FOOD AND DRUGS AUTHORITY

GUIDELINES FOR SURVEILLANCE OF ADVERSE EVENTS FOLLOWING IMMUNIZATION IN GHANA

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3 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 Program on Immunization (EPI) of the Ghana Health Service (GHS) who are committed to improving safety of immunization services throughout the country.

Dr. Kwame Amponsa-Achiano (EPI), Mr. George Sabblah (FDA) and Mrs. Delese Mimi Darko (FDA) compiled the guide with invaluable contributions from several experts in biomedical sciences. Dr. Kwadwo Odei Antwi-Agyei (Program Manager, EPI) provided technical inputs. The contributions from AEFI focal persons (from GHS and FDA) at regional and district levels are acknowledged. The World Health Organization (WHO) provided part funding for finalizing the document.
4 Foreword

Vaccines used in national immunization programs are very safe and effective. Rigorous procedures are followed before registration and sale but there is no such thing as a “perfect” vaccine with no adverse reactions. Vaccination Programs 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 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 programs 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 program itself in order to assure continued public safety.

Ghana’s Expanded Program 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) has successfully established a national system for post-marketing surveillance of vaccines used in routine immunization or immunization campaigns.

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 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 AEFI.

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 program since an immunization program can only perform better if it has the full confidence of the general public.
Sherry Ayittey  
(Hon. Minister of Health)

5 Acronyms and abbreviations

AEFI  Adverse Events Following Immunization  
BCG  Bacille Calmette Guerin vaccine  
DCD  Disease Control Department (of GHS)  
DTwP  Diphtheria-Tetanus-whole cell Pertussis vaccine  
DHIMS2  District Health Information Management System  
EPI  Expanded Program 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  
SMD  Safety Monitoring Department  
TAC  Technical Advisory Committee (of FDA)  
UNICEF  United Nations Children’s Fund  
WHO  World Health Organization  
YF  Yellow Fever vaccine
6 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, hospitalization or extension of hospitalization, or results in persistent (more than 24 hours) or significant disability or incapacity, or is life-threatening.

**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). A **severe reaction** is a term including serious reactions but also including other severe reactions.

**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
7 Introduction

The objective of the Expanded Program 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 Program vaccinates against 11 childhood vaccine-preventable diseases (including the recent addition of two new vaccines: rotavirus and pneumococcal vaccines) in its routine immunization schedules. The diseases being routinely vaccinated against are tuberculosis, poliomyelitis, diphtheria, neonatal tetanus, whooping cough, hepatitis B, haemophilus influenza type B, measles, yellow fever, rotavirus diarrhea and pneumococcal diseases. Additionally, the program routinely offers tetanol for pregnant women and also conducts mass immunization preventive or reactive campaigns against specific diseases like meningitis, yellow fever, pandemic influenza, etc.

Although all vaccines used in the immunization program are safe, no vaccine is entirely without risk. Some people experience events after immunization ranging from mild adverse events to life-threatening, but rare, illnesses. 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 “program 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 and it contributes to the credibility of the immunization program. 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 Program on Immunization and the Food and Drugs Authority. This system has worked efficiently in ensuring vaccine safety in the country. Ghana plans to introduce several new vaccines into the routine immunization program and 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 risk tolerance
- 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-Saharan 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 Programs, National Regulatory Authorities and manufacturers.
8 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 program.

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
9 The AEFI Surveillance System in Ghana

9.1 Stakeholders

The AEFI surveillance system in Ghana is a collaborative effort among the Expanded Program 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

9.2 Establishment and Scope

Routine AEFI reporting in Ghana started with the establishment of the Expanded Program on Immunization in 1978. Reporting became more structured with the establishment of a National Pharmacovigilance Center 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 vaccinations campaigns.

9.3 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.

9.4 Information Flow
9.4.1 Requirements for Reporting and Reporting Levels

9.4.1.1 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 complaints from vaccinees or their caregivers; or following linkage of complaints 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.

9.4.1.2 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).

9.4.1.3 Causality at peripheral level and Timeliness of Reporting

Reporters are not expected to assess causality which is implied when considering the cause-specific definitions of AEFI. 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 AEFI, 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 (Figure 2).
9.4.1.4 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 programs 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.

9.4.2 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 Safety 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 general medical practice, clinical pharmacy, clinical pharmacology, toxicology, epidemiology, pathology, industrial pharmacy, dermatology, and child health. The Committee additionally makes recommendations for action by FDA and EPI.

9.5 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)
- Clinical Investigation Form (Annex 3)
- Clinical Laboratory Form (Annex 4)
- Electronic Line Listing Form (Annex 5)
- Guideline for AEFI Epidemiological Investigation (Annex 6)

10 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.
10.1 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.

10.2 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 following:

- Reducing avoidable immunization-related (program) 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.

10.3 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 Program 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)

10.4 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

10.5 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 s/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

10.6 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

10.7 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 central 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

10.8 Expanded Program on Immunization/Ghana Health Service (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

10.9 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 program and taking necessary action

11 Detection and Decision Guide

11.1 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.

11.1.1 Cause-Specific Classification

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

Table 1 gives examples of some common, minor vaccine reactions.
From the five cause-specific categories of AEFIs in 11.1.1 vaccine reactions comprise vaccine product-related reactions and vaccine quality defect-related reactions. This can be minor or severe. Severe reactions (Table 2) need urgent action and reporting.

### Table 2: Selected childhood vaccines and associated severe reactions

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

$^5$Frequency: Very common $\geq$10%; Common $\geq$1% & $<10$%; Uncommon $\geq$0.1%&$<1$%; Rare $\geq$0.01%$<0.1$%; Very rare $<0.01$


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

Table 3: Examples of immunization-error related AEFIs

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

11.1.1.3 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.

### 11.1.1.4 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.

### 11.1.5 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.

### 11.1.2 Regulatory Classification

#### 11.1.2.1 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
- requires intervention to prevent permanent impairment or damage.
11.1.2.2 Non-serious AEFI

This includes mild and moderate temporary adverse events following immunization that are not classified as serious.

It is important to note that the term “serious” is not synonymous with “severe” adverse events or reactions. A serious adverse event or reaction is a regulatory term defined in 11.1.2.1 above. A severe reaction is a broader term, which includes serious reactions, but also other reactions that are severe but do not necessarily lead to long term problems that qualify to be ‘serious’.

11.2 Reporting AEFIs

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 the cause of the AEFI (if known) or the lack of association 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 remove 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.

11.2.1 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 4.

| Occurring within 24 hours of immunization | • Anaphylactic shock/Anaphylaxis/Anaphylactoid reaction |
|                                          | • Inconsolable screaming |
|                                          | • Hypotonic hypo-responsive episode (HHE) |
|                                          | • Toxic shock syndrome (TSS) |
| Occurring within 5 days                  | • Severe local reaction |

Table 4: Examples of trigger events with their periods of occurrence
<table>
<thead>
<tr>
<th>Timeframe of Immunization</th>
<th>Conditions</th>
</tr>
</thead>
</table>
| Occurring within 15 days of immunization | - Sepsis  
- Injection site abscess (bacterial/sterile)  
- Seizures, including febrile seizures (6-12 days for measles/MMR; 0-2 days for DPT)  
- Encephalopathy (6-12 days for measles/MMR; 0-2 days for DPT)  
- 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)  
- Thrombocytopenia- low platelets (15-35 days after measles/MMR) |
| Occurring within 3 months of immunization |  
- Lymphadenitis;  
- Disseminated BCG infection;  
- Osteitis/Osteomyelitis |
| 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 |

### 11.2.2 Reporting AEFI 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 reactions. There is a possibility of detection of signals through strengthening surveillance during such special immunization programs.

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.

11.2.3 Who Should Report
The reporting pathway is as shown in section 9.4. 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.

11.2.4 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. All AEFIs, including those reported immediately during the week, should be counted in routine, monthly AEFI surveillance reports.

11.2.5 How to Report
Reports should be made using the standard Reporting Form for Adverse Events Following Immunization (Annex?). 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.

11.2.6 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) 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

11.2.7 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.

11.2.8 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)

11.2.8.1 Events to be investigated
The following AEFIs need further clinical and/or epidemiological investigation

• All serious AEFIs (see section 11.1.2.1 page 26)
• AEFI clusters (See Glossary)
• Trigger events (see examples in Table 4)
• All unusual events or events of public concern

11.2.9 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 investigative 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 Program 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.

### 11.2.10 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

11.2.11 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 5: 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 5 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.

11.2.12 Management of AEFI

Managing AEFIs is critical in the any immunization program. 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 section 11.1.1.1, page 24). 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 6

Table 1 shows some known AEFIs and their treatment.

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

Immunization-error related causes of AEFI can be avoided. Therefore, health workers need to exercise extreme care when giving immunizations.
11.2.13 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

Under circumstances where an autopsy is NOT possible, an organ biopsy may be taken.

**Formalin should not be used before post mortem specimen collection**

12 Management and analysis of AEFI data

12.1 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.

12.2 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.

12.3 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 Safety 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.

12.3.1 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 12.3) 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.

13 Drafting 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.

14 Communication

14.1 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.

14.2 Communicating around AEFI

If an AEFI occurs, information must get out as quickly as possible. The public needs to know that their concerns are share, 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.

14.2.1 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.

14.2.2 Managing Rumours

14.2.2.1 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 rumors: "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.

14.2.2.2 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.

14.2.2.3 Responding to Rumours

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

Turn the rumor 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 rumors; 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 durbar, 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.

15 References


11. WHO. *Yellow Fever. Surveillance of adverse events following immunization against yellow fever: Field Guide for staff at the central, intermediate and peripheral level*. World Health Organization, 2010


Annex 1: AEFI Reporting Form
# Reporting Form for Adverse Events Following Immunisation (AEFI)

**MOH-Ghana Health Service/Food and Drugs Authority**

**Reporting Details**

- **Reporting Sub-District:**
- **District:**
- **Region:**
- **ID:**
- **Region Code:**
- **District Code:**
- **Year:**
- **Serial Number:**
- **Vaccination Card/Booklet:** Yes / No
- **Other Information:**

## A. Patient Details

- **Name:**
- **Date of Birth (dd/mm/yyyy):**
- **Age (yrs):**
- **<2yrs:**
- **mo:**
- **Wks:**
- **Mother's Name (if child):**
- **Address:**
- **Contact Telephone No. (if any):**
- **Vaccination Centre:**
- **Community:**

*Include landmarks and other contact information*

## B. Details of AEFI

- **Date (dd/mm/yyyy) of Vaccination:**
- **Onset of AEFI:**
- **Notification:**

## C. Description of AEFI

**LOCAL**
- **Severe site pain**
- **Injection site swelling or hard lump**
- **Injection site abscess**
- **Severe local reaction**
- **Lymphadenitis**

**SYSTEMIC**
- **Anaphylaxis/Anaphylactoid**
- **Loss of appetite**
- **Diarrhoea**
- **Toxic Shock**
- **Severe general weakness**
- **High Grade Fever (T>38.5°C)**
- **Severe diarrhoea**
- **Severe vomiting**
- **Acute Flaccid Paralysis**
- **Severe diarrhoea**
- **Altered Mental State**
- **Abdominal/stomach pain**
- **Convulsions/Seizures**
- **Muscle wasting/limb weakness**
- **Joint pains (Arthritis)**
- **Febrile seizure**

**CNS/MUSCULO-SKELETAL**
- **Rash/Itch**
- **Urticaria**
- **Neurological effects**
- **Other AEFI(s) (Specify):**

Was AEFI serious? Yes / No

If yes, what was the seriousness? Life threatening / Hospitalisation / Disability / Death / Unknown

## D. Outcome of AEFI

- **Fully Recovered**
- **Partially Recovered**
- **Not Recovered**
- **Unknown**

## E. Case Summary

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:

## F. Details of All Vaccine(s) Administered

<table>
<thead>
<tr>
<th>Vaccine(s)</th>
<th>Route</th>
<th>Site (if injection)</th>
<th>Lot/Batch No.</th>
<th>Manufacturer</th>
<th>Manufac. Date</th>
<th>Expiry Date</th>
<th>DILUENT (if applicable)</th>
</tr>
</thead>
</table>

## G. Specimen Collection and Dispatch (if any)

1. Type of Specimen
2. Dispatched to
3. Date of Dispatch (dd/mm/yyyy)

## H. Reporter Details

- **Name:**
- **Profession:**
- **Tel No:**
- **Name of Institution:**
- **Date:**
- **Signature:**

For District Level Office

- **Date Report Received:**
- **Checked by:**
- **Designation:**
- **Further Investigation needed:** Yes / No
- **If yes, date started:**

For Regional Level Office

- **Date Report Received:**
- **Checked by:**
- **Designation:**
- **Further Action(s) Taken:**
- **Date:**

For National/Central Level Office

- **Date Report Received:**
- **Checked by:**
- **Designation:**
- **Causality assessment:**

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

Vaccine Safety/AEFI Surveillance

MOH/Ghana Health Service/Food and Drugs Authority
Annex 2: Guidelines for Completing AEFI Reporting Form
REPORTING FORM FOR ADVERSE EVENTS FOLLOWING IMMUNISATION (AEFI)
MOH-Ghana Health Service/Food and Drugs Board

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-in appropriate boxes)

A. PATIENT DETAILS
Tick appropriate boxes or fill appropriate spaces provided

B. DETAILS OF AEFI
Indicate date of vaccination; date of onset and date of Notification in the format dd/mm/yyyy in the appropriate spaces provided. Date of Notification is the date on which the AEFI case was first brought to the attention of health staff. This may or may not correspond with the date on which this form was completed. Note that the date on which the form was completed CANNOT preceed the date of Notification of the case.

C. DESCRIPTION OF AEFI
Tick appropriate boxes. There could be multiple ticks. Indicate seriousness of AEFI using the following guide: A serious AEFI is one that is life threatening OR leads to hospitalisation OR Prolongation of Hospitalisation (if the person is already hospitalised before being vaccinated) OR causes Disability OR leads to Death; otherwise it is Non-Serious.

D. OUTCOME OF AEFI
Indicate outcome of the AEFI. A person could be partially recovered when s/he is still on admission in a hospital setting and recovering or has improved but not fully recovered in hospital or at home. A person who has not recovered has not fully recovered nor partially recovered.

E. CASE SUMMARY
Give short, brief summary of the case to the point

F. DETAILS OF ALL VACCINES ADMINISTERED
Give details of ALL VACCINES and where applicable, DILUENTS given prior to the report of the AEFI. E.g.: Name-Dose Number: Pneumo-2 etc.

G. SPECIMEN COLLECTION AND DISPATCH
Indicate if any specimens were collected, the type of specimen collected and where they were sent to. Different specimens (e.g. blood, stool) may be collected depending on case. Stool specimens should be sent to Noguchi Memorial Institute for Medical Research and Blood should be sent to Korle-Bu reference laboratory. Specimens for clinical management of patient may be processed and examined at the local level (e.g. Blood for culture and sensitivity etc.)

H. REPORTER DETAILS
The officer completing the form completes this section. E.g.: Profession-Disease Control Officer; Community Health Nurse; Medical Assistant; Doctor; etc.

1. For District Level Office; For Regional Level; 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 National EPI Office

NB: AEFI Active surveillance sites should adhere to prior arrangements agreed. Original copies should be sent directly to the Regional FDB Focal points with copies to the DHMT for routine reporting.
**Annex 3: Clinical Investigation Form**

**MINISTRY OF HEALTH-GHANA**

Adverse Events Following Immunization

CLINICAL INVESTIGATION FORM: SERIOUS AEFI

Use as hospital chart during patient's hospitalization

<table>
<thead>
<tr>
<th>Patient ID</th>
<th>Date of investigation: ........../........./.........</th>
</tr>
</thead>
<tbody>
<tr>
<td>Provisional diagnosis:</td>
<td></td>
</tr>
<tr>
<td>Place of investigation:</td>
<td></td>
</tr>
</tbody>
</table>

**GENERAL INFORMATION**

<table>
<thead>
<tr>
<th>Surname:</th>
<th>First name:</th>
<th>Age:</th>
<th>Years</th>
<th>Sex: ♂</th>
<th>♂</th>
</tr>
</thead>
<tbody>
<tr>
<td>Region:</td>
<td>District:</td>
<td>Reference Hospital:</td>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td>Community:</td>
<td>Patient's Tel:</td>
<td></td>
<td></td>
<td></td>
<td></td>
</tr>
</tbody>
</table>

1. BACKGROUND INFORMATION

Initial status of the patient: □ Alive □ Coma/Unconscious (Glasgow ___/15) □ Recovered □ Absconded □ Dead___/___

Reasons for referral:

History of presenting complaint:

Past medical history:

Drugs used within 4 weeks prior to vaccination

<table>
<thead>
<tr>
<th>Name, Formulation</th>
<th>Date started</th>
<th>Date ended</th>
<th>Dosage</th>
</tr>
</thead>
<tbody>
<tr>
<td></td>
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<td></td>
</tr>
</tbody>
</table>

Vaccines received during 4 weeks prior to vaccination (Date dd/mm/yyyy):

<table>
<thead>
<tr>
<th>Dates</th>
<th></th>
</tr>
</thead>
<tbody>
<tr>
<td></td>
<td></td>
</tr>
</tbody>
</table>

Treatment received for the AEFI before referral:

<table>
<thead>
<tr>
<th>Name, Formulation</th>
<th>Date started</th>
<th>Date ended</th>
<th>Dosage</th>
</tr>
</thead>
<tbody>
<tr>
<td></td>
<td></td>
<td></td>
<td></td>
</tr>
</tbody>
</table>
### 2. HISTORY OF THE DISEASE
(tick whenever a sign is present and fill in accordingly)

<table>
<thead>
<tr>
<th>Sign/Symptom</th>
<th>Date started</th>
<th>Date ended</th>
<th>Specify</th>
</tr>
</thead>
<tbody>
<tr>
<td>Fever</td>
<td></td>
<td></td>
<td>Axillary temperature (°C)__________________</td>
</tr>
<tr>
<td>Nausea</td>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td>Vomiting</td>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td>Asthenia (Severe general weakness)</td>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td>Myalgia</td>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td>Arthralgia</td>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td>Dyspnoea</td>
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<td></td>
<td></td>
</tr>
<tr>
<td>Skin disorder</td>
<td></td>
<td></td>
<td>Specify</td>
</tr>
<tr>
<td>Jaundice</td>
<td></td>
<td></td>
<td>Bilirubin</td>
</tr>
<tr>
<td>Liver failure</td>
<td></td>
<td></td>
<td>ALT................................... AST...............</td>
</tr>
<tr>
<td>Renal failure</td>
<td></td>
<td></td>
<td>Blood urea................................... Creatinine...................................</td>
</tr>
<tr>
<td>Tachycardia</td>
<td></td>
<td></td>
<td>Pulse</td>
</tr>
<tr>
<td>Bradycardia</td>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td>Rhabdomyolysis</td>
<td></td>
<td></td>
<td>CPK</td>
</tr>
<tr>
<td>Respiratory distress</td>
<td></td>
<td></td>
<td>Respiratory Rate</td>
</tr>
<tr>
<td>Thrombocytopenia</td>
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<td></td>
<td>Platelets</td>
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<tr>
<td>Hypotension</td>
<td></td>
<td></td>
<td>BP standing (mmHg)</td>
</tr>
<tr>
<td></td>
<td></td>
<td></td>
<td>BP supine (mmHg)</td>
</tr>
<tr>
<td>Myocarditis</td>
<td></td>
<td></td>
<td>ECG</td>
</tr>
<tr>
<td></td>
<td></td>
<td></td>
<td>Cardiac Enzymes</td>
</tr>
<tr>
<td>DIC</td>
<td></td>
<td></td>
<td>Prothrombin................................... APTT............</td>
</tr>
<tr>
<td>Haemorrhage</td>
<td></td>
<td></td>
<td>sites</td>
</tr>
<tr>
<td>Headache</td>
<td></td>
<td></td>
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<tr>
<td>Focal neurologic deficit (ataxia, aphasia, paralysis)</td>
<td></td>
<td></td>
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</tr>
<tr>
<td>Cranial nerve palsy (facial, gag, tongue...)</td>
<td></td>
<td></td>
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</tr>
<tr>
<td>Repeated convulsion</td>
<td></td>
<td></td>
<td>Type</td>
</tr>
<tr>
<td>CSF Pleocytosis ()</td>
<td></td>
<td></td>
<td>WBC</td>
</tr>
<tr>
<td>Elevated protein in CSF</td>
<td></td>
<td></td>
<td>CSF protein Level</td>
</tr>
<tr>
<td>Demyelination</td>
<td></td>
<td></td>
<td>CT scan /MRI</td>
</tr>
<tr>
<td>Neuromeninginal inflammation</td>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td>Flaccid paralysis</td>
<td></td>
<td></td>
<td>Reflexes □ absent □ hyporeflexia □ normal □ brisk</td>
</tr>
<tr>
<td>Erectile dysfunction</td>
<td></td>
<td></td>
<td>Muscle Power □□□□□/5</td>
</tr>
<tr>
<td>Altered mental status, Confusion, Lethargy, Change of behavior</td>
<td></td>
<td></td>
<td>Glasgow □□□□□/15 Specify</td>
</tr>
<tr>
<td>Coma</td>
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</tbody>
</table>
3. DAILY FOLLOW-UP OF THE PATIENT:

DATE ____/____/____

General condition: .................................................................

Skin and mucosa: .................................................................

T°C ...... Radial pulse ....../min Apical pulse ....../min Syst/Diast ....../......mmHg Resp R ....../min

Heart: ....................................................................................

Lungs: ....................................................................................

Abdomen: ..............................................................................

Muscular system: .................................................................

Consciousness: ................................................................. Meningism: .................................................................

Central Nervous System: ......................................................

Peripheral Nervous System: ..................................................

Comments: ............................................................................

DATE ____/____/____

General condition: .................................................................

Skin and mucosa: .................................................................

T°C ...... Radial pulse ....../min Apical pulse ....../min Syst/Diast ....../......mmHg Resp R ....../min

Heart: ....................................................................................

Lungs: ....................................................................................

Abdomen: ..............................................................................

Muscular system: .................................................................

Conscious: ................................................................. Meningism: .................................................................

Central Nervous System: ......................................................

Peripheral Nervous System: ..................................................

Comments: ............................................................................
### 4. DIFFERENTIAL DIAGNOSIS

For each of the following signs, tick the **DIFFERENTIAL DIAGNOSES explored/excluded**

<table>
<thead>
<tr>
<th>JAUNDICE</th>
<th>Yes</th>
<th>No</th>
</tr>
</thead>
<tbody>
<tr>
<td>Wild Yellow Fever</td>
<td></td>
<td></td>
</tr>
<tr>
<td>Hepatitis A</td>
<td></td>
<td></td>
</tr>
<tr>
<td>Hepatitis B</td>
<td></td>
<td></td>
</tr>
<tr>
<td>Hepatitis C</td>
<td></td>
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</tr>
</tbody>
</table>

Hepatitis D, E  
CMV  
EBV  
Leptospirosis  
Liver abscess  
Sclerosing cholangitis

<table>
<thead>
<tr>
<th>HEMORRHAGE</th>
<th>Yes</th>
<th>No</th>
</tr>
</thead>
<tbody>
<tr>
<td>Wild Yellow Fever</td>
<td></td>
<td></td>
</tr>
</tbody>
</table>

Dengue  
Lassa  
N. meningitidis

<table>
<thead>
<tr>
<th>GENERALIZED FEBRILE ILLNESS</th>
<th>Yes</th>
<th>No</th>
</tr>
</thead>
<tbody>
<tr>
<td>Yellow Fever</td>
<td></td>
<td></td>
</tr>
<tr>
<td>Severe Malaria</td>
<td></td>
<td></td>
</tr>
<tr>
<td>Bacterial Sepsis</td>
<td></td>
<td></td>
</tr>
<tr>
<td>Typhoid/Enteric Fever</td>
<td></td>
<td></td>
</tr>
</tbody>
</table>

<table>
<thead>
<tr>
<th>MENINGOENCEPHALITIS</th>
<th>Yes</th>
<th>No</th>
</tr>
</thead>
<tbody>
<tr>
<td>Cerebral malaria</td>
<td></td>
<td></td>
</tr>
<tr>
<td>N. meningitidis</td>
<td></td>
<td></td>
</tr>
<tr>
<td>S. pneumoniae</td>
<td></td>
<td></td>
</tr>
<tr>
<td>Syphilis</td>
<td></td>
<td></td>
</tr>
<tr>
<td>TB</td>
<td></td>
<td></td>
</tr>
<tr>
<td>HSV 1,2</td>
<td></td>
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</tr>
<tr>
<td>VZV</td>
<td></td>
<td></td>
</tr>
<tr>
<td>Enterovirus</td>
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<tr>
<td>Arbovirus</td>
<td></td>
<td></td>
</tr>
<tr>
<td>West Nile</td>
<td></td>
<td></td>
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<tr>
<td>Semliki Forest</td>
<td></td>
<td></td>
</tr>
<tr>
<td>HIV</td>
<td></td>
<td></td>
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<tr>
<td>Rabies</td>
<td></td>
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</tbody>
</table>

<table>
<thead>
<tr>
<th>ACUTE FLACCID PARALYSIS</th>
<th>Yes</th>
<th>No</th>
</tr>
</thead>
<tbody>
<tr>
<td>Other Flaviviruses</td>
<td></td>
<td></td>
</tr>
<tr>
<td>Poliovirus</td>
<td></td>
<td></td>
</tr>
<tr>
<td>Enterovirus</td>
<td></td>
<td></td>
</tr>
<tr>
<td>VZV</td>
<td></td>
<td></td>
</tr>
<tr>
<td>West Nile</td>
<td></td>
<td></td>
</tr>
<tr>
<td>Snake bite</td>
<td></td>
<td></td>
</tr>
<tr>
<td>Botulism</td>
<td></td>
<td></td>
</tr>
<tr>
<td>Toxins</td>
<td></td>
<td></td>
</tr>
<tr>
<td>HIV</td>
<td></td>
<td></td>
</tr>
<tr>
<td>Nerve injury</td>
<td></td>
<td></td>
</tr>
</tbody>
</table>

### 5. TREATMENT DURING HOSPITALIZATION:

<table>
<thead>
<tr>
<th>Name, Formulation</th>
<th>Date started</th>
<th>Date ended</th>
<th>Dosage</th>
</tr>
</thead>
<tbody>
<tr>
<td></td>
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</tbody>
</table>

Outcome:
- Recovered (date): __/__/____
- Recovering (date): __/__/____
- Sequelea (specify): __________________________
- Not recovering (specify remaining symptoms): __________________________
- Dead (date): __/__/____
6. SAMPLES COLLECTED

- Blood
- Stools
- Biopsy/Autopsy
- Urine
- Saliva
- CSF (specify aspect)

7. FINAL DIAGNOSIS

<table>
<thead>
<tr>
<th>Final Diagnosis</th>
<th>Arguments for</th>
<th>Arguments against</th>
</tr>
</thead>
<tbody>
<tr>
<td></td>
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<td></td>
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<td></td>
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</tbody>
</table>

Tick all the diagnoses you excluded:

- CRANIAL NERVE PALS
- GUILLIAN BARRE SYNDROME
- ENCEPHALITIS
- ENCEPHALOPATHY
- RENAL FAILURE
- LIVER FAILURE
- THROMBOCYTOPENIA
- RHABDOMYOLYSIS
- ANAPHYLACTIC SHOCK/REACTION
- SEPTICEMIA

Any other excluded, specify ..................................................

For the investigation team (Full name and signature OF Clinician):

TO BE FILLED BY THE NATIONAL EXPERTS COMMITTEE

Diagnoses (and arguments):

<table>
<thead>
<tr>
<th>CLASSIFICATION</th>
<th>Serious</th>
<th>Non serious</th>
</tr>
</thead>
<tbody>
<tr>
<td>Vaccine related</td>
<td>- Suspected</td>
<td>- Confirmed</td>
</tr>
<tr>
<td>Program error</td>
<td>Specify the error</td>
<td>Cold chain failure</td>
</tr>
<tr>
<td>Coincidence</td>
<td>Specify the concomitant disease</td>
<td></td>
</tr>
<tr>
<td>Other etiology</td>
<td>Specify</td>
<td></td>
</tr>
<tr>
<td>Unknown etiology</td>
<td></td>
<td></td>
</tr>
</tbody>
</table>

Recommendation of the National Experts Committee

For the Experts Committee (Full name and signature of chair):
<table>
<thead>
<tr>
<th>Test</th>
<th>Date of the test</th>
<th>Results</th>
<th>Normal range</th>
<th>Comments</th>
</tr>
</thead>
<tbody>
<tr>
<td>Thick/Thin smear</td>
<td>DD / MM / YY</td>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td>HIV</td>
<td>DD / MM / YY</td>
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<td></td>
</tr>
<tr>
<td>CD4</td>
<td>DD / MM / YY</td>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td>Hepatitis B</td>
<td>DD / MM / YY</td>
<td></td>
<td></td>
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<tr>
<td>Hepatitis C</td>
<td>DD / MM / YY</td>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td>Widal test TO/TH (titres)</td>
<td>DD / MM / YY</td>
<td></td>
<td></td>
<td></td>
</tr>
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Annex 5: AEFI Line Listing Form

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Annex 6: Guidelines for Epidemiological Investigations of AEFIs

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?
- Immunisation Programme Officers
- Physicians
- 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 vaccines
- 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(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. Data about the vaccine and diluent administered to the patient
   - Lot/batch number
   - Expiry date
   - Manufacturer
   - Vaccine storage (Cold chain, other items stored with vaccine)
   - Identify 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 immunizations, etc. in the health centre or session in which the suspected immunization(s) were given:
     - Practices followed by health workers in:
       - Storing vaccines, e.g., is PENTA or TT frozen? Are vaccines used?
       - Handling vaccines during sessions, e.g., are PENTA and TT properly shaken before use?
       - Handling vaccines after sessions, e.g., are all 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 syringes 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 Form should be completed for each person)
   - Number of unimmunized people or people immunized with other lots/batch (from the same or a different manufacturer) 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;
Annex 7: Case Definitions

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 > 37.50C. Fever can be classified (based on axillary temperature) as mild (37.5 to 38.5oC), high (38.5 to 40.4oC) and extreme (40.5oC 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 sequela 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 centred at the site of injection and one or more of the following:
- swelling beyond the nearest joint pain, redness, and swelling of more than 3 days duration
- requires 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°C (rectal) or 37.5°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.