative impact of AEFI on public health.

2.2 Case definition of adverse events following immunization and its implications

The following case definitions are used to identify and distinguish AEFIs that should be reported to the next level.

2.2.1 Adverse event following immunization (AEFI)

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 unfavorable or unintended sign, abnormal laboratory finding, symptom or disease.

2.2.2 Minor AEFI

They are caused when recipient's immune system reacts to antigens or the vaccine's components (e.g. aluminum adjuvant, stabilizers or preservatives) contained in the vaccine. Most AEFI are minor and settle on their own. Minor AEFI could be local or systemic. Local reactions include pain, swelling and redness at injection site. Systemic reactions include fever irritability and malaise. A successful vaccine reduces these reactions to a minimum while producing the best possible immunity.

Table 2- **Common minor vaccine reactions by antigen and treatment**

Vaccine	Local adverse events (pain, swelling, redness)	Fever (> 38^0C)	Irritability, malaise and systemic symptoms
BCG[1]	90%-95%	-	-
Hepatitis B	Adults up to 15% Children up to 5%	1 – 6%	-
Hib	5-15%	2%-10%	
Measles/MR/MMR	~10%	5%-15%	5% (Rash)
OPV	None	Less than 1%	Less than 1%[2]
Pertussis (DTwP)[3]	up to 50%	up to 50%	up to 55%
†Pneumococcal conjugate	~20%	~20%	~20%
Tetanus/DT/aTd	~ 10%[4]	~ 10%	~ 25%
Treatment	• Cold cloth at injection site Paracetamol*	• Give extra oral fluids, wear cool clothing, tepid sponge or bath • Paracetamol*	• Supportive treatment

[1] Local reactogenicity varies from one vaccine brand to another, depending on the strain and the number of viable antigen in the vaccine.

[2] Diarrhoea, Headache and/or muscle pains

[3] When compared with whole cell pertussis (DTwP) vaccine, acellular pertussis (DTaP) vaccine rates are lower.

[4] Rate of local reactions are likely to increase with booster doses, up to 50 -85%.

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

† Source: http://www.cdc.gov/vaccines/pubs/ACIP-list.htm

2.2.3 Severe and serious AEFI

They are caused by the body's reaction to a particular component in a vaccine. The term "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. Severe AEFI can be disabling and is rarely life threatening. Some examples are seizures, thrombocytopenia, Hypotonic Hyporesponsive Episodes (HHE), prolonged crying etc. ALL severe AEFI should be reported

A severe 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
- is a medically important event that may jeopardize the patient
- may require an intervention to prevent one of the above outcomes. This is very rare.

ALL serious AEFI should be reported, investigated and causality ascertained.

The rate of occurrence of the rare and more serious reactions has been summarized in table 3. Children less than six months or over six years of age are unlikely to have febrile seizures. If it happens, a thorough investigation should be conducted to determine the underlying cause(s).

Table 3**: Severe vaccine reactions, onset interval and frequency**

Vaccine	Reaction	Onset Interval	Rate per million (1,000,000) doses
BCG	Suppurative lymphadenitis	2-6 months	100-1000
	BCG osteitis	1-12 months	1 -700
	Disseminated BCG infection	1-12 months	~ 1-2
Hib	None		
Hepatitis B	Anaphylaxis	0 – 1 hour	1 – 2
Measles/MMR/MR[1]	Febrile seizures	6-12 days	330
	Thrombocytopenia	15-35 days	30
	Anaphylaxis	0-1 hour	~1
	Encephalopathy	6-12 days	< 1
Oral poliomyelitis	VAPP	4-30 days	0.4 - 3 million[2]
Tetanus Toxoid, DT	Brachial neuritis	2-28 days	5-10
	Anaphylaxis	0-1 hour	1 – 6
Pertussis (DTwP)	Persistent (>3 hours) inconsolable screaming	0-24 hours	1000-6000
	Seizures	0-3 days	80-570[3]
	Hypotonic, hypo responsive episode(HHE)	0-48 hours	30-990
	Anaphylaxis	0-1 hour	20
	Encephalopathy	0-2 days	0-1

Notes

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

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

3. Seizures are mostly febrile and the risk depends on age, with much lower risk in infants under the age of 4 months.

2.2.4 Isolated AEFI

This is a solitary medical incident that takes place after immunization, causes concern and is believed to be caused by immunization.

2.2.5 Cluster AEFI

A cluster is defined as two or more cases of the same or similar event, which is related in time and has occurred within the same district or geographical unit or associated with the same vaccine, same batch number administered or same vaccinator.

2.2.6 Signal

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

2.2.7 Cause-specific definitions of AEFI

a. **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.

b. **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.

c. **Immunization error-related reaction:** An AEFI that is caused by inappropriate vaccine handling, prescribing or administration and thus by its nature is preventable. This was previously known as program error.

d. **Immunization anxiety-related reaction:** An AEFI arising from anxiety about the immunization.

e. **Coincidental event:** An AEFI that is caused by something other than the vaccine product, immunization error or immunization anxiety.

Reported Adverse Events Following Immunization can either be true events (related to vaccine or vaccination - points a to d above) or coincidental. The knowledge of the background rate of the occurrence of an event in the community is very helpful to determine if the same event can be attributed to the vaccine. If the same or similar event also affected others in the same age group around the same time, but they 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.

Coincidental events are usually clearly unrelated to immunization and do not require any investigation (e.g. pneumonia). However, certain serious events may be blamed on the vaccine by the parents or community because of the close temporal association with immunization, especially if the child was previously healthy. Such cases need to be investigated to allay public fears and maintain credibility. Responding to a community's concerns about immunization safety is important in maintaining confidence in the immunization programme. During mass immunization campaigns, coincidental events become more apparent because

- The large number of doses given in a short period of time causes an apparent increase of AEFI incidence.
- There is greater sensitization of health workers and the public.

3. PREVENTION AND MANAGEMENT OF AEFI

3.1 Causes of preventable AEFI

Vaccine product related or coincidental AEFI cannot be prevented; however if adequate precautions are taken before and at the time of vaccination, it is possible to minimize or avoid

- Immunization error related AEFI and
- Immunization anxiety-related reaction

3.1.1 Causes of immunization error related AEFI

Immunization errors result from errors and accidents in vaccine storage, handling, reconstitution or administration. An immunization error may lead to a solitary or 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 errors can also affect many vials (e.g. vaccines frozen during transport leading to an increase in local reactions).

Immunization errors usually occur because:

- Health workers/vaccinators are working under pressure of vaccinating many children quickly and in due course fail to follow injection safety practices.
- Of inadequately trained staff who are unfamiliar with a given vaccine or situation resulting in errors.
- Shortage of injection logistics and supplies and the health worker improvising to immunize same number of children with fewer supplies.
- An error in the administration of the vaccine (e.g. wrong diluent) or wrong technique may precipitate a reaction to a certain vaccine.
- Erroneous administration of drugs that may have been stored in the EPI refrigerator.

Table 4 summarizes some of the common immunization errors and the adverse events that can occur

Table 4: **Immunization errors leading to adverse events**

Immunization error		Adverse Event
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 Use of a product after the expiry date	Systemic or local reactions due to changes in the physical nature of the vaccine such as agglutination of aluminum-based excipients in freeze-sensitive vaccines. Failure to vaccinate as a result of loss of potency or non-viability of an attenuated product.
Error in vaccine prescribing or non-adherence to recommendations for use	Failure to adhere to a contraindication Failure to adhere to vaccine indications or prescription (dose or schedule).	Anaphylaxis, Disseminated infection with an attenuated live vaccine. Systemic and/or local reactions. Neurologic, 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	Failure to seroconvert due to incorrect diluent. Reaction due to the

	other than the intended vaccine	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 the site of injection/ beyond the site of injection

In the past, the most common immunization error was an infection (including blood borne virus) as a result of non-sterile injection. The infection can manifest as a local reaction (e.g. suppuration, abscess), systemic effect (e.g. sepsis or toxic shock syndrome) or blood borne virus infection (e.g. HIV, hepatitis B or hepatitis C). However with introduction of Auto Disable (AD) Syringes, infection has reduced significantly. But it can cause problems in mass vaccination campaigns or in disaster situations, particularly if associated with shortage of logistics and supplies. This can be avoided by proper planning and preparedness by programme managers.

The symptoms arising from an immunization error may help to identify the likely cause. For example, children immunized with contaminated vaccine (usually the bacterium *Staphylococcus aureus*) become sick within a few hours; local tenderness and tissue infiltration, vomiting, diarrhoea, cyanosis and high temperature are the most frequent symptoms. Bacteriological examination of the vial, if still available, can confirm the source of the infection.

3.1.2 Causes of immunization anxiety related AEFI

Immunization anxiety usually occurs mainly in older children because:

- The child is apprehensive about the immunization procedure
- The absence of parents and guardians at the immunization location
- Observing other children reacting to the injection procedures
- Health workers not explaining the procedure and reassuring parents and children at the time of immunization

3.2 Prevention of adverse events following immunization

All immunization errors and immunization anxiety related AEFI can be minimized or avoided by following the *"Immunization in Practice 2010"* and other guidelines provided by UNEPI. It is also important for the vaccinating staff to know about the contraindications and side effects of all vaccines used in EPI.

3.2.1 To minimize immunization error related AEFI

- Ensure proper distribution of vaccines with their correct diluents i.e. ensure bundling of vaccines with their corresponding batches of diluents supplied by the manufacturer
    - If the correct diluent supplied by the manufacturer is not available, the vaccine has to be thrown away
- **Do not store other drugs in the EPI refrigerator, to prevent error in the vaccine reconstitution**.
- Use the *"Vaccine and Injection Materials Control Book"* to ensure that quality vaccines are used with right diluents.
- Use only auto-disable syringes and needles.
- Provide proper training of health workers involved in immunization on correct reconstitution of the vaccine and correct vaccine administration techniques.

- Provide proper and sufficient quantities of injection and waste disposal materials.
- Ensure proper cold chain maintenance. Check VVM before the vaccine is used
- Use a new reconstitution needle and syringe for diluting one vaccine vial at a time
- Health workers should be familiar with identifying the *true contraindications* and avoid immunizing individuals with true contraindications

3.2.2 To minimize immunization anxiety related AEFI

- Vaccinate in a clean environment, with adequate shade, ventilation and light.
- Avoid overcrowding; manage the queue and flow of vaccinees correctly.
- Before vaccination, briefly explain the procedure and reassure parents and children.

3.3 Contraindications and precautions

A contraindication to vaccination is a rare condition in a recipient that increases the risk for a serious adverse reaction. Ignoring contraindications can lead to avoidable vaccine reactions. Some contraindications are temporary and the vaccination can be administered later with adequate precautions.

The only absolute contraindication applicable to all vaccines is a history of a severe allergic reaction after a prior dose of vaccine or to a vaccine constituent. Precautions are not contraindications, but are events or conditions to be considered in determining if the benefits of the vaccine outweigh the risks (e.g.; Immunocompromised person, pregnancy). Precautions stated in product labeling can sometimes be inappropriately used as absolute contraindications, resulting in missed opportunities to vaccinate.

For details of the vaccine specific side effects and contraindications, refer to the *"Immunization in Practice"*. http://www.who.int/vaccines-documents/PDF-Cat/IIPmodules.pdf. Parents should be informed of the possibility of symptoms like mild fever, tenderness or redness at injection site. Parents should also be educated on how to deal with such symptoms appropriately and return to the health facility when they are concerned.

3.4 Management of AEFI

Information on the presentation and advice on managing the common expected vaccine reactions should be given to parents, as well as instructions to return if there are more serious symptoms. This will help to reassure parents about immunization and prepare them for these common reactions.

Paracetamol, at a dose of up to 15mg/kg every four hours with a maximum of four doses in 24 hours, is useful for the common minor reactions. It eases pain and reduces fever. Paracetamol can also be used at the time of DTP immunization to prevent fever.

A feverish child can be cooled with a tepid sponge or bath and by wearing cool clothing. Extra fluids need to be given to feverish children. For a local reaction, a cold cloth applied to the site may ease the pain.

Severe AEFI and serious AEFI need to be investigated in detail and they need to be provided expert medical care.

4. AEFI SURVEILLANCE SYSTEM IN UGANDA

The AEFI surveillance system in Uganda has been established to:

- Rapidly detect and respond on time to AEFI
- Identify, correct and prevent immunization errors related reactions.
- Facilitate AEFI causality assessment.
- Recognize clustering or unusually high rates of AEFI (even if considered mild).
- Identify signals of unknown vaccine reactions and generate new hypotheses
- Effectively communicate with parents, the community, media and other stake holders, to create awareness on AEFIs

- **Monthly Reporting (Fig1):** AEFI described in table 5 should be reported to the national level using AEFI reporting form (Annex 1) and details of each case should be appended into a linelist (Annex 2). On a monthly basis the total number (aggregate) of all AEFI cases should be reported to national level accompanied by the monthly linelist.

- **Immediate reporting of serious AEFI (Fig 2): A**ll serious AEFI should be **reported immediately** using reporting form (Annex 1) and linelisted (Annex 2). The case should be investigated and the finalized AEFI investigation form (Annex 3) routed to the national level. The details of each case should be included in the monthly aggregate reports and linelist and sent to the national level as described above.

In Uganda the system has been structured to ensure that there are channels for both routine reporting as well efficient and immediate reporting of severe and serious AEFI. There are two channels of reporting AEFIs

1. Monthly routine reporting of all AEFI
2. Reporting and investigation of serious AEFI

4.1 Monthly routine reporting of all AEFI

This includes reporting and linelisting of all AEFIs outlined in table 5 from the level of Health worker up to the National level through monthly progress reports using existing immunization monthly progress reports / forms HMIS 105 and 123. All AEFIs identified in any week or month should be reported through the existing disease surveillance systems (Weekly and Monthly HMIS reports) and then submitted to the national level using the current reporting system for HMIS.

ALL AEFI should be included in the monthly routine reports and should also be line listed (Annex 2). Submit the line lists to UNEPI. Minor AEFI as described in section 2.2.2 (e.g. mild fever, rash and soreness at the injection site) that are harmless and well known need not be reported as AEFIs.

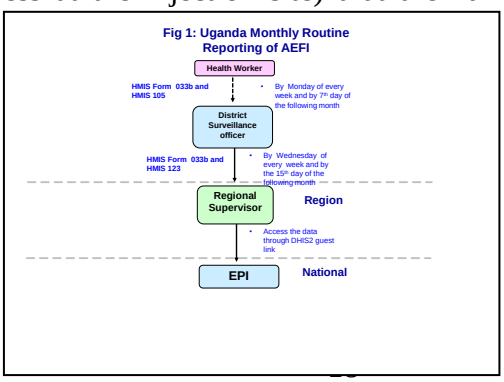


Table 5 **Case definitions of the reportable adverse events.**

AEFI	Case definition	Vaccine
Vaccine Associated Paralytic Poliomyelitis (presenting as AFP)	Acute onset of flaccid paralysis and neurological deficits, compatible with diagnosis of poliomyelitis, with isolation of vaccine virus and absence of wild virus in stool.	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 edema ▪ one or more skin manifestations, e.g. hives, facial edema or generalized edema. Do not report less severe allergic reactions	All
Anaphylaxis	A clinical syndrome characterized by sudden onset (within one hour), rapid progression of signs and symptoms involving multiple organ systems - circulatory failure with or without bronchospasm and/or laryngospasm/laryngeal edema and rash.	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 immuno-compromised individuals.	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 behavior 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.	Measles, Pertussis
Fever	The fever can be classified (based on rectal temperature) such as ▪ Mild fever: 100.4 ^{0}F to 102 ^{0}F (38 to 38.9oC), ▪ High fever: 102 ^{0}F to 104.7^{0}F (39 to 40.4^{0}C) and ▪ Extreme fever: 104.7^{0}F or higher (>40.5^{0}C).	All
Hypotonic, Hyporesponsive Episode (HHE or shock-collapse)	Event of sudden onset occurring within 48 [usually less than 12] hours of vaccination and lasting from 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	Mainly DPT, rarely others
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.	All injectable vaccines

AEFI	Case definition	Vaccine
Lymphadenitis (includes suppurative lymphadenitis)	Either at least one lymph nodes 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).	BCG
Osteitis/ Osteomyelitis	Inflammation of the bone with isolation of Mycobacterium bovis BCG strain.	BCG
Persistent inconsolable screaming	Inconsolable continuous crying lasting 3 hours or longer accompanied by high-pitched screaming.	DPT, Pertussis
Seizures	Occurrence of generalized convulsions that are not accompanied by focal neurological signs or symptoms. Febrile seizures: if temperature elevated >100.4 ^{0}F or 38 ^{0}C (rectal) Afebrile seizures: if temperature is normal	All, especially Pertussis, Measles
Sepsis	Acute onset of severe generalized illness due to bacterial infection and confirmed (if possible) by positive blood culture. Needs to be reported as possible indicator of program error.	All injectable vaccines
Severe local reaction	Redness and/or swelling centered at the site of injection and one or more of the following: ▪ Swelling beyond the nearest joint ▪ Pain, redness and swelling of more than 3 days ▪ Requires hospitalization. Local reactions of lesser intensity occur commonly and are trivial and do not need to be reported.	All injectable vaccines
Toxic shock syndrome (TSS)	Abrupt onset of fever, vomiting and watery diarrhea within a few hours of immunization. Often leading to death within 24 to 48 hours.	All injectable vaccines
Serious AEFI: Any AEFI causing • Death • Hospitalization • Disability, congenital anomaly • Other severe and unusual events		No time limit, if they are thought by health workers or the public to be related to immunization

4.2 Identifying, reporting and initiating investigation of serious AEFI

All serious AEFI outlined in table 5 are to be immediately (within 24 hours of detection), notified by the first person who identifies the event to the nearest health facility by quickest means of communication e.g. telephone, messenger etc. Notification should be followed up with a report in the AEFI reporting form (Annex1) by the health worker. The district or the regional focal person should constitute an investigation team to immediately initiate an investigation to determine the cause of the AEFI and in turn notify UNEPI by phone or Fax or Radio call. In case laboratory investigation is required, any specimen collected should be accompanied by completed AEFI laboratory request form (Annex 4). The following steps have to be initiated for serious AEFI. The first three steps are described here and the others in the respective chapters mentioned.

1. AEFI detection
2. AEFI Notification
3. AEFI Investigation
4. Laboratory testing of specimens (Chapter 5)
5. Data collation and analysis (Chapter 6)
6. Causality assessment (Chapter 7)
7. Action and response (Chapter 8)
8. Communication (Chapter 10)

4.2.1 AEFI detection

In principle, any severe or serious effect perceived to have been caused by an immunization should be considered an AEFI. AEFI could be detected by

- Parents or guardians: At the time of immunization, parents should be informed of expected AEFI such as fever and soreness of injection site (because the vaccine is "working") and should be advised to bring a child about whom they are concerned back to the health facility.
- Older patients by themselves who feel that they have an adverse event
- Health workers providing immunization services
- Health workers providing clinical treatment in health facilities: when parents bring a recently immunized, sick child for treatment, health workers should be able to detect an AEFI and to determine whether it is a trigger event requiring a report and further action.
- Researchers conducting clinical studies of field trials

4.2.2 AEFI notification

All AEFIs outlined in table 5 should be reported immediately (within 24 hours of detection). This should be followed by a systematic investigation if serious or essential. In most settings, the health worker level does not have capacity to conduct a detailed investigation and therefore it is in general, the intermediate level that takes the responsibility. As soon as a case is identified, the health worker should initiate initial primary care for the patient. The district level or the regional level (as the case may be) should be immediately notified of the case. The written details to be submitted at this point by the health worker using the AEFI reporting form (annex 1) which should include

- Details of the patient (e.g. age, sex, location etc.)
- Details of the reporter (e.g. name, designation)
- Details of the event (basic clinical presentation)
- Details of the vaccine

4.2.3 Determining the cases for detailed investigation

Once the report has been received, an assessment should be conducted at the regional level based on the recommendation at the district level to determine whether or not an investigation is needed.

The reported AEFI must be investigated if it

- is a serious event.(An AEFI which 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 or is a medically important event that may jeopardize the patient or may require intervention to prevent one of the above outcomes)
- may have been caused by immunization error.

- is on the list of events defined for AEFI surveillance.
- is causing a significant parental or public concern.

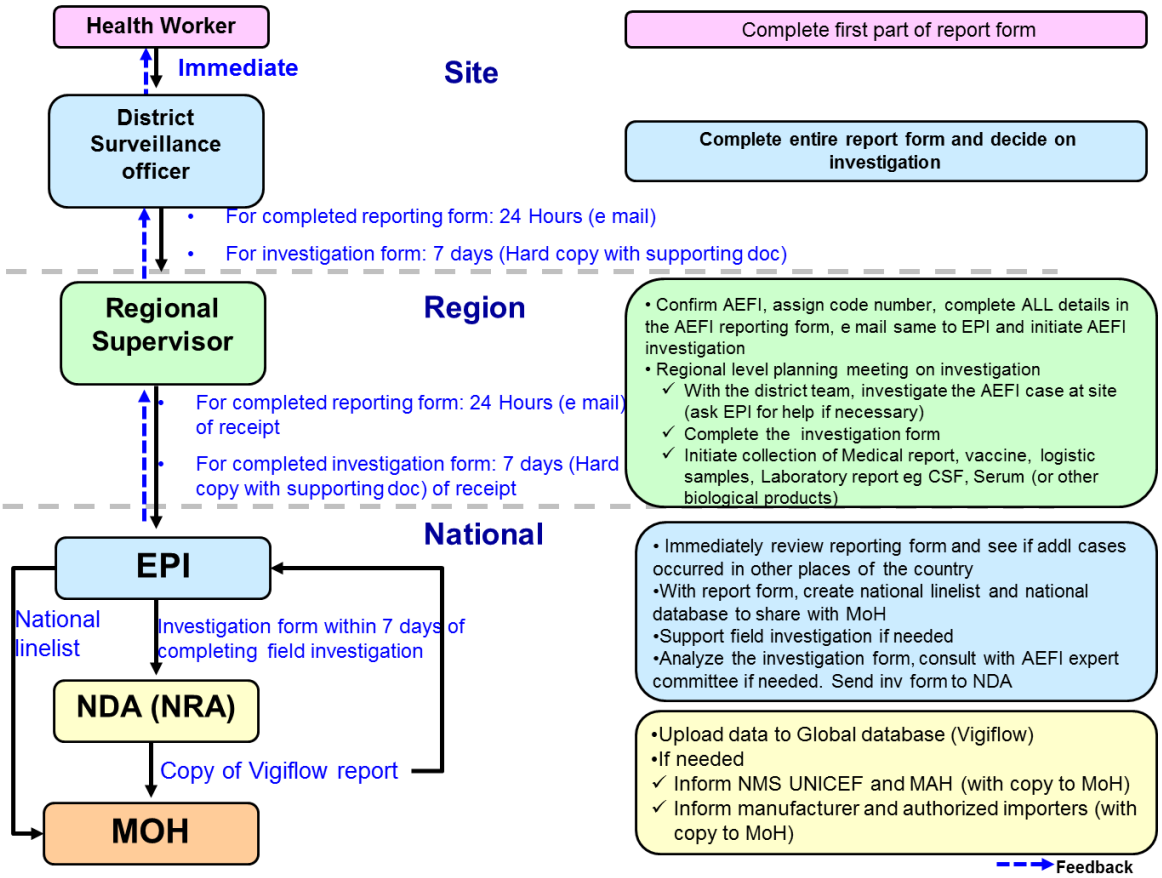
Primary participants in AEFI investigation, their roles and responsibilities

1. Health worker
2. District Surveillance Officer and District Rapid Response Team
3. Regional Supervisor
4. Uganda National EPI (if requested)

Supportive participants in AEFI investigation

1. National Drug Authority
2. National AEFI committee

Fig 2: Organizational structure & Serious AEFI Reporting & Investigation



4.3.4 Field investigation of AEFI

The ultimate goal of a case investigation is to find the cause of an AEFI and prevent recurrence. Remedial action needs to be taken promptly for immunization error related AEFI. Even if the cause cannot be identified or the cause of the event was due to some other reason, the fact that staff had investigated the incident itself will increase public confidence towards immunization.

The purpose of investigating AEFI cases are:

- To confirm the reported diagnosis or propose other possible diagnoses and clarify the outcome of the medical incident.

- To ascertain the specifications, circumstances and procedures of the vaccine used to immunize the affected recipient. Most importantly, identify any vaccine related link to the given AEFI.
- To examine the operational aspects of the programme. Even if an event seems to be vaccine induced or coincidental.
- To determine whether a reported event was a single incident or one of a cluster and if it is a cluster where the suspected immunizations were given and what vaccines were used.
- To determine whether unimmunized people are experiencing the same medical incidents.

Role of the health worker
As outlined in section 4.2.2, the main role of the health worker is to provide primary health care and report the basic details of the patient to the district / regional level.

Role of the district and the regional level
The intermediate (regional//district) level should review the information provided by the health worker and make a site visit if necessary and determine if the case warrants a detailed investigation. If yes, an investigation should be initiated immediately by mobilising a District Rapid Response Team (DRRT) that should function as the district AEFI task force. It is also essential to identify additional resources (e.g. special lab tests, logistics) for the investigation. In some cases, support for the investigation needs to be provided by the UNEPI or National AEFI Committee members.

The investigators should seek to identify system problems rather than find 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 reporting is encouraged. It is also much more likely to improve system performance. Errors provide opportunity for learning and creating a system that encourages hiding errors will cause more errors.

The activities conducted at this point will be the following
- Confirm AEFI, assign code number, complete ALL details in the AEFI reporting form and e mail the same to UNEPI and initiate AEFI investigation.
- Regional/ district level planning meeting on investigation.
- With the district team, visit the patient, the care provider and the hospital, interview relevant stakeholders (parents, health worker, treating doctor, vaccine supply focal person) investigate the AEFI case (ask EPI for help only if necessary).
- Complete the AEFI investigation form.
- Initiate collection of medical report, post-mortem report (if available), vaccine, logistic samples, and laboratory report e.g. CSF, Serum (or other biological products).

Generally before the AEFI is attributed to vaccine related problems, the investigator should rule out immunization errors and coincidental events are these are more common. Therefore, the investigation should first try to rule out immunization errors related to the storage, handling, reconstitution or administration of vaccines.

Attention can then focus on other coincidental events. Details of coincidental events can be determined by reviewing hospital admissions for similar conditions during the same period and verifying the vaccination status. A quick review of the morbidity pattern of similar conditions in the previous years can also indicate if the event is a part of a similar pattern observed in the previous years.

Once the investigation is initiated, the district / regional investigator should inform the national program manager of the UNEPI on the status and progress of investigation. This is necessary, as

a national (MOH) level officer should be the spokesperson of the government to the media and the public about the investigation. The completed case investigation form along with the supporting documents medical report, vaccine, logistic samples, laboratory reports e.g. CSF, Serum (or other biological products) should be sent to the UNEPI within 7 days of case notification. Three copies of all AEFI investigation forms should be made (one each for the investigating Health Unit, DHO and UNEPI). A short report and Form B (summary report on AEFI) should be made and a copy forwarded to UNEPI.

Investigator(s) may use WHO Aide Memoire on AEFI investigation as a resource material, available at www.who.int.immunization_safety/en

Table 6: **Steps in an AEFI investigation**

	Step	Actions
1	**Confirm** information in report	☐ Obtain patient's medical file (or other clinical record) ☐ Check details about patient and event from medical file and document the information. ☐ Obtain any details missing from AEFI Report Form.
2	**Investigate** and collect data: About the **patient:**	☐ Immunization history ☐ Previous medical history, including prior history of similar reaction or other allergies ☐ Family history of similar events.
	About the **event:**	☐ History, clinical description, any relevant laboratory results about the AEFI and diagnosis of the event ☐ Treatment, whether hospitalized and outcome.
	About the **suspected vaccine(s):**	☐ Conditions under which the vaccine was shipped, its present storage condition, state of vaccine vial monitor and temperature record of refrigerator ☐ Storage condition of vaccine at all levels before it arrived at health facility, Vaccine Vial Monitor. ☐ The date of manufacture, lot and batch numbers of vaccine and diluent
	About **other people:**	☐ Whether others received the same vaccine and developed illness and whether they need to be included in the investigation. ☐ Whether others had similar illness (may need working case definition); if so exposure of cases to suspect vaccine(s) ☐ Discuss with other immunization service providers to obtain an idea of the local standard practices
3	**Assess** the **service** provided by a**sking** about:	☐ Vaccine storage (including open vials), distribution and disposal ☐ Diluents storage and distribution ☐ Reconstitution(process and time kept) ☐ Use and sterilization of syringes and needles ☐ Number of immunizations (greater than normal?) ☐ Details of training in immunization practice, supervision and vaccinator(s)
	Observing the service in action:	☐ Refrigerator – what else is stored (note if similar containers stored next to vaccine vials which could be confused); which vaccines/diluents stored with other drugs; whether any vials

		have lost their label ☐ Immunization procedures (reconstitution, drawing up vaccine into the syringe, injection technique, safety of needles and syringes; disposal of opened vials) ☐ If any open vials look contaminated
4	**Formulate** a working hypothesis:	☐ On the likely/possible cause(s) of the event.
5	**Test** working hypothesis	☐ Does case distribution match working hypothesis? ☐ Laboratory tests may help (see text).
6	**Conclude** investigation	☐ Reach a conclusion on the cause. ☐ Complete AEFI Investigation Form ☐ Take corrective action and recommend further action.

Role of the UNEPI

When the UNEPI receives the AEFI reporting form, it is essential to review other AEFI reporting forms received from all parts of Uganda in the same period to see if there is any link between the case and other cases reported in the country earlier. This can be done by appending data into a national AEFI linelist with information from the reporting from. If similar cases were reported earlier, it is essential to determine if an epidemiological linkage can be identified. The need for technical or operational assistance for AEFI investigation of the newly reported AEFI case has to be assessed. Expert advice can be sought from the National AEFI Committee at this point.

A copy of the national line list has to be sent by the district surveillance focal persons to UNEPI/MoH on a monthly basis. The completed AEFI investigation form should be sent to the NDA to upload the data to the global database by the UNEPI surveillance officer.

Role of the supportive participants:

The NDA and the National AEFI Committee play a key role in supporting the immunization program for AEFI investigation and causality assessment. They also provide recommendations to the Uganda National Technical Advisory Group on Immunization, the NRA and EPI on vaccines based on their causality assessment findings. The NDA and the UNEPI together constitute the National AEFI secretariat and together they coordinate and provide technical support to conduct the meetings of the National AEFI Committee (Fig 8).

The completed case investigation form should be submitted to the NDA. The NDA will upload the information into the Global pharmacovigilance database – Vigiflow®. A copy of the uploaded case details in Vigiflow® will be given to the MoH and the UNEPI on a monthly basis. The NDA can provide information on the vaccines and lots distributed in the country. They can provide additional information on AEFI from other sources.

4.3 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. The exact nature of the relationship between the adverse events (e.g. duration of time, proximity of place) will differ by nature of the events and the circumstances in which they occur. The criteria defining a cluster will depend on the context, e.g. for a globally distributed vaccine, the batch may be more important than the place; however in the case of immunization errors, the place will be an important criterion. A cluster can be

understood as a special kind of signal, where not only an increase in the AEFI reporting rate has been seen but one or more common characteristics of the AEFI reports have become apparent too. The characteristics are traditionally time, place and/or vaccine, but could also be age group, genetic predisposition, disease or other characteristic of the vaccinees which could constitute a risk factor for a certain AEFI.

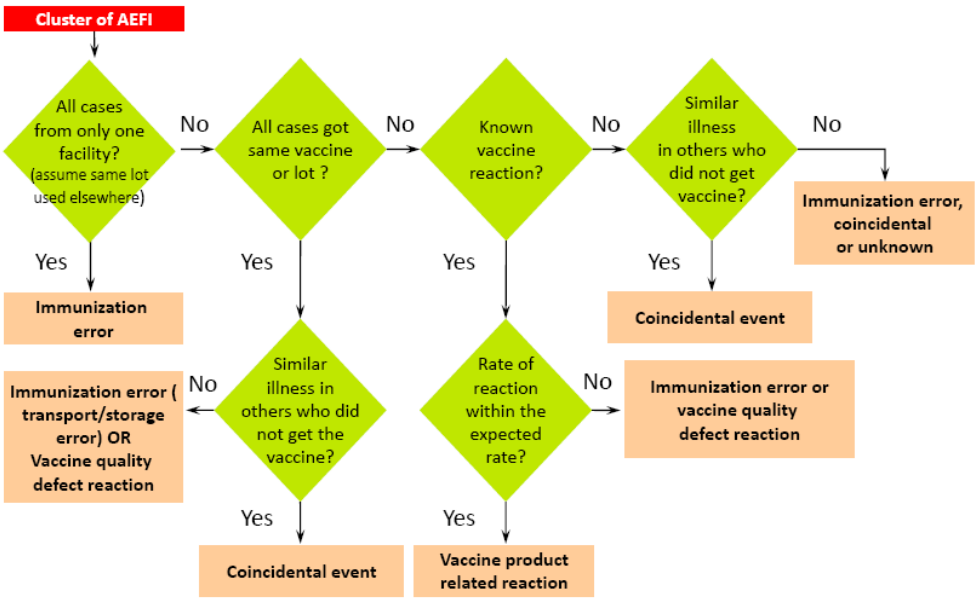
Investigation of cluster follows the same principles as indicated above with following steps:

- Establishment of a case definition
- Identification of all immunized and unimmunized population who meet the case definition.
- Obtaining immunization history (when, where and which vaccines were given).
- Identification of any other common exposures to the cases.

4.3.1 Interpretation of results from AEFI clusters

If all cases received vaccines from the same health worker/facility and there are no other cases, immunization error is likely. If all cases received the same vaccine or lot and there are no similar cases in the community not vaccinated, a problem with the vaccine is likely. If the event is a known vaccine reaction but occurring at an increased rate, an immunization error (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 (Fig 3).

Fig 3: Identifying cause of AEFI cluster



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 an immunization error vaccine or a quality defect. The possibility of immunization error must be considered when events cluster in one setting without a similar change in frequency in other settings using the same vaccine. On the other hand, if an increased frequency of events is reported from multiple settings the possibility of a quality defect must be considered more strongly. Clusters of fainting after immunization are well-recognized immunization anxiety-related reactions during immunization programmes targeting adolescent girls.

For relatively new vaccines or established vaccines used in new target populations, a cluster may represent a previously unrecognized vaccine product-related reaction. Knowledge of the background incidence of events which may occur in causal relationship with a vaccine is therefore essential for assessing a cluster in terms of the strength of the signal it may provide.

4.4 Investigation of deaths considered to be AEFI

In the event of a death following immunization the field investigation has to be initiated immediately within 24 hours and death should be notified to the all administrative levels concerned, including UNEPI. Investigation of death after AEFI should be carried out by a team of experts from relevant areas. The death investigation has to be conducted without any delay as it can cause public panic.

A post mortem is preferred and recommended following all deaths suspected to be caused by vaccine / immunization. However, decision of conducting postmortem should be within the religious, cultural acceptance and legal framework of the local population.

5. LABORATORY TESTING OF SPECIMENS

Laboratory testing of samples is not mandatory following AEFI particularly if the cause is evident such as a coincidental event or a program error. However, laboratory testing is at times required to confirm or rule out the suspected cause. The testing of specimens includes:

Human specimens

- Histopathology, body fluids etc. can be done at laboratories identified and approved by the MOH.
- Autopsy specimens at approved and accredited government forensic laboratories as identified by MOH

Vaccines and logistics

- Vaccines and diluents for sterility and chemical composition.
- Syringes and needles for sterility.

Only the appropriate specimen in the correct quantity required for the investigation should be collected. Laboratory specimens should be accompanied by clear supporting documents, reasons for specimen collection and any additional information required by the investigators. In case laboratory investigation is required, Form 4 (AEFI laboratory request form) should be completed and sent with any specimen collected.

5.1 Human Specimens

It is difficult to generalize what specimens will be required in a given situation as it will depend on the symptoms and signs of the patient and the clinical decisions made by the doctor in charge of the case. Table 7 gives a general outline of some of the specimens that could be collected. The list is not exhaustive. It is necessary to record date and time of collection and type of each and every sample collected. Documents of clinical investigations and medical records related to the incident will support correct lab investigations. It is advised to consult clinician(s) treating to make a decision on samples to be tested.

For biochemical, histo-pathological and microbiological examination, specimens should be handled at the district hospital and forwarded to the nearest laboratory, where facilities are available to carry out requested laboratory testing. If facilities for essential laboratory testing are not available at intermediate level (Region/District) institutions, sending samples to national laboratory or an accredited laboratory abroad need to be considered after discussing with UNEP.

In case of death suspected to be due to an AEFI, an autopsy needs to be performed as soon as possible (within 72 hours) to avoid tissue lysis (for e.g. in the adrenal glands), which can alter diagnosis. Samples for both toxicology and pathological examination should be sent to the reference laboratories identified by MOH/UNEPI as early as possible to avoid loss of biological samples due to decomposition. It is essential to ensure that a detailed patient's history is included in the autopsy form and submitted to the autopsy team to help them look for any underlying pathologies.

5.1.1 Guide to human specimen sample collection

The details of the type of AEFI, the tests to be performed, the specimens to be collected, the process of storage and shipment and the labs are outlined in Table 7

Table 7**: Type of AEFI, the tests to be performed, the specimens to be collected, storage and shipment procedures and the labs conducting tests**

Suspected AEFI	Diagnostic Method	Specimen	When to collect	Preparation, Storage and shipment	Referral of Specimens
Injection site abscesses	Microscopy and Culture/ sensitivity	Pus Swab	• Pus Swab Should be examined on the spot • At Contact	Use Transport media to transport Pus swabs to the next level	**Next Level with Culture and Sensitivity Facilities**
BCG lymphadenitis	Microscopy, Culture and serology	Blood, LN Aspirate or Biopsy and Suspected Vial Batch	At Contact	Wrap in leak proof and water proof container transport. Vaccine sample should be transported in reverse cold chain	**Central Public Health Laboratory**
Collapse or shock-like state	Microscopy, Culture and serology	Blood and Suspected Vial Batch	At Contact	▪ Blood smear ▪ Blood sugar tests at site ▪ Ensure asepsis for blood collection for culture	**District or Regional Hospital Lab or CPHL**
Convulsions or Seizures	Microscopy, Culture and antigen detection	Collect CSF from affected cases	At Contact	▪ Ensure aseptic techniques of LP ▪Never use vials that contained antibiotics ▪Sugar and cell counts should be done at site ▪Transport to referral laboratory immediately	**District or Regional Hospital Lab or CPHL**
Encephalitis	Microscopy, Culture and antigen detection	Collect CSF from affected cases	At Contact	▪ Ensure aseptic techniques of LP ▪Never use vials that contained antibiotics ▪Sugar and cell counts should be done at site Transport to referral laboratory immediately	**District or Regional Hospital Lab or CPHL**
Death	Serology	(1) Venus Blood (2) Vial Batch	Immediate	▪Never use vials that contained antibiotics ▪Transport to referral laboratory immediately ▪Transport sampled vial batch in reverse cold chain	**UVRI/EPI Lab**

5.2 Vaccines and logistics

Vaccines and logistics samples from the site and the distribution point(s) should be collected as soon as possible and kept in cold chain. They should be sent to the laboratory for testing only on the recommendation of the District AEFI Committee.

Testing of vaccines and logistics should be requested on a clear suspicion and not as routine and never before the working hypothesis has been formulated. Determining which samples to send, if any, depends on the working hypothesis for the cause of the event(s). If the used vial of suspect vaccine is available, it should be sent along with unused vials of the same lot.

The district cold chain person will be responsible for the packaging, cold chain maintenance and shipment of samples in the correct temperature to the national laboratory at UVRI/EPI laboratory. ALL specimens sent to the lab should be accompanied by a laboratory request form (Annex 3). The expenses for activities related to this activity should be obtained from the district surveillance budget or PHC funds after due approval by competent authority at district health office.

The laboratory will process the specimens and send the laboratory results to the NDA and the National EPI manager. Laboratories will also send a copy of the laboratory results to all persons with contact details (complete address with pin code, phone and fax numbers and email address) mentioned in the lab request form

Table 8: **Laboratory testing to investigate AEFIs by working hypothesis**

Immunization error is suspected Working hypothesis:	**Specimens to send**	**Laboratory test**
Vaccine transportation or storage	Vaccine vial	Composition (for frozen vaccine)
Reconstitution error	Vaccine vial and/or diluent	Sterility or composition (chemical)
Non-sterile injection	Needle, syringe, vaccine vial and diluent	Sterility

6. DATA AND PERFORMANCE ANALYSIS

6.1 Sources of AEFI data

Information on vaccine safety and AEFI can be obtained from clinical examinations, interviews of health workers, parents and community leaders, review of registers (ANC, OPD and Immunization), Vaccine and Injection Materials Control Books, observation of immunization administration, vaccine handling and storage and laboratory reports. Analysis of data on AEFIs consists of reviewing data from the following sources

- Data collated into a linelist
- Case investigation forms for each reported AEFI case,
- Laboratory information (Human and vaccine related)
- Records about similar events in the community
- Records of the implicated vaccine

6.2 Analysis of AEFI reports

It is essential that both non serious and serious AEFI are reported. This is particularly important in districts and regions that are rapidly improving their immunization coverage. Before the analysis, verify and reassure the data for accuracy. In addition to basic time, place and person analysis that should be done by the district and regional program managers, other key analysis include

- Timeliness and completeness of receiving AEFI forms.
- Identifying health institutions where AEFIs are not reported by checking on "zero reporting" or "nil reporting". Determine whether it is due to failure of reporting or whether there are no AEFIs to be reported.
- Assessing AEFI case reports received during stipulated time period.
- Assessing number of events and rate for 1,000 or 10,000 or 100,000 doses of vaccine used.
- Analyses by the type of AEFI
- Analyzing programme errors by number and rates per 100 or 1,000 doses of relevant vaccines used.
- Compare the rates with available or known background rates.

6.2.1 Data analysis at different levels

Data analysis could be carried out by the responsible focal persons at different levels in the immunization safety surveillance system:

- at the district level by biostatistician, surveillance focal person, EPI focal person and drug inspector
- at Regional level by regional supervisor, pharmacovigilance coordinator and hospital director
- at national level by the EPI program.

Analysis of data at district level is important to identify the programme errors. This helps to carry out corrective action in a timely manner.

6.2.3 Process of data analysis

All reported AEFI data need to be line listed. All serious AEFI and AEFI listed in table 5 should be reported using the AEFI reporting form (Annex 1) and also line listed.

Before analysis of the line list at the national level, it is important to re-check the case definitions adopted by the reporting sources. The case should fit into a case definition such as the **Brighton collaboration** cases definitions (www.brightoncollaboration.org) or any definition decided by the National AEFI Committee.

Line lists should be used to sort data by place, person and time and do analysis by antigens by type of reported adverse events (e.g. high fever, abscess). Number of doses administered for each antigen is the denominator for calculating reported AEFI rates for each antigen in a given time period (by month, quarter or year). Analysis can be expanded to AEFI rates by first or second or third dose, when the antigen is administered more than once. For this, the number of doses administered of the given antigen by first, second or third need to be used as the denominator.

The most challenging selection is to use a proper denominator. There are a few options for selecting a denominator as described in table 9.

Table 9: **Selection of denominators and their limitations**

Denominator	Limitations
Administered doses of vaccines	Most reliable, but not often available
Distributed doses	Greater than administered doses, thus may reduce rate (underestimate)
Coverage x Population	May be less accurate because of variability in coverage estimates
Target population	Proxy measure for vaccine population (may also underestimate)

Multiplier: Use of proper multiplier in data analysis is important and also varied by purpose and level of analysis. At local level, percentage (x100=%) is the best choice, whereas at regional and national levels, one may use 1000, 100,000 or million as multiplier. For common, minor vaccine reactions, percentage is recommended and for rare serious reactions, 10,000, 100,000 or 1,000,000 (million) can be used.

6.2.4 Interpretation of data

Available expected rates for each type of AEFI for a given antigen is provided at http://www.who.int/vaccine_safety/initiative/tools/vaccinfosheets/en/index.html. This can help to make decision on corrective action to be taken on reported AEFIs. It is also important to know about background rates of reported medical events in the country. Comparison of background rates with reported rates of AEFI will guide to a possibility of hypothesis of a coincidence. e.g. febrile seizures are common among young children with many etiologies and also may be possible following some vaccines such as DTwP. Therefore it is important to know the rate of febrile seizures due to other reasons and expected rates following a given antigen. This comparison will essentially lead to describe the causality.

If the values exceed the expected background rates, then one should consider true increase or coincidence due to ongoing other diseases.

Table 10 **Purpose of analysis at different level**

Programme implementation level	Suggested Analysis	Purpose of analysis at this level
Local level E.g. district	• Number of reports by clinics, hospitals, villages by a given time • Reported AEFIs by Place (clinics, hospitals), Persons and time • Reported AEFIs by antigen	• These are programme operation indicators such as timeliness and completeness • Identify immunization errors and thereby will lead to corrective action • Will identify vaccine reactions and coincidence.
Intermediate level (Regional/ town etc.,)	• Number of reports by local level • Reported AEFIs by Place (clinics, hospitals), Person and Time • Cluster analysis • Reported AEFIs by antigen	• These are programme operation indicators (timeliness, completeness) at local level • Identify immunization (programme) errors and thereby will lead to corrective action. • Cluster analysis too lead to identify immunization errors, but also coincidence and vaccine reactions too. • Will identify vaccine reactions and coincidence.
National level	• Number of reports by intermediate levels • Reported AEFIs by Place (clinics, hospitals), Persons and time • Cluster analysis • Reported AEFIs by antigen	• These are programme operation indicators (timeliness, completeness) at intermediate level • Identify immunization (programme) errors and thereby will lead to corrective action. • Cluster analysis too lead to identify immunization errors, but also coincidental events and vaccine reactions. • Will identify vaccine reactions including signal detection • Lead to take operational and policy decisions in the country.

6.3 Evaluating the performance of the AEFI surveillance system

The AEFI surveillance system performance needs to be regularly reviewed at all levels to ensure that the system is sensitive enough to identify and respond to AEFI rapidly. The different types of analysis and their purpose are outlined in table 10. Some of the key indicators that help to monitor the system include

- Timeliness and completeness of AEFI reporting
    - Percentage of AEFI cases reported on time (< 24 hours of notification) to the national level
    - Percentage of serious AEFI cases investigated on time (< 7 days of reporting) using standard formats with complete documentation.
- Number (%) of AEFI investigation conclusions supported by findings of special tests (clinical specimens, Post-mortem findings (among AEFI deaths), lab findings for vaccine samples)
- Number (%) AEFI cases where final classification including causality assessment by AEFI committee is completed within 30 days of receipt of all documentation from districts
- Number (%) AEFI cases reviewed by National AEFI committee following receipt of reported AEFI cases from region at National level.
- Number (%) AEFI cases reviewed by National AEFI committee and not assessable due to lack of information.
- Response to AEFI by the program particularly those related to programme error

7. ACTION AND RESPONSE TO AEFI

AEFI detection, investigation and analysis must lead to action if the credibility of immunization services is to remain high. The first response to an AEFI should be the treatment of the patient, followed by reporting in the AEFI reporting form (annex 1). For non-serious AEFIs line listing of cases should be done and submitted whereas for severe and serious AEFIs (Table 5) the case investigation forms must be completed. The investigating officer should communicate with parents and other members of the community.

Correction of immunization errors of peripheral health workers is critical so that it is clear what went wrong and what are the corrective measured adopted to prevent recurrence such as improving technique, logistics, cold chain, training, support supervision and communication to the parents, community and other health workers not involved in the investigation. Actions to be taken by peripheral health workers are summarized in table 11.

Table 11: **The type of AEFI and their follow up action***

Type of AEFI	**Follow-up action**
Vaccine related reaction*	In case of a higher reaction rate than expected with a specific vaccine or lot, then obtain information from the manufacturer and consult with UNICEF, vaccine procurement agency and WHO /AFRO Regional Office to consider: • withdrawing that lot • changing manufacturing specifications or quality control • obtaining vaccine from a different manufacturer.
Immunization errors	Correcting the 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 health workers • intensified supervision. Whatever action is taken, it is important to review at a later date to check that the predisposing factors to immunization errors have been corrected.
Coincidental	Communication on the actual cause of the event is needed to convince people that the event is coincidental. This communication can be challenging when there is widespread belief that the event was caused by immunization. Sometimes, it may be useful to enlist further expert investigation to convince/ensure that the event truly was coincidental. The potential for coincidental events to harm the immunization programme through false attribution is immense.

*The Decision to temporarily suspend the use of implicated batch of the vaccine/diluent/logistics cannot be made at the local level but by the national level following a causality assessment done by the AEFI committee.

Training and awareness

AEFI is an opportunity for training and awareness for staff. Irrespective of type or outcome of AEFI, one has to take advantage to update knowledge and develop skills and confidence among the staff. Awareness can be expanded beyond heath staff to involve all stakeholders linked to the immunization programme such as academia, teachers, volunteers, NGOs, policy makers, politicians and media.

8. COMMUNICATION

8.1 Communication with parents and community

Communication with parents, other members of the community, health staff and media need to be carried out under all circumstances. They should be kept informed about the investigation, results and action taken already or going to be taken regarding the AEFI. It is crucial to highlight the benefits of immunization while communicating on AEFI with the public/ medical/stake holders.

Key points to consider when communicating with the parents/ relations of the patient, community and health staff

- Listen to parents and their concerns empathetically.
- Reassure and support the parent or recipient but do not make false promises.
- Assist the parents/guardian for hospitalization if necessary.
- Frequent communication with the parents/guardian regarding the progress of the patient.
- Prepare a fact sheet on adverse event for parents, community, health staff and media.
- Build up and maintain relationship among health staff, community and media.
- Inform individual parent about possible common adverse events and how to handle them.
- Continuously communicate with parent and community during the investigation period to assure understanding the risk-benefit of vaccination.
- Not to blame health worker and instead focus on the correction and quality of the EPI system.

8.2 Communication with health staff

- Communicate among all level of health authorities involved
- Reassure the staff confidence on immunization programme: quality of the vaccine and services provided
- Reinforce their knowledge, ability, skills and performances.
- Update them on investigation process, progress and findings.

8.3 Communicating with stakeholders

Vaccine safety information needs to be shared with other stakeholders in order to ensure dissemination of correct information and thereby ensuring the smooth functioning of national immunization programme in the country. The following stakeholders may be informed in two stages: sharing preliminary information at initial stage and final data/report after completion of investigation/causality assessment at a later stage.

- Ministry of Health
- National Regulatory Authority (NRA) /National Control Laboratory (NCL)
- Politicians
- Professionals / Academia
- International agencies: WHO, UNICEF
- Manufacturers

8.4 Communicating with media before AEFI

The media is an important gateway to inform the public and shapes their view and attitudes towards vaccines and immunization. In the long-term, building partnerships with the media is

key to keep the public regularly informed about immunization, its benefits and to motivate families and communities to make use of immunization services. The media is likely to publicize events where there are deaths or AEFI, where the national press has unearthed "ominous facts" or where they have obtained information before the health professionals have done so. Health professionals may become the centre of a crisis if they are accused of not having done their job properly or were found not to be truthful.

The media likes: a fast response, accurate and simple, statistics with explanation, context (part of a wider picture), comments or explanation from the highest authority possible and both or multiple sides of the story. A program manager needs to be aware of how the media functions.

8.4. 1 Information specific to media characteristics

- Local media: May have first covered the story. Read and believed by more people in the community than national media.
- National media: Seen by government and national opinion leaders. Has a wide reach and influences national agendas.
- International media: Seen and read in headquarters of international organizations. Have resources to produce investigative reporting. Can influence national agendas.

8.4.2 Advance preparedness

Effective communication with the media includes efficient coordination with the field staff, a plan, trained personnel, budget and practiced responses to potential issues around AEFI. It should be in place before an immunization campaign starts and as part of the on-going communication support to routine immunization programmes.

8.4.3 A database of journalists

It is essential to maintain a database of print and electronic media journalists covering health (local, national, international) with contact information. They need to be contacted and informed about the circumstances of the AEFI.

8.4.4 Information packages:

Keep media informed through email or hardcopy by sending regular updates on any plans, programs, decisions, etc. Sensitize media about health benefits of immunization and its impact globally and nationally. Prepare monthly or quarterly updates. Provide an updated information package with documents including Frequently Asked Questions (FAQs) on immunization in general, for specific disease and AEFI. (fact sheet or a technical brief on a specific vaccine preventable disease etc.).

8.4.5 Draft media release:

The draft media release must specifically answer the 6 W's for journalists:

- Who is affected/is responsible?
- What has happened? What is being done?
- Where has it happened?
- When did it happen?
- Why did it happen?
- Will it happen again?

In the media release, mention the name and contact details of the AEFI focal person(s) and the name and contact details of the official spokesperson for further details should journalists have additional questions (at the end).

8.4.6 A spokesperson system:

Identify in advance an appropriate spokesperson who can manage media meetings. Share contact details of spokesperson(s) before an immunization campaign starts with all concerned focal points at the district, state and national levels. This limits the possibility of conflicting messages coming from different sources. Ensure spokesperson(s) has experience or some training in dealing with media.

8.4.7 Orientation workshops and field visits for media:

Regular orientation workshops and field visits for journalists will help them achieve a better understanding of immunization advantages as well as the complexities of an immunization programme. This will also help to identify in advance the kind of questions or concerns that journalists specifically have.

8.5 Media Management during an AEFI crisis

While every single AEFI must be investigated in detail, all AEFI cases may not be crisis situation. A crisis often occurs from inaction rather than from taking appropriate action on AEFI.

8.5.1 Monitor-media:

When an AEFI occurs, substantive inaccuracies can get reported; for example, regarding the number of AEFI cases, gravity of the case, allegations of negligence or simple rumors about vaccine procurement. The AEFI Committee should move very quickly to correct them, because the longer misinformation remains in the information environment, the more difficult it becomes to correct. The AEFI Committee could take the following immediate actions:

- Analyze rumor, its level and potential to cause damage.
- Anticipate how situations might evolve following response; prepare before responding.
- Deal with a simple mistake in reporting with a simple solution. If it is an isolated error, make a polite call to the reporter and offer to help the reporter with correct data and facts then and in the future.
- If the rumor is confined to a small audience, correct it within that group only. If the error is widely reported, it may be necessary to call a media conference to present the correct facts before it leads to further damage.
- Plan how to prevent future rumors.

8.5.2 Prepare messages:

The best messages get to the heart of the problem without lengthy explanations. Listeners and viewers remember that one key message if they remember nothing else. Try to repeat the message at least once during an interview with the media. For example, *"Immunization is the most cost-effective health intervention"* or *"Immunization is the right of every child."*

"We have well-established immunization safety surveillance in place", "Immunization safety is of paramount importance and even the slightest suspicion of a problem is investigated", "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", "Vaccines do cause some reactions, but these are rarely serious and hardly ever cause long-term problems" (have data ready and available to substantiate this fact).

8.5.3 Prepare a media release:

An effective media release should include a complete account of the event, framed in its context (e.g. an isolated event or a cluster of AEFI or coincidental event). The media release must specifically answer the '6 Ws' and free from technical jargon. It should have

- An outline of actions taken or planned (such as the AEFI investigation).
- A description of the cause of the event (but only when this is known with certainty).
- An assurance that corrective action has been taken or will be taken.
- Reference to any relevant publication, video material or web site.
- Sender's name and spokesperson's details.
- Limited to one page of matter (400-500 words max).
- Short sentences (not exceeding two lines).

Quotes from key officials may be used after seeking their permission. The quotes must be positive and carry the key messages.

8.5.4 Call a media conference:

Media conferences may need to be conducted if AEFI is being reported extensively and widely and there is a need to provide accurate facts and de-sensationalize the story. A media conference enables all journalists to have the same information, thus there is then less likely of event being 'sensationalized'. Media conferences need to be used judiciously, as there are also dangers, especially if preparation for it is weak and the journalists are assertive. Especially when different stakeholders will be present, everything must be planned well in advance. Consider the following steps when preparing for the media conference:

- AEFI Committee takes the lead but identifies who facilitates the press conference.
- If there are several members on the panel, agree beforehand on the key message(s) in response to the AEFI.
- Agree on roles of each panel member beforehand, including the type of questions (media, political etc. each panel member may best handle);
- Panel members must avoid contradicting each other in the press conference unless it is critical to clarify something incorrect that has been said.
- Have a media kit ready and share it with journalists. The media kit may consist of a media release) with all the essential information, supplementary background information (e.g. on the benefits of immunization) and a set of frequently asked questions (FAQs) about immunization.

8.6 Media Management post AEFI

8.6. 1 Keeping promises to the media:

If it has been promised that media will be kept updated about the investigation findings, make sure the media is updated by the promised date. If the findings have been delayed, ensure the media is informed because they would be expecting answers.

8.6.2 Providing answers to unanswered questions:

During media conferences, if a question could not be answered for any reason – for example due to absence of data or if you were unprepared to answer the questions – get back to the media with the answers as soon as possible.

8.6.3 Keeping media informed about subsequent developments:

If any decision or action is taken at the highest levels following AEFI investigations or during the investigations and the public must know about it, keep the media informed though a press release or hard copy document. The national immunization website www.health.go.ug can be used as an excellent inter-phase to update the media.

AEFI Reporting ID Number:

ANNEX 1: REPORTING FORM FOR ADVERSE EVENTS FOLLOWING IMMUNIZATION (AEFI)

***Patient name*:** ***Patient's full Address*:** Telephone: Sex: ☐M ☐ F ***Date of birth (DD/MM/YYYY)*: __ __ / __ __ / __ __ __ __** *OR Age at onset :* ☐☐*Years* ☐☐ *Months* ☐☐☐ *Days* *OR Age Group:* ☐*< 1 Year* ☐ *1 to 5 Years* ☐ *> 5 Years*	***Reporter's Name*:** Institution / Designation, Department & address: Telephone & e-mail: **Date today (DD/MM/YYYY)*: __ __ / __ __ / __ __ __ __*

Health facility (or vaccination centre) name:

***Name of Vaccines Received**	***Date of vaccination**	***Time of vaccination**	Dose (e. g. 1st, 2nd, etc.)	***Batch/ Lot number**	Expiry date

Adverse event (s): ☐ Severe local reaction ☐ *>3 days* ☐ *beyond nearest joint* ☐ Seizures ☐ *febrile* ☐ *afebrile* ☐ Abscess ☐ Sepsis ☐ Encephalopathy ☐ Toxic shock syndrome ☐ Thrombocytopenia ☐ Anaphylaxis ☐ Fever≥38°C ☐ Other (specify)..... Date & Time AEFI started (DD/MM/YYYY)**:** __ __ / __ __ / __ __ __ __ . ☐☐ Hr ☐☐Min Was the patient hospitalized? ☐Yes ☐No Date patient notified event to health system (DD/MM/YYYY): __ __ / __ __ / __ __ __ __	Describe AEFI (Signs and symptoms):
Outcome: ☐ Recovering ☐ Recovered ☐ Recovered with sequelae ☐ Not Recovered ☐ Unknown ☐ Died If died, date of death (DD/MM/YYYY): __ __ / __ __ / __ __ __ __ Autopsy done: ☐Yes ☐No ☐Unknown	
Past medical history (including history of similar reaction or other allergies), concomitant medication and other relevant information (e.g. other cases)**.** *Use additional sheet if needed* **:**	

First Decision making level to complete:

Investigation needed: ☐ Yes ☐ No	If yes, date investigation planed (DD/MM/YYYY): __ __ / __ __ / __ __ __ __

National level to complete:

Date report received at national level (DD/MM/YYYY): __ __ / __ __ / __ __ __ __	AEFI worldwide unique ID **:**
Comments:	

**Compulsory field*

AEFI LINE LISTING

													(a) Name/ID
													(b) Village/Town/District
													(c) Date of birth(dd/mm/yyyy) and Age
													(d) Date of immunisation(dd/mm/yyyy)
													(e) Adverse Event
													(f) Outcome(Recovered/ Recovering /Disabled/ Died)
													(g) Suspect vaccine (name and dose, e.g. Penta-2)
													(h) Vaccine batch/Lot number
													(i) Diluent batch number
													(j) Onset time interval (**h**ours, **d**ays, **w**eeks)
													(k) Date reporting (dd/mm/yyyy)
													(I) Investigated?(If yes, date)
													(m) Cause (code as outlined in table below)

Coding for cause of AEFI is shown here:

[A1] Vaccine related	[A2] Immunization error related	[A3] Immunization Anxiety Related	[B] Indeterminate	[C] Coincidental	[D] Inadequate information to classify

AEFI INVESTIGATION FORM

(Only for Serious Adverse Events Following Immunization - Death/ Disability/ Hospitalized/ Cluster)

Section A Basic details

Province/State **District** **Case ID**

Place of Vaccination *(✓)* : ☐Govt. Health Facility ☐Private Health Facility ☐Other Specify _____
Vaccination in *(✓)* : ☐Campaign ☐Routine ☐Other Specify _____
Type of site *(✓)*☐Outreach ☐Health Center ☐Dist Hospital ☐Province Hospital ☐Medical College ☐Other _____

Address of vaccination site:

Name of Reporting Officer: Date of filling this form __ __ / __ __ / __ __ __ __

Designation:

Telephone Land Line (with Code): Mobile No. e mail

Patient Name* Sex: ☐M ☐ F

* use separate form for each case in a cluster

Date of birth (DD/MM/YYYY): __ __ / __ __ / __ __ __ __

OR *Age at onset :* __ __ *Years* __ __ *Months* __ __ __ *Days* ***OR*** *Age Group:* ☐*< 1 Year* ☐*1 to 5 Years* ☐*> 5 Years*

Patient's full address with landmarks *(Street name, house number, locality, phone number etc.)*:

Name of vaccines received by patient	Date of vaccination	Time of vaccination	Dose (e. g. 1st, 2nd, etc.)	Batch/ Lot number	Expiry date

Date of first symptom *(DD/MM/YYYY)*: __ __ / __ __ / __ __ __ __ Time of first symptom *(HH/ MM)*: __ __ / __ __

Date of Hospitalization *(DD/MM/YYYY)*: __ __ / __ __ / __ __ __ __ Time of Hospitalization*(HH/ MM)*: __ __ / __ __

Date of First Information *(DD/MM/YYYY)*: __ __ / __ __ / __ __ __ __

Date of Investigation*(DD/MM/YYYY)*: __ __ / __ __ / __ __ __ __

Condition on the date of investigation (✓) : ☐Died ☐Disabled ☐Recovering ☐Recovered completely ☐Unknown

If died, date and time of death *(DD/MM/YYYY)*: __ __ / __ __ / __ __ __ __ *(HH/ MM)*: __ __ / __ __

Post mortem done? (✓)☐ Yes ☐ No ☐Planned on (date) _____ If Yes, Date_____ Time_____ Attach report (if available)

Section B Relevant patient information prior to immunization:

Criteria	Finding	Remarks
Past history of similar event	Yes / No/ UK	
Reaction after previous vaccination	Yes / No/ UK	
History of allergy	Yes / No/ UK	
Pre-existing illness / congenital disorder	Yes / No/ UK	
History of hospitalization in last 30 days with cause	Yes / No/ UK	
Recent history of trauma with date, time and site	Yes / No/ UK	
For adult women • Currently pregnant?	Yes / No/ UK	

• Currently Breastfeeding	Yes / No	
For infants • Natal history • Delivery	 • Full term / pre mature / post dated • Normal / Caesarian / Assisted birth / any complication (specify)	
Was the patient on any concurrent medication for any illness (if Yes : name the drug, indication, doses & date)	Yes / No /Unknown	
Family history of any disease or allergy	Yes / No/ UK	

Section C Details of first examination** of serious AEFI case

Source of information (✓ *all that apply*): ☐**Examination by the investigator** ☐**Documents** ☐**Verbal autopsy** ☐**Other**_____

If from verbal autopsy, please mention the source (✓)	Name of the person who first examined the patient :_ Other sources (specify)

Signs and Symptoms in Chronological order:

The clinical details below are filled up by_____	Designation:	Date/ time

****Instructions – Attach copies of ALL available documents (including case sheet, discharge summary, case notes, lab and autopsy reports) and then complete additional information NOT AVAILABLE in existing documents.** i.e.

- ***If patient has taken medical care*** - Attach copies of all available documents (including case sheet, discharge summary, laboratory reports and post mortem reports - if available) and write only information unavailable in the attached documents belo
- ***If patient has not taken medical care*** – examine the patient and write down your findings below (add additional sheets)

Provisional / Final Diagnosis:

Section D Details of vaccines provided at the site linked to AEFI on the corresponding day

Number of beneficiaries immunized for each antigen at session site. Attach record if available.											
	Vaccine name										
	No of doses										

a) When was the patient immunized? (✓ *below*)

☐ Within the first vaccinations of the session ☐ Within the last vaccinations of the session ☐ Unknown

☐Within the first few doses of the vial administered ☐ Within the last doses of the vial administered ☐Unknown

b)	Was there an error in prescribing or non-adherence to recommendations for use of this vaccine?	Yes@ / N
c)	Based on your investigation, do you feel that the vaccine (ingredients) administered could have been unsterile?	Yes@ / N
d)	Based on your investigation, do you feel that the vaccine's physical condition (e.g. color, turbidity, foreign substances etc.) was abnormal at the time of administration?	Yes@ / N
e)	Based on your investigation, do you feel that there was an error in vaccine reconstitution / preparation by the vaccinator (e.g., wrong product, wrong diluent, improper mixing, improper syringe filling etc.)?	Yes@ / N
f)	Based on your investigation, do you feel that there was an error in vaccine handling? (e.g. Break in cold chain during transport, storage and/or immunization session etc.)?	Yes@ / N
g)	Based on your investigation, do you feel that the vaccine was administered incorrectly (e.g. wrong dose, site or route of administration, wrong needle size, not following good injection practice etc.)?	Yes@ / N
h)	Number of OTHER beneficiaries immunized from the concerned vaccine vial/ampoule	
i)	Number of OTHER beneficiaries immunized with the concerned vaccine in the same session	
j)	Number of OTHER beneficiaries immunized with the concerned vaccine having the same batch number in other locations. Specify locations _____	
k)	Is this case a part of a cluster?	Yes@ / No/
i.	If yes, How many other cases have been detected in the cluster?	
a.	Did all the cases in the cluster receive vaccine from the same vial?	Yes@ / No/
b.	If No, Number of vials used in the cluster (enter details separately)	

@It is compulsory for you to provide explanation for these answers separately

Section E Immunization practices <u>at the place (s) where concerned vaccine was used</u>

(fill up this section by asking & or observing practice)

Syringes and Needles Used:

• Are AD syringes used for immunization?	Yes / No/ U

If No, specify the type of syringes used: ☐Glass ☐Disposable ☐Recycled disposable ☐other _____

Specific key findings/additional observations and comments:

Reconstitution: (complete only if applicable, ✓ NA if not applicable)

• Reconstitution procedure (✓)			
Same reconstitution syringe used for multiple vials of same vaccine?	Yes	No	N
Same reconstitution syringe used for reconstituting different vaccines?	Yes	No	N
Separate reconstitution syringe for each vaccine vial?	Yes	No	N

Separate reconstitution syringe for each vaccination?	Yes	No	N
• Are the vaccines and diluents used same as recommended by the manufacturer?	Yes	No	N

Specific key findings/additional observations and comments:

Injection technique in vaccinator(s): (Observe another session in the same locality – same or different place)	
• Correct dose and route?	Yes / No
• Time of reconstitution mentioned on the vial *(in case of freeze dried vaccines)?*	Yes / No
• Non-touch technique followed?	Yes / No
• Contraindication screened prior to vaccination?	Yes / No
• How may AEFI reported from the centre that distributed the vaccine in last 30 days?	
• Training received by the vaccinator : *(If Yes specify date of last training_____)*	Yes / No/ U

Specific key findings/additional observations and comments:

Section F Cold Chain and Transport

(fill up this section by asking & or observing practice)

Last vaccine storage point:	
• Temp of refrigerator	
• Temp of deep freezer	
• Correct procedure of storing vaccines, diluents and syringes followed?	Yes / No/ U
• Any other item (other than EPI vaccines and diluents) in the refrigerator or freezer?	Yes / No/ U
• Partially used reconstituted vaccines in the refrigerator?	Yes / No/ U
• Unusable vaccines (expired, no label, VVM stage 3 & 4, frozen) in the refrigerator?	Yes / No/ U
• Unusable diluents (expired, manufacturer not matched, cracked, dirty ampoule) in the store?	Yes / No/ U

Specific key findings/additional observations and comments:

Vaccine Transportation:	
• Type of vaccine carrier used	
• Vaccine carrier sent to the site on the same day of vaccination?	Yes / No/ U
• Vaccination carrier returned from the site on the same day of vaccination?	Yes / No/ U
• Conditioned ice-pack used?	Yes / No/ U

Specific key findings/additional observations and comments:

Section G Community Investigation (Please visit locality and interview parents/ others)

Any similar events reported recently in the locality? Yes / No/ UK
If Yes, Describe:

If Yes, How many events / episodes?

Of those effected, How many are

- Vaccinated:_____
- Not Vaccinated:_____
- Unknown:_____

Other comments:

ANNEX 3: LABORATORY REQUEST FORM

This form should be sent with specimens to the laboratory and be completed by the person sending the specimens
Country
Referring Health Facility
Patient's Full Name
Date of Birth*
District
Sub county
Parish
Village / LC 1
Guardian's Name
Occupation
Date of vaccination
Suspected vaccine/product
Date of onset of symptoms of AEFI
Date of collection of specimen sent
Name of laboratory where specimens are being sent
Date specimen(s) sent to the laboratory
Precise description of the samples (e.g ampoule, syringe, stool, blood, pus swab, culture tube)
How were the specimens shipped (e.g with dry ice, ice-pack)
Tests requested
Preliminary clinical diagnosis (working hypothesis)
Name of person to whom laboratory results should be sent
Complete address
Telephone number
email address
Fax number
*If date of birth is unknown, try to indicate year and if possible month of birth