MINISTRY OF HEALTH

Guideline for Monitoring, Reporting and Managing Adverse Events Following Immunization (AEFI) in Kenya

Pharmacy and Poisons Board

Vaccinate to Protect.
Ministry of Health

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ABBREVIATIONS

AD	Auto-disable
AEFI	Adverse Events Following Immunization
AFP	Acute Flaccid Paralysis
BCG	Bacilli de Calmette Guerin
CNS	Central Nervous System
DHIS	District Health Information System
DPT-Hib-HepB	Diphtheria, Pertussis, Tetanus toxoid, Haemophilus Influenzae type B and Hepatitis B vaccine
EPI	Expanded Programme on Immunization
HIV	Human Immunodeficiency Virus
KEPI	Kenya Expanded Program for Immunization
MAH	Marketing Authorization Holder
MOH	Ministry of Health
NRA	National Drug Authority
NVIP	National Vaccines and Immunization Program
NVSAC	National Vaccine Safety Advisory Committee
OPV	Oral Polio Vaccine
PPB	Pharmacy and Poisons Board
SCHMT	Sub County Health Management Team
SCHRIO	Sub County Health Records Information Officer
SCMOH	Sub County Medical Officer of Health
SCPHN	Sub County Public Health Nurse
SCPHO	Sub County Public Health Officer
Td	Tetanus toxoid and diphtheria
TT	Tetanus Toxoid
VAPP	Vaccine Associated Paralytic Polio
VVM	Vaccine Vial Monitor
WHO	World Health Organization

FOREWORD

The Ministry of Health through the National Vaccines and Immunization Program is committed to offering quality immunization services in Kenya as a major contribution in line with the Sustainable Development Goals and to ensurethat all Kenyans enjoy dignity, health and prosperity.

The impact of immunization services in reducing child mortality and morbidity in the country has been significant. Vaccination has greatly reduced the burden of infectious diseases. Overall, the burden due to vaccine preventable diseases has reduced by 70%, from the year 2000.

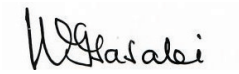
The Pharmacy and Poisons Board ensures that medicines used in the market are safe,efficacious and of good quality. The vaccines used in the program are safe and effective. However, like other pharmaceutical products, vaccines are notentirely free of risk, either real or perceived.

The formulation of these guidelines by the National Vaccines and ImmunizationProgram in conjunction with Pharmacy and Poisons Board is a step towards the right direction and articulates implementation strategies of the Ministry's core values and mandate. This guideline is to be applied alongside each program's policy guidelines.

The overall objective of these guidelines is to ensure efficient flow of information regarding all Adverse Events Following Immunization (AEFI) and appropriate response to vaccine safety concerns. The guidelines articulate the roles andresponsibilities of all stakeholders and spell out the Government's commitment to ensure appropriate actions are taken promptly.

The implementation of these guidelines will positively influence the heath seekingbehaviors, increase information sharing and demand for immunization services as they ensure continued community confidence in immunization services.

The Ministry of Health acknowledges the work that has been accomplished to develop these guidelines and advises all stakeholders to support the implementation of these guidelines.



Dr. J. Wekesa Masasabi
Ag. DIRECTOR GENERAL FOR HEALTH

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This Guideline for Monitoring, Reporting and Managing Adverse Events Following Immunization (AEFI) is the result of teamwork, concerted effort, commitment and extensive consultations. The guidelines were drafted under the guidance and coordination of the drafting working group whose members were drawn from Ministry of Health, National Vaccines Immunization Program (NVIP), Pharmacy and Poisons Board (PPB) and development partners for health. The Ministry of Health acknowledges with appreciation the invaluable contributions made by members of the working group and their commitment to ensure a comprehensive, elaborate andquality document is finalized.

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List of Contributors

NAME	INSTITUITION
Professor Ezekiel Wafula	University of Nairobi
Dr Collins Tabu	MOH-NVIP
Dr Fred Siyoi	MOH-PPB
Dr Edward Abwao	MOH-PPB
Dr Jonathan Meriakol	MOH-PPB
Dr Bibiana Njue	MOH- PPB
George Muthuri	MOH-PPB
Dr Ali Arale	MOH-PPB
Dr Christabel Khaemba	MOH-PPB
Dr Martha Mandale	MOH-PPB
Steve Mwangi	MOH-NVIP
Dr Joyce Charo	MOH-NVIP
Samson Thuo	MOH-NVIP
Pamela Ochieng'	MOH-NVIP
Dr Lucy Mecca	MOH-NVIP
Dr Rose Jalang'o	MOH-NVIP
Christine Miano	MOH-NVIP
Edwina Anyango	MOH-NVIP
Catherine Munyao	MOH-NVIP
Nancy Chongwony	MOH-NVIP
Carol Mbogori	MOH-NPHLS
Dr Sujeet Jain	WHO
Dr Iheoma Onuekwusi	WHO
S.M. Kamau	Micronutrient Initiative
Dr Jayesh Pandit	Bayer EA
Olga Menang	PATH
Chris Odero	PATH
Dr Isaac Mugoya	USAID/MCSP
Dr Peter Okoth	UNICEF

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 factorand disease with no other factors intervening in the process.

Causality Assessment - Causality assessment is the systematic review of data about an AEFI case to determine how likely it is that a certain vaccine caused a certain event

Coincidental event - An AEFI that is caused by something other than the vaccineproduct, immunization error or immunization anxiety.

Cluster - Two or more cases of the same event or similar events related in time, geography, and/or the vaccine administered. National programme managers may decide upon a more precise definition.

Herd Immunity - Is a form of immunity that occurs when the vaccination of a significant portion of a population (or herd) provides a measure of protection for individuals who have not developed immunity.

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

Immunization error-related reaction (formerly programmatic error) - An AEFI that is caused by inappropriate vaccine handling, prescribing or administration and thus, by its nature, is preventable.

Immunization safety - The public health practices and policies dealing with the various aspects of the correct administration of vaccines, focusing on minimizing therisk 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.

Signal (safety signal) - Information (from one or multiple sources) which indicates a potential link between a vaccine and an event previously unknown or incompletely documented, that could affect health. The signal will suggest a new and potentially causal association, or a new aspect of a known association, between a vaccine and an event or set of related events, either adverse or beneficial.

Surveillance - The continuing, systematic collection of data that is analysed and disseminated to enable decision-making and action to protect the health of populations.

Vaccine - A 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 AEFI and other vaccine- or immunization-related issues, and to the prevention of untoward effects of the vaccine or immunization.

Vaccine product - All components of a given vaccine formulation, including the immunogen(part of the vaccine that stimulates an immune response) and others that may be present such as the adjuvant, preservative and other additives used during the manufacturing process to confirm product quality/stability (e.g. potassium or sodium salts, albumin,gelatin), support growth and purification of specific immunogens (e.g. egg or yeast proteins,antibiotic) or inactivate toxins (e.g. formaldehyde).

Vaccine product-related reaction - An AEFI that is caused or precipitated by a vaccine dueto one or more of the inherent properties of the vaccine product, whether the activecomponent or one of the other components of the vaccine (e.g. adjuvant, preservative or stabilizer).

Vaccine quality defect-related reaction - An AEFI that is caused or precipitated by avaccine that is due to one or more quality defects of the vaccine product, including its administration device as provided by the manufacturer.

1. INTRODUCTION

Vaccines are biological substances that are administered to individuals to elicit immunity (protection) against specific diseases. With the exception of safe water, nothing else, (not even antibiotics) has had such a major impact on the reduction of mortality (deaths) and morbidity (illness and disability) and on population growth like vaccination. Immunization is one of the most cost-effective public health intervention that has led to global eradication of diseases such as small pox and elimination of diseases such as tetanus.

The benefits of vaccination are felt both at individual level and community level through herd immunity. Herd immunity is achieved once a critical number/ proportion of individuals are vaccinated. In order to achieve and maintain high immunization coverage, there is need to maintain public confidence in immunization.

1.1 TYPES OF VACCINES	Live Attenuated Vaccines	Inactivated (Killed) Antigen
	BCG, Yellow fever vaccine, Measles Rubella vaccine, Oral Polio Vaccine	whole cell Pertussis(wP), Inactivated Polio vaccine
Subunit (purified) antigen	**Conjugate vaccine**	**Toxoid (inactivated toxin)**
acellular pertussis(aP), Hepatitis B	Haemophilus influenzae type B (Hib), Pneumococcal vaccine	Tetanus Toxoid (TT), Diphtheria toxoid

1.2 Common components of vaccines

A vaccine consists of many parts, only one of which is the antigen by which it is known, and it is also known as the immunogen. A vaccine formulation contains other components such as diluents, stabilizers, adjuvants, preservatives, buffers, surfactants, and proprietary ingredients (such as viscosity controlling agents and osmotic pressure controlling agents).

Antigen - Is the principle part of any vaccine and has evolved over several years from killed or denatured (Attenuated) whole bacterium or viruses, to parts of the disease-causing agent such as the capsule or genetically engineered components that mimic the disease causing agent.

Adjuvants - Substances that are added to some vaccines to enhance the body's immune response to the Antigen. Examples are aluminium hydroxide gel, emulsigen, aluminium phosphate, calcium phosphate, quillaja saponin and ginsenoids

Antibiotics - Prevent bacterial contamination e.g. neomycin

Diluents - Include water, aqueous buffer (such as buffered saline), alcohols and polyols (e.g. glycerol). Vaccines marketed as suspensions or solutions already have the diluent constituted into the vaccine. Some diluents are provided separately from the lyophilized (freeze dried) vaccine for reconstitution at the time of use.

Preservatives - Chemical additives to vaccines to ensure that they remain microbiologically stable. That is, they prevent the growth of microorganism and fungi during the long time of storage as well as during its use (especially with multi-dose vials) e.g. formaldehyde, phenol, Thimerosal, beta-propiolactone etc. Not all vaccines contain preservatives.

Stabilizers - Chemical substances added to vaccines in micro-quantities to maintain vaccine integrity under varying external conditions of temperature and light, and also to sustain physical properties such as solubility. e.g. lactose, gelatin

Trace components - These are left over from the process of manufacture of the vaccine e.g. formaldehyde

1.3 Overview of Immunization in Kenya

The Ministry of Health established The Kenya Expanded Programme on Immunization (KEPI) in 1980 with the main aim of providing immunization against six childhood diseases, namely Tuberculosis, Polio, Diphtheria, Whooping Cough, Tetanus, and Measles to all children in the country before their first birthday, and Tetanus Toxoid vaccination to all pregnant women.

KEPI is currently rebranded as the National Vaccines and Immunization Program (NVIP) due to its extended scope to cover all vaccination services previously coordinated by other divisions within the Ministry of Health. These include routine infant childhood immunization, Tetanus toxoid for pregnant women, emergency vaccination (anti-rabies, anti-snake venom, meningococcal vaccine and tetanus toxoid for trauma,) and also vaccination for special groups (typhoid vaccine for food handlers, hepatitis B for health workers and yellow fever vaccine for travelers).

The overall mandate of the NVIP is to coordinate Immunization services for all vaccine preventable diseases through ensuring equitable access to effective high quality and safe vaccination services for all.

The role of the NVIP is to ensure:

- Policy regulation and oversight of immunization services in the country
- Commodity security & quality assurance of vaccines and vaccination services in the country
- Monitoring and evaluation of immunization services
- Advocacy, communication, social mobilization for immunization
- Resource Mobilization and Capacity strengthening for immuniza tion service delivery
- Conduct of appropriate operational research

Immunization is a shared function between the national level and the 47 Counties who are responsible for delivery of immunization services.

Vaccine	Birth	6 Weeks	10 Weeks	14 Weeks	6 Months	7 Months	9 Months	18 Months	24 Months	10 Years
BCG	x									
Oral Polio Vaccine	x	x	x	x						
Rotavirus Vaccine		x	x							
DPT-HepB-Hib		x	x	x						
Pneumococcal Vaccine		x	x	x						
Inactivated Polio Vaccine				x						
Measles Rubella							x	x		
Yellow Fever Vaccine (Selected counties)							x			
Malaria Vaccine (Selected Counties)					x	x	x		x	
Human Papilloma Virus Vaccine (girls)Vaccine (girls)										x

Table 1. Current routine EPI schedule

The immunization program aims to vaccinate at least 90% of the target population with routine vaccines. In addition, as part of prevention and response to disease outbreaks, and as part of the broader disease control, elimination and eradication strategy,

the immunization program conducts supplemental immunization activities (SIA) from time to time to boost population immunity and interrupt transmission of disease.

The vaccines used in the program are safe and effective when used as intended, however, like other pharmaceutical products, vaccines are not entirely free of risk. Adverse events,either real or perceived may occasionally follow vaccination. Serious adverse events following immunization, though rare, have the potential to dent public confidence in immunization and cause refusals for immunization. This can result in populations that aresusceptible to disabling and life-threatening vaccine preventable diseases.

1.4 The role of the National Regulatory Authority

Adverse Events Following Immunization (AEFI) surveillance is a collaborative initiative between the National Regulatory Authority (NRA), which is the Pharmacy and Poisons Board(PPB) and NVIP. The two institutions are responsible for the safety of vaccines and otherbiological products. Amongst its many functions as spelt out in Cap 244, laws of Kenya, the PPB has charted out a mission to ensure accessibility, quality, safety and efficacy of human and veterinary medicines and vaccines.

The role of the NRA is:

- Licensing of vaccines for use in the country
- Evaluating clinical trials of the vaccine
  - Controlling and releasing each batch or lot of vaccine
  - Recalling the vaccine
- Performing Laboratory testing
- Monitoring safety of vaccines
- Inspecting Manufacturing facilities regularly.

The main function of the PPB's AEFI surveillance system is to ensure the continued quality and safety of vaccines in the Kenyan market by monitoring adverse events following immunization with vaccines.

2. PURPOSE OF THE GUIDELINES

Vaccines are usually given to healthy people unlike drugs that are used for treatment of disease.It has been shown that with declining prevalence of vaccine preventable disease, people become increasingly intolerant to the risk of vaccine associated reactions. In addition, new vaccines are being introduced thereby heightening the need to monitor for adverse events in the local setting.

In order to maintain confidence in vaccines there is need to have a clear guideline of detecting, reporting, investigating and responding to AEFIs. This guideline should be read and used alongside *The Guidelines for the National Pharmacovigilance System in Kenya and The National Policy Guidelinesfor Immunization.*

The purpose of these guidelines is to provide health care managers and frontline health workers with information and guidance on:

1. **What constitutes an AEFI**
2. **Types of AEFI**
3. **Known vaccine reactions and their expected rates of occurrence**
4. **How to prevent AEFIs**
5. **How to detect, investigate, report and respond to AEFIs**

These guidelines will enable the health worker at the field level to minimize and appropriately respond to AEFI when they occur; this will help sustain public confidence in the immunization program.

2.1 What is an Adverse Event Following Immunization?

The World Health Organization defines and adverse event following immunization as any untoward medical occurrence which follows immunization and which does not necessarily have a causal relationship with the usage of the vaccine. In simple terms, *An adverse event following immunization (AEFI) is an unwanted or unexpected health effectthat happens after someone receives a vaccine, which may or may not be caused by or related to the vaccine.*

The adverse event may be any unfavorable or unintended sign, abnormal laboratory finding symptom or disease.

AEFIs can occur even in the most careful of circumstances but only rarely is there a direct causal relationship between the vaccine and the adverse event. AEFIs may be localized to the site of administration or generalized to the whole body.

3. TYPES OF AEFI

AEFI can be classified into 5 types, depending on the cause of the reaction.

i) Vaccine product-related reaction
ii) Vaccine quality defect-related reaction
iii) Immunization error-related reaction
iv) Immunization anxiety-related reaction
v) Coincidental event

3.1 Vaccine Product Related Reaction

An event that is caused or precipitated by a vaccine due to one or more of the inherent properties of the vaccine product. This type of reaction may occur even when the vaccine has been prepared, handled and administered correctly.

- Most are as a result of interaction of the immune system and antigens contained in the vaccine e.g. pain, fever, swelling, loss of appetite
- Other vaccine components can also trigger reactions e.g. adjuvants,preservatives

The minor vaccine reactions are common while others (more serious ones) are very rare.

Common, non-serious reactions

Local reactions including mild pain and swelling and/redness at the injection site may occur in about 10% of vaccinees. This is more common with DPT-Hib-HepB vaccine.

While mild fever is a common reaction, high to extreme temperatures are rare and need to be investigated to rule out the possibility of other causes. The client should be advised to return to the facility in case of a persistent or high fever or any other symptom that is a concern to the caregiver. Other symptoms such as irritability, malaise and loss of appetite are also frequently reported with DPT-Hib-HepB vaccine and usually resolve naturally.

Measles vaccine may cause mild symptoms such as rash or conjunctivitis, akin to those seen in a measles infection. However, such symptoms are usually mild. The severity may increase in severely immunocompromised children.

These common reactions appear one or two days after the administration of the vaccine, except for the mild fever and general symptoms produced by Measles and Rubella vaccine 5 to 12 days after vaccination. These usually resolve without any serious consequences.

Rare vaccine reactions

Some of the more serious vaccine reactions (e.g., seizures, hypotonic hypo responsive episodes) occur rarely and usually do not lead to long-term problems. Anaphylaxis, while potentially fatal, is treatable without long term sequelae.

An increase in the expected frequency of rare, serious reactions may indicate either a problem with a specific vaccine batch or a programme error.

The picture below is of a child who got BCG lymphadenitis, which is a rare vaccine reaction

Table 2. Known vaccine product-related reactions and their expected rates of occurrence

Vaccine	Common non-serious reactions			Serious reactions		
	Local reaction (pain swelling redness)	Fever	Irritability, malaise and non-specific symptoms	Reaction	Onset Interval	Number of events per million doses
BCG	Common	-	-	Suppurative lymphadenitis BCG osteitis Disseminated BCG infection	2-6 months 1-12 months 1-12 months	100-1000 1-700 2
Hepatitis B	Adults up to 30% Children up to 5%	1-6%	-	Anaphylaxis Guillain-Barre Syndrome (plasma derived)	1.1. Hour 1-6 Weeks	1-2 5
Measles	Up to 10%	Up to 5%	Up to 5%	Febrile seizures Thrombocytopa enia (low plate-lets)Anaphylaxis	5-12 days 15-35 days 0-1 hours	333 33 1-50
OPV	None	Less than 1%	Less than 1%	Vaccine-associated paralytic polio (VAPP)	4-30 days	1.4-3.4
Tetanus	Up to 10%	Up to 10%	Up to 25%	Brachial neuritis Sterile abscess	2-28 days 1-6 weeks	5-10 1-6 6-10
DPT- Hib-HepB	Up to 50%	Up to 50%	Up to 60%	Persistent (>3 hours) inconsolable screaming Seizures Hypotonic hyporesponsive episode (HHE) Anaphylaxis / shock Encephalopathy	0-24 hours 0-3 days 0-24 hours 0-3 days	1,000-60,000 570 570 20 0-1

3.2 Vaccine Quality Defect-related reaction

An event 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. For example, Failure by the manufacturer to completely inactivate a lot of inactivated poliovaccine may lead to cases of paralytic polio.

An increase in the expected frequency of certain reactions may indicate either a problem with a specific vaccine batch. Due to current stringent quality assurance measures during manufacture and procurement, this kind of reaction is very rare. Vaccines undergo lot release which means that each vaccine batch has to undergo quality assurance procedures before release. Health workers however still need to be on the lookout for this rare occurrence.

3.3 Immunization error-related reactions

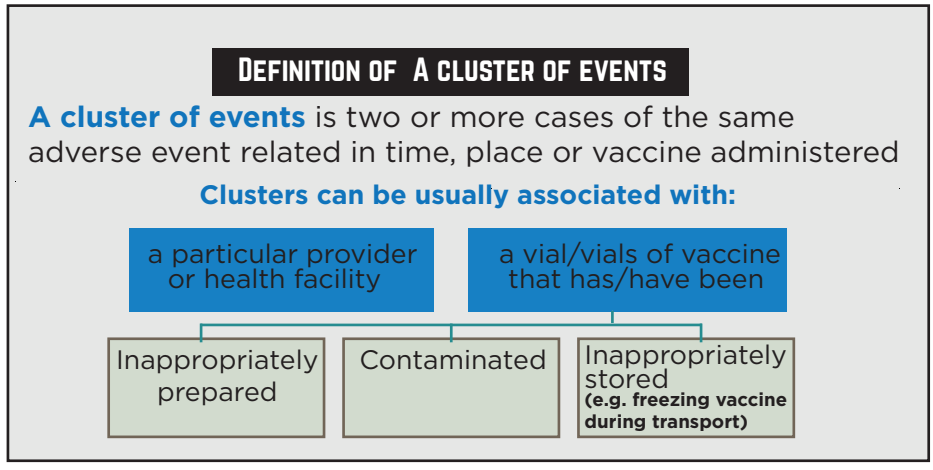
Immunization error-related reactions are probably the most commonly reported adverse events. These are also known as ‘program errors’.

These occur as a result of inappropriate storage, handling, preparation and administration of vaccines. Reconstitution with wrong diluent may lead to serious AEFIs, for example if adifferent product is confused with the diluent where they have been inadvertently stored together. Thermal shock may also occur where the diluent is stored at room temperature andis used to reconstitute a refrigerated vaccine. This may lead to an increase in local reactions.

The table below, though not exhaustive provides examples of events that could occur after an immunization error.

ERROR	POSSIBLE AEFI
Non-sterile injection • Contaminated vaccine or diluent • Wiping the needle with a swab • Administering injection over clothes	Local reaction, abscess, Toxic Shock Syndrome
Injection at incorrect site/ route • BCG given subcutaneously • Pentavalent/ TT given superficially • Injection into buttocks	Local reaction, abscess, sciatic nerve damage
Reconstitution with incorrect diluent e.g Drug substituted for vaccine diluent	Negative effect of drug (e.g., insulin,oxytocin, muscle relaxants)
Re-use of reconstituted vaccine at subsequent sessions, beyond the time limit	Toxic shock syndrome
Vaccination staff ignoring or not becoming familiar with contraindications with a vaccine	Avoidable serious reaction
Incorrect vaccine transportation/storage incorrect	Local reaction from frozen vaccine, ineffective vaccine
Re-use of disposable syringe and needle	Transmission of blood-borne infections such as Hep B, HIV, Hep C

AEFI occurring as a cluster usually points to an immunization error



3.4 IMMUNIZATION ANXIETY-RELATED REACTION

Vaccinated children or adults can react in anticipation to an injection of any kind.

This reaction is unrelated to the content of the vaccine. Examples of immunization anxiety reactions include fainting, light-headedness, dizziness, tingling around the mouth and in the hands, breathe holding in younger children, which in some cases can lead to unconsciousness.

Immunization anxiety-related reactions have been observed commonly in adolescents and therefore worth considering when carrying out vaccination exercises in this age group. In a group situation, mass hysteria is possible, especially if a vaccinee is seen to faint or have some other reaction.

It is important to provide the parents and community with clear explanations about the immunization in a calm and confident manner. In addition, where possible, parents should be allowed to accompany the child being vaccinated to reassure the child and to feel reassured about the vaccination process.

3.5 Coincidental events

Children are usually given vaccines at an age when they are susceptible to many diseases e.g. malaria, respiratory illnesses etc. Therefore, situations may arise when an adverse event is falsely attributed to the vaccine. In other words, because an event occurred after immunization, it is automatically believed that the event occurred because of the vaccination.

For example, a fever can occur at the time of the vaccination (temporal association) but is in fact caused by malaria.

These events can occur especially during mass immunization campaigns when there are large numbers of individuals being vaccinated. For example, death of child due to pneumonia after polio vaccination may be wrongfully blamed on the vaccine.

Classification AEFIs by Seriousness/ Severity

Adverse events can also be classified in terms of seriousness

An AEFI will be considered serious, if it:

- results in death,
- is life-threatening,
- requires in-patient hospitalization,
- results in persistent or significant disability
- is a congenital anomaly/birth defect, or
- requires intervention to prevent permanent impairment

Non-serious: an adverse event that is not serious

It is important to remember that not all Serious AEFI are actually caused by the vaccines themselves. Most are due to immunization errors or underlying medical problems in the patient. To determine the exact cause of serious AEFI, all serious suspected vaccine reactions should be reported and investigated. In the case of program errors, the immunization program can correct these once the cause has been determined

Use of the term 'severe'

Severe event

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 (e.g. Fever is a common relatively minor medical event, but according to its severity it can be graded as mild fever or moderate fever).

4. DETECTION OF AEFI

It is important for health workers to be able to detect AEFI in order to respond appropriately. Cases of AEFI can be detected as follows:

a) Observe the client after vaccination for any immediate reactions such as anaphylaxis. Clients should be kept at the site of vaccination for at least 30 minutes of vaccination in order to detect any immediate events

b) Patients with an AEFI may present for treatment at outpatient. Health workers at outpatient should be well oriented on detection and response to AEFI.

c) Reports from the caregiver after vaccination or even during the next visit. The health worker should listen to caregivers and report any concerns that are reported by the caregivers when the caregiver returns to the facility for the next visit

d) Reports from the community. Community Health Volunteers may detect AEFI within the community. Community members may also report directly to the health worker. The health worker should follow up any AEFI reported to them by community health volunteers or by other community members. This alsoincludes reports from outreach sites and others.

e) Media reports

It is important to ascertain that the event being reported began after vaccination

5. RESPONDING TO AEFI

Once an AEFI has been detected relevant actions should be taken including:

a) Management of AEFI as per presentation and according to standard guidelines

b) Reporting of AEFI

c) Investigation of selected AEFI

d) Causality assessment

e) Communicating to stakeholders including caregivers and the community

6. MANAGEMENT AND PREVENTING OF AEFI

The immediate steps to take when a serious AEFI occurs are:

1.Triage the affected child and take him/her to the resuscitation room or a safe place away from any crowd and give the correct treatment as per the condition (See Table 4. Below).

2. Ask or shout for help from colleagues

3. Re-assure the parent as the child gets treatment

4. Collect the vaccine vial and the diluent which were used using sterile procedures and document the details (date of manufacture, expiry date, batch number and manufacturer)

5. Take a sample specimen as per the condition and take for laboratory analysis

6. Observe until the child's condition improves if the condition does not improve within 2 hours refer to the next level

7. Report the AEFI within 24 hours and investigate within 48 hours.

6.1 Management of Selected AEFIs

The table below provides guidance on management of selected AEFIs. Rule out any coincidental illness as you manage the patient.

Table 4: Management of selected AEFI

AEFI	TREATMENT
Local reaction (pain, swelling, redness)	• Cold cloth at injection site • Give paracetamol
Fever (> 38◦ C)	• Exposure-remove extra clothing • Tepid sponging • Give Paracetamol at 15mg/kg, if the fever persists. If child is vomiting with fever, give per rectal paracetamol at 15mg/kg • Follow up a child with fever in 3 days • Fever is a common symptom in children, and so **persistent fever** should be investigated for the common childhood illness • **Avoid premedication with antipyretics before vaccination**
Irritability, malaise	• Give extra fluids • Give paracetamol
Injection site abscess	Give the child analgesics, start on appropriate antibiotic, review and drain the abscess
Febrile convulsions	Control fever with paracetamol and undress the child refer if child has altered conscious level
Toxic Shock Syndrome	Ensure the basics (A, B, C, D). Secure a line and start antibiotics, analgesics and then refer to a hospital for admission and further investigations.

6.1.1.1. ANAPHYLAXIS

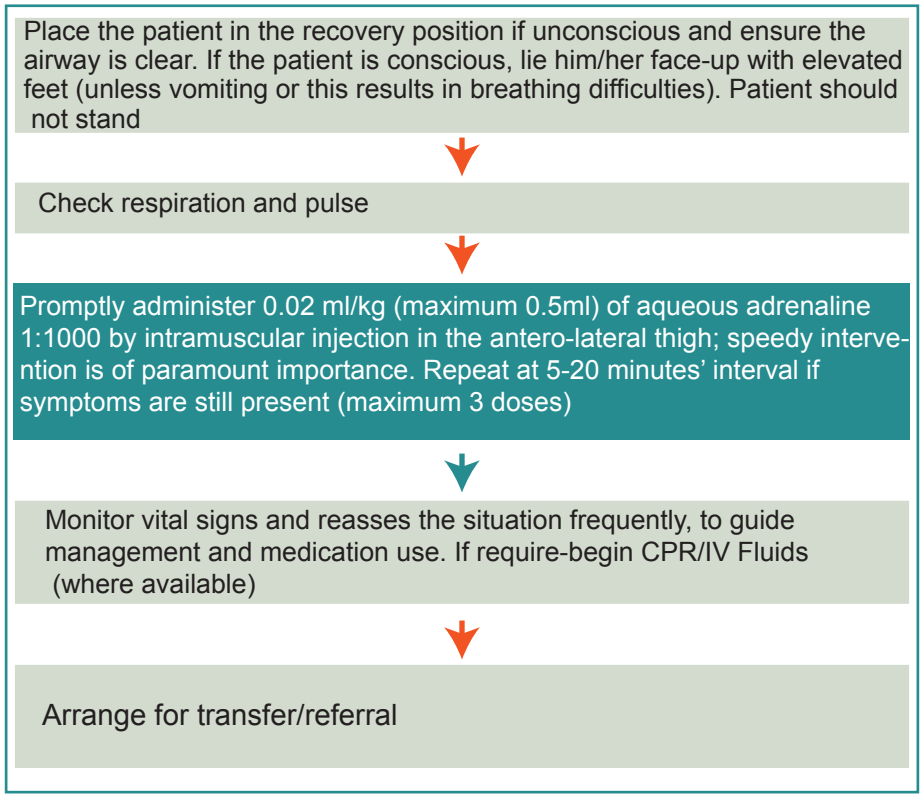
Anaphylaxis is an acute hypersensitivity reaction with multi organ system involvement that can present as or rapidly progress to a life-threatening reaction. It is a rare medical emergency but potentially fatal condition irrespective of current symptoms. It is important to start treatment immediately and make appropriate plans for referral to the next level.

Table 5: Signs and symptoms of anaphylaxis

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

Steps in managing anaphylaxis

ABCD: Airway should be secured. Breathing: Initiate CPR,Circulation: Monitor vitals, secure an IV line then refer for further management



Dosage of adrenaline

- 0.01ml/kg up to a maximum of 0.5 ml injected intramuscularly
- Children under 3 years: 0.1 ml
- Children 4-6 years: 0.2 ml
- 6-12 years: 0.3ml
- >12 years 0.5ml; 0.3ml for small stature

Ensure that the anaphylactic reaction has been clearly recorded on the mother child health booklet or patient card. It is important that health workers recognize the difference between fainting and anaphylaxis.

Table 6. Clinical features of Fainting vs Anaphylaxis

	Fainting	Anaphylaxis
Onset	Usually at the time or soon after injection	Usually some delay between 5–30 minutes after injection
Symptoms		
Skin	Usually at the time or soon after injection	Usually some delay between 5–30 minutes after injection
Respiratory	Normal to deep breaths	Noisy breathing from airways obstruction
Cardiovascular	Bradycardia Strong carotid pulse	Tachycardia Weak carotid pulse
	Transient hypotension	Hypotension
Gastrointestinal	Nausea/Vomiting	Abdominal cramps
Neurological	Transient loss of consciousness, good response once in recovery position	Loss of consciousness, little response once in recovery position

Health workers should be aware that some AEFI are unavoidable at their level while others can be prevented

Unavoidable AEFIs include:

a) Vaccine product-related reaction
b) Vaccine quality defect-related reaction
c) Coincidental event

Preventable AEFI include:

a) Immunization anxiety-related reaction
b) Immunization error-related reaction

However, it is necessary to **prepare to respond** to both **avoidable and unavoidable** AEFIs.

Anticipate. Do not wait until a crisis develops. Prepare for the unavoidable. Ensure that an emergency kit is available within the reach of the vaccinator

During campaigns, each team should have:

- An emergency plan of action
- The team supervisor should have Adrenaline injection (2 amps), two syringes and needles
- A designated health facility to receive serious AEFIs in each catchment area
- Complete emergency kit for each fixed post/ designated health facility
- AEFI forms

Keep children at site for 15 – 30 minutes after vaccination in order to identify any immediate reactions

- Train vaccination personnel at all levels to respond appropriately.
- Confirm all the facts before making any public statements. Only the designated spokesperson should address the media.
- Prepare a plan to respond to a crisis when it occurs. The plan should include communication to different levels of management.

6.2 Preventing Immunization Anxiety Reactions

To prevent immunization anxiety-related reactions, it is important to provide the parents and community with clear explanations about the immunization in a calm and confident manner. Children of a certain age, for example, adolescents should also be provided with this information. This is likely to reduce the likelihood of such an event occurring. Inaddition, where possible, parents should be allowed to accompany the child being vaccinated to reassure the child and to feel reassured about the vaccination process.

Minimize crowding in outreach sessions, for example let children come into the vaccination room one by one.

6.3 Preventing Immunization Errors

Observe the following to prevent immunization errors:

a) Vaccinators should be trained clinicians

b) Immunization workers must be adequately trained and closely supervised to ensure that proper procedures are being followed

c) Vaccines must only be reconstituted with diluents supplied by the same manufacturer

d) Observe the Multi dose vial policy

e) Reconstitute and administer vaccines using aseptic technique

f) Ensure correct route, site and dosage is used during administration

g) Avoid storing other drugs or substances in the same refrigerator as vaccines

h) Follow correct storage and handling practices for vaccines

i) Observe absolute contraindications to vaccines

General contraindications and precautions for vaccination

a) Previous serious reaction to vaccine or any vaccine components

b) It is generally considered safe to vaccinate pregnant women with the following vaccinations; Inactivated us influenza vaccine,tetanus vaccine (TT), Tetanus- diphtheria (Td), Hepatitis B, Meningococcal polysaccharide vaccine. Caution should be observed when considering live vaccines

c) Live vaccines are contraindicated during severe immunocompromised state

d) Precaution is required when administering injectable vaccines to patients with haemophilia

e) Precaution when administering vaccines during severe illness Refer to the vaccine specific guidelines for further guidance.

7. REPORTING OF AEFI

7.1 What to report

Complete the AEFI reporting form when any Adverse Event Following Immunization (AEFI) occurs and especially those of parental and/or health worker concern

Any adverse event that happens after getting a vaccine should be reported, even if one is not sure that the vaccine caused the adverse event.

The Following AEFIs Must Be Reported

- Allergic reaction- Anaphylaxis, Urticaria, Bronchospasm, Edema
- Febrile convulsions
- Injection site abscess
- Clusters of events (2 or more cases of same event related in time, place or vaccine administered)
- Serious Events (Life-threatening or results in death, hospitalization, persistent or significant disability or birth defect)
- Events reported to you by the parent
- Events you are concerned about as a health worker
- Any uncommon or unexpected events that may be of public concern

7.2 Who should report?

Reporting of AEFIs is a critical component in the management of AEFIs. The health worker should detect and report AEFIs. Reporting of the AEFIs can also be done by parents, guardians, the patients/clients, next of kin, community health volunteers to the health worker who will then report to higher levels, fill in the reporting form and submit as per schema in the following section.

Market authorization holders (MAHs) shall also submit AEFI reports as per the existing guidelines on the vigilance of medical products and health technologies

7.3 When to Report

When serious and or clusters of AEFI occur, the Sub-County Public Health nurse/ Sub County Pharmacist /Sub County Medical Officer for Health should be notified by phone immediately. This notification shall be followed with a filled reporting form and submitted to the Sub-County Public Health nurse/ Sub County Pharmacist /Sub County Medical Officer for Health within 24 hours. All other AEFI reports should be submitted within seven days.

Health workers are encouraged to report AEFI even if they are not certain that the vaccine caused the event.

MAHs shall submit the AEFI reports as per the existing pharmacovigilance guidelines in terms of the timelines for submitting reports.

Any Serious and or cluster of AEFI should be reported immediately to the next level (by phone) and the reporting form filled and submitted to the next level within 24 hours. All other AEFI reports should be submitted within seven days

7.4 Where to Report

AEFI should be reported using the AEFI report form (Annex 1) and submitted to the sub-county public health nurse/ Sub County Pharmacist/Sub county Medical Officer of Health. At sub-county level, the AEFI report will be uploaded to the DHIS 2 AEFI event capture module by the Sub County Health Records and Information Officer (SCHRIO) and submitted to NVIP.

Reports can also be submitted online through the PPB pharmacovigilance online system at

www.pv.pharmacyboardkenya.org

7.5 How to Report

The health worker should fill in the AEFI form in triplicate. Submit two copies to the SCHRIO for entry into the AEFI event capture module on DHIS2 and file the third copy. When all information is not available, an initial report will be done followed by a follow-up report once additional information is available.

MAHs shall also submit reports to PPB in the E2b or CIOMS format. All AEFIs detected at the Health facility, once confirmed should also be recorded in Mother Child Health Booklet and in the MOH 702 form (Immunization Tally Sheet) then summarizedon a monthly basis into the MOH710. The summary report shall be sent to the sub-county for entering into the DHIS 2 as an aggregate report.

AEFIs detected within the private sector, as well as those detected during supplementary immunization activities should be reported immediately by the healthcare worker using the above channels.

Note: Submission of a report does not mean admission that the health worker or manufacturer or the product caused or contributed to the event. Reports are submitted in confidence and will not be shared with unauthorized persons.

Do not address the media without facts, refer the media to the relevant agency- County director/NVIP

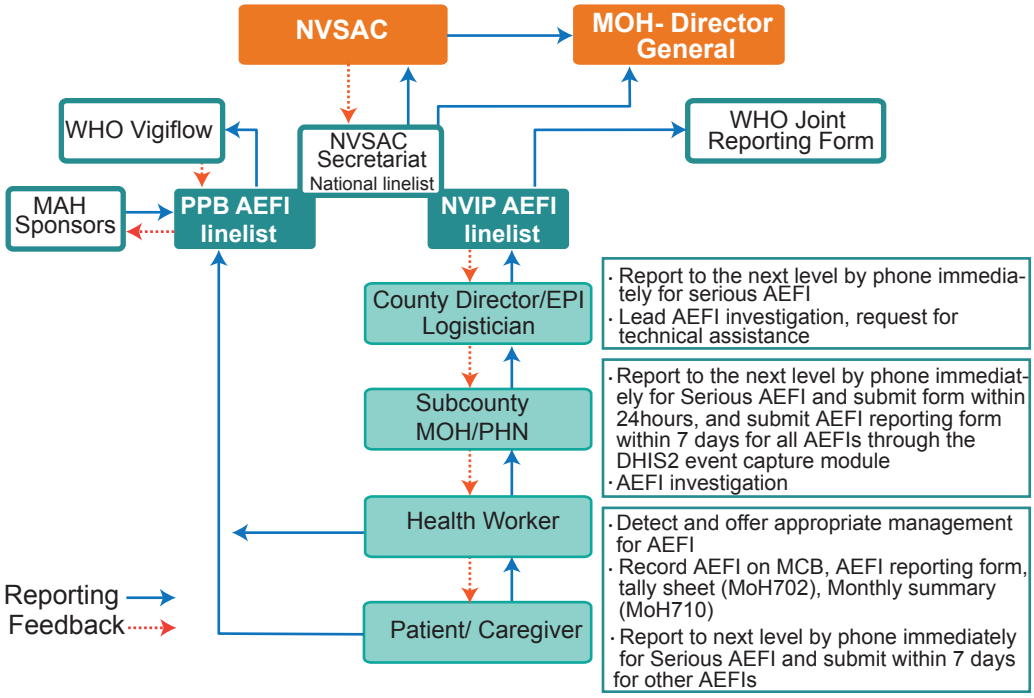
7.6 Importance of Reporting

Reporting of AEFIs provides vital information for monitoring vaccine safety. This enhances confidence in immunization by appropriately responding to parental/community concerns about immunization safety while increasing awareness (public and professional) on the same. In addition, reporting enhances availability of local data on vaccine safety to inform policy and decision making and to ensure that coincidental events are not falsely blamed on immunization.

Reporting AEFIs will also enable early detection of risks and enable corrective action for immunization errors, detect an increase in frequency of expected reactions, identify unusual high rates of AEFIs with specific vaccine lots and brands.

If you are unsure whether to report an AEFI, be proactive and report the event

7.7 AEFI Reporting Pathway



7.8 Confidentiality of AEFI Reports

Individual AEFI reports should be kept confidential just as a patient's clinic information is kept unless otherwise required by a court of law.

It is unethical to divulge patient information without their consent. Therefore, data analysis and reports on aggregate level should be unlinked to individual client's identifiers to preserve anonymity. Submitted reports will also be handled confidentially.

7.9 Handling Cases of Death

The health worker should inform the sub-county Medical officer of Health/Public Health Nurse immediately (by phone). For any death suspected to be immunization-related, an autopsy (postmortem) is required and the next of kin should be so-advised. Postmortem must be conducted as early as possible. The need for autopsy must be explained to next of kin to obtain consent. Under circumstances where an autopsy is not possible, an organ biopsy may be taken.

8. Investigation of AEFI

Some AEFI reports will need further investigation in order to:

a) To confirm the existence of an AEFI, and the diagnosis

b) Identify the factors associated with the AEFI

c) To determine the possible cause of AEFI, including product related AEFIs, immunization errors, coincidental events and take corrective measures where possible

d) Decision-making

e) Investigating and communicating AEFIs increases the public and community's confidence in the health care system and the immunization in particular

8.1 Which AEFI reports should be investigated?

Not all AEFI reports need investigation.

Once the report has been received, an assessment should be made to determine whether or not an investigation is needed.
The following AEFI reports should be investigated:

a) All serious events e.g. deaths, hospitalization, disability

b) Clusters (A Cluster is defined as two or more cases of the same adverse event related in time, place or vaccine administered)

c) Significant events of unexplained cause, with temporal relationship to immunization (within 30 days of vaccination)

d) An **increased number** or rates of known adverse reactions

e) Events following immunization causing significant parental or **public concern**

Investigation should begin as soon as possible; ideally within 24 hours of detection by the health worker. This is in order to avoid loss of information, collect samples and be able to take timely corrective action.

Components of AEFI investigation include:

- Identify specifications of implicated vaccine
- Examine operational aspects of the vaccine: *Vaccine management, handling and administration; Health facility and Human resource capacity etc.*
- Search for other potential AEFI cases/clustering
- Compare expected risk to reported rate of AEFI
- Come up with differential diagnosis; confirm the diagnosis and outcome

(Laboratory Investigation, epidemiological linkage and in the case of death autopsy findings). Seek an independent advisory expert opinion on the case.

8.2 WHO SHOULD INVESTIGATE?

All the above AEFIs should be investigated immediately upon notification of the event by the health worker.

A team should be constituted at sub-county level to initiate the investigations consisting of members from the SCHMT (Sub-county public health nurse, Sub County EPI Logistician, Sub-county Medical Officer of Health, Sub-county Pharmacist)

The county investigation team will conduct investigations in collaboration with the sub-county and should consist of County Director of Health, County Public Health Nurse,County Pharmacist, EPI Logistician, and a PediatricianThe County Director of Health will initiate an investigation within 24 hours of being notified.

The County Director of Health should notify the NVIP and PPB immediately he or she becomes aware of the serious AEFI. NVIP and PPB may join the investigation team asrequired. Other stakeholders may also join as needed including (but not limited to): NVSACmembers, WHO and UNICEF.

8.3 How to investigate

It is important to investigate suspected adverse events promptly and completely. The investigating team will need to clinically review the suspected reaction, obtain more information from the patient/parent and or community members, interview the health workers and supervisors, observe the vaccine management practices and collect the necessary samples (Vaccine vials- both open and unused (Closed),injection devices,diluents- both open and unused (Closed), relevant clinical samples from the vaccine- Blood,swabs, biopsies etc. among other clinical investigations). The information collected (and conclusions) should be recorded on an AEFI Investigation Form (Annex 2). An AEFI investigation form will be filled for all serious cases (hospitalization/death/disability). A separate investigation form should be filled for each patient.

8.4 STEPS IN AN AEFI INVESTIGATION

Start case investigation immediately if possible or within 48 hours of the initial report. Steps in an investigation are as follows:

Table 7. Steps in AEFI investigation

Step	Actions
1) Confirm information in AEFI report	• Check details about patient and event from medical file, document information, interview health workers who attended to the patient • Verify information on report form and obtain any details missing from AEFI Report Form. • Identify any other cases that need to be included in the investigation
2) Collect data about the patient	• Check immunization history • Obtain previous medical history, current illnesses or concomitant medication, prior history of simila reaction or other allergies • Family history of similar events.
3) Collect data about the event	• Clinical description of event, any relevant laboratory results about the AEFI and diagnosis of the event • Treatment of the event, whether hospitalized and outcome (e.g. recovered, ongoing problems, died etc.)
4) Supply chain and storage conditions: About the suspected vaccine(s):	• Storage of vaccine before it arrived at health facility, where it has come from higher up the cold chain e.g. sub-county depot. Check vaccine ledger • Present storage condition, state of vaccine vial monitor, and temperature record of refrigerator.Check the record on of Fridge tag-2®
5) Observe and assess immunization service delivery	• Reconstitution (process and time kept). Ask if not able to observe, • Whether AD syringes are available and used • Details of training in immunization practice, supervision and vaccinator(s)/health worker • Health worker experience in immunization • The aliquot number for multi dose vials • Number of immunizations greater than normal?

Specimen/Sample collection (when applicable)

This is guided by clinical presentation. Laboratory results need to be included in the investigation

In case of death:

- Autopsy needs to be performed within 72 hours to avoid tissue lysis
- Samples for both toxicology and pathological examination should be sent to reference laboratories
- Include detailed patient's history in the autopsy form to look for any underlying pathologies.

Testing vaccine quality RARELY needed

- Testing of vaccines and logistics is not a routine requirement but may be a partof an investigation and would be done by the set down procedures following the regulations and protocols.
- The used vaccine vial, diluent ampoules and reconstitution syringes should be secured in case they are needed

The algorithm on investigation of clusters is annexed (ANNEX 3)
All data collected during an investigation should be recorded in the AEFI Case Investigation Form (ANNEX 2).

9. CAUSALITY ASSESSMENT AND SIGNAL DETECTION FOR AEFI

AEFI reports once received will be analyzed at county level and by PPB and NVIP. The line lists from PPB and NVIP will be examined and merged into a National AEFI database by the National Vaccine Safety Advisory Committee (NVSAC) secretariat (Annex 5). The NVSAC secretariat consisting of PPB and NVIP will meet periodically to share and analyze AEFI reports and guide on appropriate action to be taken,

and also present to the NVSAC for further analysis. NVSAC is a committee set up by the Ministry of Health composed of experts from different professional backgrounds to provide advice to the ministry on matters regarding vaccine safety.

Analysis of AEFI reports includes:

1. Signal detection
2. Causality assessment
3. Timeliness and completeness of reports
4. Number of reports per 100,000 surviving infants. This can be compared with the WHO reporting requirement of at least 10 AEFI reports per 100,000 surviving infants.
5. Number of reports versus background rates of reaction

9.1 National Vaccine Safety Advisory Committee

The National Vaccine Safety Advisory Committee (NVSAC) consists of experts who provide advice to the Ministry of Health regarding vaccine safety issues. It consists of Pediatricians, Vaccinology experts,Epidemiologists,Pharmacologist,Physicians,Pharmacists Pharmacovigilance experts, Infectious disease specialists, Pathologist and others. Selected Serious and Unusual AEFI will further be presented to the National Vaccine Safety Advisory Committee for expert causality assessment.

Role of National Vaccine Safety Advisory Committee

a) Provide recommendations on vaccine safety
b) Advise on potential and/or already identified vaccine safety signals
c) Advise on the safety profiles and approaches to safety monitoring of newvaccines not in use in Kenya, pilot vaccine interventions and vaccine trials
d) Keep authorities and the immunization program updated on the latest scientific developments in the area of vaccines and vaccine preventable diseases
e) Conduct causality assessment for Adverse Events Following ImmunizationThe NVSAC operates as per their terms of reference

9.2 Signal Detection

A vaccine safety signal is information that indicates a potential link between a vaccine and an event previously unknown or incompletely documented,that could affect health. It can either be adverse or beneficial. Both qualitative and quantitative methods are used to detect signals. A safety signal shows that there could be a potential relationship between a vaccine and the event. More information is usually required to confirm safety signals.The NVSAC secretariat consisting of PPB and NVIP will meet periodically to analyze AEFI reports for possible signals. Recommendation(s) will be provided for further action including seeking advice from NVSAC and any other programmatic or regulatory action.

9.3 Causality Assessment

Causality assessment is the systematic review of data about an AEFI case to determine how likely it is that a certain vaccine caused a certain event. Whether an AEFI is, or is not,attributable to the vaccine or the vaccination programme determines what, if any, steps need to be taken to address the event.

Causality assessment is a critical part of an AEFI monitoring and enhances confidence in vaccines. Causality assessment will be done at the national level, though counties may conduct causality assessment where expertise is available. Causality assessment needs to be done for:

- Serious AEFI
- Clusters of AEFI (the cause for each case in the cluster should be determined separately). Line-listing of data may identify patterns that could constitute a signal
- Occurrence of events above the expected rate or of unusual severity
- Signals resulting from single or cluster cases

- Other AEFI as determined by the review committee or an investigation team

The NVSAC will conduct causality assessment for the above.
The MOH will provide feedback to the counties on causality assessment results

Causality assessment of AEFI should be performed at several different levels. The first is the population level, where it is necessary to test if there is a causal association between the use of a vaccine and a particular AEFI in the population. Secondly, at the level of the individual AEFI case report, one should review previous evidence and make a logical deduction to determine if an AEFI in a specific individual is causally related to the use of the vaccine. The third level of assessment is in the context of the investigation of signals.

The quality of the causality assessment depends upon:

1. The quality of the AEFI report and the effectiveness of the reporting system

2. Completeness of the investigation report. The investigation form should be filled for every report undergoing causality assessment

3. The quality of the causality assessment process. Poor quality causality assessment can lead to erroneous conclusions, crises and loss ofconfidence in the national immunization programme. Causality assessment should follow established scientific methods.

There are four steps in AEFI causality assessment at individual level. The steps and their purpose are outlined below:

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

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

Step 3. Algorithm:

to obtain direction as to the causality with the information gathered in the checklist.

Step 4. Classification:

to categorize the AEFI's association to the vaccine/vaccination on the basisof the direction determined in the algorithm.

At the end of causality assessment AEFI causality will be categorized as:

- Consistent Causal Association to Immunization
  - Vaccine product-related reaction
  - Vaccine quality-defect related reaction
  - Immunization error-related reaction
  - Immunization anxiety-related reaction
- Indeterminate
- Inconsistent Causal Association to Immunization
- Unclassifiable

It should also be noted that AEFI causality may be indeterminate due to lack of clear evidence for a causal link, or conflicting trends, or inconsistency with causal association to immunization. It is nevertheless important not to disregard the above reports of AEFI because at some point they may be considered a signal and may lead to hypotheses regarding a link.

between a vaccine and the event in question, with research and specific studies designed to test for a causal association. Pooling of data on individual cases is very helpful in generating hypotheses.

9.4 Taking Action

When the investigation is finalized and the results obtained, they should be shared through the existing MOH mechanisms with the relevant stakeholders. The specific remedy for the adverse event will depend on the cause. The following actions need to be undertaken:

1. Communicate to parents, community and public at large about AEFI's and reassure them about immunization safety

2. Train all concerned persons as a corrective measure for any operational challenges such as knowledge and skills gap

3. Conduct regular supportive supervision, to institutionalize vaccine management practices and give feedback

4. Improve availability of supplies and the working condition of the equipment to minimize immunization errors e.g. high temperatures could lead to growth of bacterial in opened unused multi-dose vaccines leading to adverse events. Freezing of freeze sensitive vaccines could lead to aseptic abscesses.

Rarely will it be necessary to stop immunization services; such action should not be taken hastily as it will lead to decreased demand for immunization and increase the risk of disease outbreaks in a community. It can only be considered in consultation with NVIP and PPB.

The following table provides a summary of specific actions that may be considered at different levels when the different types of AEFIs occur.

Table 8. Actions to be taken after investigation/causality assessment

Type of AEFI	Action
Vaccine reaction (Vaccine product-related reactions and Vaccine quality defect- related reactions)	If a higher reaction rate than expected from a specific vaccine or lot/batch, the NVIP/PPB may consider: – Obtaining more information from the manufacturer, supplier and WHO – Withdrawing that lot/batch – Changing manufacturing specifications or quality control – Obtaining vaccine from a different manufacturer.
Immunization error-related reaction	Correcting the cause of the error. This may mean one or more of the following: – Review the Vaccine management procedures in place at the depot, during distribution and at the health facility level – Training of health workers – Intensified support supervision. Whatever action is taken, it is important to review at a later date to check that the same has been institutionalized
Immunization anxiety-related reaction	– Minimize stress in those waiting for the injection by reassuring them, making them comfortable – Prepare the injection out of their view and privacy during the procedure. – Carry out vaccinations in an ambient and safe environment
Coincidental:	Communication to the community and public at large about the AEFI and reassure them about immunization safety, ensuring that the community is persuaded that the link is coincidental.
Unknown:	Depending on the nature of the event, its extent and whether it is ongoing, a further investigation and research by experts in the subject matter may be needed. However, it must be accepted that in some cases the relationship to immunization is not clear. In addition to sharing the findings of the investigations with relevant stakeholders, the reason that no conclusion was drawn should be indicated, along with whatever progress was made. stakeholders, the reason that no conclusion was drawn should be indicated, along with whatever progress was made.

10. VACCINE SAFETY COMMUNICATION

Communicating about AEFI and vaccine safety is of utmost importance and various stakeholders need to be targeted. It is essential in at least three situations, namely:

- Explaining properly the benefits and expected AEFIs of a recommended vaccine;
- Addressing public concerns and upcoming or persistent rumors about vaccine safety
- Preparing to address vaccine safety crises if and when they occur.

Communication needs to be done even before an AEFI has happened

10.1 TARGET: HEALTH WORKERS

Vaccinators at various levels need to be able to provide information to care givers and handle queries from the community, especially from parents. Those who routinely administer vaccines, or who evaluate and treat patients, including medical officers, clinical officers and nurses, should receive training and regular updates on vaccine safety and quality issues,news and research.

Health workers and vaccinators should be trained in interpersonal communication skills with families and communities. This means that health workers are able to share accurate immunization facts, respond to questions, can clarify possible doubts, and motivating families to adopt healthy behavioral practices, including using immunization services.

Health workers are an essential source of information in the AEFI investigation. It is important to reassure the health worker/ vaccinator and keep them informed of the results of investigations. It is essential that health workers taking care of the patient are given feedback about reports submitted, results of investigations and any actions taken as a result of the report.

The feedback should also include future management of the client especially concerning the need for additional doses of the vaccine(s) and the outcome of the report. Personal blame should be avoided even in the case of immunization errors, instead emphasis should be on system related factors that may have resulted in the error. Health workers are usually members of the community in which an AEFI took place. Therefore, they need to be supported and provided with the appropriate information to respond to community concerns.

The NVIP and PPB will routinely provide feed-back and updates of findings of the National Vaccine Safety Advisory Committee or findings of any AEFI investigations carried out, to counties and other relevant stake holders.

10.2 Target: Patient/ Client/Family members

Inform caregivers of common reactions such as pain, fever and encourage them to return to the facility in case of high or persistent fever, extensive swelling. Immediate steps need to be taken to verify the facts around the AEFI. Listen to a parents' concerns empathetically and reassure them where appropriate, even when the AEFI is coincidental.

Promptly visiting the affected family and community, particularly if a serious AEFI has occurred, is part of a good response. Meeting with and listening to affected families and community representatives are essential to understanding their concerns and fears, as well as to demonstrate commitment that the event is being addressed.

1. Keep the caregiver informed with follow-up information and facts on what is known, what is not known, what is being done, what they should do Provide updated, key information to community and encourage them to give feedback
2. Continuously communicate with the client, parent or guardian and community during the investigation period to assure understanding the risk benefit of vaccination

3. Disseminate a consistent set of easy to understand key messages on immunization to concerned families and communities

4. For example:

Vaccines are safe. Any licensed vaccine is rigorously tested across multiple phases of trials before it is approved for use, and regularly reassessed once it ison the market. Scientists are also constantly monitoring information from several sources for any sign that a vaccine may cause an adverse event.

10.3 TARGET: COMMUNITY

When communicating on AEFIs to the community, it is important to develop links with local community leaders and the local peripheral health workers as they can be a tremendous resource in assuaging fears and misconceptions about immunization. Sustaining this information flow is important throughout the investigation period.

During investigation the designated spokesperson should provide key messages as follows:

- On the benefits of immunization in preventing serious diseases, disabilities and death compared to the rare risks associated with vaccines
- An immunization error which can be corrected, or coincidental illness are much likely than the vaccine reactions
- There are strategies in place and appropriate actions are being taken to arrest the situation while safeguarding the public

On completion of the investigation, the cause of the event must be communicated immediately and details on the steps being undertaken to correct the situation and prevent reoccurrences in order to build trust to the community.

10.4 TARGET: MASS MEDIA

Media play a vital role in the public's perception of immunization and it can be positive or a negative influence. It is fast in disseminating information and has the advantage of reaching huge populations in a short time. Whether or not the media report immunization, particularly following the announcement of a negative event, may depend to a considerable extent onthe strategic relationship-building effort made by the programme.

In the long-term, building partnerships with the media is key to keeping the public regularly informed about immunization, the benefits and motivate families and communities to make use of immunization services. The media can be complementary allies when given clear messages on the benefits of immunization and vaccine safety.

When using the media there is need to appoint a well-traine spokesperson who is clear on the event.

A communication response can be done through media engagement as follows

- Holding a media conference
- Issuing a press statement
- Conducting call-in programs in the media
- Writing public notices, supplements or news column in newspapers
- Briefing health reporters on immunizations and the event

The following components and considerations are essential when engaging the media

Table 9. Considerations when engaging media

Component	Description
A database of journalists	An updated list of print and electronic media journalists covering health (local, national, international) with contact information.
Information packages	• An information package may contain the following documents both in hard copy and e-copies: • Frequently Asked Questions (FAQs) on immunization in general,for specific disease, and AEFIs. • A factsheet or a technical brief on a specific vaccine preventable disease. • Recent updates: statistics, progress made in immunization • Contact addresses of spokespersons (experts) in the ministry.
The draft media release	Must specifically answer the six Ws for journalists: • Who is affected/or responsible? • What happened? • What is being done? • Where did it happen? • When did it happen? • Why did it happen? • Will it happen again?
Information specific to media type	Local radio stations and other media are believed by more people in the community than national media. National and international media has a wider reach and influences national agendas
A spokesperson system	• Identify in advance an appropriate spokesperson(s) as per government regulations. • Share contact details of spokesperson • Ensure spokesperson(s) has experience or some training in dealing with the media.
Media conference	Media conferences may need to be conducted if AEFI occur andbecome a sensational part of media broadcasts. This is in order toprovide accurate facts. If there are several members on the panel,agree beforehand on the key messages in response to the AEFI. Panel members must avoid contradicting each other in the press conference unless it is critical to clarify something incorrect thathas been said
Follow up	Keeping media informed about subsequent developments, actionsand answers for unanswered questions as soon as possible is necessary

Refer to risk communication guideline for detailed guidelines on responding to media

10.5 Target: Other Stakeholders

Other stakeholders should also be provided with relevant information in order to ensure dissemination of correct information. Depending on the need stakeholders mentioned below will be given preliminary information at the initial stage and final report after completion of investigation and causality assessment at a later stage

- National Immunization Technical Working Group
- National Immunization Inter-Agency Coordinating Committee
- Kenya National Immunization Technical Advisory Group (KENITAG)
- Council of Governors
- Politicians
- Professional associations
- Universities and hospitals
- International agencies and development partners
- Manufacturers/Suppliers

11. ROLES AND RESPONSIBILITIES OF STAKEHOLDERS

Collaboration of various stakeholders is key to an efficient and responsive AEFI monitoring system. The roles and responsibilities of the various stakeholders are outlined in the table below

Table 10. Roles and responsibilities

No.	Stakeholder	Responsibility
1.	Ministry of Health	• Policy formulation • System and database maintenance (DHIS) • Resource mobilization
2.	National Vaccines and Immunization Program	• Provision of vaccines • Training of health workers • Feedback and information sharing • Share Information with PPB immediately for Serious AEFI • NVSAC secretariat • Participating in investigation • Participate in Post-market surveillance • Reporting through Joint Reporting Form • Signal detection • Causality assessment • Maintenance of database and AEFI line list
3.	Pharmacy and Poisons Board	• Regulatory action • Feedback and information sharing • Share Information with NVIP immediately for Serious AEFI • NVSAC secretariat • Participating in investigation • Licensing of vaccines • Post-market surveillance • Reporting through Vigiflow® • Signal detection • Causality assessment • Provision of reporting tools • Training of health workers • Maintenance of database and AEFI line-list
4.	County Government	• Provision of vaccination services • Training of health workers • Feedback and information sharing to lower level • Lead AEFI investigation, request Technical Assistance

No.	Stakeholder	Responsibility
		• Participate in Post-market surveillance and pharmacovigilance activities • Reporting of AEFI • Maintenance of AEFI line-list • Resource mobilization
5	Sub-county health management team	• Provision of vaccination services • Training of health workers • Feedback and information sharing to lower level • Initiate AEFI investigation • Participate in Post-market surveillance and pharmacovigilance activities • Reporting of AEFI • Maintenance of AEFI line list • Resource mobilization • Entering of AEFI reports into DHIS 2 by HRIO
6	Health Care worker	• Detection, management and timely reporting of AEFI • Provision of vaccination services • Providing information on vaccines to clients • Feedback to caregivers
7	Development partners	• Resource mobilization • Technical assistance
8	World Health Organization	• Technical assistance • Providing information/guidance documents
9	Media	• Responsible reporting • Support awareness creation
10	Caregiver/client	• Report AEFI • Adhere to guidance of health worker
11	Laboratories: NQCL, Government Chemist, NPHLS	• Timely testing of specimen • Provide advice
12	NVSAC	• Advisory role- Refer to NVSAC Terms of Reference
13	NVSAC secretariat	• Merge and update the joint NVIP & PPB national line list • Select cases for NVSAC to review, summarize findings from NVSAC deliberations • Share recommendations of NVSAC to NVIP and PPB • Coordinate investigations

ANNEXES

1. AEFI REPORTING FORM

MINISTRY OF HEALTH

NATIONAL VACCINES AND IMMUNIZATION PROGRAM

AEFI Reporting Form

(To be filled in triplicate) ☐ Initial Report ☐ Follow-up report

NAME OF REPORTING INSTITUTION…… INSTITUTION MFL CODE……..…

COUNTY…….. SUB-COUNTY……..…..

Patient Details

PATIENT'S NAME…….…….…… IP/OP NO…...DATE OF BIRTH (or age)…....

GENDER……NAME OF GUARDIAN (If patient is a child)……..……..……..

ADDRESS…… PHONE NUMBER (self or nearest contact)……..……..……..

VILLAGE…….. WARD……..…... SUB-COUNTY……..…... COUNTY……..…..

VACCINATION CENTRE…… COUNTY OF VACCINATION CENTRE……

TYPE OF VACCINATION SERVICE (static, mass, outreach)……..……..

Type of AEFI	Please tick:			Brief details on the event (including timeline of occurrence)
BCG Lymphadenitis	☐	Anaphylaxis	☐	.....
Convulsion	☐	Encephalopathy, Encephalitis/Meningitis	☐	.....
Generalized urticaria (hives)	☐			.....
High Fever	☐	Paralysis	☐	.....
Injection site abscess	☐	Toxic shock	☐	.....
Severe Local Reaction	☐	Others (specify)……	☐	.....

Onset of event: Date ..... /..... /..... Time .....

Suspected vaccine(s)

Name of Vaccine(e.g. BCG, DPT-Hib- HeB)	Dose No.	Date vaccina-ted	Time vaccin-ated	Route, site of vaccina-tion (i.m.,s.c.)	Details of Vaccine			Details of Diluents		
					Lot/Bat-ch No.	Manufa-cturer's Name	Expiry Date	Lot/Batch No.	Manufact-urer's Name	Expiry Date

Past medical history (including history of similar reaction or other allergies, concomitant medication/ vaccine,concomitant illness, other cases,pregnacy status and other relevant information *(continue on separate sheet if necessary)*

.....

.....

Action taken ☐ Treatment given (specify)……

☐ Specimen collected for investigation (specify type(s) of specimen)……

AEFI Outcome ☐ Recovered ☐ Recovering ☐ Not recovered ☐ Unknown ☐ Died

Name of Person Reporting…… Phone number……

Designation…… Signature: ……

Final Classification of AEFI (*to be filled at national level):*

(See back of cover page for guidelines on how to complete the form)

Guidelines On Completion Of The Form

When to complete this form

An adverse event following immunization (AEFI) is defined as any unfavourable medical occurrence which follows immunization and which may or may not be caused by the usage of the vaccine.The adverse event may be any unfavourable or unintended sign, abnormal laboratory finding, symptom or disease.

Complete the AEFI reporting form when any Adverse Event Following Immunization (AEFI) occurs and especially those of parental and /or health worker concern

MUST BE REPORTED

- Allergic reaction- anaphylaxis, urticaria, bronchospasm, edema
- Febrile convulsions
- Injection site abscess
- Clusters of events (2 or more cases of same event related in time, place or vaccine administered)
- Serious Events (Life-threatening or results in death, hospitalization, persistent orsignificant disability, or birth defect)
- Events reported to you by the parent
- Events you are concerned about as a health worker
- Any Uncommon or Unexpected Events that may be of public concern

- Report even if you are not certain the vaccine caused the event or you do not have all the details.

- Indicate if it is an initial or follow-up report.

- Information on the Manufacturer and Expiry dates of the Vaccine and/or diluents may be obtained from the label of its container. If multiple vaccines are suspected, provide the required information on each of them.

- *Enter date of birth if available, if not enter the age at the time the AEFI began*

- *Where more than one AEFI occurs in the same patient and at the same timetick the multiple options provided, also provide a description of the AEFI in the space provided*

Where to report

After completing this form, forward two copies to the sub-county public health nurse/officer/DMOH, who will liaise with the Sub-county HRIO to submit the report to NVIP through the AEFI reporting module in DHIS2. One copy will be sent to the Head, National Vaccines and Immunization Program, P.O Box 43319-00100, Nairobi. Notify the next level immediately in case of serious AEFI or Clusters of Events.

What happens to submitted reports

Data obtained from this and other reports will be assessed an used improve policy and service delivery in the Ministry of Health.Information is handled in strict confidence

Submission does not mean admission that the health worker or manufacturer or the product caused or contributed to the event.

AEFI INVESTIGATION FORM

This form shall be filled in case of serious AEFI, clusters, suspected immunization errors, or events causing significant public concern

Section A | Basic details

Place of vaccination ☐Public health facility ☐Private health facility ☐Other (specify) _____

Vaccination in : ☐Campaign ☐Routine ☐Other (specify) _____

Name and Address of vaccination site:

Name of Reporting Officer:

Designation:

Mobile: e-mail:

Date of investigation: __ __ / __ __ / __ __ __ __

Date of filling this form: __ __ / __ __ / __ __ __ __

This report is: *First* *Interim* *Final*

Patient Name: Sex: ☐M ☐F

(use a separate form for each case in a cluster)

Date of birth: __ __ / __ __ / __ __ __ __

OR *Age at onset:* __ __ *years* __ __ *months* __ __ __ *days*

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

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

Type of site ☐Fixed ☐Mobile ☐Outreach ☐Other (Specify_____

Date of first/key symptom __ / __ _ / __ __ __ _ _ Time of first symptom *hh/mm):* __ / __ __

Date of hospitalization __ / __ __ / __ __ __ _ _ ☐ N/A

Date first reported to the health authority: __ __ / __ __ / __ __ __ __

Status on the date of investigation: ☐ Disabled ☐Recovering ☐Recovered completely ☐Unknown

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

Autopsy done? : ☐ Yes (date)_____ ☐No. Planned on (date)_____ Time_____

Attach report (if available)

Section B Relevant patient information prior to immunization

Criteria	Finding	Remarks (If yes provide details)
Past history of similar event	Yes / No / Unkn	
Adverse event after previous vaccination(s)	Yes / No / Unkn	
History of allergy to vaccine, drug or food	Yes / No / Unkn	
Pre-existing illness (30 days) / congenital disorder	Yes / No / Unkn	
History of hospitalization in last 30 days, with cause	Yes / No / Unkn	
Patient currently on concomitant medication? (If yes, name the drug, indication, doses & treatment dates)	Yes / No / Unkn	
Family history of any disease (relevant to AEFI) or allergy	Yes / No / Unkn	

For adult women

- Currently pregnant? ☐ Yes (weeks) _____ ☐No ☐ Unknown
- Currently breastfeeding? ☐Yes ☐ No

For infants

The birth was ☐full-term ☐pre-term ☐post- term. ☐ Birth weight ☐ Current weight

Delivery procedure was ☐Normal ☐Caesarean ☐ Assisted (forceps, vacuum etc.) ☐ with complication (specify)

Name **AEFI Report ID**

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

Source of information *(tick all that apply)* ☐**Examination by the investigator** ☐**Documents** ☐**Verbal Autopsy** ☐**Others** _____

If from verbal autopsy, please mention source _____

Name and contact of the person who first examined/treated the patient: _____

Name and contact of other persons treating the patient: _____

Other sources who provided information (specify): _____

Signs and symptoms in chronological order from the time of vaccination:

Name and contact information of person completing these clinical details:	Designation:	Date/time

****Instructions - Attach copies of ALL available documents (including case sheet, discharge summary, case notes, laboratory reports and autopsy reports)**

Documents attached:

☐**Discharge summary** ☐**Case Notes** ☐**Laboratory reports** ☐**Autopsy report**

☐**Case sheet** ☐**Others**_____

Provide below any additional information NOT AVAILABLE in existing documents, i.e.

- ***If patient has received medical care -*** attach copies of all available documents (including case sheet, discharge summary, laboratory reports and autopsy reports, if available) and write only the information that is not available in the attached documents below

- ***If patient has not received medical care -*** obtain history, examine the patient and write down your findings below(add additional sheets if necessary)

Provisional / Final diagnosis:

Name **AEFI Report ID**

Section D	**Details of vaccines provided at the site linked to AEFI on the corresponding day** *(Complete this section by interviewing the health workers, caregivers,observing and checking individual/facility records)*						
Number immunized for each antigen at session site. Attach record if available.	Vaccine name						
	Number of doses						

a)	When was the patient vaccinated? *(Select below and respond to ALL questions)* ☐ Within the first vaccinations of the session ☐Within the last vaccinations of the session ☐ Unknown In case of multi-dose vials, was the vaccine given ☐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 / No / Unable to asses
c)	Based on your investigation, do you feel that the vaccine (ingredients) administered could have been unsterile?	
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 / No / Unable to asses
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 / No / Unable to asses
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 / No / Unable to asses
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 / No / Unable to asses
h)	Number immunized from the concerned vaccine vial/ampoule	
i)	Number immunized with the concerned vaccine in the same session	
j)	Number immunized with the concerned vaccine having the same batch number in other locations. Specify locations:	
k)	Is this case a part of a cluster? 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? b) If no, number of vials used in the cluster (enter details separately)	Yes / No / Unknown

• It is compulsory for you to provide explanations for these answers separately

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

(Complete this section by asking and/or observing practice)

Syringes and needles used:			
Are AD syringes used for immunization?			Yes / No / Unknown
If no,specify the type of syringes used: ☐Glass	☐ Disposable	☐Recycled disposable	Other_____
Specific key findings/additional observations and comments:			

Reconstitution: (complete Yes or No , NA if not applicable)

Reconstitution procedure (circle as appropriate)	Status		
Same reconstitution syringe used for multiple vials of same vaccine?	Yes	No	NA
Same reconstitution syringe used for reconstituting different vaccines?	Yes	No	NA
Separate reconstitution syringe for each vaccine vial?	Yes	No	NA
Separate reconstitution syringe for each vaccination?	Yes	No	NA
• Are the vaccines and diluents used the same as those recommended by the manufacturer?	Yes	No	NA
Specific key findings/additional observations and comments:			

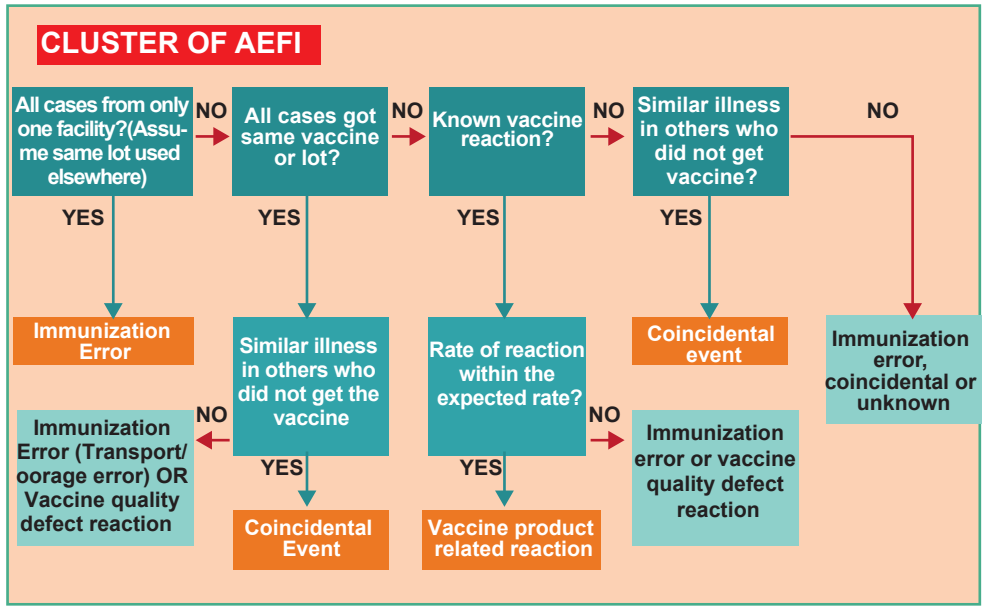
Name **AEFI Report ID**

Section F	**Cold chain and transport** *Complete this section by asking and/or observing practice)*
Last vaccine storage point:	
• Is the temperature of the vaccine storage refrigerator monitored?	Yes / No
○ If "yes", was there any deviation outside of 2-8° C after the vaccine was placed inside?	Yes / No
○ If "yes", provide details of monitoring separately.	
•Was the correct procedure for storing vaccines, diluents and syringes followed?	Yes / No /Unknown
•Was any other item (other than EPI vaccines and diluents) in the refrigerator or freezer?	Yes / No /Unknown
•Were any partially used reconstituted vaccines in the refrigerator?	Yes / No /Unknown
•Were any unusable vaccines (expired, no label, VVM at stages 3 or 4, frozen) in the refrigerator?	Yes / No /Unknown
•Were any unusable diluents (expired, manufacturer not matched, cracked,dirty ampoule) in the store?	Yes / No /Unknown
Specific key findings/additional observations and comments:	
Vaccine transportation:	
•Type of vaccine carrier used	
•Was the vaccine carrier sent to the site on the same day as vaccination?	Yes / No /Unknown
•Was the vaccine carrier returned from the site on the same day as vaccination?	Yes / No /Unknown
•Was the vaccine carrier returned from the site on the same day as vaccination? Yes / No /Unknown	Yes / No /Unknown
• Was a conditioned ice-pack used? Yes / No /Unknown	Yes / No /Unknown
Specific key findings/additional observations and comments:	

Section G	**Community investigation (Please visit locality and interview parents/others)**
Were any similar events reported within a time period similar to when the adverse event occurred and in the same locality? Yes / No / Unknown If yes, describe:	
If yes, how many events/episodes?	
Of those affected, how many are • Vaccinated:_____ • Not vaccinated:_____ • Unknown:_____	
Other comments:	

Section H	**Other findings /observations/ comments**

3. Algorithm for investigation of cluster



4. Case definitions

Adverse event	Case definition
Acute flaccid paralysis (Vaccine associated paralytic poliomyelitis)	Acute onset of flaccid paralysis within 4 to 30 days of receipt of oral poliovirus vaccine (OPV), or within 4 to 75 days after contact with a vaccine recipient **and** neurological deficits remaining 60 days after onset, or death.
Anaphylaxis	Anaphylaxis is likely when all of the following three criteria are met: · sudden onset and rapid progression of symptoms · life-threatening airway and/or breathing and/or circulation problems · skin and/or mucosal changes (flushing, urticaria,angioedema).
Encephalopathy	Acute onset of major illness characterized by any two of the following three conditions: • seizures • severe alteration in level of consciousness lasting for one day or more • distinct change in behaviour lasting one day or more. Needs to occur within 48 hours of DTP vaccine or from 7 to 12 days after measles vaccine, to be related to immunization
Fever	The fever can be classified (based on rectal temperature) as Mild fever: 38ºC to 38.9ºC, High fever: 39ºC to 40.4º C) and Extreme fever: >40.5º C
Hypotonic, hypo-responsive episode (HHE or shock-collapse)	Event of sudden onset occurring within 48 [usually less than 12] hours of vaccination and lasting from one minute to several hours, in children younger than 10 years of age. All of the following must be present: • limpness (hypotonic) • reduced responsiveness (hypo responsive) • pallor or cyanosis – or failure to observe/ recall

Adverse event	Case definition
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** Infection on culture. **Sterile abscesses** are usually due to the inherent properties of the 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 BCGvaccine, on the same side as inoculation (mostly axillary).
Persistent inconsolable screaming	Inconsolable continuous crying lasting 3 hours or longer accompanied by high-pitched screaming.
Convulsion	Occurrence of generalized convulsions that are **not** accompanied by focal neurological signs or symptoms. **Febrile** convulsions: if temperature elevated >38OC (rectal) **Afebrile convulsions:** if temperature is normal
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 programme error.
Severe local reaction	Redness and/or swelling centered at the site of injection and one or more of the following: • swelling beyond the nearest joint • pain, redness, and swelling of more than 3 days duration • requires hospitalization.
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. Needs to be reported as possible indicator of programme error.

5. AEFI Line List

ID	County	Sub-county	Age in months at time of vaccination	Sex	Date of vaccination	Date of AEFI onset	Brief description of AEFI	Reaction type (Serious /Minor)	Allergies Co-morbidities/ Concomitant medication/	Investigations	Action	Outcome	Suspect Vaccine	Manufacturer	Vaccine Batch or Lot Number	Diluent Batch Number	Onset time Interval (Hours)	Date of Reporting	Final Diagnosis	Provisional Classification	Comment
XXXY																					
XXXXY																					
XXXY																					

References

1. Adverse Events Following Immunization (AEFI) : A Manual Of Procedure For Surveillance And Response To AEFI in Phillipines available at https://www.doh.gov.ph/node/9933 (accessed 03-05-2019)

2. Guidelines for Surveillance of Adverse Events Following Immunization in Tanzania available at https://www.medbox.org/tanzania-guidelines-for-surveillance-of-adverse-events-following-immunization/download.pdf (accessed 03-05-2019)

3. Guidelines for The National Pharmacovigilance System in Kenya. February 2009, Second Edition available at http://apps.who.int/medicinedocs/en/m/abstract/Js18079en/

4. Immunization Manual for Health Workers available at http://www.mchip.net/sites/default/files/mchipfiles/Immunization%20Manual%20for%20Health%20Workers.pdf (accessed 03-05-2019)

5. National Policy Guidelines on Immunization 2013 available at http://guidelines.health.go.ke:8000/media/Immunization_Policy_Guidline.pdf (accessed 03-05-2019)

6. WHO Global Manual on Surveillance of Adverse Events Following Immunization available at https://www.who.int/vaccine_safety/publications/Global_Manual_revised_12102015 pdf?ua =1 (accessed 03-05-2019) .

7. WHO vaccine safety basics available at https://vaccine-safety-training.org/(accessed 03-05-2019)