GUIDELINES
FOR SURVEILLANCE ON ADVERSE EVENTS FOLLOWING IMMUNIZATION IN GHANA

December 2014

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Acknowledgement

This document, Surveillance of Adverse Events Following Immunization (AEFI) in Ghana, is the result of collaborative work between staff of the Food and Drugs Authority (FDA) and the Expanded Programme on Immunization (EPI) of the Ghana Health Service (GHS) who are committed to improving safety of immunization services throughout the country.

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Foreword

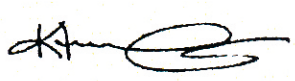
Vaccines used in national immunization programmes are considered safe and effective. Rigorous procedures are followed before registration and sale but there is no such thing as a "perfect" vaccine which has no adverse events. Vaccination Programmes are usually complex in nature and in spite of all precautions taken, some people may be affected by adverse events following immunization (AEFI) caused by vaccine product(s) and or composition or by an error in its administration or in most cases, such events may be unrelated to vaccines or vaccination at all.

Although careful testing and clinical trials are done before vaccines are approved, safety data are based on relatively small numbers and restricted populations studied. Therefore, it is critical for national immunization programmes to have in place a strong post-marketing surveillance system to detect less common adverse events not recognized in pre-registration trials and also to check on ongoing safety of the programme itself in order to assure continued public safety.

Ghana's Expanded Programme on Immunization (of the Ghana Health Service), in collaboration with the Food and Drugs Authority, the authorized regulatory agency for all medicines and biologicals including vaccines (both of the Ministry of Health) have successfully established a national system for post-marketing surveillance of vaccines used in routine immunization or immunization campaigns.

The development of the Guidelines for Surveillance of Adverse Events Following Immunization in Ghana is a collaborative effort between the two agencies. It is intended to consolidate the efforts of the Ministry of Health and the Government of Ghana in providing safe vaccination as well as enable the health system to effectively respond to vaccine safety challenges through clearly assigned roles and responsibilities of health staff. It provides the tools for both public health and clinical staff at all levels to enable them respond appropriately to adverse events in a timely manner as well as help prevent immunization-error related AEFIs.

This document is expected to further strengthen the AEFI surveillance and response system in the country and help build public confidence in the national immunization programme since an immunization programme can only perform better if it has the full confidence of the general public.



Dr. Kwaku Agyeman-Mensah
(Hon. Minister of Health)

"Ghana`s Expanded Programme on immunization in collaboration with the Food and Drugs Authority, the authorized regulatory agency for all medicines and biologicals including vaccines (both of the Ministry of Health) have successfully established a national system for post-marketing surveillance of vaccines used in routine immunization or campaigns."

Acronyms & Abbreviations

AEFI
Adverse Events Following Immunization

BCG
Bacille Calmette Guerin vaccine

DCD
Disease Control Department (of GHS)

DFP
District Focal Person

DPT Hep B Hib
Diphtheria- Pertussis-Tetanus Hepatitis B
Haemophilis influenza type b vaccine

DHIMS 2
District Health Information Management System

EPI
Expanded Programme on Immunization

FDA
Food and Drugs Authority

GHS
Ghana Health Service

Hep B
Hepatitis B vaccine

Hib
Haemophilus Influenza type B vaccine

NGO(s)
Non-Governmental Organization(s)

OPV
Oral Polio vaccine

PCV
Pneumococcal Conjugate vaccine

Rota
Rotavirus vaccine

SMD
Safety Monitoring Department

TAC
Technical Advisory Committee (of FDA)

UNICEF
United Nations Children's Education Fund

WHO
World Health Organization

YF
Yellow Fever vaccine

Glossary

Active Surveillance:
The type of surveillance system that monitors events reported by health care providers and clients e.g. vaccinees, which actively seeks out and collects data or measure outcomes using protocols.

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

Cluster:
Two or more cases of the same adverse events following immunization related in time, place, or the vaccine administered.

Coincidental event:
An AEFI that is caused by something other than the vaccine product, immunization error or immunization anxiety. E.g.: A fever occurs at the time of the vaccination (temporal association) but is in fact caused by malaria. Coincidental events reflect the natural occurrence of health problems in the community with common problems being frequently reported.

Immunization anxiety-related reaction:
An AEFI arising from anxiety about the immunization. E.g.: Vasovagal syncope or fainting in an adolescent during/following vaccination.

Immunization error-related reaction:
An AEFI that is caused by inappropriate vaccine handling, prescribing or administration and thus by its nature is preventable. E.g.: Transmission of infection by contaminated multi-dose vial.

Immunization:
The process by which a person or animal becomes protected against a disease. This term is often used interchangeably with vaccination or inoculation.

Non-serious AEFI:
Includes minor and moderate temporary adverse events following immunization that are not classified as serious.

Passive Surveillance:
The type of surveillance system that monitors events reported by health care providers and clients e.g. vaccinees and do not actively seek out and collect data or measure outcomes using study protocols.

Pharmacovigilance:
The science and activities relating to the detection, assessment, understanding and prevention of adverse effects or any other drug-related problems.

Primary reporter:
Person who first reports an AEFI to the surveillance or health system.

Serious AEFI:
Any unpleasant medical occurrence after immunization that results in death, is life-threatening, requires in-patient hospitalization or prolongation of existing hospitalization, results in persistent or significant disability/ incapacity, or is a congenital anomaly/birth defect. Any medical event that requires intervention to prevent one of the outcomes above may also be considered as serious.

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).

Trigger event:
A medical incident that stimulates a response, usually a case investigation.

Vaccination:
Introduction of a killed or weakened infectious organism or its product into the body in order to prevent diseases.

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

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. E.g.: Extensive limb swelling following DTP vaccination.

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. E.g.: Failure by the manufacturer to completely inactivate a lot of inactivated polio vaccine leads to cases of paralytic polio.

Vaccinee (Vaccine Recipient):
A person receiving a vaccine.

1. Introduction

The objective of the Expanded Programme on Immunization (EPI) in Ghana is to protect all persons especially children and pregnant women living in Ghana against vaccine preventable diseases. At the moment the Programme vaccinates against 12 childhood vaccine-preventable diseases (including the recent addition of rubella) in its routine immunization schedules. The other diseases are tuberculosis, poliomyelitis, diphtheria, neonatal tetanus, whooping cough, hepatitis B, *Haemophilus influenza* type B infections, measles, yellow fever, rotavirus diarrhoea and pneumococcal diseases. Additionally, the programme routinely offers tetanus toxoid (TT) for pregnant women and also conducts mass immunization preventive or reactive campaigns against specific diseases like meningitis, yellow fever and pandemic influenza. Table 1 shows the schedule for immunization and Vitamin A Supplementation in children.

Table 1: National Immunization and Vitamin A Supplementation Schedule

Age	Vaccines	Doses	Route and Site of Injection
At birth	BCG OPV0	0.05ml 2 drops	Intra-dermal, right upper arm Oral
6 weeks	DPT -HepB - Hib1 OPV1 Pneumo 1 Rota 1	0.5ml 2drops 0.5 ml 1.5 ml vial	Intra-muscular, lateral aspect of left thigh Oral Intra-muscular, lateral aspect of right thigh Oral
10 weeks	DPT -HepB -Hib2 OPV2 Pneumo 2 Rota 2	0.5ml 2drops 0.5 ml 1.5 ml vial	Intra-muscular, lateral aspect of left thigh Oral Intra-muscular, lateral aspect of right thigh Oral
14 weeks	DPT -HepB -Hib3 OPV3 Pneumo 3	0.5ml 2drops 0.5 ml	Intra-muscular, lateral aspect of left thigh Oral Intra-muscular, lateral aspect of right thigh
6 months	Vitamin A	100,000 IU	Oral
9 months	Measles-Rubella Yellow Fever	0.5ml 0.5ml	Subcutaneous, left upper arm Subcutaneous, right upper arm
12 months	Vitamin A	200,000 IU	Oral
18 months	Measles Vitamin A	0.5ml 200,000 IU	Subcutaneous, left upper arm Oral
After 18 months Vitamin A is given every 6 months till child is 5 years old 18 months – Give Long lasting Insecticide Treated Nets (LLINs) to the child			

Although all vaccines used in the immunization programme are safe, no vaccine is entirely without risk. Some people experience events after immunization ranging from mild adverse events to life-threatening and even death. In some cases, these events are caused by the vaccine; in others, they are caused by an error in the administration of the vaccine; and in the majority of cases, there is no relationship.

An increase in vaccine use (e.g. mass immunization campaigns) will lead to more vaccine reactions as well as more coincidental events. Immunization-error related events (previously known as "programme errors") may also increase. Reporting and investigating Adverse Events Following Immunization (AEFI) can be used to identify and correct immunization-error related reactions and may help to distinguish a coincidental event from a vaccine-related AEFI.

An Adverse Event Following Immunization (AEFI) is any untoward medical occurrence which follows immunization and which does not necessarily have a causal relationship with the usage of the vaccine. The adverse event may be any unfavorable or unintended sign, abnormal laboratory finding, symptom or disease. Reported adverse events can either be a result of the vaccine or immunization process, or coincidental events that are not due to the vaccine or immunization process but are temporally associated with immunization.

Surveillance of AEFIs is an effective means of monitoring immunization safety. While contributing to the credibility of the immunization programme, it allows for proper management of AEFIs and avoids inappropriate responses to reports of AEFIs that can create a sense of crisis in the absence of safety surveillance.

In Ghana, the AEFI surveillance system is a collaborative effort between the Expanded Programme on Immunization and the Food and Drugs Authority. This system has worked efficiently in ensuring vaccine safety in the country. As several new vaccines become available and get introduced into the routine immunization programme pharmacovigilance of these vaccines is imperative for a number of reasons:

- Vaccines as opposed to medicines are for prevention in healthy, larger population. Therefore, there is lower tolerance to risk
- Vaccines are biological products, therefore are more prone to lot/batch variation and instability
- For vaccines unlike medicines, there are relatively limited number of products
- With single dose, there is a greater potential for temporal "coincidence" adverse events
- Vaccines are prone to "programme error" (techniques, skills, appropriate logistics etc. often required)
- Vaccines are mostly injectables and are more likely to have injection "reaction"
  Cold chain is often critical in Immunization
- Vaccines are commonly administered in mass campaigns: many doses in short time in defined population: therefore, more prone to many "reactions" in a short time.
- Vaccines are associated with politics of access/safety

Most importantly, some vaccines are developed for the prevention of diseases specific to sub-Sahara Africa (e.g. Meningococcal A meningitis and malaria). Monitoring is crucial in identifying new safety issues that were not identified during clinical studies.
Vaccine pharmacovigilance therefore, requires better collaboration between Public Health departments, National Immunization Programmes, National Regulatory Authorities, manufacturers and other stakeholders.

2. Purpose, goal and objectives **of the guidelines**

The purpose of this guideline is to make readily available comprehensive, simple and standardized information for health workers and other stakeholders on surveillance of Adverse Events Following Immunization in Ghana. The overall goal is ensuring public safety and assuring confidence in the immunization programme.

The objectives of the guidelines are to;

- Safeguard an effective system for AEFI surveillance;
- Provide standards for detection, management and treatment of AEFIs;
- Provide standards for effective communication with the public, including crises communication and measures to combat rumors that jeopardize vaccination activities;
- Standardize investigations into AEFIs
- Provide clear roles and responsibilities for the key stakeholders and players in the AEFI surveillance system

3. The AEFI Surveillance System in Ghana

3.1 Stakeholders

The AEFI surveillance system in Ghana is a collaborative effort among the Expanded Programme on Immunization (Ghana Health Service), the Food and Drugs Authority, the World Health Organization, and UNICEF. Other stakeholders include recipients of vaccines, parents and caregivers (if vaccinees are children), community members, Civil Society, Private (for-profit and non-for-profit) Health Providers, the media and the general public (Figure 1).

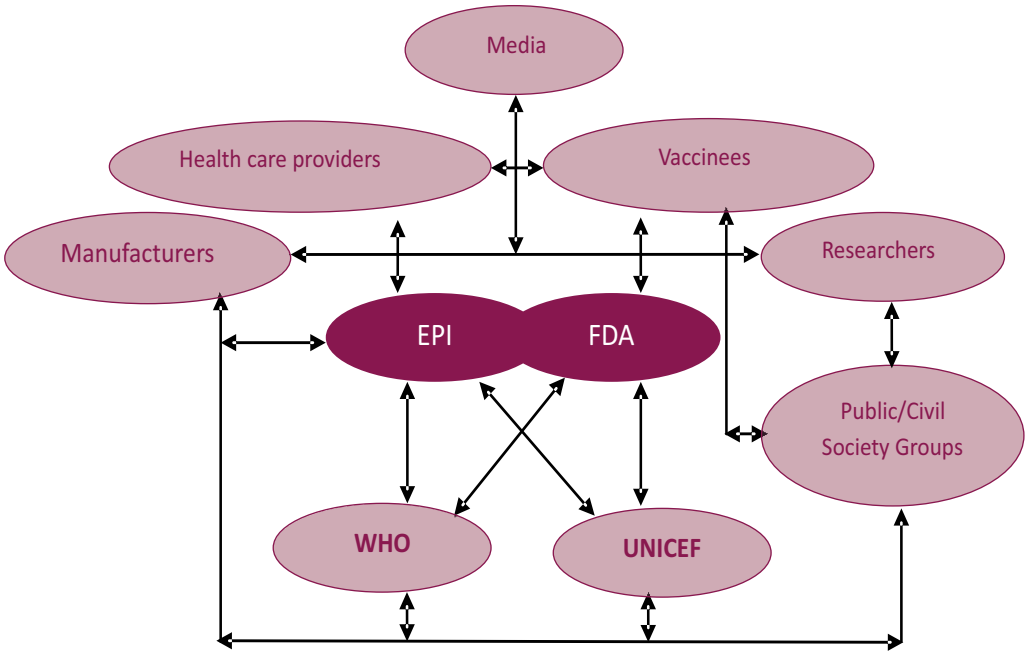


Figure 1: Stakeholders for AEFI, Ghana

3.2 Establishment and Scope

Routine AEFI reporting in Ghana started with the establishment of the Expanded Programme on Immunization in 1978. Reporting became more structured with the establishment of a National Pharmacovigilance Centre in 2001 situated at the Food and Drugs Authority which serves as a focal point and resource center for pharmacovigilance activities in Ghana. The system ensures channels for reporting AEFI during both routine immunization and mass vaccination campaigns.

3.3 Goal and Objectives of the AEFI Surveillance System

The overall goal of the surveillance system is to promptly detect and manage AEFIs, real or perceived. Specifically, the surveillance system is to

- Detect, correct and prevent immunization error-related AEFIs caused by errors in vaccine preparation, handling, storage or administration
- Identify problems with vaccine lots or brands leading to vaccine reactions caused by the inherent properties of a vaccine.
- Prevent false blame arising from coincidental adverse events following immunization, which may have a known or unknown cause unrelated to immunization,
- Maintain confidence by properly responding to parent/community concerns, while increasing awareness (public and professional) about vaccine risks

- Generate new hypotheses about vaccine reactions specific to defined populations in Ghana
- Estimate rates of occurrence of AEFIs in the local Ghanaian population compared with clinical trial and international data, particularly for newly introduced vaccines.

3.4 Information Flow

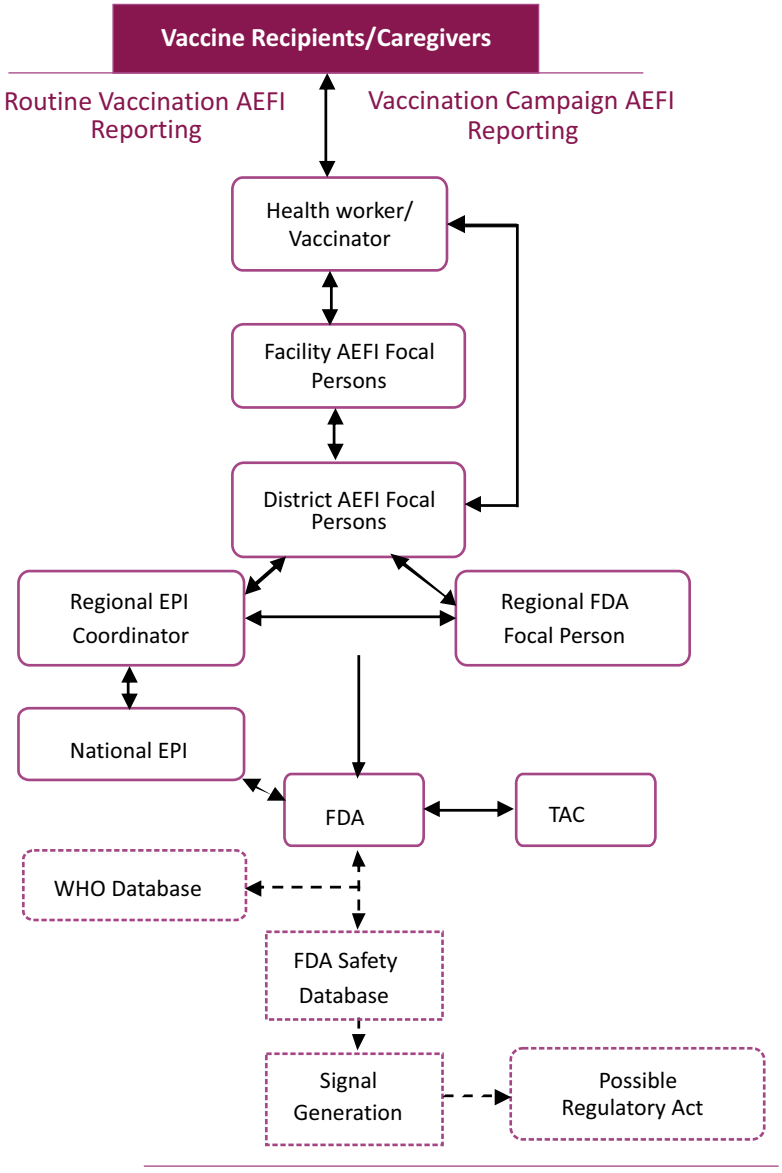


Figure 2: Flow chart for AEFI Surveillance in Ghana

3.4.1 Requirements for Reporting and Reporting Levels

3.4.1.1 Reporters and General Requirements

Case detection is the first and most important step in AEFI surveillance. The primary reporter may be a public health worker, vaccinator, clinic or hospital staff, volunteer or caregiver (parent) or any other person who detects the AEFI. A suspicion alone is sufficient for reporting. Following receipt of complains from vaccinees or their caregivers; or following linkage of complains to vaccination, the health worker completes and submits an AEFI form (Annex 1) to the Facility or District AEFI Focal Person or the District EPI Coordinator. The report is submitted to the Regional EPI Focal point and then in turn to the National EPI or FDA depending on whether it is routine or campaign immunization (refer 2).

3.4.1.2 Reporting during Routine Vaccination and Mass Campaign

During mass immunization campaigns, four levels of communication are identified namely, health worker, district, regional and national levels while for routine immunization, AEFI reporting goes through the Ghana Health Service reporting system: health worker, district disease control officers, regional EPI coordinators, National EPI AEFI coordinator and then to FDA with copies to relevant levels as necessary (**Figure 2**).

3.4.1.3 Timeliness of Reporting

Reporters are not expected to assess causality which is implied when considering the cause-specific definitions of AEFIs. However, rapid detection and evaluation of possible vaccine link is essential to ensure the continued safety of vaccines. Thus, in case of suspicion, a report must be submitted on a timely basis rather than waiting for all aspects of an investigation to be completed. This is particularly true for reports which meet the criteria to be considered serious AEFIs, AEFI clusters and trigger events.

The reports are evaluated and endorsed at each level and eventually, by FDA for causality assessment and feedback provided to all levels.

3.4.1.4 Training for Peripheral Actors

To improve the detection capacity, a good knowledge of the primary reporter on AEFI, its types, and purpose of AEFI surveillance is necessary. Regular training and awareness programmes are necessary to update knowledge and sustain interest among all reporters. Therefore, FDA and EPI regularly provide training for peripheral health workers on AEFI reporting.

3.4.2 The Technical Advisory Committee (TAC) and Causality Assessment

Reports received from health workers and parents/vaccine recipients are presented to Technical Advisory Committee (TAC) for Vaccines and Related Biological Products for evaluation and causality assessment if necessary. This Committee which is constituted by the Food and Drugs Authority has expertise which includes but not limited to pediatrics, general medical practice, clinical pharmacy, epidemiology, pathology, internal medicine (gastroenterology and neurology) and consumer representative. The Committee additionally makes recommendations for action by FDA and GHS/EPI.

3.5 Tools

Tools for AEFI surveillance, investigation and reporting made available to actors in the country to help promote AEFI reporting include:

Guidelines for Surveillance of Adverse Events Following Immunization in Ghana

AEFI Reporting Form	(Annex 1)
Guidelines for Completing AEFI Reporting Form	(Annex 2)
AEFI Investigation Form	(Annex 3)
Clinical Laboratory Form	(Annex 4)
Electronic Line Listing Form	(Annex 5)
Guideline for AEFI Epidemiological Investigation	(Annex 6)

4. Roles and Responsibilities of Key Players

The AEFI surveillance system involves several stakeholders (Figure 1). The system in Ghana is designed such that major decisions are taken at all levels. In particular, issues requiring immediate decision and action can be taken at the lower level and communicated to the next higher level as soon as possible. This section outlines roles and responsibilities of key actors in carrying out AEFI surveillance activities in the country.

4.1 Vaccine Recipients and Caregivers (Parents)

Vaccine recipients and caregivers should preferably, report all AEFIs to their health care providers. However, reports may also be made directly to the Food and Drugs Authority: reports so received are documented as for any other report received from health workers.

4.2 Health workers/ Vaccinators

This is the lowest administrative level in the AEFI surveillance system which provides immunization services to the public. During provision of immunization services health workers and vaccinators are responsible for the following:

- Reducing avoidable immunization-related (programme) errors: inappropriate vaccine handling, prescribing or administration
- Communicating possible adverse events to vaccinees and/or caregivers before vaccination
- Counseling vaccinees and caregivers on how to manage mild and common vaccine reactions
- Detecting, managing and reporting AEFI cases as per the AEFI guideline

Information about the immunization(s) should be provided well ahead of the clinic day or the day of visit. This affords parents the time to understand the information well and empowers them to ask questions that will increase their trust.

4.3 Facility AEFI Focal Person

These are health workers based in clinics and hospitals who have received training from the Food and Drugs Authority and the Expanded Programme on Immunization. They are responsible for the following:

- Sensitizing all health workers at the health facility to detect, manage and report AEFI cases
- Conducting clinical investigations and reporting AEFI cases
- Compiling weekly AEFI reports and forwarding to the District AEFI Focal Person (including Zero reporting-when no AEFI cases are detected) ·

4.4 District AEFI Focal Person

These are mostly surveillance officers (or other health workers) who are designated by the District Health Authorities as Focal persons for AEFI and have received training from FDA and EPI. They are responsible for the following:

- Organizing training and/or orientation program for facility AEFI focal persons and other health workers in the district.
- Ensuring availability of tools (AEFI reporting forms and guidelines) at all facilities in the district.
- Validating AEFI reports, completing ALL details in the AEFI reporting form and assigning codes (unique patient identifiers) to the AEFI reports
- Leading investigations into AEFI cases which fulfill case definitions with support from the District Health Management Team

- Facilitating the referral of suspected serious AEFI cases to the reference hospital during campaigns in conjunction with the District Director of Health Services and team.
- Taking corrective action based on the findings from investigations, in conjunction with the District Director of Health Services and team.
- Maintaining AEFI database at the District level in conjunction with the District Director of Health Services, District Health Information Officer and Team
- Analyzing AEFI data to determine distribution and patterns of AEFI occurrence
- Compiling AEFI reports from community and health facilities and submitting same to the Regional EPI Coordinator and/or FDA Regional Focal person.
- Submit daily AEFI line-listing to the FDA Regional Focal person with copies to the Regional Health Directorate and relevant levels during vaccination campaigns
- Supervising AEFI surveillance activities in the district

4.5 District Director of Health Services

The District Director of Health Services is the 'owner' of the AEFI surveillance system at the District level just as she/he does for all other health issues. The responsibility includes but not limited to:

- Ensuring Free treatment of all AEFI cases
- Supporting referral of serious AEFIs when necessary
- Support District and Facility Focal Persons in their roles
- Ensure data availability and use at the district level
- Communicate findings to the community with support from the District and Facility AEFI Focal Person.

4.6 Regional EPI Coordinator and Deputy Director Public Health

Together with the Deputy Director of Public Health at the Regional level, the Regional EPI Coordinator performs the following:

- Organizing training/orientation for District and Facility Focal Persons and other health workers
- Supporting AEFI investigation (including epidemiological and clinical investigations) at the District level
- Assisting the District Director of Health Services and District Focal Person in referral of suspected serious AEFI cases to reference hospitals
- Taking corrective action based on findings from investigations
- Supervising AEFI surveillance activities throughout the region
- Maintaining a regional database of AEFI
- Analyzing Regional AEFI data to determine distribution and patterns of AEFI occurrence
- Compiling monthly AEFI reports from districts and submitting same to national EPI
- Leading public communication on AEFI for the Region
- Assisting FDA Regional Focal person in collation of AEFI reports during mass vaccination campaigns

4.7 FDA Regional Focal Person

These are FDA staff in the Regional offices and are responsible for the following activities during mass immunization campaigns:

- Assisting in training of District AEFI focal persons and other health workers
- Ensuring availability of tools (e.g. AEFI Reporting Form) and guidelines at all levels of the area covered in the Region, particularly during campaigns

- Collecting, validating and ensuring reports from reference hospitals are completed
- Gathering and qualifying reports from district focal persons
- Forward all reports to national FDA (Central Team)
- Facilitate referral of suspected serious cases to reference hospital and monitor the quality of the case documentation
- Ensuring compliance with Standard Operating Procedures for AEFI Reporting

4.8 Expanded Program on Immunization/Ghana Health Service (EPI/GHS)

In the National AEFI surveillance system, EPI/GHS is responsible for

- Designing, establishing, maintaining and evaluating AEFI surveillance system in the country in conjunction with FDA
- Revising and updating AEFI surveillance reporting tools and guidelines
- Ensuring accessibility of tools (AEFI Reporting Form; Guidelines etc.) to the Regional Health Directorate
- Training peripheral level health staff on AEFI activities
- Maintaining a database at the National EPI Office
- Analyzing AEFI data and providing feedback to peripheral levels
- Providing support to District and Region on AEFI reporting and investigations as needed
- Submitting AEFI reports received from routine immunization to Food and Drugs Authority on timely basis
- Communicating AEFI and immunization safety at the National level
- Responding to Rumors and managing crises as necessary
- Providing data on vaccine performance on regular basis to the FDA

4.9 Food and Drugs Authority

The Food and Drugs Authority has the legal obligation of ensuring that every pharmaceutical product (including vaccines) used within Ghana is of good quality, effective, and safe for the purpose or purposes for which it is proposed. The FDA is responsible for the following:

- Assisting the EPI/GHS in continuous development and/or revision of tools and guidelines for AEFI surveillance
- Constituting an Expert Committee to evaluate AEFI reports and assess causality
- Analyzing and providing feedback to EPI, healthcare professionals, caregivers and other stakeholders on the AEFI reports
- Monitoring the effectiveness of the AEFI surveillance system
- Conducting supportive supervision of AEFI surveillance activities
- Assisting in the training of personnel involved in AEFI surveillance
- Sharing information with international agencies (WHO, UNICEF) and manufacturers
- Carrying out risk benefit analysis of vaccine used in the immunization programme and taking necessary action
- Registration of vaccines and devices used in Ghana.

5. Detection and Decision Guide

5.1 AEFI Classification

All vaccines used in Ghana's EPI are approved, safe and effective but no vaccine is completely risk-free and adverse events will occasionally result after an immunization.

5.1.1 Cause-Specific Classification

Based on specific causes, AEFI is categorized into 5 broad areas in line with international literature as follows:

- Vaccine product-related reaction
- Vaccine quality defect-related reaction
- Immunization error-related reaction
- Immunization anxiety-related reaction
- Coincidental event
- Unknown

5.1.1.1 Vaccine product-related reaction

A vaccine reaction is an individual's response to the inherent properties of the vaccine, even when the vaccine has been prepared, handled and administered correctly. Examples of some common, minor vaccine reactions are given in Table 2 below:

Table 2: Common, minor vaccine reactions and treatment.

	Local reactions	Systemic reactions	
	(pain, swelling, redness)	Fever > 38°C	Irritability , malaise and systemic symptoms
BCG[a]	90% - 95%	-	-
Hepatitis B	Adults up to 15% Children up to 5%	1 - 6%	-
Hib	5 - 15%	2% - 10%	
Measles/MR/ MMR	- 10%	5% - 15%	5% (Rash)
OPV	None	Less than 1%	Less than 1%
Pertussis (DTwP)[c]	up to 50%	up to 50%	up to 55%
Pneumococcal conjugate[e]	- 20%	- 20%	- 20%
Tetanus/ DT/aTd	- 10%[d]	- 10%	- 25%
Treatment	• Cold cloth at injection site • Paracetamol[f]	• Give extra oral fluids • Wear cool clothing • Tepid sponge or bath • Paracetamol[f]	• Give extra oral fluids

From the five cause - specific of AEFIs in 5.1.1 vaccine reactions comprise vaccine product-related reactions and vaccine quality defect-related reactions. This can be minor or severe. Severe reactions need urgent action and reporting.

Table 3 : Selected childhood vaccines and associated severe reactions

Vaccine	Reaction	Onset interval	Frequency per doses given
BCG	Fatal dissemination of BCG infection	1-12 months	0.2-1.6/1,000,000
	BCG Osteitis	-	Very rare
OPV	VAPP	4-30 days	2-4/1,000,000
DTwP	Prolonged crying and seizures	0-24 hours	<1/100
	HHE	0-24 hours	<1/1,000-2/1,000
Hib	None known	-	-
Measles	Febrile seizures	6-12 days	1/3,000
	Thrombocytopenia	15-35 days	1/30,000
	Anaphylaxis (Hypersensitivity)	0-few hours	1/100,000
	Encephalitis	4-9 /Months	1/3,000,000
Rotavirus	None reported to WHO	-	-
PCV -13	None known yet	-	-
Yellow	Anaphylaxis (Hypersensitivity)	0-few hours	Very rare
Fever	Acute Neurotropic Disease (YEL - AND)	Up to 30 days	Very rare
(YF)	Acute Viscerotropic Disease (YEL - AVD)	Up to 10 days	1-40/100,000
Hep B	Anaphylaxis (Hypersensitivity)	0-few hours	Very rare

Frequency: Very common ≥10%; Common ≥1% &< 10%; Uncommon ≥ 0.1%&<1%; Rare ≥0.01%<0.1%; Very rare <0.01

Adapted from: World Health Organization. Vaccine Safety Basics: Learning Manual. *WHO,* Geneva 2013

5.1.1.2 Immunization error-related reaction

Immunization errors (formerly referred to as programme errors) often constitute the greatest proportion of preventable AEFIs. They result from errors in vaccine preparation, handling, storage or administration.

E.g.: Deaths associated with the reconstitution of vaccines with an incorrect diluent or a drug (e.g. insulin). They are preventable and can negate the benefits of the immunization programme.

Double Vaccination especially during vaccination campaigns are regarded as immunization error-related and must be reported as such.

The identification and correction of these incorrect immunization practices are of great importance.

Table 4: Examples of immunization-error related AEFIs

Immunization error	Possible AEFI
Non-sterile injection • Reuse of disposable syringe or needle leading to contamination of the vial, especially in multi-dose vials, • Improperly sterilized syringe or needle, • Contaminated vaccine or diluent.	• Local injection site reactions (e.g., adscess, swelling, cellulitis, induration), • Sepsis, • Toxic shock syndrome, • Blood-borne transmission of disease, e.g., hepatitis B, HIV, • Death
Reconstitution error • Inadequate shaking of vaccine, • Reconstitution with incorrect diluent, • Drug substituted for vaccine or diluent, • Reuse of reconstituted vaccine at subsequent session.	• Local abcess, • Vaccine ineffective • Effect of drug, e.g., insulin, oxytocin, muscle relaxants, • Toxic shock syndrome, • Death.
Injection at incorrect site BCG given subcutaneously, DTP/DT/TT too superficial, Injection into buttocks.	• Local reaction or abscess or other local reaction, • Local reaction or abscess or other local reaction, • Sciatic nerve damage.
Vaccine transported/stored incorrectly	• Increased local reaction from frozen vaccine, • Ineffective vaccine
Contraindication ignored	Avoidable severe reaction

5.1.1.3 Immunization Anxiety-related

Individuals can react in anticipation to and as a result of an injection of any kind. These reactions are not related to the vaccine, but to fear of the injection. There are four reactions which may be encountered: Fainting or syncope which is common and usually occur in older children above 5 years; vomiting and rarely, convulsion in younger children; and hyperventilation. Fainting does not require any management beyond placing the patient in a recumbent position. The likelihood of faints can be anticipated when immunizing older children e.g. mass vaccination in schools. Fainting can be reduced by minimizing stress in those awaiting injection, through short waiting times, comfortable room temperatures, preparation of vaccine out of recipient's view, and privacy during the procedure. Convulsion as a result of anxiety only needs reassurance after it has been aborted with an anticonvulsant e.g. diazepam.

5.1.1.4 Coincidental events

Coincidental events occur after a vaccination has been given but are not caused by the vaccine or its administration. Vaccinations are normally scheduled in infancy and early childhood, when illnesses are common and congenital or early neurological conditions become apparent. Coincidental events are inevitable when vaccinating children in these age groups, especially during a mass campaign. Applying the normal incidence of disease and death in these age groups along with the coverage and timing of immunizations allows estimation of the expected numbers of coincidental events after immunization.

5.1.1.5 Events with Unknown causes

In some cases, the cause of the AEFI remains unknown either because there is inadequate information or because all information does not point to any specific cause.

5.1.2 Regulatory Classification

5.1.2.1 Serious AEFI

An AEFI is considered serious, if it:

- Results in death, or
- Is life-threatening, or
- Requires in-patient hospitalization or prolongation of existing hospitalization, or
- Results in persistent or significant disability/incapacity, or
- Is a congenital anomaly/birth defect, or
- Is a medical event that requires intervention to prevent one of the outcomes above

It is important to note that the term "serious" is not synonymous with "severe". A serious adverse event is a regulatory term defined in 5.1.2.1 above whereas a severe adverse event is a broader term used to describe the intensity of a specific event (as in mild, moderate or severe) which may include serious events which do not necessarily lead to long term problems.

5.1.2.2 Non-serious AEFI

An AEFI is considered non-serious if the event does not pose a potential risk to the health of the recipient. This includes mild and moderate temporary adverse events following immunization. Non-serious AEFI should also be carefully monitored because they may signal a potentially larger problem with the vaccine or immunization, or may have an impact on the acceptability of immunization in general.

5.2 Reporting AEFIs

The primary reporter (i.e. the one who first reports an AEFI) may be a field health worker, clinic or hospital staff, a volunteer, parent or any other person who detects the AEFI. Suspicion alone is sufficient for reporting, and the primary reporter is not expected to assess causality. Rapid detection and evaluation of a possible link to vaccines is essential to ensure the continued safety of vaccines.
When an AEFI is identified, the ultimate responsibility of the health system is to

- Manage the patient
- Communicate with the client and/or parents and/or the community to explain what is being done and reassure them, thereby addressing rumours and fear
- Improve or correct service delivery procedures if the AEFI was caused by immunization-related error
- Identify and if needed suspend any implicated vaccine

Reporting of AEFIs is important but should lead to prompt case investigation (within 24-48 hours of receipt of report) where necessary for further actions. The ultimate goal is protection of the community and guaranteeing the health of Ghanaians.

5.2.1 What Events to Report

All serious AEFIs, AEFI clusters, any unusual event should be reported as well as any event about which a client makes a complaint. Trigger events must be reported. Examples of trigger events with their periods of occurrence are listed in Table 5.

Table 5: Examples of trigger events with their periods of occurrence

Occurring within 24 hours of immunization	• Anaphylactic shock/Anaphylaxis/Anaphylactoid reaction • Inconsolable screaming • Hy potonic hypo-responsive episode (HHE) • Toxic shock syndrome (TSS)
Occurring within 5 days of immunization	• Severe local reaction • Sepsis • Injection site abscess (bacterial/sterile)
Occurring within 15 days of immunization	• Seizures, including febrile seizure s (6-12 days for measles/MMR; 0-2 days for DPT) • Encephalopathy (6-12 days for measles/MMR; 0-2 days for DPT)
Occurring within 3 months of immunization	• Acute flaccid paralysis (4 -30 days for OPV recipient; 4 -75 days for contact) • Brachial neuritis -inflamed nerves in neck & shoulder region (2 -28 days after tetanus containing vaccine) • Thrombocytopaenia- low platelets (15-35 days after measles/MMR)
Occurring between 1 and 12 months after BCG immunization	• Lymphadenitis; • Disseminated BCG infection; • Osteitis/Osteomyelitis
No time limit	• Any death, hospitalization, or other severe or unusual events that are thought by health workers or the public to be related to immunization

5.2.2 Reporting AEFIs during immunization campaigns

A campaign is an opportunity to strengthen or establish immunization safety surveillance. It involves a large number of doses given over a short period of time. Hence, it may lead to more vaccine reactions and coincidental events. The rate of events usually remains unchanged but the increased number of events becomes more apparent as staff and the public notice high numbers as a result of heightened awareness. This is particularly so when injectable vaccines are used.

On the other hand, a real increase in immunization error-related events is possible because field staff may be unfamiliar with a new vaccine or feel the pressure of crowding in vaccination centres particularly where there is no crowd control. Therefore, safe injection practices may be compromised. Additionally, campaigns usually target older children than during routine vaccination. Even experienced vaccinators may have less experience in dealing with immunization-anxiety related adverse events e.g. syncope (fainting). Anti-vaccine lobbyists and other antagonists may also exaggerate any concerns about AEFI during the campaign in order to justify criticism of the campaign.
Also during special campaigns, a new vaccine may be introduced with no prior experience or with little information on adverse events. There is a possibility of detection of signals through strengthening surveillance during such special immunization programmes.

Unless an event is properly investigated or analysed, it can cause concern among the public and also may affect the campaign and the entire immunization programme.
Proper planning to reduce immunization error-related reactions, monitor and respond to AEFI can minimize adverse events and their effects during a campaign. Careful planning will limit the potential for negative publicity from an AEFI.

5.2.3 Who Should Report

The reporting pathway is as shown in section 3.4. The primary reporter may be a public health worker, vaccinator, clinic or hospital staff, volunteer or caregiver (parent) or any other person who detects the AEFI. The DFP is the link person between the primary reporter and higher levels of the reporting pathway. During mass vaccination campaigns, the FDA may receive reports directly from the community in which case recording and follow-up is made through relay of information to Regional and District Focal persons.

5.2.4 When to Report

AEFIs are to be reported immediately to the next level when the reporter gets to know of the event. Serious AEFIs should receive immediate attention and reported within 24 hours of detection. Trigger events such as abscesses, lymphadenitis etc. should be reported immediately as they may cause community concern. Immediate reports may be made by telephone to the Food and Drugs Authority. All AEFIs, including those reported immediately during the week, should be counted in routine, monthly AEFI surveillance reports.

5.2.5 How to Report

Reports should be made using the standard Reporting Form for Adverse Events Following Immunization (Annex1). In incidents with many cases or a high level of community concern, an urgent phone call should be made to the Focal Person at the District or directly to the FDA for further action to be taken.

5.2.6 Information to be provided on the Reporting Form

The minimum package of information to be collected for every case of AEFI has been standardized for Surveillance (**refer REPORTING FORM Annex 1**) and the following five (5) broad areas are covered:

- Source of information (including details of the reporter);
- Information on vaccinee/patient;
- Details of the immunization and the adverse event.
- Details of the adverse event
- Specimen collected and dispatched (If any)
- Reporter details

5.2.7 Confidentiality of AEFI Reports

Ensuring confidentiality of reports is paramount in any surveillance systems. 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.

5.2.8 Investigating AEFI

Certain AEFI reports will require additional investigation. The purpose of conducting the investigation is to:

a) Confirm the diagnosis (or propose other diagnoses) and determine the outcome of the medical incident(s)
b) Identify specifications of implicated vaccine(s) used to immunize patient(s)
c) Examine operational aspects of the immunization programme, which may have led to immunization errors or aggravation of severity of events possibly due to other causes
d) To determine whether a reported event was a single incident or one of a cluster and justify the search for other AEFI cases
e) To determine whether unimmunized people are experiencing the same medical incident(s)

5.2.8.1 Events to be investigated

The following AEFIs need further clinical and/or epidemiological investigation

- All serious AEFIs
- AEFI clusters(See Glossary)
- Trigger events (see examples in Table 5)
- All unusual events or events of public concern

5.2.9 Who should investigate

Investigating an AEFI is team work. The initial step is a preliminary investigation by the health worker who first detects the event. If no further investigation is made, the health worker will complete an AEFI Reporting Form (Annex 1) and report to a supervisor, preferably the Facility or District Focal Person. The composition of the investigation team will depend on the type of AEFI suspected.

Serious AEFIs should be investigated by trained clinicians, laboratory staff from the District and/or Regional level and referral clinicians at Reference hospitals.

For epidemiological investigations the team should include Immunization Programme Officers, Clinicians, Laboratory staff, Vaccinators and other Public Health Staff.

An epidemiologist(s)/Public health specialist(s), laboratory staff and clinicians from the national level (who are members of the Central AEFI team) will provide support for investigation missions in collaboration with the regional and district health authorities as required.

5.2.10 Data to be collected

The following data should be the minimum to be collected

A **Data on each patient**

- Demographic data about patient, including a unique case number
- History of patient's present illness - symptoms, when they appeared and their duration, treatment, outcome; diagnosis
- History of patient's past illnesses - reactions to previous doses, drug allergies, pre-existing neurological disorders, current medications
- Immunization history - vaccine, number of doses received, date, and place of last Immunization or immunizations, site of injection
- Laboratory results about blood, stool, or other samples, if appropriate

B **Data about the vaccine administered to the patient**

- Lot or batch number
- Expiry date
- Manufacturer
- When was the vaccine received
- From where the vaccine was received
- Laboratory results about vaccine, if appropriate

C **Program-related data**

- Common practices in storing and handling vaccines (cold chain temperature, other items stored with vaccine), and vaccine administration in the health center in which the suspected immunization was given. This may help identify products mistakenly used instead of vaccine or diluent

D **Data on other people in the area or community**

- Establish if cases have been reported from elsewhere and actively look for additional cases among other vaccinees and in the community.

E **Information on Health worker who gave the immunization**

All of these data should be included in an AEFI investigation report

5.2.11 Steps in epidemiological investigation of AEFI

The following steps should guide the investigation. Although attempts should be made to proceed systematically in order not to miss crucial steps, there should be flexibility in the order.

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

STEP	KEY AREAS TO EXAMINE
1. Prepare for field work	Administrative arrangements; personal and family considerations; logistics for field work e.g., transport, fuel, digital camera; laptop computer or 'smart' phone etc.; clarify roles of team members; who relates with media?
2. Confirm AEFI	Confirmation of immunization (Immunization records)
3. Verify the diagnosis	Patient history, physical examination; laboratory tests
4. Define and look for additional cases	Use of field guide; internet resources; levels of case definition; use of community structures, hospital records for more cases
5. Do descriptive analysis	Who are the cases? Where are they from? When did event occur?
6. Develop hypothesis	Possible cause(s) of event(s): ask patients, health workers, community; observe Do not communicate working hypothesis until confirmed If working hypothesis indicates immunization -related errors, correct them If vaccine problem suspected, withhold the suspect vaccine(s) from use
7. Test hypothesis	Does descriptive analysis, other investigations support hypothesis?
8. Refine hypothesis and do additional studies	Alternative explanation or causes; Additional clinical laboratory; vaccine testing (Central level only)
9. Implement control/ remedial measures	Treatment; Removal of suspected vaccine; cold chain maintenance; staff training; further corrective action
10. Communicate findings	Completion of AEFI Reporting forms; report writing; media communication

The steps listed in **Table 6** are presented in conceptual order; in practice, however, several steps may be done at the same time, or the circumstances of the event may dictate that a different order be followed. For example, the order of the first three listed steps is highly variable. For e.g. remedial measures may start soon after identifying the event or may be part of developing the hypothesis.

5.2.12 Management of AEFI

Managing AEFIs is critical in the any immunization programme. Non-serious AEFIs should be managed at the local level. Any injection may result in local pain, redness and swelling of one or two days. A cold, wet cloth will help to relieve this (see Table 7). Sometimes, a small, hard lump may persist for some weeks or more. This is no cause for concern. If reactions are persistent or severe, the immediate supervisor should be informed for investigation.

NB: Application of herbs, chemicals, disinfectants, detergents and alcohol to the injection site, should be avoided as these may damage vaccines.

Serious AEFIs should be managed by trained clinicians. However, the first worker who sees the patient should give 'first aid' as needed. Table 7 shows some known AEFIs and their management or treatment.

Table 7: Some known AEFIs, case definitions and treatment

Adverse event	Case definition	Treatment
Anaphylactoid reaction (acute hypersensitivity reaction)	Exaggerated acute allergic reaction, occurring within 2 hours after immunization, characterized by one or more of the following: wheezing and shortness of breath due to bronchospasm, Laryngospasm/laryngeal edema. One or more skin manifestations, e.g. hives, facial edema, or generalized edema.	Self-limiting; anti-histamines and steroids may be helpful but should be given by a trained person
Anaphylaxis	Severe immediate (within 1 hour) allergic reaction leading to circulatory failure with or without bronchospasm and/or laryngospasm/laryngeal edema	Adrenaline injection 1: 1000 formulation 0.01ml/kg Up to 0.5ml to be given by a trained person
Arthralgia	Joint pain usually including the small peripheral joints. Persistent if lasting longer than 10 days, transient: if lasting up to 10 days.	Self-limiting; Paracetamol up to 15mg/kg every 4 hours
Diarrhea	3 or more loose or watery stools in 24 hours	Give extra fluids ORS
Fever	The fever can be classified (based on rectal temperature) as mild (38 to 38.9^{0}C), high (39 to 40.4^{0}C) and extreme (40.5^{0}C or higher). Fever on its own does not need to be reported except for new vaccines.	Tepid sponge or bath Paracetamol Up to 15mg/kg every 4 hours Wear cool clothing
Injection site abscess	Fluctuant or draining fluid-filled lesion at the site of injection. Bacterial if evidence of infection (e.g. purulent, inflammatory signs, fever, culture), sterile abscess if not.	(Refer to hospital). Incision and drainage; antibiotics if bacteria
Persistent inconsolable screaming	Inconsolable continuous crying lasting 3hours or longer accompanied by high-pitched screaming.	Settles within a day or so; paracetamol may help.
Seizures (Fits)	Occurrence of generalized convulsions that are not accompanied by focal neurological signs or symptoms. Febrile seizures: if temperature elevated >38^{0}C (rectal) Afebrile seizures: if temperature normal	Self-limiting; supportive care; paracetamol and cooling if febrile; rarely anticonvulsants. Always refer to hospital for further evaluation
Severe local reaction	Redness and/or swelling centred at the site of injection and one or more of the following: swelling beyond the nearest joint pain, redness, and swelling of more than 3 days duration requiring hospitalization. Local reactions of lesser intensity occur commonly and are trivial and do not need to be reported if clients do not report.	Settles spontaneously within a few days to a week. Symptomatic treatment with analgesics. Antibiotics are inappropriate. Cold compress at injection Give adequate hydration.

Immunization-error related causes of AEFI can be avoided. There, health workers need to exercise extreme care when giving immunizations.

5.2.13 Handling Cases of Death

For any death suspected to be immunization-related, an autopsy (post mortem) is mandatory as required by law.

- The focal person and the AEFI central team must be alerted immediately (through District and Regional Health Authorities)
- The need for autopsy must be explained to relevant relatives and their corporation solicited (in conjunction with Regional Health Authorities)
- The pathologist will be immediately alerted by the Regional Health Authorities or the Central AEFI team as needed.
- Post mortem must be conducted as early as possible and is free (i.e. paid for by GHS)
- Under circumstances where an autopsy is not possible, an organ biopsy may be taken.

NB: Formalin should not be used before post mortem specimen collection

6. Management and analysis of AEFI data

6.1 Sources and type of Data

There are several sources of AEFI data including but not limited to:

OPD and Consulting Room registers; client clinic notes and records; child health record books; maternal health record booklets; vaccine ledgers; surveys; epidemiologic investigations reports; and reports from community members. However, three basic types of data are collected:

- Data collected routinely via the AEFI surveillance system
- Data obtained and collected from all investigations carried out into a specific AEFI and
- Data from investigations of AEFI clusters.

6.2 Data Input

Data input is expected to occur at district, regional and central levels for AEFIs detected during routine immunization. A common electronic database template developed at the central level should be used at all levels. Electronic line listing database has been developed for common use and to facilitate immediate reporting from district level through the regional level to the central level via e-mail. AEFI line lists should be merged at each stage of the reporting pathway. For GHS, data input should be the responsibility of the Focal Persons with support from the various information officers. Data must be available in DHIMS2 data platform as required by the service. During campaigns, overall data input may be performed on completion of surveillance, investigation and post-campaign survey activities. All reporting forms and other data-collection tools completed during the investigations and surveys must be submitted to the Central level with copies kept at various levels.

6.3 Data analysis

Supervisors must monitor AEFI reports for completeness, timeliness, and accuracy and recognize and correct programme-related errors before they lead to problems that may derail the objectives of the immunization programme. At the aggregate level, data analysis should give the following indicators:

- Total number of AEFI, broken down into non-serious and serious AEFI;
- Reporting rate of AEFI (non-serious/serious) among the population vaccinated
- Distribution of reported cases by specific AEFI (e.g. septicaemia, anaphylaxis);
- Distribution of AEFI by time and place;
- Characteristics of AEFI by age and sex of patient;
- Outcome of AEFI cases (death, recovered fully, recovered with sequelae); and
- Description of case management for each aetiology.

Data analysis will also involve comparison of the reporting data and the data

- From post-campaign AEFI surveys if available;
- Distribution of AEFI by cause (vaccine reaction, immunization-error related or coincidental)- Central level only;

A meeting of the Technical Advisory Committee for Vaccines and Related Biological Products should discuss, carry out causality assessment of the serious AEFI cases and validate the results, draw conclusions and make recommendations to improve the Immunization programme and promote the safety of vaccinees.

6.3.1 Who should be involved

Data analysis will be performed by epidemiologist(s) and/or Public Health Specialists or members of staff qualified to produce the results needed from the data analysis (Section 6.3) at the central level with the assistance of the other members. Data analysis should be performed at every level. At the District level, the District Health Management Team (DHMT) is responsible while at the regional level, a team from both Regional Public Health Unit and FDA, led by the Deputy Director Public Health will be responsible.

7. Writing the AEFI Surveillance **Report**

The central team will be required to prepare a final report on all types and cases of AEFI that have been detected. The report will be circulated to all those involved in surveillance at the central, regional and district levels. For campaigns, the report will describe:

- Background of AEFI surveillance;
- Activities carried out and the methods and tools employed;
- Results of AEFI surveillance; and
- Conclusions, recommendations.

For routine immunization, surveillance reports should be continuous and compiled on weekly, monthly, quarterly and yearly basis mainly looking at results and recommendations.

8. Communication

8.1 Why Communicate

Building and maintaining public trust in immunization is not a onetime effort; it is a continuous well planned endeavour. Any vaccine rumour or misinformation or poorly managed AEFI, whether true or perceived, can have a long-term impact on Ghana's immunization efforts. A proactive approach to communication makes it possible to mitigate potential negative impact of rumours and misinformation on immunization. There is therefore, a need to listen to what the public is saying and try to understand their concerns and the underlying reasons: this includes understanding the local perception of diseases, perception of injections and perception of the vaccine.

8.2 Communicating around AEFI

If an AEFI occurs, information must get out as quickly as possible. The public needs to know that their concerns are shared, that the situation is being investigated and that they will be kept informed. All partners must give out the same message. Explicit communication messages must be tailored to the specific situation. Technical/academic terms and long words or sentences must be avoided when explaining. Media is the gateway to public opinion. The media and the public must be informed. The needs of the media should be identified and met.

It is useful to differentiate between the general public and the medical community and their respective information needs.

8.2.1 Crises Communication

In crises, when the population of the entire area concerned by the immunization programme is reluctant to be vaccinated, a careful analysis of the situation must be made as quickly as possible. A broader communication effort may be warranted involving, for example, a press conference and TV or radio interviews to be broadcast nationwide. To improve the credibility of information, the Minister of Health or his/her representative will lead the communication process and appeal to the population concerned. A contribution from WHO and UNICEF and other partners (e.g. ROTARY International) may also help to convince the population. If rumours or information that compromise immunization is circulating in a precisely defined area, the local press and radio might be a means of solving the problem without alarming neighbouring populations. In such cases, the director of health in the area concerned (or their representative) and the relevant health authority should be involved in the public relations effort.

8.2.2 Managing Rumours

8.2.2.1 Who starts rumours

People who may have contradicting vested interests: they could be the health workers themselves, traditional healers, medical practitioners, the press, politicians/political groups, anti-vaccine lobbyists, religious/cultural objectors. Examples of rumours: "Polio vaccine is a contraceptive to control a population to limit a certain ethnic group"; "Oral Polio Vaccine is contaminated by the AIDS virus or mad-cow disease"; "The vaccine has expired" etc.

8.2.2.2 What fuels rumours

Inadequate/inaccurate knowledge; mistrust of the government; past untoward or negative experiences with vaccines; poor treatment by health workers; ulterior motives (greed); desire for publicity; coincidental events etc.

8.2.2.3 *Responding to Rumours*

Analyze the situation:
Move quickly to respond to rumours; but first, clarify the extent of the rumour or misinformation (type of messages, circulating, source, persons or organizations spreading the rumour); determine the motivation behind the rumour (lack of information, questioning of authority, religious opposition etc.)

Turn the rumour around:
Go to the source. Ask the source what the concern is; acknowledge shortcomings if necessary and offer the source the chance to be part of the solution.

Advocate:
Target key opinion leaders for meetings (politicians, traditional/religious leaders, community leaders, health workers); launch a corrective campaign at the highest level, e.g. the Minister of Health, Regional Ministers, District Chief Executives, etc.; meet with local leaders at sites where the individuals/groups are comfortable and can feel at ease to ask questions and have peers present.

Strengthen Alliances:
Involve all immunization partners through social mobilization committees, Inter-Agency Coordinating Committee (ICC), etc.; alert and collaborate with relevant ministries and NGOs; encourage onward briefings (i.e. cascade effect).

Conduct Training:
Train volunteers and health workers to handle rumours; disseminate tailored information on common misconceptions and guidelines on response; promote positive key messages.

Mobilize communities:
Empower local people to address and take responsibility for the issue; "demystify" for e.g. polio eradication, taking the initiative to community durbars, schools, community seminars, discussion groups, etc.

Recruit assistance from the health community:
Establish linkages and good interpersonal relationships with and seek collaboration from doctors in the public and private sectors, nurses and vaccinators, immunization volunteers, other members of partner organizations, e.g. Rotarians, Red Cross.

Use mass media:
Involve all appropriate media, e.g. TV, radio, newspapers, street theatre (national and local stations/editions); seek out media that have been misinforming the public; call on previously established relationships with the media; delegate spokesperson to handle the media questions; display confidence, e.g. photograph and publicize prominent personalities such as the First Lady or other personalities with good charismatic appeal while giving a vaccine (e.g. Rota virus or oral polio vaccine to her/his own baby or to a baby in the presence of its mother); interview pop idols/sports persons explaining the truth; print resources where appropriate, e.g. questions and answers on common misconceptions and, positive messages.

8.2.2.4 *Preventing Rumours*

Provide information to the general public before a campaign or introduction of a new vaccine through a press briefing, development of leaflets and/or question and answer briefs etc. These education materials to health workers and communities help to prevent rumours as they become well-informed.

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REPORTING FORM FOR ADVERSE EVENTS FOLLOWING IMMUNISATION (AEFI)
MOH-Ghana Health Service/Food & Drugs Authority

Reporting: Sub-District: District: Region

AEFI Reporting ID Number
Region Code ☐☐☐ District Code ☐☐☐ Year ☐☐ Serial Number ☐☐☐

Vaccination Card/Booklet ☐Yes ☐ No

If no, state other source of information:

A. PATIENT DETAILS

*Name :

Sex: ☐ M ☐ F

Mother's Name (if child):

Contact Phone No:

Vaccination centre:

Community:

*Date of birth (DD/MM/YYYY): _ _/_ _/_ _ _ _

OR Age at onset: ☐☐Years ☐☐ Months ☐☐☐ Days

OR Age Group: ☐< 1 Year ☐ 1 to 5 Years ☐ > 5 Years

*Address (landmarks and other contact information):

***B. DESCRIPTION OF AEFI**

☐ Severe local reaction ☐ >3 days ☐ beyond nearest joint
☐ Seizures ☐ febrile ☐ afebrile
☐ Abscess
☐ Sepsis
☐ Encephalopathy
☐ Toxic shock syndrome
☐ Thrombocytopenia
☐ Anaphylaxis
☐ Fever≥38°C
☐ Other (specify).....

Date AEFI started (DD/MM/YYYY): __ __ / __ __ / __ __ __ __

Time AEFI started ☐☐ Hr ☐☐Min

Signs and symptoms - please give a summary of the case, including any prior disease(s)/condition and patient's medicines before vaccination

Indicate treatment given for the AEFI:

***C. SERIOUSNESS AND OUTCOME OF AEFI**

***Serious**[¶]: ☐ Yes ☐ No; ➔ If Yes ☐ Death ☐ Life threatening ☐ Disability ☐ Hospitalization ☐ Congenital anomaly

☐ Other important medical event (Specify_____)

***Outcome:** ☐ Recovering ☐ Recovered ☐ Recovered with sequelae ☐ Not Recovered ☐ Unknown

☐ Died If died, date of death (DD/MM/YYYY): __ __ / __ __ / __ __ __ __ Autopsy done: ☐Yes ☐No ☐Unknown

D. DETAILS OF ALL VACCINE (S) ADMINISTERED

VACCINE(S)							DILUENT (if applicable)				
*Name	*Date and time of Vaccination		*Route (if injection indicate L/R site)	*Lot / Batch No.	Manufacturer	Expiry Date	Manufacturer	*Lot / Batch No.	Expiry Date	Date and time of reconstitution	
	Date	Time								Date	Time

E. REPORTER DETAILS

*Name: Profession/Designation: Tel No.:

Name of Institution: Today's Date: _ _ /_ _ /_ _ _ _ Signature:

For District Level Office

Date Report Received: _ _ /_ _ /_ _ _ _	Checked by:	Designation:
Investigation needed: ☐ Yes ☐ No	If yes, date started: _ _ /_ _ /_ _ _ _	

For National/Central Level Office

Date Report Received: ___ /___ /_____	Checked by:	Designation:
Comments (include results of Causality Assessment):		

*Mandatory fields

[¶]All serious AEFIs & AEFI clusters (two or more cases of the same adverse event related in time, place or vaccine administered) should be investigated.

REPORTING FORM FOR ADVERSE EVENTS FOLLOWING IMMUNISATION (AEFI)
MOH-Ghana Health Service/Food & Drugs Authority

GUIDELINES FOR COMPLETING FORM

Reporting: Complete the Sub-district, District and Region as appropriate e.g.:
Sub-District: Sekyedumasi **District**: Ejura-Sekyedumasi **Region**: Ashanti

ID: This is a unique identifier to be given or completed by the District EPI coordinator or the District AEFI focal person. The ID is made up of a three-letter Regional Code, a three-letter District Code and the last two digits of the year followed by the serial number of the AEFI case. E.g. **ASH-EJS-12-006** represents the 6th AEFI case reported from Ejura-Sekyedumasi in the Ashanti Region.

Assignment of serial numbers follows that for routine case-based surveillance. If in doubt, consult the District Disease Control Officer

Vaccination Card/Booklet: Indicate as appropriate (Tick **Yes** if seen; **No** if not seen-in appropriate boxes). A proof of vaccination is required for AEFI detection; in the absence of a card, a documentary proof of vaccination is required.

A. PATIENT DETAILS

Tick appropriate boxes or complete appropriate spaces provided.

B. DESCRIPTION OF AEFI

Tick appropriate boxes. Multiple selections are allowed. Indicate the date and time the AEFI started. For case definitions, see accompanying guidelines/ Standard Operating Procedures (SOPs). Give a short and brief summary of the case including any prior disease/condition and indicate treatment given for the AEFI.

C. SERIOUSNESS AND OUTCOME OF AEFI

Indicate the **seriousness** of AEFI using the following guide: A **serious AEFI** is one that is life threatening or leads to hospitalization or prolongation of hospitalization (if the person is already hospitalized before being vaccinated) or causes disability for > 24 hours or leads to death; otherwise it is **non-serious.**
Indicate outcome of the AEFI. A person is said to be recovering when s/he is still on admission in a hospital setting and improving or has improved but not fully recovered in hospital or at home. A person who has not recovered has not observed any improvement in his condition. A person has sequelae when there is a residual complication that is not likely to resolve. If there is death, provide date patient died and autopsy report if performed.

D. DETAILS OF ALL VACCINES ADMINISTERED

Give details of **ALL VACCINES** and where applicable, **DILUENTS** given prior to the AEFI. Provide details of vaccinations given, including the date and time of vaccination as well as the route of administration. The date and time of reconstitution of the vaccine should also be provided if applicable.

E. REPORTER DETAILS

The officer completing the form completes this section with the information needed.

For District Level Office; For National/Central Level Office: These sections are to be completed by respective levels.

Please submit completed form through the District and Regional Levels to the EPI and FDA offices.
NB: Copies MUST be kept at all levels.

AEFI INVESTIGATION FORM

MINISTRY OF HEALTH GHANA HEALTH SERVICE/FOOD AND DRUGS AUTHORITY

(Only for Serious Adverse Event Following Immunization – Death / Disability / Hospitalization / Cluster)

Section A Basic details

Region **District** **Case ID**

Place of vaccination (✓): ☐ Govt. health facility ☐ Private health facility ☐Other (specify) _____
Vaccination in (✓): ☐ Campaign ☐ Routine ☐ Other (specify) _____

Address of vaccination site:

Name of Reporting Officer:

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

Designation / Position:

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

Telephone # landline (with code): Mobile: e-mail:

Patient Name Sex: ☐M ☐ F

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

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

OR *Age at onset:* __ __ *years* __ __ *months* __ __ __ *days* ***OR*** *Age group:* ☐ *< 1 year* ☐ *1–5 years* ☐ *> 5 years*

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. 1st, 2nd, etc.)	Batch/Lot number	Expiry date
				Vaccine	Vaccine
				Diluent	Diluent
				Vaccine	Vaccine
				Diluent	Diluent
				Vaccine	Vaccine
				Diluent	Diluent
				Vaccine	Vaccine
				Diluent	Diluent
				Vaccine	Vaccine
				Diluent	Diluent

Type of site (✓) ☐ Fixed ☐ Mobile ☐ Outreach ☐ Other _____

Date of first/key symptom *(DD/MM/YYYY)*: __ __ / __ __ / __ __ __ __ Time of first symptom *(hh/mm)*: __ __ / __ __
Date of hospitalization *(DD/MM/YYYY)*: __ __ / __ __ / __ __ __ __
Date first reported to the health authority *(DD/MM/YYYY)*: __ __ / __ __ / __ __ __ __

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

If died, date and time of death *(DD/MM/YYYY)*: __ __ / __ __ / __ __ __ __ *(hh/mm)*: __ __ / __ __
Autopsy done? (✓) ☐ Yes (date)_____ ☐ No ☐ Planned on (date)_____ Time_____
Attach report (if available)

Section B Relevant patient information prior to immunization

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

For adult women
- Currently pregnant? Yes (weeks) _____ / No / Unknown
- Currently breastfeeding? Yes / No

For infants
The birth was ☐ full-term ☐ pre-term ☐ post-term. Birth weight:

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

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

Source of information (✓ *all that apply*): ☐ **Examination by the investigator** ☐ **Documents** ☐ **Verbal autopsy** ☐ **Other**_____ *If from verbal autopsy, please mention source* _____

Name of the person who first examined/treated the patient:_____
Name 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) and then complete 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:

Section D	**Details of vaccines provided at the site linked to AEFI on the corresponding day**									
Number immunized for each antigen at session site. Attach record if available.	Vaccine name									
	Number of doses									

a)	When was the patient immunized? (✓ the ☐ below and respond to ALL questions)	
	☐ Within the first vaccinations of the session ☐ Within the last vaccinations of the session ☐ Unknown	
	In case of multidose vials, was the vaccine given ☐ within the first few doses of the vial administered? ☐ within the last doses of the vial administered? ☐ unknown?	
b)	Was there an error in prescribing or non-adherence to recommendations for use of this vaccine?	Yes* / No
c)	Based on your investigation, do you feel that the vaccine (ingredients) administered could have been unsterile?	Yes* / No / Unable to assess
d)	Based on your investigation, do you feel that the vaccine's physical condition (e.g. colour, 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?	Yes* / No / Unkn
	i. If yes, how many other cases have been detected in the cluster?	
	a. Did all the cases in the cluster receive vaccine from the same vial?	Yes* / No / Unkn
	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__

Section E Immunization practices at the place(s) where concerned vaccine was used

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

Syringes and needles used:

• Are AD syringes used for immunization?	Yes / No / Unkn
If no, specify the type of syringes used: ☐ Glass ☐ Disposable ☐ Recycled disposable ☐ Other _____	
Specific key findings/additional observations and comments:	

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

	Status		
• Reconstitution procedure (✓)			
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:

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

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

Were any similar events reported within a time period similar to when the adverse event occurred and in the same locality?
Yes / No / Unknown If yes, describe:

If yes, how many events/episodes?

Of those effected, how many are
- Vaccinated:_____
- Not vaccinated:_____
- Unknown:_____

Other comments:

Section H Other findings/observations/comments

MINISTRY OF HEALTH - GHANA

Adverse Events Following Immunization

CLINICAL LABORATORY FORM: SERIOUS AEFI

IDENTIFICATION

Full name of the patient : ....

Age: __________ (yrs) Sex: ☐F ☐M Date of hospitalization: ___/___/2012

Place of investigation: .... Name of the investigator: ....

Provisional diagnosis: ....

TESTS REQUESTED FOR

Blood:

☐ Complete blood count + Platelet
☐ Blood urea
☐ Blood creatinine
☐ Blood glucose
☐ ALT + AST
☐ Bilirubin (Direct + Indirect)
☐ Malaria thick smear

☐ Electrolytes
☐ Coagulation test (PT, APTT)
☐ Gamma GT
☐ ALP
☐ Amylase
☐ CPK

☐ Hepatitis B serology
☐ Hepatitis C serology
☐ Widal test
☐ HIV serology
☐ Blood culture

CSF: ☐ Cytology ☐ Protein ☐ Sugar ☐ Gram staining ☐ Culture ☐ Soluble Ag

Urine: ☐ Cytology ☐ Reactive strips ☐ Gram staining ☐ Culture ☐ Soluble Ag

Other exams: ....

....

....

FOLLOW - UP OF THE SAMPLES

REFERENCE HOSPITAL LABORATORY			ZONAL LAB (TAMALE)/NATIONAL CENTRAL LABORATORY KORLEBU		
Sample code	Date of collection	Time of collection	DATE OF RECEIPT	# OF SAMPLES	PHYSICAL APPEARANCE
	DD / MM / YY	...... h .... min	DD / MM / YY		
	DD / MM / YY	...... h .... min	DD / MM / YY		
	DD / MM / YY	...... h .... min	DD / MM / YY		
	DD / MM / YY	...... h .... min	DD / MM / YY		
	DD / MM / YY	...... h .... min	DD / MM / YY		
	DD / MM / YY	...... h .... min	DD / MM / YY		
	DD / MM / YY	...... h .... min	DD / MM / YY		
	DD / MM / YY	...... h .... min	DD / MM / YY		

Samples collected by (full name, function): **Signature**

______________________________ ______________________________

TESTS RESULTS

Test	Date of the test	Results	Normal range	Comments
Thick/Thin smear	DD / MM / YY			
HIV	DD / MM / YY			
CD4	DD / MM / YY			
Hepatitis B	DD / MM / YY			
Hepatitis C	DD / MM / YY			
Widal test TO/TH (titres)	DD / MM / YY			
Widal test AO/AH (titres)	DD / MM / YY			
Widal test BO/BH (titres)	DD / MM / YY			
Widal test CO/CH (titres)	DD / MM / YY			
CBC : - Hemoglobin - Leucocytes - Neutro (%) - Lympho (%) - Platelets	DD / MM / YY			
Blood urea	DD / MM / YY			
Creatinine	DD / MM / YY			
Blood glucose	DD / MM / YY			
AST	DD / MM / YY			
ALT	DD / MM / YY			
Bilirubin total / direct	DD / MM / YY	/	/	
Gamma GT	DD / MM / YY			
Alkaline Phosphatases	DD / MM / YY			
Prothrombine Test	DD / MM / YY			
Amylase	DD / MM / YY			
Creatine Phosphokinase (CPK)	DD / MM / YY			
Electrolytes K+/Ca++/Cl-	DD / MM / YY	/ /	/ /	
CSF: - Leucocytes - Proteins - Glucose - Gram staining - Soluble Ag - Culture	DD / MM / YY			
Urinalysis: - Leucocytes - Erythrocytes - Proteins - Glucose - Gram staining - Soluble Ag - Culture	DD / MM / YY			
Other:				
	DD / MM / YY			
	DD / MM / YY			
	DD / MM / YY			
	DD / MM / YY			
	DD / MM / YY			

Comment, stamp and signature of the biologist _____

_____

_____

MINISTRY OF HEALTH - GHANA

AEFI LINE LISTINGFORM

Patient Code	Age (yrs)	Sex (M/F)	Community	Vacc. Card (Y/N)	Date of Vaccination	Place of Vaccination	Date of onset of AEFI	Vaccine Batch no	Diluent Batch No.	Description of reaction	Serious (Y/N)	Clinical Outcome	Detection Mode

Checklist for EPIDEMIOLOGICAL INVESTIGATION of AEFIs

This checklist is to be used for epidemiological investigation of serious AEFIs, AEFI clusters, Trigger Events; community deaths or other events of special interest where epidemiologic investigation is required. Investigations should be started within 24-48 hours of notification of the event.

Purpose of Investigation is to gather data :

- To quickly identify and address immunization - related error
- For causality assessment
- For program decision-making
- To raise research questions
- As basis for communication

Who should be involved in the Investigation?

Immunization Programme Officers Clinicians Laboratory staff Vaccinators / other Public Health Staff

Investigate and collect data

- Ask about the patient
- Ask about the vaccine and other drugs potentially received
- Ask about other vaccinees
- Ask about immunization services
- Observe the service in action if appropriate
- Ask about cases in unvaccinated persons
- Establish a more specific case definition if needed
- Formulate a hypothesis as to what caused the AEFI
- Test formulated hypothesis

Collect Specimens if appropriate

- From the patient the vaccine and diluent the syringes and needles

Key data to be collected

1. Data on each patient

- Demographic data about patient, including a unique case number/id, age, sex, place of residence, family history
- History of patient's present illness - symptoms and when each appeared and its duration, treatment, outcome, diagnosis
- History of patient's past illnesses e.g., reactions to TT or other vaccines, drug allergies;
- Pre-existing disorders, current medications;
- Immunization history - vaccine, number of doses received, date and place of immunization or immunization(s), mode and site of administration;
- Laboratory results about blood, stool, or other samples, if appropriate and available
- Full autopsy report with toxicological screening and histopathological analysis (in case of death)
- Look for common environmental exposures between patients

2. Date about the vaccine and diluent administered to the ` patient
   - Lot/batch number
   - Expiry date
   - Manufacturer
   - Vaccine Storage (Cold chain, other items store with vaccine)
   - Identity where the vaccine was distributed
   - Whether other clients were immunized with same lot/batch at same session and elsewhere
   - Results of procedures to control vaccine quality
   - Laboratory test results about vaccine, if appropriate(applicable only at central level)

3) Programme - related data

Common practices in storing and handling vaccines, giving immunization, etc. in the health centre or session in which the suspected immunization(s) were given:

- Practice followed by health workers in
  - Storing vaccines e.g. is PENTA or TT frozen? Are expire vaccines used?
  - Handing vaccines during sessions, e.g. are all open vials discarded after sessions?
- Practices in reconstituting vaccines and giving immunizations
  - Are the right diluents used?
  - Are diluents used sterile?
  - Are the correct doses given?
  - Are vaccines injected by the right route and in the right place?
  - Is there pre-filling of syringes?
- Availability of needles and syringes
  - Are Auto-Disable syrings used for each injection?
  - Are mixing syringes used appropriately
  - Infection prevention practices e.g. sterilizing equipment

4. Background data

- Number of people who received immunizations with vaccine from the same lot/batch or in the same immunization session, or both, and the number of these who fell ill and \ their symptoms (A separate AEFI Case Report From should be completed for each person)
- Number of unimmunized people or people immunized with other lots/batch (from the same or a different manufacture) who fell ill with similar symptoms

5. Vaccinator(s) Details

- Details of person(s) who gave the immunization(s)
  - Name; category of health staff, designation; rank; number of years in service etc.

Abscess (injection site): Fluctuant or draining fluid-filled lesion/swelling at the site of injection. Bacterial if evidence of infection (e.g., purulent/pus, inflammatory signs, fever, culture); sterile abscess if not.

Anaphylactic reaction (Acute hypersensitivity reaction): Exaggerated acute allergic reaction, occurring within 2 hours after immunization, characterized by one or more of the following:

- wheezing and shortness of breath due to bronchospasm
- laryngospasm/laryngeal edema
- one or more skin manifestations, e.g. hives, facial edema, or generalized edema.

Anaphylaxis: Severe immediate (within 1 hour) allergic reaction leading to circulatory failure with or without bronchospasm and/or laryngospasm/laryngeal edema. Symptoms of anaphylaxis may include breathing difficulties, loss of consciousness, and a drop in blood pressure (anaphylactic shock). This condition can be fatal and requires immediate medical attention.

Anorexia: A complain of poor appetite that interferes with individual's normal eating habits

Arthralgia: Reported generalized joint pains that interferes with individual's function

Asthenia: (See fatigue)

Brachial neuritis: Inflamed nerves in neck & shoulder region

Bronchospasm: Clinical syndrome characterized by bilateral wheeze (noisy breathing-out) and difficulty in breathing ± Cough ± dyspnea (shortness of breath).

Convulsions (generalized): Witnessed sudden loss of consciousness and generalized tonic, clonic, tonic-clonic or atonic motor movements: Same as seizures.

Diarrhea: An increase in frequency of bowel movements (above normal or baseline) occurring within a 24-h period with a runny or liquid consistency of these stools.

Dizziness: Complain of difficulty in spatial perception and stability.

Eczema: History or present evidence of presence of itchy skin conditions with scales and loss of epithelial integrity (cracks in skin);

Encephalitis: Refers to an encephalopathy caused by an inflammatory response in the brain. This is usually manifested with systemic constitutional symptoms, particularly fever and pleocytosis (increased cells) of the cerebrospinal fluid. However, the terms encephalopathy and encephalitis have been used imprecisely and even interchangeably in the literature.

Encephalopathy: Acute onset of major illness characterized by any two of the following three conditions:

- seizures
- severe alteration in level of consciousness lasting for one day or more
- distinct change in behavior lasting one day or more

Fatigue: Complain of tiredness (or a synonym) that is the primary complaint and is not relieved by rest, and interferes with an individual's function. Synonyms for fatigue may include asthenia, run down, lassitude, tiredness, exhausted, loss or lack of energy, lethargy. Synonyms are also culture- and language-specific and can be adjusted accordingly.

Febrile: Relating to fever; feverish. A febrile seizure is a seizure or convulsion that occurs during a high fever

Fever: Raised body temperature > 37.5^{0}C. Fever can be classified (based on axillary temperature) as mild (37.5 to 38.5^{0}C), high (38.5 to 40.4^{O}C) and extreme (40.5^{O}C or higher).

Flaccid Paralysis: Sudden onset of muscle weakness and low tone (hypotonic muscles).

Headache: A new complain of pains in the head region that is severe enough to interfere with individual's function.

Hives: (see urticaria)

Hypotonia: Low muscle tone (the amount of tension or resistance to movement in a muscle). May or may not be associated with paralysis.

Hypotonic hypo-responsive episode-HHE: A recognized serious reaction to immunization, especially pertussis-containing vaccine. It is defined as an acute loss in sensory awareness or loss of consciousness accompanied by pallor and muscle hypotonicity. No long-term sequelae have been identified in the small number of children who have had long term follow-up. HHE is not a contraindication for further doses of pertussis vaccine.

Insomnia (Sleeplessness): is an individual's reported sleeping difficulties (reduction in sleep).

Local Reaction: Redness and/or swelling centered at the site of injection and one or more of the following:

- swelling beyond the nearest joint pain, redness, and swelling of more than 3 days duration
- requires hospitalization.

Laryngeal edema: Swelling of the throat characterized by stridor (noisy breathing-in) and difficulty breathing

Lethargy: (see fatigue)

Lymphadenitis/Lymphadenopathy: Inflammation and/or enlargement of one or more lymph nodes. Most cases indicate an immune response in the lymph node to local infection or antigen stimulation, for example in a vaccine. Generalized lymphadenitis is a widespread inflammation of the lymph nodes due to systemic (circulating) infection.

Meningitis Syndrome: Fever and stiff neck or other signs of meningism ±headache, vomiting, photophobia and high cell count in CSF determined as: >5 leukocytes/mm ±microorganism on Gram stain of CSF ± positive bacterial or CSF culture.

Myalgia: Reported generalized muscle pain that interferes with individual's function

Nausea: a complain of subjective feeling of sensation to vomit ± vomiting

Persistent (uncontrollable) crying: The presence of crying which is continuous and likely to be unaltered for >3 h or unaltered for >3 h and likely to be continuous.

Persistent Nodule: The presence of a discrete or well-demarcated soft tissue mass or lump that is firm and is at the injection site in the absence of abscess formation and erythema and warmth.

Pruritus (itchiness): Itchiness without objective rash/skin or mucosal change.

Purpura: condition characterized by mucosal bleeding and bleeding into the skin in the form of multiple petechiae (small purplish spots), most often evident on the limbs, and scattered small bruises at sites of minor trauma.

Rash: Any skin or mucosal change (either new or a worsening of a previous condition) localized or generalized.

Seizure (see Convulsions): Occurrence of generalized convulsions that are not accompanied by focal neurological signs or symptoms. Febrile seizures: if temperature elevated >38^{0}C (rectal) or 37.5^{0}C axillary. Afebrile seizures: if temperature normal.

Sepsis (also known as "blood stream infection"): 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 immunization-related error.

Somnolence (Excessive Sleeping): is an individual's reported excessive sleeping that is unexpected or not due to sleep drugs.

Syncope: Fainting attacks as result of vaso-vagal reaction

Thrombocytopaenia: Serum platelet count of less than 50,000/ml leading to bruising and/or bleeding.

Toxic shock syndrome: 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 immunization-related error. It is a life-threatening illness that is caused by toxins (poisons) that circulate in the bloodstream. Bacteria that have infected some part of the body release these toxins. People with toxic shock syndrome develop high fever, rash, low blood pressure, and failure of multiple organ systems in the body. It is a rare serious adverse event resulting from improper vaccine preparation and injection practices.

Toxidermia: Fever PLUS rash (any generalized skin or mucosal change--either new or an worsening of a previous condition).

Urticaria (hives): The eruption of reddened marks on the skin that are usually accompanied by itching. This condition can be caused by an allergy (e.g., food, vaccine, drugs), stress, infection, or physical agents (e.g., heat, cold).

Vomiting: Reported forceful expulsion of the contents of one's stomach through the mouth and sometimes the nose. Synonyms: emesis, throwing up.