



Ministry of Health

# Guidelines for MONITORING, REPORTING AND MANAGING ADVERSE EVENTS FOLLOWING IMMUNIZATION (AEFI) IN KENYA



Vaccinate. Protect.



Pharmacy and  
Poisons Board





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# ABBREVIATIONS

	ORGANIZATION
<b>AD</b>	Auto-disable
<b>AEFI</b>	Adverse Events Following Immunization
<b>AFP</b>	Acute Flaccid Paralysis
<b>BCG</b>	Bacilli de Calmette Guerin
<b>CNS</b>	Central Nervous System
<b>KHIS</b>	Kenya Health Information System
<b>DPT-Hib-HepB</b>	Diphtheria, Pertussis, Tetanus toxoid, Haemophilus Influenzae type B and Hepatitis B vaccine
<b>EPI</b>	Expanded Programme on Immunization
<b>HIV</b>	Human Immunodeficiency Virus
<b>KEPI</b>	Kenya Expanded Program for Immunization
<b>MAH</b>	Marketing Authorization Holder
<b>MOH</b>	Ministry of Health
<b>NDR</b>	National Drug Authority
<b>NVIP</b>	National Vaccines and Immunization Program
<b>NVSAC</b>	National Vaccine Safety Advisory Committee
<b>OPV</b>	Oral Polio Vaccine
<b>PPB</b>	Pharmacy and Poisons Board
<b>SCHMT</b>	Sub County Health Management Team
<b>SCHRIO</b>	Sub County Health Records Information Officer
<b>SCMOH</b>	Sub County Medical Officer of Health
<b>SCPHN</b>	Sub County Public Health Nurse
<b>SCPHO</b>	Sub County Public Health Officer
<b>Td</b>	Tetanus toxoid and diphtheria
<b>TT</b>	Tetanus Toxoid
<b>VAPP</b>	Vaccine Associated Paralytic Polio
<b>VVM</b>	Vaccine Vial Monitor
<b>WHO</b>	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 ensure that 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 not entirely free of risk, either real or perceived.

The formulation of these guidelines by the National Vaccines and Immunization Program 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 and responsibilities 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 health seeking behaviors, 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.



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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 the 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 and quality document is finalized. The Ministry of Health appreciates the technical support given by World Health Organization, Africa Centers for Disease Control, Mastercard Foundation, Akros Research and other stakeholders.





# GLOSSARY

**Adverse Event Following Immunization (AEFI)** - Any untoward medical occurrence which follows immunization, and which does not necessarily have a causal relationship with the usage of the vaccine. The adverse event may be any unfavorable or unintended sign, abnormal laboratory finding, symptom or disease.

**Causal association** - A cause-and-effect relationship between a causative factor and 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 vaccine product, 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 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.

**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 due to one or more of the inherent properties of the vaccine product, whether the active component or one of the other components of the vaccine (e.g. adjuvant, preservative or stabilizer).

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









1.

# INTRODUCTION



## 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
<b>TYPEs OF VACCINEs</b>	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 ginsenosides

**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 care 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 immunization 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.



**Table 1. Current routine EPI schedule**

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

\* Yellow fever selected counties: Baringo, Turkana, Elgeyo Marakwet and West Pokot

\* Malaria selected counties: Kisumu, Kakamega, Siaya, Homa-bay, Migori, Bungoma, Vihiga, Busia

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 are susceptible 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 monitoring of vaccines and other biological 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 as follows;

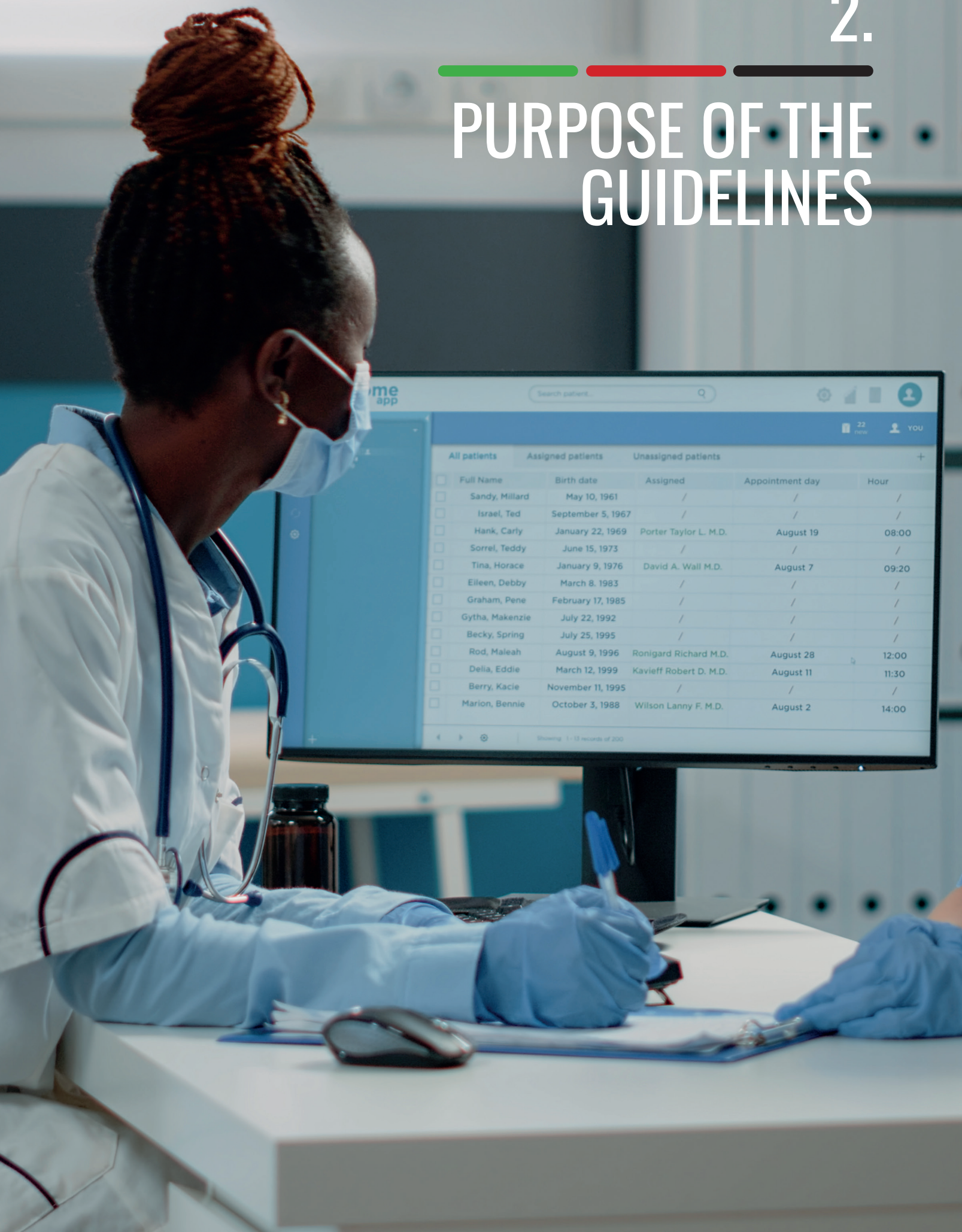
- Collect and collate all adverse events following immunization (AEFIs) through the pharmacovigilance electronic reporting system (PvERS)
- Call for a secretariat meeting (PPB and NVIP) to review the AEFI reports received
- Actively participate as secretariat in the NVSAC meetings during causality assessment
- Implement NVSAC recommendations
- Provide feedback to reporters (patient, public, community and health care providers)





2.

## PURPOSE OF THE GUIDELINES





## 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 Guidelines for Immunization.

The purpose of these guidelines is to provide health care managers and frontline health care 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 care 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 an 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 effect that 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





### 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 on the right 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**

<b>VACCINES</b>	<b>Common non-serious reactions</b>			<b>Serious reactions</b>		
	Local reaction (pain swelling redness)	Fever	Irritability, malaise and non-specific symptoms	Reactions	Onset interval	Number of events per million doses
<b>BCG</b>	Common	-	-	Suppurative lymphadenitis BCG	2-6 months	100-1000
				osteitis	1-12 months	1-700
				Disseminated BCG infection	1-12 months	2
<b>HEPATITIS B</b>	Adults up to 30% Children up to 5%	1-6%	-	Anaphylaxis Guillain-Bare Syndrome (plasma derived)	1.1 Hour 1-6 Weeks	1-2 5
<b>MEASLES</b>	Up to 10%	Up to 5%	Up to 5%	Febrile seizures	5-12 days	333
				Thrombocytopaenia	15-35 days	33
				Low platelets)	0-1 hours	1-50
				Anaphylaxis		
<b>OPV</b>	None	Less than 1%	Less than 1%	Vaccine-associated paralytic polio (VAPP)	4-30 days	1.4-3.4
<b>TETANUS</b>	Up to 10%	Up to 10%	Up to 25%	Brachial neuritis	2-28 days	5-10
				Sterile abscess	1-6 weeks	1-6
						6-10
<b>DPT-Hib-HepB</b>	Up to 50%	Up to 50%	Up to 60%	Persistent (>3 hours) inconsolable screaming seizures	0-24 hours	1,000-60,000
				Hyporesponsive episode (HHE)	0-3 days	570
				Anaphylaxis/shock	0-24 hours	570
				Encephalopathy	0-3 days	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 polio vaccine 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 care 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 a different 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 and is 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**

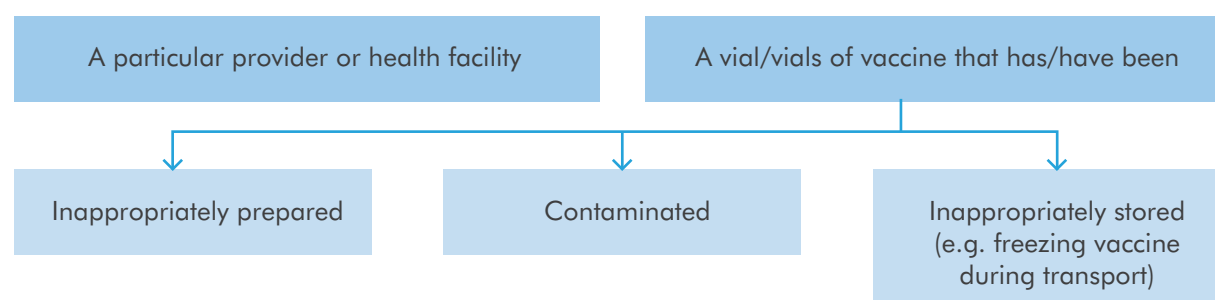
ERROR	POSSIBLE AEFI
Non-sterile injection <ul style="list-style-type: none"> <li>Contaminated vaccine or diluent</li> <li>Wiping the needle with a swab</li> <li>Administering injection over clothes</li> </ul>	Local reaction, abscess, Toxic Shock Syndrome
Injection at incorrect site/ route <ul style="list-style-type: none"> <li>BCG given subcutaneously</li> <li>Pentavalent/ TT given superficially</li> <li>Injection into buttocks</li> </ul>	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.

## DEFINITION OF A CLUSTER OF EVENTS

A cluster of events is two or more cases of the same adverse event related in time, place or vaccine administered

Clusters can be usually associated with:



### 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

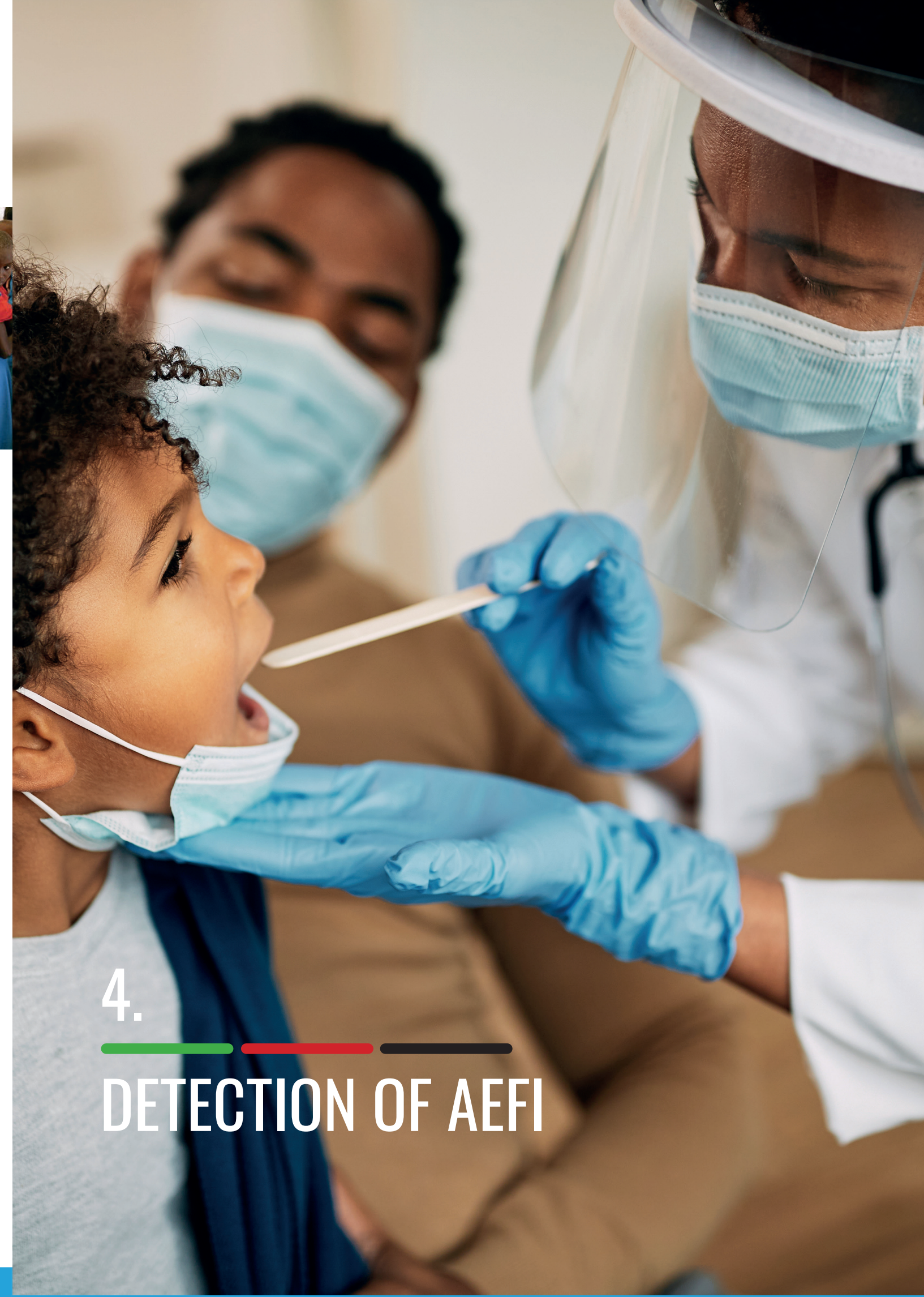
It is important to remember that not all Serious AEFI are actually caused by the vaccines themselves. Most are due to immunization errors or underlying medical problems in the patient. To determine the exact cause of serious AEFI, all serious suspected vaccine reactions should be reported and investigated.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

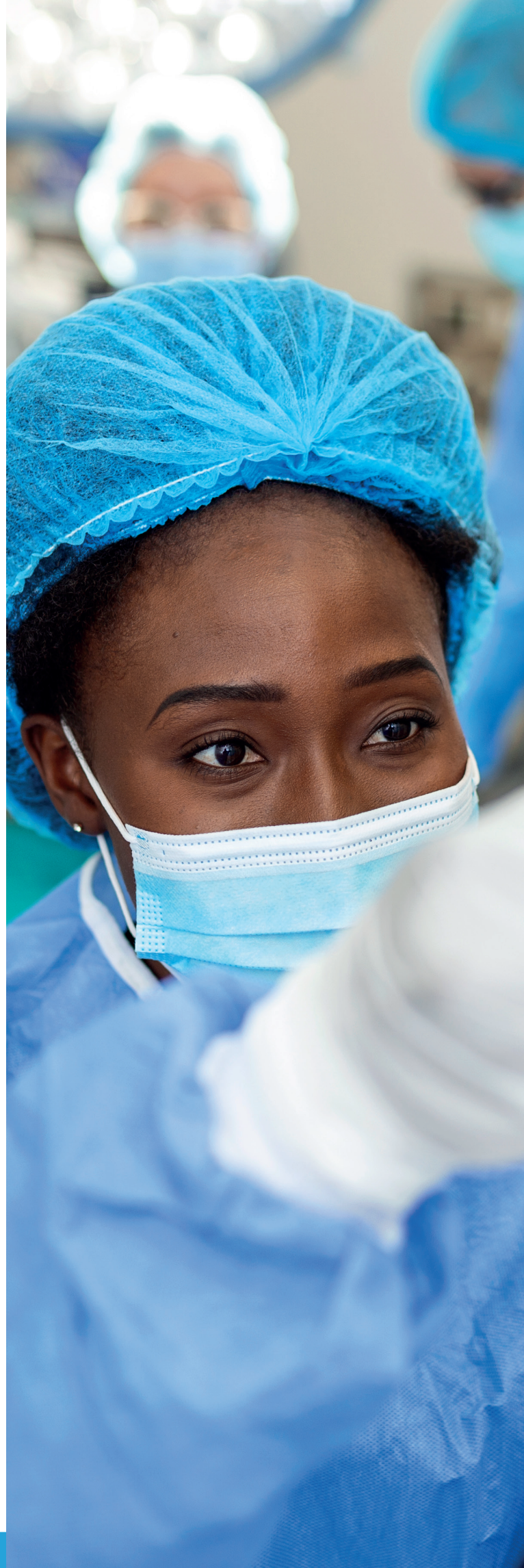


## 4. DETECTION OF AEFI

It is important for health care 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 care 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 care 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 care worker. The health care worker should follow up any AEFI reported to them by community health volunteers or by other community members. This also includes reports from outreach sites and others.
- e) Media reports

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







# 5.

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## 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.

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## MANAGEMENT AND PREVENTION OF AEFI



## 6. MANAGEMENT AND PREVENTION 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)	<ul style="list-style-type: none"> <li>• Cold cloth at injection site</li> <li>• Give paracetamol</li> </ul>
Fever ( $>38^{\circ}\text{C}$ )	<ul style="list-style-type: none"> <li>• Exposure-remove extra clothing</li> <li>• Tepid sponging</li> <li>• Give Paracetamol at 15mg/kg, if the fever persists. If child is vomiting with fever, give per rectal paracetamol at 15mg/kg</li> <li>• Follow up a child with fever in 3 days</li> <li>• Fever is a common symptom in children, and so persistent fever should be investigated for the common childhood illness</li> <li>• Avoid premedication with antipyretics before vaccination</li> </ul>
Irritability, malaise	<ul style="list-style-type: none"> <li>• Give extra fluids</li> <li>• Give paracetamol</li> </ul>
Injection site abscess	<ul style="list-style-type: none"> <li>• Give the child analgesics, start on appropriate antibiotic, review and drain the abscess</li> </ul>
Febrile convulsions	<ul style="list-style-type: none"> <li>• Control fever with paracetamol and undress the child refer if child has altered conscious level</li> </ul>
Toxic Shock Syndrome	<ul style="list-style-type: none"> <li>• 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.</li> </ul>

6.1.1 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

Place the patient in the recovery position if unconscious and ensure the airway is clear. If the patient is conscious, lie him/her face-up with elevated feet (unless vomiting or this results in breathing difficulties). Patient should not stand
↓
Check respiration and pulse
↓
Promptly administer 0.02 ml/kg (maximum 0.5ml) of aqueous adrenaline 1:1000 by intramuscular injection in the antero-lateral thigh; speedy intervention is of paramount importance. Repeat at 5-20 minutes' interval if symptoms are still present (maximum 3 doses)
↓
Monitor vital signs and reassess the situation frequently, to guide management and medication use. If require-begin CPR/IV Fluids (where available)
↓
Arrange for transfer/referral



## 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 care workers recognize the difference between fainting and anaphylaxis.

**Table 6: Clinical features of Fainting vs Anaphylaxis**

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

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

### Unavoidable AEFIs include:

- Vaccine product-related reaction
- Vaccine quality defect-related reaction
- Coincidental event

### Preventable AEFI include:

- Immunization anxiety-related reaction
- 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. 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.

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. 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 care 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 care 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 care 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 care 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 safety and vigilance of health products and 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 care 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.

**Note:** Submission of a report does not mean admission that the health care 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.

## 7.4 WHERE TO REPORT

### Health care providers

Health care providers are encouraged to report all adverse events following immunization using the AEFI forms (Annex 1) available in the pharmacovigilance electronic reporting (PvERS) platform or the hard copy manuals provided at the facilities. AEFIs detected within the private and public sector, as well as those detected during supplementary immunization activities should be reported immediately by the healthcare worker using the below channels. The reporting channels are as follows:

### Electronic reports

Online at the Pharmacovigilance electronic reporting system (PvERS) at [www.pv.pharmacyboardkenya.org](http://www.pv.pharmacyboardkenya.org).

mPvERS mobile application for both Android (Play Store) and iOS (App Store).

E-mail scanned filled forms or details of the reaction at [pv@pharmacyboardkenya.org](mailto:pv@pharmacyboardkenya.org)

### Manual reports

Manual reporting forms are available at the public and private health facilities, while downloadable soft copies are found on the PPB website at [www.pharmacyboardkenya.org/pharmacovigilance/](http://www.pharmacyboardkenya.org/pharmacovigilance/).

The health care worker should fill in the AEFI form in triplicate. The filled AEFI forms shall be submitted to the sub-county public health nurse/ Sub County Pharmacist/Sub county Medical Officer of Health. At the vaccination clinic, the health care worker should tally on the immunization tally sheet. 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 summarized on 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.

At sub-county level, the aggregate AEFI report will be uploaded to the KHIS by the Sub County Health Records and Information Officer (SCHRIO) and the form uploaded onto the PvERS by the sub county pharmacist.

This reports can also be hand delivered, posted or sent through the Board's address as:  
Pharmacy and Poisons Board, P.O. Box 27663 – 00506, Nairobi.  
Lenana Road Opp. DOD • Tel: +254 709770100

### General public/patients

They can report via the USSD code \*271# and follow the prompts or call, text, WhatsApp on +254795743049.

The patients or general public can also report via the link (<https://pv.pharmacyboardkenya.org/padrs/add>) PADR provided on the PPB website for reporting.

### Marketing Authorization

MAHs shall report in the ICH-E2B format through an xml file via email at [pv@pharmacyboardkenya.org](mailto:pv@pharmacyboardkenya.org) or report directly by filling the relevant form or uploading the ICH-E2B XML file on the PvERS at <https://pv.pharmacyboardkenya.org>.

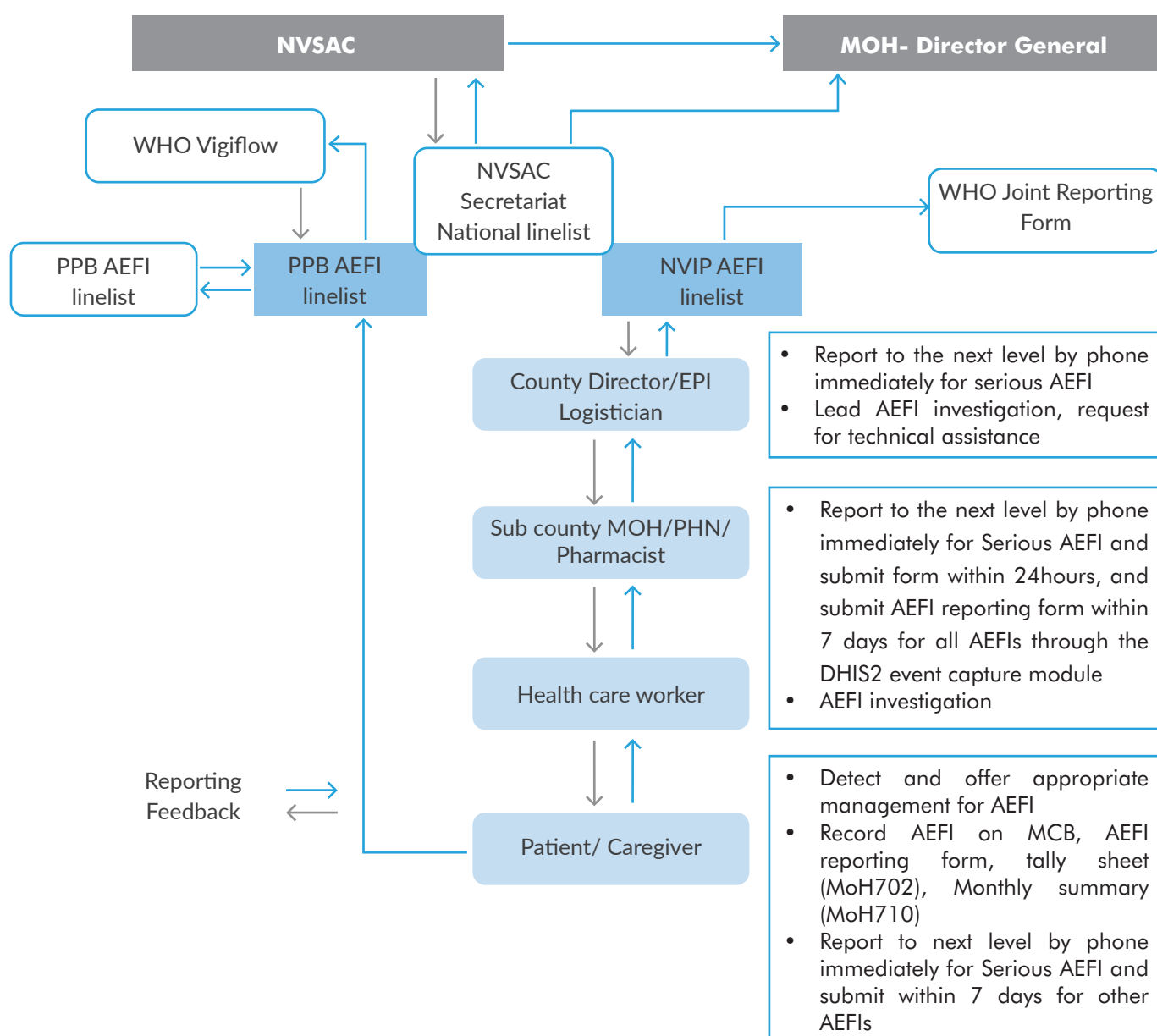
## 7.5 IMPORTANCE OF REPORTING

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.

## 7.6 AEFI REPORTING PATHWAY





## 7.7 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.

## 7.8 HANDLING CASES OF DEATH

The health care 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 and where the next of kin declines, this should be put in writing as much as possible. Under circumstances where an autopsy is not possible, an organ biopsy may be taken.







8.

## INVESTIGATION OF AEFI



## 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?

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 care 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.

NB: Not all AEFI reports need investigation.

### 8.2 WHO SHOULD INVESTIGATE?

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



AEFI investigations should be carried out by sub-county health management teams. Investigations are initiated by the sub-county teams which are led by the sub-county medical officer of health (MOH) with the support of EPI logisticians/public health nurse, pharmacists / pharmacovigilance focal persons, disease surveillance coordinators, health records information officers and communication officers. County health management teams, PPB and the NVIP could provide support for case investigations when required.

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 Physician. The 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 as required. Other stakeholders may also join as needed including (but not limited to): NVSAC members, 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 care 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. The investigating team should provide regular updates to the county team and the NVIP during investigation. Once investigations are concluded the investigation form is completed and a narrative report written. Other documentations of the case should be retrieved from the health facility where the case was managed (hospital case notes and records including discharge summary notes and treatment given, results of laboratory investigations etc.).

The completed investigation forms, narrative report and copies of the hospital case notes and records and results of laboratory investigations should be shipped to the national level (NVIP) through the county team by the fastest possible means as well as scanned and mailed to the NVIP. The documentation should reach the national level (NVIP) within seven days of completion of the investigation.

## 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	<ul style="list-style-type: none"> <li>Check details about patient and event from medical file, document information, interview health care workers who attended to the patient</li> <li>Verify information on report form and obtain any details missing from AEFI Report Form.</li> <li>Identify any other cases that need to be included in the investigation</li> </ul>

Step	Actions
2. Collect data about the patient	<ul style="list-style-type: none"> <li>• Check immunization history</li> <li>• Obtain previous medical history, current illnesses or concomitant medication, prior history of similar reaction or other allergies</li> <li>• Family history of similar events.</li> </ul>
3. Collect data about the event	<ul style="list-style-type: none"> <li>• Clinical description of event, any relevant laboratory results about the AEFI and diagnosis of the event</li> <li>• Treatment of the event, whether hospitalized and outcome (e.g. recovered, ongoing problems, died etc.)</li> </ul>
4. Supply chain and storage conditions: About the suspected vaccine(s):	<ul style="list-style-type: none"> <li>• 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</li> <li>• Present storage condition, state of vaccine vial monitor, and temperature record of refrigerator. Check the record on of Fridge tag-2®</li> </ul>
5. Observe and assess immunization service delivery	<ul style="list-style-type: none"> <li>• Reconstitution (process and time kept). Ask if not able to observe,</li> <li>• Whether AD syringes are available and used</li> <li>• Details of training in immunization practice, supervision and vaccinator(s)/health care worker</li> <li>• Health care worker experience in immunization</li> <li>• The aliquot number for multi dose vials</li> <li>• Number of immunizations greater than normal?</li> </ul>
6. Hypothesis and Investigation Conclusion	<ul style="list-style-type: none"> <li>• Formulate a working hypothesis on the likely/possible cause(s) of the event.</li> <li>• Test working hypothesis by compiling all relevant documents to determine if the case distribution matches the working hypothesis.</li> <li>• Conclude the investigation by identifying the cause of the event.</li> <li>• Complete AEFI Investigation Form.</li> <li>• Transmit investigation report to the next higher level, take corrective action, and recommend further action.</li> </ul>

### 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 part of 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.

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# CAUSALITY ASSESSMENT AND SIGNAL DETECTION FOR AEFI





## 9. CAUSALITY ASSESSMENT AND SIGNAL DETECTION FOR AEFI

AEFI reports once received at the National Pharmacovigilance Centre at the PPB 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 as prescribed in the procedure for review of AEFI reports periodically to share and analyze AEFI reports and guide on appropriate action to be taken, and also presented 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 new vaccines 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 Immunization The 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 of confidence 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 basis of 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.

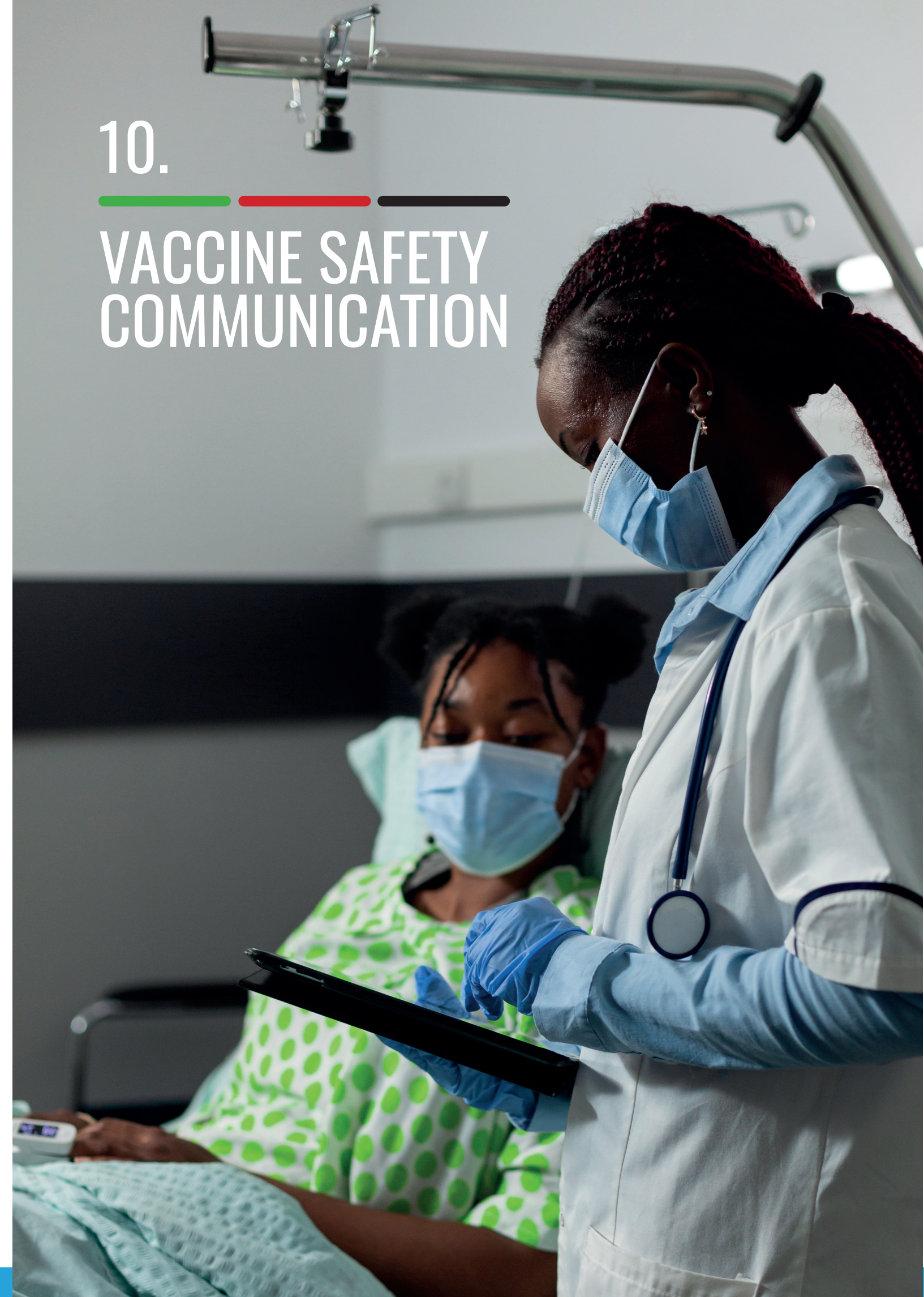


Type of AEFI	Action
Vaccine reaction (Vaccine product-related reactions and Vaccine quality defect-related reactions)	<p>If a higher reaction rate than expected from a specific vaccine or lot/batch, the NVIP/PPB may consider:</p> <ul style="list-style-type: none"> <li>• Obtaining more information from the manufacturer, supplier and WHO</li> <li>• Withdrawing that lot/batch</li> <li>• Changing manufacturing specifications or quality control</li> <li>• Obtaining vaccine from a different manufacturer.</li> </ul>
Immunization error-related reaction	<p>Correcting the cause of the error. This may mean one or more of the following:</p> <ul style="list-style-type: none"> <li>• Review the Vaccine management procedures in place at the depot, during distribution and at the health facility level</li> <li>• Training of health care workers</li> <li>• Intensified support supervision.</li> </ul> <p>Whatever action is taken, it is important to review at a later date to check that the same has been institutionalized</p>
Immunization anxiety-related reaction	<ul style="list-style-type: none"> <li>• Minimize stress in those waiting for the injection by reassuring them, making them comfortable</li> <li>• Prepare the injection out of their view and privacy during the procedure.</li> <li>• Carry out vaccinations in an ambient and safe environment</li> </ul>
Coincidental:	<p>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.</p>
Unknown:	<p>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.</p>



10.

VACCINE SAFETY  
COMMUNICATION





## 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 CARE 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 care workers and vaccinators should be trained in interpersonal communication skills with families and communities. This means that health care 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 care workers are an essential source of information in the AEFI investigation. It is important to reassure the health care worker/ vaccinator and keep them informed of the results of investigations. It is essential that health care 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 care 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 following are recommended roles of Healthcare Professionals when responding to community concerns.

Health care worker Roles/ Responsibilities	How
• <b>Remind the client to report any AEFI</b>	• Remind the client (s) to report any AEFI they may experience at the nearest facility or through available channels
• <b>Raise clients awareness on the vaccine</b>	• Gather information through questioning and listening • Reassure the client(s) and share all necessary information
• <b>Communicate on vaccine safety</b>	• Assure the client(s) that the vaccine is safe • Reassure clients and encourage them to report any AEFI experienced after vaccination • Seek help from the nearest facility if you develop AEFI symptoms .e.g. injection site tenderness, pain, bleeding, body weakness or any other

Health care worker Roles/ Responsibilities	How
<ul style="list-style-type: none"> <li>Addressing misinformation, misconception rumours and myths</li> </ul>	<ul style="list-style-type: none"> <li>Ask questions to identify the source of the misinformation</li> <li>Share facts, accurate and credible information about vaccination</li> <li>Acknowledge safety, benefits and risks of vaccines</li> </ul>
<ul style="list-style-type: none"> <li>Benefits of completion of vaccination schedule</li> </ul>	<ul style="list-style-type: none"> <li>Remind the client to keep the Mother and Child Booklet safe</li> <li>Remind the client on the importance of completing the doses to get the best protection</li> </ul>
<ul style="list-style-type: none"> <li>Create public confidence on routine immunization</li> </ul>	<ul style="list-style-type: none"> <li>Inform the public on the importance of continued routine immunization</li> <li>To disseminate the national immunization schedule</li> </ul>

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. Individual case based feedback reports will be drafted using conclusions from the NVSAC causality assessment as well as the final classification, endorsed by the Director General of Health and disseminated to all relevant stakeholders (county, sub-county, health facility, community). These reports will include identified gaps in documentation of the case (s) and correction of wrong practices of health care workers, advice for the improvement in the immunization programme and safety communication and risk communication and reassurance and confidence building of clients and communities.

## 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 is on 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 care 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 on the 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-trained 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
<b>A database of journalists</b>	An updated list of print and electronic media journalists covering health (local, national, international) with contact information.
<b>Information packages</b>	<ul style="list-style-type: none"> <li>• An information package may contain the following documents both in hard copy and e-copies:</li> <li>• Frequently Asked Questions (FAQs) on immunization in general, for specific disease, and AEFIs.</li> <li>• A factsheet or a technical brief on a specific vaccine preventable disease.</li> <li>• Recent updates: statistics, progress made in immunization</li> <li>• Contact addresses of spokespersons (experts) in the ministry.</li> </ul>
<b>The draft media release</b>	<p>Must specifically answer the six Ws for journalists:</p> <ul style="list-style-type: none"> <li>• Who is affected/or responsible?</li> <li>• What happened?</li> <li>• What is being done?</li> <li>• Where did it happen?</li> <li>• When did it happen?</li> <li>• Why did it happen?</li> <li>• Will it happen again?</li> </ul>
<b>Information specific to media type</b>	<p>Local radio stations and other media are believed by more people in the community than national media.</p> <p>National and international media has a wider reach and influences national agendas</p>
<b>A spokesperson system</b>	<ul style="list-style-type: none"> <li>• Identify in advance an appropriate spokesperson(s) as per government regulations.</li> <li>• Share contact details of spokesperson</li> <li>• Ensure spokesperson(s) has experience or some training in dealing with the media.</li> </ul>
<b>Media conference</b>	Media conferences may need to be conducted if AEFI occur and become a sensational part of media broadcasts. This is in order to provide 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 that has been said
<b>Follow up</b>	Keeping media informed about subsequent developments, actions and 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.

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## ROLES AND RESPONSIBILITIES OF STAKEHOLDERS



## 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;

Stakeholder	Responsibility
Ministry of Health	<ul style="list-style-type: none"> <li>• Policy formulation</li> <li>• System and database maintenance (DHIS)</li> <li>• Resource mobilization</li> </ul>
National Vaccines and Immunization Program	<ul style="list-style-type: none"> <li>• Provision of vaccines</li> <li>• Training of health care workers</li> <li>• Feedback and information sharing</li> <li>• Share Information with PPB immediately for Serious AEFI</li> <li>• NVSAC secretariat</li> <li>• Participating in investigation</li> <li>• Participate in Post-market surveillance</li> <li>• Reporting through Joint Reporting Form</li> <li>• Signal detection</li> <li>• Causality assessment</li> <li>• Maintenance of database and AEFI line list</li> </ul>
Pharmacy and Poisons Board	<ul style="list-style-type: none"> <li>• Regulatory action</li> <li>• Feedback and information sharing</li> <li>• Share Information with NVIP immediately for Serious AEFI</li> <li>• NVSAC secretariat</li> <li>• Participating in investigation</li> <li>• Licensing of vaccines</li> <li>• Post-market surveillance</li> <li>• Reporting through Vigiflow®</li> <li>• Signal detection</li> <li>• Causality assessment</li> <li>• Provision of reporting tools</li> <li>• Training of health care workers</li> <li>• Maintenance of database and AEFI line-list</li> </ul>
County Government	<ul style="list-style-type: none"> <li>• Provision of vaccination services</li> <li>• Training of health care workers</li> <li>• Feedback and information sharing to lower level</li> <li>• Lead AEFI investigation, request Technical Assistance</li> <li>• Participate in Post-market surveillance and pharmacovigilance activities</li> <li>• Reporting of AEFI</li> <li>• Maintenance of AEFI line-list</li> <li>• Resource mobilization</li> </ul>



<b>Sub-county health management team</b>	<ul style="list-style-type: none"> <li>• Provision of vaccination services</li> <li>• Training of health care workers</li> <li>• Feedback and information sharing to lower level</li> <li>• Initiate AEFI investigation</li> <li>• Participate in Post-market surveillance and pharmacovigilance activities</li> <li>• Reporting of AEFI</li> <li>• Resource mobilization</li> <li>• Entering of AEFI reports into DHIS 2 by HRIO</li> </ul>
<b>Health Care worker</b>	<ul style="list-style-type: none"> <li>• Detection, management and timely reporting of AEFI</li> <li>• Provision of vaccination services</li> <li>• Providing information on vaccines to clients</li> <li>• Feedback to caregivers</li> </ul>
<b>Development partners</b>	<ul style="list-style-type: none"> <li>• Resource mobilization</li> <li>• Technical assistance</li> </ul>
<b>World Health Organization</b>	<ul style="list-style-type: none"> <li>• Technical assistance</li> <li>• Providing information/guidance documents</li> </ul>
<b>Media</b>	<ul style="list-style-type: none"> <li>• Responsible reporting</li> <li>• Support awareness creation</li> </ul>
<b>Caregiver/client</b>	<ul style="list-style-type: none"> <li>• Report AEFI</li> <li>• Adhere to guidance of health care worker</li> </ul>
<b>Laboratories: NQCL, Government Chemist, NPHLS</b>	<ul style="list-style-type: none"> <li>• Timely testing of specimen</li> <li>• Provide advice</li> </ul>
<b>NVSAC</b>	<ul style="list-style-type: none"> <li>• Advisory role- Refer to NVSAC Terms of Reference</li> </ul>
<b>NVSAC secretariat</b>	<ul style="list-style-type: none"> <li>• Merge and update the joint NVIP &amp; PPB national line list</li> <li>• Select cases for NVSAC to review, summarize findings from NVSAC deliberations</li> <li>• Share recommendations of NVSAC to NVIP and PPB</li> <li>• Coordinate investigations</li> </ul>

# 1. AEFI REPORTING FORM

 <b>MINISTRY OF HEALTH</b> <b>NATIONAL VACCINES AND IMMUNIZATION PROGRAM</b> <b>AEFI Reporting Form</b> 									
(To be filled in triplicate)					<input type="checkbox"/> Initial Report		<input type="checkbox"/> 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)				
<input type="checkbox"/> BCG Lymphadenitis <input type="checkbox"/> Convulsion <input type="checkbox"/> Generalized urticaria (hives) <input type="checkbox"/> High Fever Injection site abscess					<input type="checkbox"/> Anaphylaxis <input type="checkbox"/> Encephalopathy, <input type="checkbox"/> Encephalitis/Meningitis <input type="checkbox"/> Paralysis Toxic shock				
Severe Local Reaction			Others (specify).....						
Onset of event:			Date ..... /..... /.....				Time .....		
Suspected vaccine(s)									
Name of Vaccine (e.g)		Dose No.	Date	Time	Route,		Details of Vaccine		Details of Diluents
BCG, DPT-Hib-HeB)					vaccination(i.m.,s.c.)		Lot/Batch		
<b>Past medical history</b> (including history of similar reaction or other allergies, concomitant medication/vaccine, concomitant illness, other cases, pregnancy status and other relevant information (continue on separate sheet if necessary)									
<b>Action taken</b>		Treatment given (specify)..... Specimen collected for investigation (specify type(s) of specimen).....							
<b>AEFI Outcome</b>		Recovered	Recovering	Not recovered		Unknown		Died	
Name of Person Reporting					Phone number.....				
Designation					Signature: .....				
<b>Final Classification of AEFI ( to be filled at national level):</b> (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 unfavorable 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 unfavorable 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 care worker concern*

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#### 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 care 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 time tick 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 and used to improve policy and service delivery in the Ministry of Health. Information is handled in strict confidence

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



## 2. 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 <input type="checkbox"/> Public health facility <input type="checkbox"/> Private health facility <input type="checkbox"/> Other (specify) Vaccination in : <input type="checkbox"/> Campaign <input type="checkbox"/> Routine <input type="checkbox"/> Other (specify)					
<b>Name and Address of vaccination site:</b>					
<b>Name of Reporting Officer:</b> Date of investigation: ___/___/___ Date of filling this form: ___/___/___ Designation: This report is: <input type="checkbox"/> First <input type="checkbox"/> Interim <input type="checkbox"/> Final Mobile: e-mail:					
<b>Patient Name:</b> Sex: <input type="checkbox"/> M <input type="checkbox"/> F (use a separate form for each case in a cluster) Date of birth: / / <b>OR</b> 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 1,2 <sup>nd</sup> )	Batch/Lot number	Expiry date
				Vaccine Diluent	Vaccine Diluent
				Vaccine Diluent	Vaccine Diluent
				Vaccine Diluent	Vaccine Diluent
Type of site <input type="checkbox"/> Fixed <input type="checkbox"/> Mobile <input type="checkbox"/> Outreach <input type="checkbox"/> Other (Specify) Date of first/key symptom ___/___/___ Time of first symptom hh/mm: / Date of hospitalization ___/___/___ <input type="checkbox"/> N/A Date first reported to the health authority: ___/___/___ Status on the date of investigation: <input type="checkbox"/> Disabled <input type="checkbox"/> Recovering <input type="checkbox"/> Recovered completely <input type="checkbox"/> Unknown If died, date and time of death (DD/MM/YYYY) ___/___/___ (hh/mm): ___/___/___ Autopsy done? : <input type="checkbox"/> Yes (date) <input type="checkbox"/> 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? <input type="checkbox"/> Yes ( weeks) <input type="checkbox"/> No • Unknown Currently breastfeeding? <input type="checkbox"/> Yes <input type="checkbox"/> No					



**Name****AEFI Report ID**

For infants

The birth was ☐ full-term ☐ pre-term ☐ post-term. ☐ Birth weight ☐ Current weightDelivery procedure was ☐ Normal ☐ Caesarean ☐ Assisted (forceps, vacuum etc.) ☐ with complication (specify)**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:

<b>Section D</b>		<b>Details of vaccines provided at the site linked to AEFI on the corresponding day</b> (Complete this section by interviewing the health care 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) <input type="checkbox"/> Within the first vaccinations of the session <input type="checkbox"/> Within the last vaccinations of the session <input type="checkbox"/> Unknown						
	In case of multi-dose vials, was the vaccine given <input type="checkbox"/> within the first few doses of the vial administered? <input type="checkbox"/> within the last doses of the vial administered? <input type="checkbox"/> unknown?						
b	Was there an error in prescribing or non-adherence to recommendations for use of this vaccine?						Yes / No / Unable to assess
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 assess
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 assess
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 assess
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 assess
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?						Yes / No / Unknown	
b) If no, number of vials used in the cluster (enter details separately)							

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

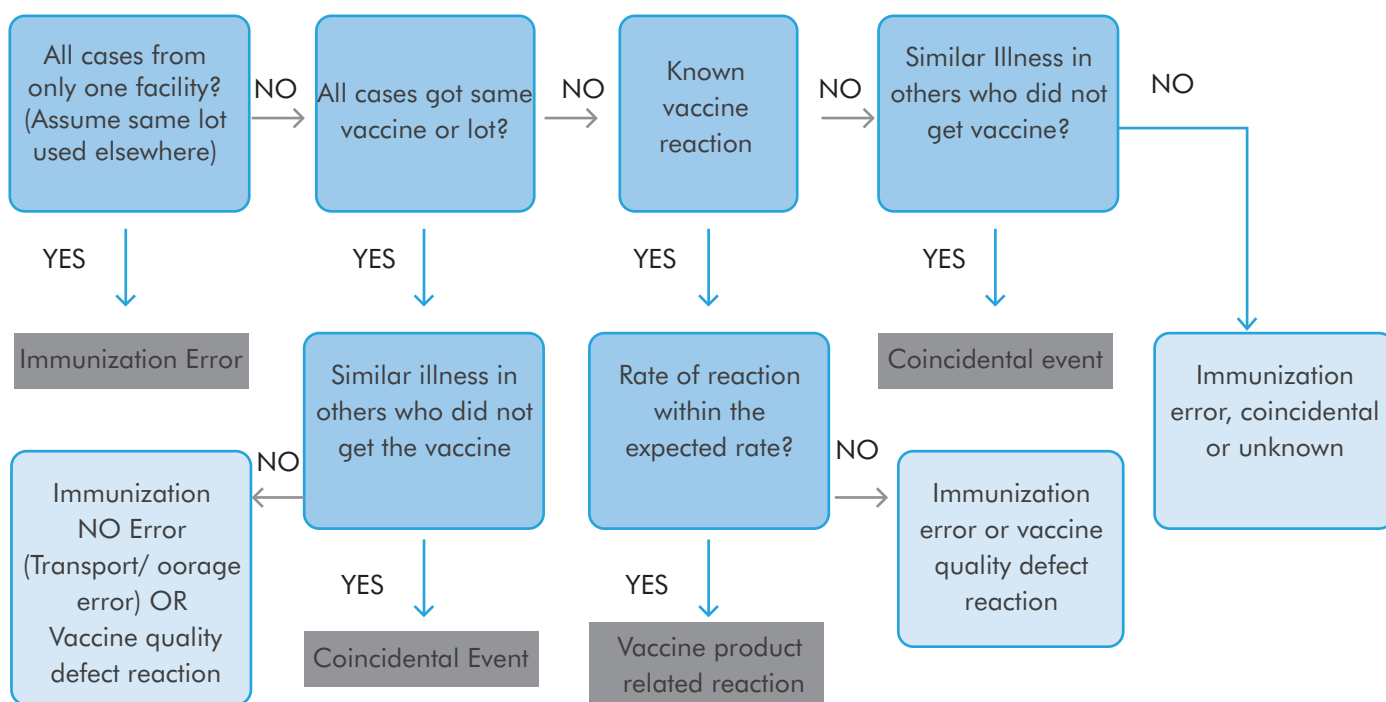
<b>Section E</b> <b>Immunization practices at the place(s) where concerned vaccine was used</b> (Complete this section by asking and/or observing practice)				
Syringes and needles used:				
Are AD syringes used for immunization?				Yes / No / Unknown
If no, specify the type of syringes used:	<input type="checkbox"/> Glass	<input type="checkbox"/> Disposable	<input type="checkbox"/> Recycled disposable	Other _____
Specific key findings/additional observations and comments:				
<b>Reconstitution: (complete Yes or No , NA if not applicable)</b>				

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:			
<b>Section F</b> <b>Cold chain and transport</b> Complete this section by asking and/or observing practice)			
<b>Last vaccine storage point:</b>			
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:			
<b>Vaccine transportation:</b>			
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:			
<b>Section G</b> <b>Community investigation (Please visit locality and interview parents/others)</b>			
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:			
<b>Section H</b> <b>Other findings /observations/ comments</b>			



### 3. ALGORITHM FOR INVESTIGATION OF CLUSTER

#### CLUSTER OF AEFI



Adverse event	Case definition
<b>Acute flaccid paralysis (Vaccine associated paralytic poliomyelitis)</b>	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.
<b>Anaphylaxis</b>	Anaphylaxis is likely when all of the following three criteria are met: <ul style="list-style-type: none"> <li>• sudden onset and rapid progression of symptoms</li> <li>• life-threatening airway and/or breathing and/or circulation problems</li> <li>• skin and/or mucosal changes (flushing, urticaria, angioedema).</li> </ul>
<b>Encephalopathy</b>	Acute onset of major illness characterized by any two of the following three conditions: <ul style="list-style-type: none"> <li>• seizures</li> <li>• severe alteration in level of consciousness lasting for one day or more</li> <li>• distinct change in behavior lasting one day or more.</li> </ul> Needs to occur within 48 hours of DTP vaccine or from 7 to 12 days after measles vaccine, to be related to immunization

Adverse event	Case definition
Fever	The fever can be classified (based on rectal temperature) as Mild fever: 38°C to 38.9°C, High fever: 39°C to 40.4°C and Extreme fever: >40.5°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: <ul style="list-style-type: none"> <li>• limpness (hypotonic)</li> <li>• reduced responsiveness (hypo responsive)</li> <li>• pallor or cyanosis – or failure to observe/ recall</li> </ul>
Injection site abscess	Fluctuant or draining fluid-filled lesion at the site of injection. <b>Bacterial</b> if evidence of infection (e.g. purulent, inflammatory signs, fever, culture), <b>Sterile</b> Infection on culture. <b>Sterile abscesses</b> are usually due to the inherent properties of the vaccine.
Lymphadenitis (includes suppurative lymphadenitis)	<b>Either</b> 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).
Persistent inconsolable screaming	Inconsolable continuous crying lasting 3 hours or longer accompanied by high-pitched screaming.
Convulsion	Occurrence of generalized convulsions that are <b>not</b> accompanied by focal neurological signs or symptoms. <b>Febrile</b> convulsions: if temperature elevated >38°C (rectal) <b>Afebrile convulsions:</b> 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: <ul style="list-style-type: none"> <li>• swelling beyond the nearest joint</li> <li>• pain, redness, and swelling of more than 3 days duration</li> <li>• requires hospitalization.</li> </ul>
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

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

ID	County	Sub-county	Age in months at time of vaccination	Sex	Date of vaccination	Date 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
XXX																				
XXX																				
XXX																				



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