

Field Surveillance Guide **for *ADVERSE EVENTS*** ***FOLLOWING*** ***IMMUNIZATION***

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Introduction

Children Morbidity, disability and mortality rates had witnessed a major decrease during the last decades thanks to the use of vaccines to immune from the infections by the targeted diseases. Although the vaccines used are safe, but there is no such thing as 100% free of adverse events-vaccine. Thus, companies tries to manufacture vaccines with the least adverse events rate possible.

The creation of Surveillance System for Adverse Events Following Immunization (AEFI) would have an effective role in enhancing the extended immunization program and maintaining community's trust in the program.

Most of AEFI are simple with no sustained effect to the vaccinated individuals. Many of adverse events are wrongly thought to have been induced by the vaccine, where in matter of fact vaccine has nothing to do with them. Among these events are the symptoms and diseases that coincide with vaccination but has nothing to do with taking the vaccine. It is worth mentioning that some of the adverse events may occur due to a fault or negligence in the vaccination process or in dealing with the vaccine and its equipment (program errors).

Thus, the epidemiological surveillance of adverse events and necessary investigations of the detected cases, to find out the real reason behind such events, will help health staff and community in understanding the recorded events that have nothing to do with the vaccine. In return, this will help in winning community's trust in the vaccines and maintaining the willingness of people to have immunization services. AEFI surveillance system will also show vulnerabilities of immunization activities within vaccination centers and vaccine stores by identifying the errors of the program then taking the required measures to prevent their occurrence again.

AEFI surveillance and necessary investigations will show the community the degree of interest the health system pays to the health of the individuals, which will enhance community's trust in the program.

One of the main tasks of AEFI surveillance program is raising awareness among medical and health staffs about the severe health consequences the community will suffer in case of not using vaccines and that AEFI are incomparable by the diseases, disabilities and mortalities that children would suffer because of the negligence of using the vaccines.

This guide is designed to help medical and health staff at the central and regional levels in monitoring the adverse events that may occur following vaccination and how to address those effects.

It starts by defining the adverse events and their types and then elaborating on how to report adverse events and investigate them.

This guide also includes a detailed narrative of AEFI surveillance system and the tasks and duties of its medical and health staff, in addition to a detailed explanation on how to follow-up and evaluate the activities of the surveillance system. The annex of this guide introduces some cases of recorded adverse events, methods of treatment and the vaccines causing them.

Adverse Event Following Immunization (AEFI)

Definition of Adverse Event Following Immunization (AEFI):-

An unwanted medical occurrence that happens to an individual after vaccination (immunization) and thought to be resulted from the vaccination. Although, the majority believe that the side effects consequent to the vaccination but many of these effects are coincidental with the vaccination (i.e. has nothing to do with the vaccination). There is also another wrong assumption that the vaccine is the main reason of the occurrence of these events, while the main reason of these effects might be from the immunization process (program errors) that can be avoided. Detection, reporting and investigation on these effects are essential to figure out the real reason behind these events and that is what this guide targets. Annex (1) introduces some cases of recorded adverse events, methods of treatment and the vaccines causing them.

Types of Adverse Events

Adverse events following immunization are categorized as follows:-

1. Vaccine Induced Adverse Events

The reason behind these events is vaccine's active substance or other ingredient like (Antibiotics, Stabilizers, Adjuvants & preservatives)

Most adverse events caused by the vaccine are simple and do not leave any lasting effect on the vaccinated individuals and can be treated and handled by family members through guidance and advice provided by health and medical staffs during vaccination. The type and incidence of such events are known and expected, and can be used as an indicator to assess the sensitivity of AEFI surveillance system.

The adverse events caused by the vaccine are classified into two types:-

- a. Common adverse events
- b. Serious rare adverse events
- a. Common adverse events are either local like (pain, redness, swelling centered in the site of vaccine injection) or in the body such as (mild fever, headache, anorexia, sialadenitis, diarrhea, eye infection), as table (1) shows.
- b. Serious adverse events:- they are rare, for example (epileptic seizures, encephalopathy, thrombocytopenia, vasogenic shock, persistent screaming for three hours or more) as shown in table (2).

Table (1): Common Adverse Events Following Immunization with Rates

Vaccine	Local adverse event (pain, redness and swelling)	Fever	Irritability, malaise and unclassified diseases
BCG	Common	-	-
Haemophilus Influenzae Type b	5- 15%	2-10%	-
Hepatitis B	30% with adults 5% with children	1-6%	-
MMR	10%	5%	5%
Oral Poliomyelitis Vaccine	N/A	<10%	<10%
Tetanus / Diphtheria	10% **	10%	25%
Triple Vaccine (DTP)***	To 50%	To 50%	To 60%

- * Diarrhea, headache and pains are in muscle.
- ** Local reaction probably will increase after taking the enhanced doses to reach 50-80%
- *** Acellular pertussis rates may be lower.

Table (2): Serious Rare Adverse Events Following Immunization with Rates and onsets

Vaccine	Adverse event	Adverse event onset	The rate in every one million doses
BCG	Purulent lymphadenitis Osteitis following BCG Disseminated BCG Infections	2-6 months 1-12 months 1-12 months	100-1000 1-700 2
Haemophilus Influenzae Type b	Adverse events are unknown		
Hepatitis B	Vasogenic shock GBS	0-1 hour 1-6 weeks	1-2 5
MMR	Fevers Thrombocytopenia Vasogenic shock	5-12 days 35-15 days 0-1 hour	333 33 1-50
Oral Poliomyelitis Vaccine	Poliomyelitis	4-30 days	104-304
Tetanus	Brachial neuritis Vasogenic shock Sterile Abscess	2-28 days 0-1 hour 1-6 weeks	5-10 1-6 6-10
Triple Vaccine (DTP)***	Persistent screaming (for three hours) Epileptic seizures Vasogenic shock Encephalopathy	0-24 hours 0-2 days 0-1 hour 0-3 hours	1000- 60000 570 ;20 0-1
Amarillic typhus (yellow fever)	Encephalitis	7-21 days	500-4000 in infants under 6 months

2. Adverse Events due to Program Errors: - This type of AEFI is considered the most dangerous type of adverse events since these events can be totally avoided. These events can affect a large number of vaccinated people. Not to mention the consequence of community's lack of trust in immunization program due to these events and, ultimately, a set back and decrease of immunization coverage ratio followed by an increase of diseases' infection rates for program's targeted diseases.

Errors in vaccination process that lead to the occurrence of adverse events:-

- Administering more than the required dose.
- Injecting the vaccine in the wrong site such as the injection of vaccine in the buttock for children under 2 years of age
- The use of unsterilized syringes or needles.
- The use of a single injection to re-form (dissolve) several vials of vaccines.
- The use inept solvent for the vaccine when recomposing.
- The use of inappropriate amount of solvent.
- An error in the preparation of the vaccine.
- Contamination of the vaccine or solvent.
- Vaccine poor storage.
- Ignoring vaccination contraindications.
- Saving and re-using the remaining melted vaccines (MMR and BCG) after the vaccination session, instead of disposing them in the following days.

Table (3): Program Errors and Consequences

Program error	Expected adverse event
Unsterilized syringes: Reusing the discarded syringe or needle Contamination of the vaccine or solvent Reusing the recomposed vaccine in further vaccination sessions	Many infections like local abscesses in injection sites, toxic shock syndrome in addition to the transmission of blood transmitted infections such as hepatitis B and AIDS.
An error in recomposing (dissolving) the vaccine: Recomposing by using inept solvent Using another drug instead of the vaccine or solvent	Local abscess caused by not shaking the vial of the vaccine appropriately. The adverse event of the drug like the insulin is death, ineffectiveness of the vaccine
Injecting in the wrong site: Administering BCG subcutaneous injection Administering the triple vaccine or tetanus toxoid vaccinations in a skin-deep site in the buttock injections	Reaction or local abscess Interaction or local abscess Damaging sciatic nerve
Inappropriate vaccine transportation or storing	Local interaction for the frozen vaccine Lack of vaccine effectiveness
Ignoring vaccination contraindications	Avoidable acute interaction

3. Coincidental Adverse Events: - Such events have nothing to do with the vaccine or immunization process and vaccination equipment, but coincide with the occurrence of immunization process or after it. The age of children, during which the vaccination takes place, is characterized as children being subject to many diseases during this age that may coincide with or after vaccination. The incidence of such events depends on the incidence of such diseases in the community and the ratio of vaccine coverage.

Recording such events and knowing the reasons behind them would bring back confidence and assurance to health and medical staffs and community in vaccines and contribute to the promotion of immunization activities.

4. Adverse Event due to Injection and have nothing to do with the vaccine or the vaccination:- Such reaction occurs in children of five years of age and elder because of fear or pain from the injection process. That may cause a drop in child's blood pressure leading him to fall on the ground, which in turn could cause some wounds. Usually, such symptoms occur when there is a large number of kids in one place, where the occurrence of such interaction in one child may lead to the reoccurrence with several other children. Another interaction as a result of the injection process is persisting screaming.
5. Unknown Adverse Events: - The reasons of some recorded adverse events cannot be known in spite of conducting all the necessary investigations.

How to avoid the occurrence of the AEFI: -

Adverse Events Caused by the Vaccine

To avoid such events, the following should be considered: -

- Never ignoring vaccination contraindications, which are:-
 - a- Children with serious, moderate or severe disease.
 - b- People who had anaphylactic shock due to taking certain vaccine, accordingly they should not be vaccinated with the same vaccine in the future.
 - c- People with HIV should not be vaccinated with vaccines that contain living weakened bacteria or viruses.
- Avoiding the use of expired vaccine
- Avoiding the use of measles, polio and BCG vaccines if exposed to sunlight.
- Avoiding the use of Freeze-sensitive vaccines (quartet, quintet, hepatitis type b, tetanus toxoid and DT vaccines for children and adults) if frozen, unless passing the shake test successfully.

Adverse Events Due to Program Errors

- The vaccine should not be administered by larger dose.
- The vaccine should be administered in the specified site and in the right way (IM, subcutaneous injection (Sc) or in the skin).
- Avoid injecting the vaccine in the buttock for Children under 2 years of age
- Avoid using unsterilized needles, which touched vaccinator's hand or any other object.
- Using sterilized injection and needle for each vial of reformed (dissolved) vaccine.
- Using the solvent suitable for the vaccine.
- Keeping the vaccine or solvent uncontaminated during vaccination session.
- Making sure that no other drug is administered instead of the vaccine.

AEFI Surveillance System

A monitoring system aims to ensure the security and safety of vaccination through the detection, reporting, investigation and response to the recorded AEFI.

AEFI Surveillance System aims to:-

1. Detect adverse events caused by errors in vaccination process, correct those errors and prevent them from happening in the future.
2. Find out the incidence of adverse events caused by the vaccine and compare it with conventional rates to determine any increase in those rates, which is associated with certain portion of the vaccine.
3. Detect adverse events that coincide with vaccines to maintain the trust of the medical and health staff and community in immunization program.
4. Respond to the questions raised by society members; share their concerns about vaccines and show them the extent to which health institutions care about their health.
5. Come up with new assumptions about the types and rates of recorded adverse events in relation to the local community and compare them with what is recorded in global studies and researches.

Adverse events to be detected and reported: -

1. All abscesses that appear in site of the vaccine injection.
2. All cases of Lymphadenitis following BCG vaccines.
3. All deaths that occur after vaccination which health workers or members of the community believe to have happened as a result of vaccination.
4. Each case of hospital admission following vaccination which health workers or members of the community believe to have happened as a result of vaccination.
5. Any unusual medical event that occurs after vaccination and raises the interest of the community.
6. Severe local reaction (swelling that extends to the near joint or swelling, redness and pain for more than three days, or the need to enter the hospital).

Who should be responsible on detecting and reporting AEFI?

The responsibility of detecting and reporting AEFI is on: -

- The persons who are responsible on immunization activities in all PHCCs.
- The persons who are responsible of treating adverse events cases in PHCCs, Public Hospitals and Private Hospitals and Clinics.
- Family members of a person who have adverse events..

- Researchers and scholars of clinical and field studies in relation to the security and safety of vaccines.

Therefore, it is important to explain to the parents and community the interactions that might happen after vaccination and to ask them to bring the baby in any such cases. They also should know how to treat simple symptoms following vaccination like the mild increase in body temperature ($<39^{\circ}\text{C}$), swelling or pain in injection site. Such information may help parents when simple symptoms occur.

When to report AEFI?

Reporting is either immediate or on monthly basis depending on the case, given that reporting would be in the respective form of each case (Appendix 2 and Appendix 3 respectively). Immediate reporting is either by telephone, fax, in person or by writing.

It is necessary to immediately report all (must-reported) cases mentioned above with the exception of severe local interaction, cases of high body temperature ($\geq 39^{\circ}\text{C}$) and children persistent screaming for three hours with a sharp tone following vaccination, where these cases shall be reported on monthly basis.

Note: - The monthly report must also include the cases that were reported immediately. In case there is no adverse events to be recorded during the month, health institutions should send the monthly report and in such case it is called zero monthly report.

Investigation of AEFI

The main objective of AEFI Investigation is to know the reason of the emergence of these events, whether individual or cluster grouping and to correct the errors of immunization process if those cases were the result of an error in the vaccination.

The objectives of the investigation of recorded AEFI cases are: -

1. Confirming the primary diagnosis of the case or providing the potential diagnoses of it.
2. Knowing the characteristics of the used vaccine (the name of the vaccine, manufacturer's name, number of vaccine and dates of manufacture and expiration) and the way of keeping and handling the vaccine.
3. Examining the practical steps for the immunization program, even if the case looks as if it was caused by the vaccine itself or coincidental with the vaccine because program errors may increase the severity of the case or increase the number of cases.
4. Knowing whether the case is an individual case or within a group of cases, where in such circumstances the places of vaccination and all detected cases must be investigated.
5. Identifying whether there were cases similar to the recorded ones among unvaccinated people.
6. Notifying the community on the attention health authorities pay to the health of their children and reassuring them.

Adverse events cases that must be investigated: -

1. All abscesses that appear in the site of the vaccine injection.
2. All cases of lymphadenitis following BCG vaccination.
3. All deaths that occur within a month after vaccination.
4. All cases of hospital admission that occur within one month after vaccination.
5. Any unusual medical event that occurs after vaccination and raises community concern if health workers or members of the community believe it occurred because of the vaccination.

Investigation must be done within 48 hours from reporting on the case for the purpose of early detection of any error in the immunization process, avoiding the occurrence of other cases and showing the community the extent of interest in their health.

The responsibility of conducting Investigation on discovered cases of adverse events: -

- The medical and health staff in PHCCs and immunization officials in PHC sectors should carry out the investigations on simple and individual cases.
- In the case of group of adverse events cases or serious cases emerge, the investigation is conducted with the participation of health and medical staffs of the Directorate of Health or Ministry headquarters.

Sources of data collection for the must-investigated adverse events cases: -

1. Recorded adverse events cases.
2. Immunization centers where detected cases were vaccinated.
3. Health and medical staffs that have vaccinated the case or the recorded cases.
4. Medical and health staffs responsible on the treatment of the case or cases.
5. Family members where the case was recorded.
6. The members of the community where case or cases were recorded.

Data collection methods for recorded adverse events: -

Data is collected in the following ways: -

- Conducting clinical examinations for the case or cases recorded.
- Personal interviews of cases, medical and health staff and members of the community.
- Reviewing the medical records of the case or cases.
- Visiting vaccination center or centers and vaccine stores to witness the vaccination process and the way the vaccine is stored and handed.

Adverse events investigation Steps: - recorded adverse events investigation activities include the following steps: -

1. Proving the authenticity of the information contained in the report.
2. Collecting the necessary data.
3. Analyzing the information and developing a hypothesis about the factor that causes the adverse event.
4. Testing the hypothesis.
5. The conclusion, taking the necessary measures and making recommendations.
6. Contacting with the parents and other members of the community.

1. Proving the authenticity of the information contained in the report by:-
 - a. Reviewing patient's medical record.
 - b. Comparing between patient information and the disease.
 - c. Taking the information from patient's record if they were not recorded in the report.
2. Data collection: - for a successful investigation on the case or group of cases, the following data should be collected: -
 - A. Data for each patient and they include: -
 1. The current medical history of the case: -
 - Patient's symptoms, history of appearance, description of the clinical status and the results of laboratory tests of blood or stool samples or any other samples that have been taken.
 - The treatment the patient took.
 - The diagnosis of the case.
 - Have the patient been entered to the hospital and the final result of the disease.
 2. Previous medical history of the case and it includes: -
 - The emergence of similar reactions associated with previous doses of the vaccine, which is believed to be the reason for the appearance of the case.
 - Sensitivity for some medications.
 - Former neurological disease.
 - The drugs the patient took before and after vaccination.
 3. Vaccination history of the case: - The number of doses, the date of each dose, the site of injection and the health center in which each vaccination took place.
 - B. Data of the used vaccine, which is believed to be the cause of occurrence of adverse event:
 1. Vaccine name and number.
 2. Vaccine manufacturer's name.
 3. Dates of vaccine production and expiry.

4. The results of vaccine tests done by the National Center for Drug Control and Research.
5. The store that delivered the vaccine, the temperature at which it was stored and CCM status if available.

C. Data related to the immunization program: - information of vaccines storing and handling and the practice of administering the vaccine in the center or centers where cases have emerged. This data can be obtained by the following ways: -

1. Asking about the following: -

- Taking into account the prevention of freeze-sensitive vaccines (like quintet and quartet vaccines, hepatitis (b), tetanus toxoid and DT vaccines for adults and children) from being congealed and not using those vaccines when exposed to Congelation only after passing the shake test.
- The method of storing and distributing vaccines and disposing of vaccination sharp items.
- The method of storing and distributing solvents.
- The method of re-composing (dissolving) the vaccine and the period of use.
- The quality and quantity of the used syringes and needles.
- Training and supervision activities for those in charge of immunization activities.
- The size of vaccination sessions and is the number of vaccinated children more than the standard numbers.

2. Observing the following immunization activities on site: -

- Vaccines refrigerator and that includes form of temperature follow-up, how to arrange vaccines in the fridge and are there other drugs stored in the refrigerator with the vaccines.
- (VVM) and (CCM) status if found.
- Vaccination method, which includes dissolving the vaccine, drawing and administering methods, in addition to safe vaccination steps and how deal with sharp wastes.
- Does any vaccine vial look contaminated.

D. Data of the community in which cases were recorded: -

1. The number of vaccinated people with the same vaccine and in the same vaccination session, and the number of infected people and their symptoms. Each case should have separate investigation case.
2. Are there other people in the community infected with the same disease and given the same suspected vaccine or not.

E. The name of the vaccinator who have vaccinated the case or cases.

3. Analyzing the information and developing a hypothesis about the factor that causes the adverse event: - Information analysis includes a review investigation forms for all cases to arrive at a final diagnosis and determine the probable cause for the occurrence of adverse event, if possible.

The role of the laboratory in analyzing the information and finding the reason of the adverse event: -

The role of the laboratory in the analysis is rarely considered the main factor in the investigation. The other function of the laboratory is testing the vaccine for the following purposes:-

- Ensure that the contents of the vaccine vial is the same written content on the tag of the vial.
- Ensure that freeze-sensitive vaccines (like quintet and quartet vaccines, hepatitis (b), tetanus toxoid and DT vaccines for adults and children) are not damaged.
- Confirming the contamination or non-contamination of the vaccine used, especially in the case of the emergence of abscess in the site of injection if the vials of the vaccine were used.
- In cases of late local interaction, the percentage of aluminum in the vaccine must be measured.
- Confirming the contamination or non-contamination of the solvent used in the case of the vaccinated people had abscesses in one vaccination session with a vaccine that was dissolved before using.

The next table shows the type of recorded adverse event and the kind of specimens that should be laboratory tested.

Table (4): Sample-Taking Guide after the Emergence of Some Vaccination Adverse Events

Event	Sample	Vaccine &/or Solvent
Severe local symptoms Abscess Lymphadenitis	??+ Blood Blood	Yes Yes
Side effects of central nervous system Neurological symptoms without paralysis Neurological symptoms with paralysis *	Spinal fluid + Blood Stool *	Yes Yes*
Other symptoms Vasogenic shock Toxic shock	Blood + Blood culture	Yes Yes
Death	Tissue samples as the doctor sees	Yes

*If poliomyelitis appears after OPV, stool samples would be important.

Samples must be sent to the laboratory according to the specified form (Appendix 4).

The physicians who discovered the case and conducted the investigation can do information analysis on site.

The services of an epidemiologist can be useful to analyze the information. The formation of a committee at the central or local level can also help in the analysis of information and review of reports, which will contribute in finding out the cause of the case.

Data analysis in order to find the causative factor of the case or cases of recorded adverse events includes answering the following questions: -

1. Is it known that the event peculiar to the vaccine?
2. What is the incidence of adverse event?
 - a. Very common (> 1/10)
 - b. Common (> 1/100)
 - c. Uncommon (> 1/1000)
 - d. Rare (> 1/10000)

- e. Very rare (<1/10000)
 - f. Never reported.
3. Are there similar events known to be associated with other diseases?
 4. Can the event be explained as relevant to the biological characteristics of the vaccine?
 5. Does the interval between vaccination and the appearance of the event relate to the event or not?
 6. Are there similar symptoms the patient suffered in the past?
 7. Has the patient been on drug treatment prior to or by the time of the vaccination?
 8. Is there a medical condition by the time of or prior vaccination?
 9. Are there other factors that might help the occurrence of event?

Determining the causal category: -

- **Likely/ definite:** - the clinical event that has a reasonable temporal relationship with administering the vaccine and cannot be explained by a coincidental disease.
- **Probable:** - the clinical event that has a reasonable temporal relationship with administering the vaccine and is not likely to be resulted from a coincidental disease.
- **Possible:** - the clinical event that has a reasonable temporal relationship with administering the vaccine, but can be explained by a coincidental disease.
- **Unlikely:** - the clinical event that the temporal relationship between its occurrence and administering the vaccine makes the causal relationship unlikely, but can be explained by a coincidental disease.
- **Irrelevant:** - the clinical event that has no suitable temporal relationship with administering the vaccine and can be explained by coincidental disease.
- **Impossible to Categorize:** - the clinical event on which there is no enough information to evaluate and determine its cause.
 4. Testing the hypothesis: - this includes determining whether the distribution of recorded cases is identical with the hypothesis that have been developed or not. Annex No.5 represents a chart on how to find out the causative factor for a group of recorded adverse events cases.
 5. Conclusion and recommendations: -
 1. Determining the causative factor of the adverse event through investigation.
 2. Taking the required measures and making recommendations necessary to prevent the occurrence of such events in the future.
 3. The preparation of investigation activities report and submit it to the higher level.

Taking the required measures and making necessary recommendations

Following the detection of the adverse event of the vaccine and the investigation and analysis of the available information to discover the cause of the adverse event, necessary measures must be taken to deal with the case or the recorded cases and recommendations should be made to prevent or reduce the incidence of such events in the future.

Taking measures and recommendations depends on the type of the recorded adverse event and the reasons that led to its occurrence, as follows: -

a. Adverse events resulting from the vaccine

If recorded adverse events rate was higher than expected from a particular vaccine, an arrangement is done with the manufacturer and World Health Organization (WHO) to take one or more of the following measures: -

- Withdrawing this pack from all vaccination centers.
- Changing the manufacturing specifications of the vaccine in terms of quantity and quality.
- Changing the source of vaccine production.

b. Events resulting from program errors

Correcting program errors by taking one or more of the following measures: -

- Change in the plan of vaccines distribution and vaccination equipment.
- Change in the methods used in vaccine storing, vaccination sessions and disposal of vaccination sharp waste within the health center.
- Training health staff.
- Enhancement in the supervision on vaccination services activities.

c. Adverse events coincidental with vaccination

The main objective of the actions taken in such cases is ensuring that members of the community realize that the vaccine has nothing to do with the occurrence of these events.

d. Adverse events of unknown cause

The procedure taken depends on the severity of the event, the number of the recorded events and whether cases are still being recorded (in such cases, there may be a need to hire experts in order to find out the real reason and treat it). Despite these measures, the reason cannot be identified for some of the cases.

Preparation of investigation activities report

After investigation, the final report should be done and must include all actions taken or recommendations to be taken then submitted to the higher level.

- a. If an adverse event occurred, the investigator should determine the reasons of its occurrence then report it to the higher level using the investigation form.
- b. In case of the occurrence of more than one case, the report should include the following information:-
 1. The number of the infected individuals with the same adverse event.
 2. The vaccine that caused the occurrence of the adverse event.
 3. The common symptoms among all cases that occurred after vaccination.
 4. The number of the vaccinated individuals with the same pack of vaccine, which might be a reason in the occurrence of the adverse events given that all cases are interviewed.
 5. The names of the health centers that used the same vaccine pack.
 6. The number of the children in the catchment area of the health center who have not been vaccinated with the same vaccine but have the same symptoms.
 7. The period between the vaccination and the occurrence of the symptoms.
 8. Explanation of the vaccination process and how the vaccine was administered, given and stored, and the efficiency of the cold chain in health center(s) in which the vaccination took place.

The report should also contain the following information:-

- The names of the individuals in charge of diagnosing and recording cases.
- The names of the individuals in charge of the investigation on cases.
- The date of investigation commencement.
- The name of the laboratory in which tests took place.

6. Contacting with the parents and other members of the community

Assuring the parents, the community and medical and health staffs and showing the benefits of immunization and that these symptoms are controllable not to mention informing them with last measures, results and recommendations. If the real reasons of the occurrence of cases could not be identified, they should be informed.

Regional officer duties (PHCC physician)

- Awareness of the diagnosis and treatment of danger signs of vaccines adverse events cases.
- Reporting recorded adverse events cases to immunization official at the sector level.
- Informing the parents and community members of the benefits of vaccines, assuring them and explain the diseases that their children might suffer from if not vaccinated.
- Improving immunization services performance in the health center.

AEFI Surveillance Data Documentation:-

There are six kinds of forms and records used in the documentation of AEFI activities and they are:-

1. Immediate case reporting form (Annex 2)
2. Monthly report form (Annex 3)
3. Laboratory sample submission form (Annex 4)
4. Case investigation form:- should be filled in by the physician responsible for investigation in the health center or sector given that a form is filled in for each case (Annex 6)
5. Adverse events cases record:- all information of each case should be filled in by the person responsible of the record.
6. Case description record:- filled in with detailed description, brief on the symptoms and investigation results of each case separately.

AEFI Surveillance Activities Evaluation

AEFI surveillance activities should be followed on regular basis to enhance the work. The indicators used to evaluate these activities are:-

1. The completion of the number of submitted monthly reports from PHCCs and the way of calculating the completion of the monthly reports is as follows:-

$$\text{Monthly reports completion } \times 100 = \frac{\text{the number of submitted reports}}{\text{the total number of required reports}}$$

2. Submitting the monthly reports in time:- certain date should be specified for receiving adverse events monthly reports submitted by health centers to PHC sectors and this indicator can be calculated as follows:-

$$\text{The delivery of monthly reports in time } x = \frac{\text{the number of submitted reports in time}}{\text{the total number of required reports}} 100$$

3. Are serious adverse events cases reported within 24 hours from detecting them and further investigated within 48 hours from reporting date.
4. Are necessary measures taken to avoid program errors so as to prevent the reoccurrence of such case.
5. Follow-up on the coverage rates of extended immunization program vaccination. The increase of coverage rate of extended immunization program vaccination is one of the AEFI surveillance system success indicators.

Important Note:-

Though this guide had focused on AEFI, we must put in mind that the events following the vaccination against measles, poliomyelitis or tetanus are incomparable of what could happen if children are not vaccinated because the infection and complications, which may cause disability or death.

Annex (1)

Case definitions and treatments for AEFI

event	Case definition	Treatment	Vaccines
Acute flaccid paralysis (Vaccine associated paralytic poliomyelitis)	Acute onset of flaccid paralysis within 4 to 30 days of receipt of oral poliovirus vaccine (OPV), or within 4 to 75 days after contact with a vaccine recipient and neurological deficits remaining 60 days after onset, or death.	No specific treatment available; supportive care	OPV
Anaphylactoid reaction (acute hypersensitivity reaction)	Exaggerated acute allergic reaction, occurring within 2 hours after immunization, characterized by one or more of the following: <ul style="list-style-type: none"> wheezing and shortness of breath due to bronchospasm laryngospasm/laryngeal oedema one or more skin manifestations, e.g. hives, facial oedema, or generalized oedema. Less severe allergic reactions do not need to be reported. Exaggerated acute allergic reaction, occurring within 2 hours after immunization, characterized by one or more of the following: <ul style="list-style-type: none"> wheezing and shortness of breath due to bronchospasm laryngospasm/laryngeal oedema one or more skin manifestations, e.g. hives, facial oedema, or generalized oedema. Less severe allergic reactions do not need to be reported.	Self-limiting; antiemetic may be helpful.	All
Anaphylaxis	Severe immediate (within 1 hour) allergic reaction leading to circulatory failure with or without bronchospasm and/or laryngospasm/laryngeal oedema	Adrenaline injection	All
Arthralgia	Joint pain usually including the small peripheral joints. Persistent if lasting longer than 10 days, transient: if lasting up to 10 days.	Self-limiting; Analgesics	Rubella, MMR
Brachial neuritis	Dysfunction of nerves supplying the arm/shoulder without other involvement of nervous system. A deep steady, often severe aching pain in the shoulder and upper arm followed in days or weakness by weakness and wasting in arm/shoulder muscles. Sensory loss may be present, but is less prominent. May present on the same or the opposite side to the injection and sometimes affects both arms.	Symptomatic only; analgesics.	Tetanus
Disseminated BCG infections	Widespread infection occurring within 1 to 12 months after BCG vaccination and confirmed by isolation of <i>Mycobacterium bovis</i> BCG strain. Usually in immunocompromised individuals.	Should be treated with anti-tuberculous regimens including isoniazid & rifampicin.	BCG
Encephalopathy	Acute onset of major illness characterized by any two of the following three conditions: <ul style="list-style-type: none"> seizures severe alteration in level of consciousness lasting for one day or more distinct change in behavior lasting one day or more. Needs to occur within 48 hours of DTP vaccine or from 7 to 12 days after measles or MMR vaccine, to be related to immunization.	No specific treatment available; supportive care.	Measles, Pertussis
Fever	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.	Symptomatic; paracetamol.	All
Hypotonic, hyporesponsive episode (HHE or shock-collapse)	Event of sudden onset occurring within 48 [usually less than 12 hours of vaccination and lasting from one minute to several hours, in children younger than 10 years of age. All of the following must be present: <ul style="list-style-type: none"> limpness (hypotonic) reduced responsiveness (hyporesponsive) pallor or cyanosis – or failure to observe/ recall 	The episode is transient and self-limiting, & does not require specific treatment. It is not a contraindication to further doses of the vaccine.	Mainly DTP, Rarely others

Injection site abscess	Fluctuant or draining fluid-filled lesion at the site of injection. Bacterial if evidence of infection (e.g. purulent, inflammatory signs, fever, culture), sterile abscess if not.	Incise and drain; antibiotics if bacterial.	All
Lymphadenitis (includes suppurative lymphadenitis)	Either at least one lymph nodes enlarged to >1.5 cm in size (one adult finger width) or a draining sinus over a lymph node. Almost exclusively caused by BCG and then occurring within 2 to 6 months after receipt of BCG vaccine, on the same side as inoculation (mostly axillary).	Heals spontaneously (over months) and best not to treat unless lesion is sticking to skin. If so, or already draining, surgical Drainage & local instillation of antituberculous drug. Systemic treatment with anti-tuberculous drugs is ineffective	BCG
Osteitis/ Osteomyelitis	Inflammation of the bone with isolation of Mycobacterium bovis BCG strain.	Should be treated with anti-tuberculous regimens including isoniazid and rifampicin.	BCG
. Persistent inconsolable screaming	Inconsolable continuous crying lasting 3 hours or longer accompanied by high-pitched screaming.	Settles within a day or so; analgesics may help.	DTP, Pertussis
Seizures	Occurrence of generalized convulsions that are not accompanied by focal neurological signs or symptoms. Febrile seizures: if temperature elevated >38°C (rectal) Afebrile seizures: if temperature normal	Self-limiting; supportive care; paracetamol & cooling if febrile; rarely anticonvulsants.	All, especially Pertussis, Measles
Sepsis	Acute onset of severe generalized illness due to bacterial infection and confirmed (if possible) by positive blood culture. Needs to be reported as possible indicator of programme error. Critical to recognize and treat early.	Urgent transfer to hospital for parenteral antibiotics & fluids.	All
Severe local reaction	Redness and/or swelling centred at the site of injection and one or more of the following: <ul style="list-style-type: none"> • swelling beyond the nearest joint • pain, redness, and swelling of more than 3 days duration • requires hospitalization. Local reactions of lesser intensity occur commonly and are trivial and do not need to be reported.	Settles spontaneously within a few days to a week Symptomatic treatment with analgesics. Antibiotics are inappropriate.	All
Thrombocytopenia	Serum platelet count of less than 50,000/ml leading to bruising and/or bleeding	Usually mild and self-limiting; occasionally may need steroid or platelets.	MMR
Toxic shock syndrome (TSS)	Abrupt onset of fever, vomiting and watery diarrhea within a few hours of immunization. Often leading to death within 24 to 48 hours. Needs to be reported as possible indicator of programme error. Critical to recognize and treat early.	Urgent transfer to hospital for parenteral antibiotics & fluids.	All

AEFI Immediate Reporting Form

Province.....

Sector.....

Health Center.....

Patient's Full Name.....

Address.....

Birth Date:- / /

Symptoms.....

Symptoms Emergence Date:- / /

Date of Discovering the Case:- / /

Date of Case Reporting:- / /

Suspected Vaccine Name.....

Date of Administering the Vaccine:- / /

The Number of Vaccine Pack.....

Vaccine Production Date:- / /

Vaccine Expiry Date:- / /

Vaccine Manufacturer Name.....

Case Reporter Name

Health Institute Name

Signature

Health Institute Manager's Name

Date

Signature

Date

Annex 3: AEFI Surveillance Activities Monthly report form

..... health directorate for the month of..... 2012

#	Full Name	Age in Months	Adverse Event Type	Symptoms Emergence Date	Reporting Center	Vaccination Center	Vaccine					Final Result		
							The Date of the Last Vaccine	Causing Vaccine Type	Manufacturer	Manufacturer Nationality	Pack Number	Expiry Date	Recovery	Hospital Admission
1														
2														
3														
4														
5														
6														
7														
8														
9														
10														
11														
12														
13														
14														
15														

Adverse events types..... the number of the adverse event should be put in (adverse event type).

- | | |
|---|--|
| 1. Abscess in injection site. | 8. Acute Anaphylaxis |
| 2. BCG Lymphadenitis | 9. Increase of temperature (39 C* or higher) |
| 3. Swelling and redness in injection site | 10. Toxic Shock |
| 4. Acute flaccid paralyses | 11. Purulent in injection site |
| 5. Meningitis | 12. Intussuption |
| 6. Encephalitis | 13. Other (any adverse event thought to be caused by the vaccine and have not been mentioned above given that adverse events details are to be mentioned in addition to writing No. 13). |
| 7. Convulsions (seizures) | |

Form Organizer's Name & Signature

Immunization Unit Manager Name and Signature

Public Health Departments Manager Name and signature

Annex 4:

Laboratory Samples Submission Form

..... Health Directorate

Patient's Name:-.....

Gender:-.....

Date of Birth:-.....

Patient's Address:-.....

Patient's adverse events:-.....

Case initial diagnosis:-.....

Date and time of adverse events emergence:-

.....

Type of the submitted sample:- vaccine, injection, stool, blood

Sample taking date:-.....

The required test:-.....

Sample submission date:-.....

**Immunization Unit Manager
Health Department Head**

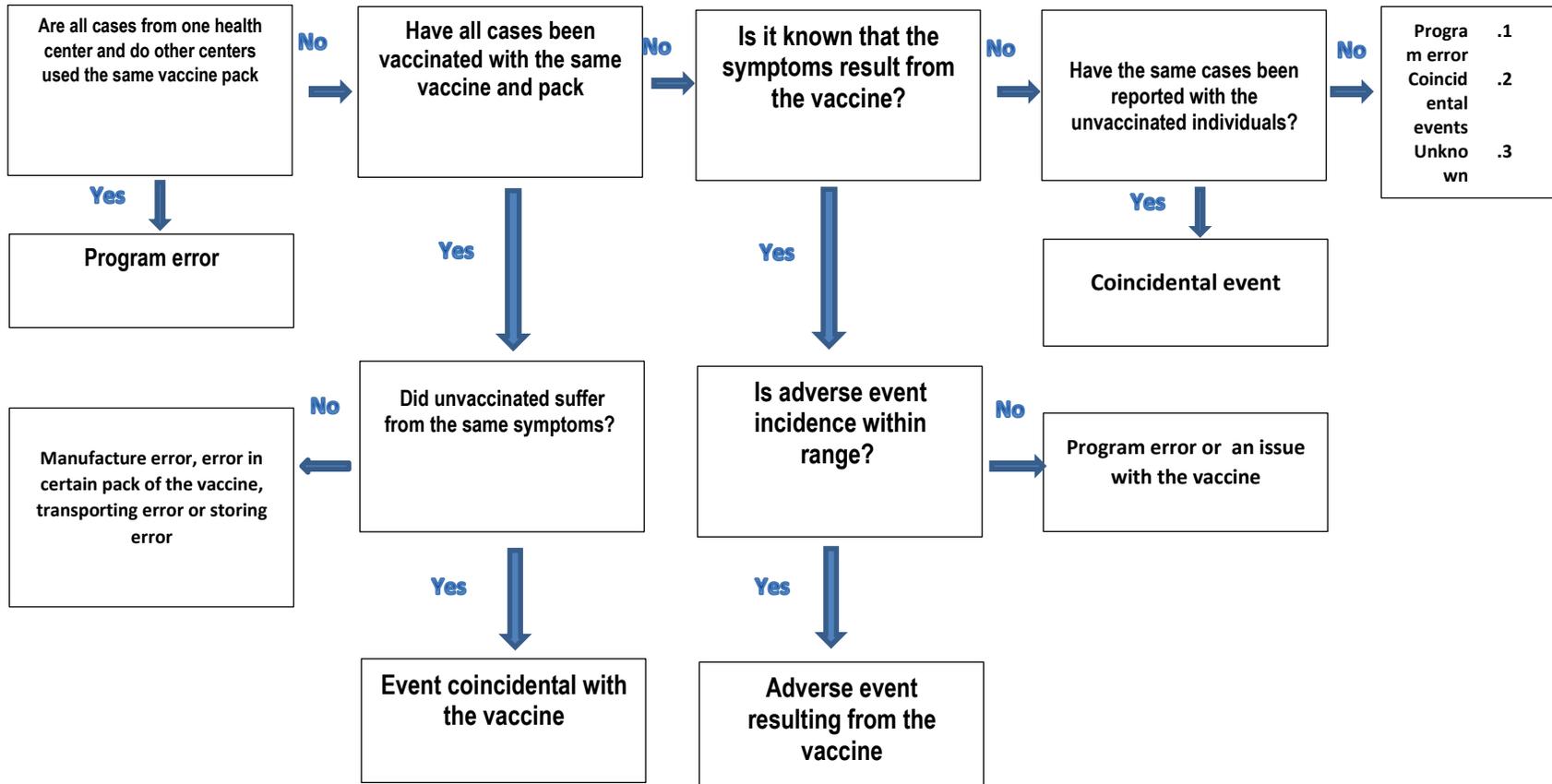
Public

Date and time of sample delivery to the laboratory:.....

Sample receiver's name and address:-.....

Annex 5

Determining the Causative Factor for Group of Adverse Events Cases



CASE INVESTIGATION FORM FOR SUSPECTED AEFI

Patient's name: - ID No.

Patient's residence

Governorate District
 Mahall ZUkak House's No.

Date of notification / / Reporter's name:
 Date of investigation / / Investigator's name:

Sex: - Male Female

Date of birth: - / / if unknown age in months

Date of onset of symptoms: - / /

Date of vaccination with suspected causative vaccine:- / /

Interval between vaccination & symptoms onset: -

Months Days Hours

I. Type of AEFI

A. Local :

Injection site abscess	YES	NO
UNKNOWN		
BCG Lymphadenitis	YES	NO
UNKNOWN		
Sever local reaction	YES	NO
UNKNOWN (describe)		

B. Central Nervous System

Acute flaccid paralyses	YES	NO
UNKNOWN		
Encephalitis / meningitis	YES	NO
UNKNOWN		
Convulsions	YES	NO
UNKNOWN		

C. Other possible reactions

Anaphylaxis YES NO
 UNKNOWN
 Fever YES NO
 UNKNOWN (How high)
 Toxic shock syndrome YES NO
 UNKNOWN
 Others YES NO
 UNKNOWN (specify)

2. Immunization history

	Vaccine	Date of immunization				
		1 st dose	2 nd dose	3 rd dose	4 th dose	5 th dose
1	BCG					
2	Penta					
3	Tetra					
4	Rota					
5	OPV					
6	DTP					
7	Hepatitis B					
8	Measles					
9	MMR					
10	TT					
11	Td or TD					
12	Others					

3. History of reaction to previous doses or drug allergies

4. Treatment

Treatment required? YES NO
 UNKNOWN

Physician's Name Telephone No.:
 Hospitalized? YES NO if so, where

5. **Specimens collected** YES NO
 UNKNOWN

- What are the specimens (if done)
- Lab. Finding (if done)

6. **Outcome of patient** CURE STILL UNDER TREATMENT DEATH

7. Suspected vaccine (s):-

I. List vaccines* most likely to cause reaction.

	Name of vaccine	Vaccination date	Manufactured by	Manufacturing date	Batch number	Expiry date
1						
2						
3						

*could be one or more

II. Suspected Diluent(s)*: - if used

	Name of diluent	Vaccination date	Manufactured by	Manufacturing date	Batch number	Expiry date	Storage temperature
1							
2							
3							

*could be one or more

III. Suspected Syringes* if used

	Name of syringe	Vaccination date	Manufactured by	Manufacturing date	Batch number	Expiry date
1						
2						
3						

*could be one or more

8. Conclusions

I. Type of AEFI

- a. Vaccine induced
- b. Programme error
- c. Coincidental
- d. unknown

II. Causative vaccine (if it is a vaccine induced AEFI)

III. What are the taken measures?

Investigator's name

Signature

Date

References

1. **AEFI Surveillance Investigators' Guide: Iraqi Ministry of Health 2001**
2. **GUIDELINES FOR MANAGERS OF IMMUNIZATION PROGRAMMES ON REPORTING AND INVESTIGATING ADVERSE EVENTS FOLLOWING IMMUNIZATION, WPRO/EPI/99.01.**
3. **Supplementary information on vaccine safety, Part 2: Background rates of adverse events following immunization, WHO/V&B/00.36**
4. **A Aide Memoire AEFI Investigation, WWW.who.int/immunization_safety/en, AEFI Investigation- Evaluation & Surveillance of Vaccines (Management of Immunization, Vaccines and Biomaterials) WHO**
5. **AEFI_causality_AR.pdf, WWW.who.int/immunization_safety/en, AEFI: Causality Estimation (Management of Immunization, Vaccines and Biomaterials) WHO**