

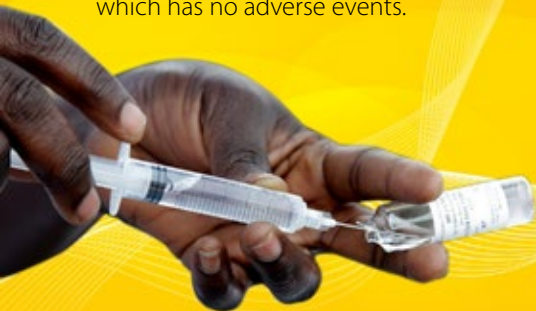
Monitoring of Adverse Events Following Immunization in Ghana

What Health Workers
Need to Know



Introduction

Vaccines used in national immunization programmes are considered safe and effective because careful procedures are followed before they are registered and used. However, there is no such thing as a “perfect” vaccine which has no adverse events.



In spite of all the safety measures taken in making vaccines and passing them for public use, some people may experience unpleasant events known as adverse events following immunization (AEFI). An AEFI may be caused by the vaccine itself, other products in the vaccine or the vaccine diluent or by an error in prescribing and/or giving the vaccine or in most cases, such events may not be related to vaccine or the vaccination process at all. These may occur because vaccination programmes are usually complex in nature.

What is an AEFI?

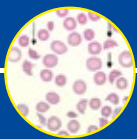
An AEFI is any untoward medical occurrence which follows immunization and which does not necessarily have a causal relationship with the usage of the vaccine. The adverse event may be any unfavourable or unintended sign, abnormal laboratory finding, symptom or disease.



Symptom



Sign



Lab Finding



Disease

In simple terms, an AEFI is any unpleasant event which happens after vaccination and which may or may not be related to the vaccine or the vaccination process.

An AEFI may be serious or non-serious. An AEFI is serious if it:

- results in death or
- is life threatening or
- requires in-patient hospitalization or prolongation of an existing hospitalization or
- results in persistent or significant disability/incapacity or
- causes a congenital anomaly (birth defect)

AEFI falls into six categories based on the cause:

| | |
|--|--|
| Vaccine product-related reaction | Due to inherent properties of the vaccine: Eg. Anaphylaxis due to reaction to some vaccine component(s) |
| Vaccine defect-related reaction | Due to manufacturing defect : Eg. Failure to attenuate a live - attenuated vaccine properly leading to infection (polio, yf, measles etc.) |
| Immunization error-related reaction | Due to errors in handling, prescribing, storage, or administration of the vaccine: essentially, a program related error Eg. Abscess at the site following injection |
| Immunization anxiety-related reaction | Due to anxiety to vaccination or the processes of vaccination: Eg. Fainting attacks among teenagers in a queue during a mass vaccination campaign exercise |
| Coincidental event | Unrelated to vaccine or vaccination: Eg. Malaria occurring after vaccination |
| Unknown | Cause cannot be determined |

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.

Vaccinating a child two times in a row, especially during vaccination campaigns, is regarded as immunization error related problem and must be reported as such.

What events should be reported

Report all serious and non-serious AEFIs. Report every AEFI whether you think the vaccine caused it or the vaccine did not cause it or even if you know the vaccine can possibly cause such an event.



When to report

AEFIs are to be reported to the next level as soon as you get to know of the event (within 24 hours). Serious AEFIs should receive particular attention and reported immediately.

How to Report

Reports should be made using the standard Reporting Form for Adverse Events Following Immunization. If there are many cases or there is high level of community concern, an urgent phone call should be made to the immediate supervisor or the Focal Person at the District or Regional level or directly to the National level or FDA for further action to be taken.

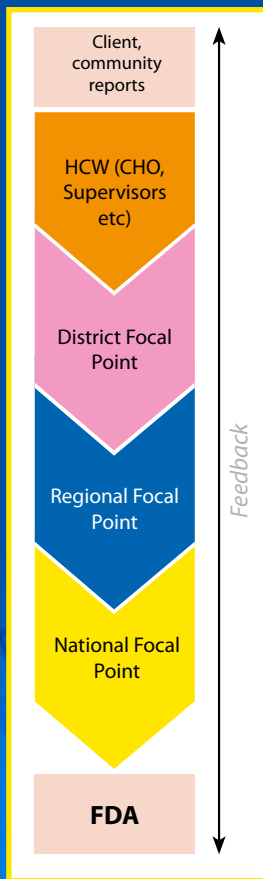


Fig. 1: Pathway for AEFI Reporting

You can also report online using the FDA online reporting system (The SafetyWatch System) at

<http://adr.fdaghana.gov.gh>

Summary of what to do in case of an AEFI

- Manage the client including referral to health facility, if necessary
- Complete and submit an AEFI form
- Report AEFI to the next level of the health system immediately (Refer to Fig. 1)
- Conduct an investigation, if necessary

Points to Remember

- Always educate parents and child caregivers on benefits of immunization and reporting AEFI.
- Report all serious and non-serious AEFI.
- Report known and unknown AEFI



For all questions relating to AEFIs, please contact:

GHANA HEALTH SERVICE:

0302678078, 0244171537

FOOD AND DRUGS AUTHORITY:

Landline: +233 (0302) 233 200/ 235 100

Mobile: +233 (024) 4310 297

Hotline: +233 (029) 9802932/3

Toll Free Line: 0800151000
(only for Vodafone & Airtel)

Fax: +233 (0302) 229 794

E-mail: drug.safety@fdaghana.gov.gh

Shortcode: 4015 (SMS Only)