Republic of the Philippines
Department of Health
OFFICE OF THE SECRETARY

FEB 2 9 2016

ADMINISTRATIVE ORDER
No. 2016 - 0006

SUBJECT: **Revised Guidelines on Surveillance and Response to Adverse Events Following Immunization**

I. BACKGROUND AND RATIONALE

In 2010, the Department of Health (DOH) issued Administrative Order (AO) No. 2010-0017 otherwise known as the ***"Guidelines in Surveillance and Response to Adverse Events Following Immunization"*** as part of its commitment to enhance its AEFI surveillance system and ensure delivery of safe and effective vaccine and immunization services at all levels. The guideline was made and disseminated to guide the concerned stakeholders on the early detection, reporting, investigation and appropriate response to adverse events following immunization (AEFI). Since then, the Philippines had a functional AEFI surveillance system. However, inadequate information and delayed investigation was still observed in most of the regions reporting serious AEFI cases. This significantly affected the quality of causality assessment during case review and classification.

In 2013, the World Health Organization – Western Pacific Regional Office (WPRO) issued a revised Immunization Safety Guidelines Manual which consists of additional information about vaccine safety, common/unusual event for old and new vaccines including its rate per million doses and a new algorithm for AEFI causality assessment. Hence, for further strengthening of the current AEFI surveillance, it is beneficial to adopt it.

In the same year, a group of consultants from WHO were invited to provide technical expertise and support improvement of the country's AEFI surveillance system and assist the country in aligning national guidelines with the WHO's revised immunization safety guidelines. Together with representatives from Epidemiology Bureau and partner offices, an Adverse Event Following Immunization (AEFI) Comprehensive National Assessment was then conducted.

Anchored on the learning and insights from the said AEFI surveillance strengthening activities in the country and the revised immunization safety surveillance manual, new protocols have been adopted and concomitant changes to policies and guidelines are imminent for scale-up and full-implementation. This revision of AO 2010-0017 is hereby provided to guide implementers at all levels of health care delivery system.

II. OBJECTIVES

This AO is issued to provide guidelines for concerned stakeholders on the early detection, reporting, investigation and appropriate response to adverse events following immunization.

Further, this issuance aims to establish mechanisms for collaboration between and among Epidemiology Bureau, Food and Drug Administration, Family Health Office and other stakeholders involved in AEFI surveillance and response.

III. SCOPE AND COVERAGE

This issuance shall apply to health professionals who are providing all vaccines administered under the Expanded Program on Immunization (EPI) and other vaccines given by DOH nationwide. It shall also be applied in all DOH concerned offices and attached agencies, epidemiology and surveillance units, private and government health facilities treating AEFI cases, local government units and the community involved in the surveillance and management of AEFIs.

Private sectors and/or medical institutions handling immunization services and treating AEFI cases from non-DOH vaccines are mandated to report to the Food and Drug Administration per existing rules and regulations.

IV. DEFINITION OF TERMS

a. Adverse Event Following Immunization (AEFI)	-	Any untoward medical occurrence which follows immunization and which does not necessarily have a causal relationship with the usage of the vaccine. The adverse event may be any unfavorable or unintended sign, abnormal laboratory finding, symptom or disease.
b. Causality Assessment	-	A systematic review of data about an AEFI case to determine the likelihood of a causal association between the event and the vaccine(s) received.
c. Cluster	-	Two or more cases of the same or similar event related in time, geography, and/or vaccine administered.
d. Immunization Safety	-	The public health practices and policies dealing with the various aspects of the correct administration of vaccines, focusing on minimizing the risk of transmission of disease with vaccination and maximizing the effectiveness of the vaccine. The term encompasses the spectrum of events from proper manufacture to correct administration.
e. Minor AEFIs	-	These are AEFIs that are not included or categorized as serious AEFIs. These include local adverse events (such as pain, swelling, redness) and systemic reaction (fever) that are expected after immunization as part of the immune response of the vaccine recipient to induce immunity.
f. Pharmacovigilance	-	The science and activities relating to the detection, assessment, understanding and prevention of adverse effects or any other possible drug-related problems.

g. Philippine Integrated Disease Surveillance and Response - The Philippine Integrated Disease Surveillance and Response (PIDSR) in an integrated disease surveillance system established in compliance to 2005 IHR for early detection and response to epidemics.

h. Safe injection practice - Those public health practices and policies which ensure that the process of injection carries the minimum of risk, regardless of the reason for the injection or the product injected.

i. Serious AEFI - An event that is causing a potential risk to the health/life of recipient leading to death, life-threatening conditions, congenital abnormalities/birth defects, disability/incapacity or hospitalization.

j. Uppsala Monitoring Center - A WHO collaborating center for international drug/vaccine monitoring.

V. GENERAL GUIDELINES

1. AEFI Surveillance in the Epidemiology Bureau shall follow the basic principles for surveillance as stipulated in the implementing guidelines of the Philippine Integrated Surveillance and Response (PIDSR) system (AO 2007-0036). It shall be encouraged at all levels for early detection and execution of appropriate measures.
2. AEFI investigation shall follow the standard epidemiological investigation principles.
3. Reported AEFIs in the Epidemiology Bureau shall be submitted to the Food and Drug Administration for reporting to Uppsala Monitoring Center.
4. The National and Regional AEFI Committees shall be responsible in determining the final causality assessment of an AEFI case of cluster of AEFIs and will be based on the World Health Organization (WHO) Causality Assessment of an AEFI, User Manual for the Revised WHO Classification (March 2013).
5. Response and follow-up activities shall be based on findings of investigations, causality assessments and recommendations by the investigation team and expert committees. Preliminary response shall be done at the LGU level and shall include medical treatment, risk communication and immunization safety interventions.

VI. IMPLEMENTING GUIDELINES

A. Surveillance

1. Detection and Reporting

a. Responsibility of Reporting

The following shall be responsible for the detection and/or reporting of AEFIs:

i. All health professionals providing immunization services and clinical treatment of AEFIs.
ii. Individuals who received the vaccination can report AEFIs to any health professional. In cases of minors, parents or guardians can report the same.
iii. Researchers, sponsors, investigators and research laboratories involved in clinical studies or field trials that result to AEFIs.

iv. Vaccine manufacturers or distributors.

b. Timing and Flow of Reporting

i. All AEFI cases including minor AEFIs such as local reactions, fever and self-limiting systemic symptoms shall be reported to the next higher epidemiology and surveillance unit (ESU) level on a weekly basis using the AEFI Case Report Form (**Annex A**).

ii. In cases of serious/ cluster of AEFI cases, notification shall be made to the epidemiology and surveillance unit of the next higher ESU level and the Epidemiology Bureau within 24-48 hours of case detection by the fastest means possible. Initial notification can be verbal using the telephone, text message or via facsimile or email. This is to notify the next higher level that an in-depth case investigation is warranted (**Annex B**).

2. Investigation

a. Once report has been received by the epidemiology and surveillance unit, an assessment shall be done to determine whether or not an investigation is needed.

b. Reported AEFIs shall be investigated if it is:

i. A Serious event of known or unknown cause; all hospitalizations
ii. A Cluster of minor AEFIs
iii. Events associated with newly introduced vaccine
iv. Suspected to be caused by immunization error
v. Appears on the list of events defined for AEFI surveillance (**Annex C**)
vi. Causing a significant parental or public concern
vii. All AEFIs suspected to be caused by the vaccine

c. AEFI investigations shall be conducted by a team composed of duly authorized representatives from the following and observe respective roles during investigation:

i. Epidemiology and Surveillance Unit (ESU) – conduct epidemiologic investigation
ii. EPI Coordinator/ Cold Chain Manager – observe safe injection practice, cold chain management
iii. FDA/ Food and Drug Regulation Officer (FDRO) – observe, inspect and review compliance to cold chain management, review of vaccine lot/batch number including diluent. A review of the product file shall be conducted by the Center for Drug Regulation and Research when deemed necessary.
iv. Health Promotion Officer – shall lead in conducting risk communication activities during and after investigation

d. AEFI investigations shall be led by the Local Government Unit (City/Province). The regional office shall provide technical assistance as needed by the LGU.

e. Complete investigation and initial response activities shall be conducted within 48 hours upon reporting of a serious AEFI. The AEFI Case Investigation Form (**Annex D**) shall be used in the investigation of cases.

f. The investigators shall look directly at the suspected reaction as well as gather information from the patient/parent, health workers and supervisors, and community members. In addition, investigation of the vaccine(s), immunization techniques and procedures, and service in action shall be conducted.

g. The investigating team shall also be allowed to access medical records of the case and photocopy records as needed to support the investigation.

h. Laboratory testing of vaccines and/or human samples may be done only on a clear suspicion and not as routine and never before the working hypothesis.

i. In case of laboratory testing of suspected vaccines, the cost of the laboratory test(s) shall be borne by the FDA-Marketing Authorization Holder (MAH) or the DOH in case of WHO-assisted purchased vaccines under the EPI and shall be paid directly to the laboratory.

j. The completed CIF together with all supporting documents shall be submitted within 48 hours or immediately after completion of investigation to the RESU for initial causality assessment by the Regional AEFI Committee (RAEFIC).

3. Data Management

a. Epidemiology Bureau shall consolidate all AEFI reports submitted (serious and minor) on a monthly basis and shall submit it to Food and Drug Administration (FDA).

b. The PIDSR system shall be utilized to maintain a database (paper-based or electronic) of AEFIs that is easily accessible to all reporting units.

c. Data analysis shall be carried out at different levels in the surveillance system. Epidemiology and Surveillance Units of the different levels shall lead the epidemiological analysis.

d. Corresponding EPI managers and FDA staff shall coordinate with the ESUs and provide additional information (e.g. number of children immunized, status of vaccine pre-qualification, international rates, etc.) that will make the analysis more comprehensive.

4. Feedback

a. There shall be a regular (at least quarterly) and timely feedback within and between all levels of the health delivery system (national, regional, province, city) including data on investigation results, classification of cases and data analysis among others.

B. Response

1. Case Management

a. Prompt treatment shall be the first response to an AEFI. Treatment may vary depending on the signs and symptoms of the AEFI case.

b. If the AEFI is due to vaccine related-reaction occurring at a higher reaction rate than expected from a specific vaccine or lot, the Secretary of Health

or FDA Director General can suspend corresponding immunization activity and declare product recall and advisory.

c. If the AEFI is due to immunization errors, actions shall mainly focus in correcting the case of the error and review at a later date that the immunization errors have been corrected.

d. If the AEFI is coincidental, the priority action shall focus on developing and implementing risk communication plan directed to the affected family and the general public.

2. Program Support

a. The EPI program managers in their corresponding levels shall take the lead to provide corrective actions and monitor outcomes of response interventions.

b. LGUs shall immediately implement corrective actions based on the preliminary investigation findings and causality assessment of the Regional AEFI committees and implement all other measures recommended by RAEFIC and/or NAEFIC.

C. Causality Assessment

1. A Regional AEFI Committee shall be established and suggested to be composed of the following:
   a. 4 Clinical Experts (medicine/infectious disease/pediatrics)
   b. Research specialist (academe), pharmaco-epidemiologist
   c. Regional Director or Assistance Regional Director (observer)
   d. Regional Food and Drug Authority (observers)
   e. EPI Program Manager and cold chain manager (observer)
   f. RESU head/staff (secretariat)
2. The Regional AEFI Committee shall conduct preliminary causality assessment as soon as possible upon receipt of the AEFI case investigation reports. The RAEFIC may require conduct of additional investigation.
3. The investigation team may offer a "first opinion" on the causality of a particular AEFI or cluster of AEFIs. The first opinion can be derived from the result of the investigation done by the team in collaboration with key stakeholders at the regional and sub-regional levels.
4. AEFI investigations that have not reached conclusions and cases that are not classified by the RAEFIC shall be presented to the National AEFI Committee (NAEFIC) for final causality and provision of recommendations.
5. The minimum document requirement to facilitate an evidence-based causality assessment are as follows:
   a. Completed Case Investigation Form (**Annex C**)
   b. A "valid diagnosis" for the unfavorable or unintended sign, abnormal laboratory finding, symptom or disease in question
   c. Hospital Records / Medical Charts / Laboratory Results
   d. Preliminary Investigation Report / IMRAD
   e. Death Certificate / Autopsy Report (for cases of deaths)
6. The expert committee may ask for additional supporting evidences as needed to provide a final causality assessment.

D. Assistance to AEFI cases

1. The LGU shall ensure that serious AEFI cases are provided with immediate assistance which may include hospitalization and transport to medical facility.
2. The LGU shall collaborate with the Regional Offices to discuss appropriate assistance to the patient. The LGU shall provide to the extent possible any immediate assistance to serious AEFI cases.
3. An autopsy shall be preferred and recommended following all deaths suspected to cause by vaccine / immunization. The DOH shall provide the necessary assistance to find or coordinate with an appropriate agency/facility for autopsy upon approval of consent.
4. Patients with serious AEFI shall be managed at a DOH retained and other government hospitals for free. If medical services, diagnostics or laboratory capacities needed by an AEFI case are not available in a public facility, the patient shall be referred to a private health facility. Hospital expenses incurred shall be shouldered by the LGU or the DOH. If the patient opts to be confined at a private health facility, hospital expenses shall be shouldered by the patient themselves.

E. Assistance to health worker

1. Concerned public health professionals shall not be held liable for any AEFI as long as DOH standard operating procedures on immunization safety practices are complied and with proper assessment by National AEFI Committee.
2. DOH Legal Service shall collaborate with the Public Attorney's Office (PAO)/Office of the Solicitor General (OSG)/Integrated Bar of the Philippines (IBP) /Law Schools/volunteer lawyers in providing appropriate legal assistance to public health professionals as necessary if any case is filed against them for acts committed in the performance of their duty and in good faith.
3. Local police force may provide assistance to any health worker/s for any threats received.
4. In case of physical injury, the health worker shall be provided with free medical assistance in DOH-retained and other government hospitals. In case of referral to a private hospital is required, the expenses incurred shall be reimbursed by the LGU or DOH.
5. As mandated by E.O. 663 and A.O. No 2007-0028, the concerned health worker/s shall be given due process for any administrative, civil or criminal sanctions filed against him/her. In addition, assistance shall be given to the concerned health workers by LGU for any expenses incurred in the conduct of this activity.

F. Risk Communication

1. Risk communication for AEFI shall be the responsibility of the health sector at all levels particularly the health promotion officers.
2. Risk communication shall be comprehensive to cover the following target audiences: family, community, general public, media, and health workers.
3. All media coverage on AEFI shall be coursed through the OSEC-Media Relations Unit (MRU) at the national level and HEPO-PIO (Health Education Promotion Office - Public Information Office) at the regional level. The OSEC-MRU and the Regional HEPO-PIO shall refer those concerns to the appropriate offices.

4. Press releases shall be done when the AEFI incident has been publicized (by local, national or international media). Other AEFI incidents that had been investigated and resolved may not necessarily require press releases as determined by the MHO or Local Chief Executives (LCE).
5. At the city/provincial level, the LCE, or his duly designated official, shall be the spokesperson for inquiries related to AEFI. The MHO/CHO, in consultation with the regional AEFI committee, shall provide technical inputs to the LCE.
6. The health promotion officer, in coordination with the program coordinators shall formulate a health communication plan pertaining to AEFI and prepare key messages for advisories and press releases.
7. At the regional level, the Regional Director shall convene a meeting with the concerned LGU for synchronous press releases.
8. At the national level, the Secretary of Health or his duly designated official shall act as the spokesperson for national matters related to AEFI.
9. The DOH through the Health Promotion and Communications Service (HPCS) in coordination with the Family Health Office (FHO), Epidemiology Bureau and Food and Drug Administration (FDA) shall prepare risk communication plan and key messages for advisories.
10. The MRU shall prepare and disseminate press releases and facilitate press conferences.
11. Upon clearance by the Secretary of Health, the Epidemiology Bureau, being the International Health Regulation (IHR) focal point, shall notify the WHO and other concerned international organizations of the serious AEFI incidents and the response taken. Likewise, FDA as the National Regulatory Authority (NRA) shall notify international partners.

G. Post Incident Evaluation (PIE)

1. The Chair of the Regional AEFI Committee (RAEFIC) shall facilitate the conduct of post incident evaluation for all serious AEFIs. This shall be attended by the members of the regional AEFI committee, provincial, city/municipal EPI coordinators, PHO, MHO/CHO, surveillance staff, and DOH representatives.
2. The focus of the PIE shall include critical examination on the elements of the AEFI surveillance and response and come up with recommendations to improve AEFI surveillance and response and the immunization program.
3. The National AEFI Committee and the LGU concerned shall be given feedback of the PIE results.

H. Monitoring and Evaluation

1. The role of monitoring is delegated to all government health units at all levels. It shall be done by person/s knowledgeable with AEFI surveillance and safe immunization practices who can easily track discrepancies and give immediate action to it. Hence, epidemiologist, DSO/DSCs, EPI coordinators and FDA/FDRO shall be responsible of the monitoring system.
2. The surveillance system shall be monitored and evaluated regularly (at least annually) based on the following criteria:
    a. The data reported by the AEFI surveillance system (reporting rate, number of adverse reactions reported)
    b. Timeliness, completeness and accuracy of AEFI reporting
    c. Timeliness, completeness of investigations

d. Audit of corrective action

VII. ROLES AND RESPONSIBILITIES

A. National Immunization Committee (NIC) shall:

1. Provide direction and technical support on policies and plans pertaining to the immunization program as prescribed in Department Personnel Order No. 2007-0323.

B. Regional Adverse Events Following Immunization Committee (RAEFIC) shall:

1. Deliberate preliminary causality assessment upon receipt of complete AEFI case investigation reports from the provincial/regional investigating team. The committee should convene at least quarterly or as need arise.
2. Provide immediate written report regarding the deliberated preliminary assessment to EB and concerned LGU, copy furnish FHO and FDA.
3. Provide information of the final causality assessment and recommendations to the Regional Offices/PHO/CHO and concerned LGU.
4. Monitor implementation of the recommendations by the responsible program/offices.

C. National Adverse Events Following Immunization Committee (NAEFIC) shall:

1. Review all reported serious and cluster of AEFI cases presented for expert opinion on a quarterly basis or as the need arise, and provide a final causality assessment of the AEFI cases as well as the cases that were not classified by the Regional AEFI Committee.
2. Ensure evidence-based causality assessment by recommending further investigation and data collection as needed.
3. Make final decisions on causality assessment of inconclusive investigations.
4. Ensure standard protocols for AEFI surveillance and investigation are correctly followed.
5. Engage with other national and international experts when requirements arise in establishing causality and vaccine quality issues.
6. Provide recommendations to the EPI Program, Epidemiology Bureau and National Cold Chain Manager on improving immunization service delivery, compliance with injection safety and effective vaccine management, etc. based on lessons from the AEFI cases.
7. Serve as technical advisory group to the Secretary of Health and the FDA on vaccine and immunization safety-related issue of highest consideration such as immediate recall of vaccine from NIP and/or market or temporary/permanent withdrawal of a vaccine from the immunization program.
8. Serve as resource person in other AEFI related meetings, conferences or capacity building activities as requested.

D. Family Health Office shall:

1. Modify EPI program policies and programs based on NAEFIC recommendations.
2. Coordinate with Epidemiology Bureau for any reported AEFI cases.

3. Provide the Epidemiology Bureau of the data necessary for analysis (i.e. vaccine doses administered/ doses used / doses distributed).
4. Provide technical assistance during AEFI investigation and immunization program reviews at all levels.
5. Provide technical assistance for corrective actions and improving quality of immunization service.
6. EPI program managers together with the FDA in their corresponding levels shall take the lead to provide corrective actions and monitor outcomes of response interventions.

E. Epidemiology Bureau (EB) shall:

1. Oversee the design and implementation of the National AEFI surveillance system.
2. Lead in the conduct of case investigation and comprehensive data analysis.
3. Provide technical assistance or training to develop/enhance capacity of regional/local AEFI surveillance.
4. Convene meetings of and serves as secretariat for the NAEFIC (quarterly).
5. Provide AEFI surveillance information to all stakeholders for policy and program use.
6. Coordinate AEFI surveillance activities with EPI and FDA both at the national and regional levels.
7. Maintain database of all reported AEFIs and submits database to FDA within the prescribed timeline.

F. Health Promotion and Communications Service (HPCS) shall:

1. Develop and oversee the implementation of the national AEFI risk communication plan.
2. Support sub-national levels in developing and implementing their respective risk communication plans including monitoring and evaluation tools.
3. Monitor and evaluate implementation of risk communication plan at all levels and provide feedback to all stakeholders.

G. Media Relations Unit (MRU) shall:

1. Coordinate with HPCS, Epidemiology Bureau, FDA and FHO in preparing and developing key messages for advisories and press statement.
2. Facilitate in the dissemination of press releases.
3. Facilitate in the preparation and conduct of press conference.

H. Food and Drug Administration (FDA) shall:

1. Communicate international vaccine safety signals and all serious AEFIs reported through the Pharmacovigilance Unit to Epidemiology Bureau, FHO and other stakeholders.
2. Provide the Epidemiology Bureau, Epidemiology and Surveillance Unit counterparts and EPI Program of the data necessary for analysis (i.e. status of vaccine pre-qualification, international rates, etc.).

3. Conduct collection of samples of implicated vaccine and facilitates laboratory testing by a WHO-recognized National Control Laboratory.
4. Implement regulatory action/s and issues timely advisory to the public on serious AEFI implicated vaccine.
5. Inspect warehouse and storage areas (cold chain facilities and equipments) of vaccines under EPI at all levels.
6. The FDA being the National Regulation Authority shall submit reports to the Uppsala Monitoring Centre.

I. Regional Offices shall:

1. Provide technical assistance (e.g. training, advocacy activities), logistics to local AEFI investigations and response.
2. Establish a functional Regional AEFI Committee (RAEFIC).
3. RESU shall organize an AEFI investigation team (s) when needed and take the lead in the investigation.
4. Regional EPI program managers in their corresponding levels together with the FDRO shall be involved in the investigation and take the lead to provide corrective actions and monitor outcomes of response interventions.
5. Regional EPI program managers and FDRO shall provide the RESU of the data necessary for analysis (i.e. vaccine doses administered/ doses used / doses distributed, status of vaccine pre-qualification).
6. Develop, implement and monitor regional risk communication plan through the Regional HEPO/PIO, and provide technical assistance in the development of the LGU risk communication plan.
7. The regional office shall track and monitor the compliance of public and private hospitals in the implementation of PIDSR and AEFI surveillance as part of the requirements for renewals of license to operate. The regional director shall issue a regional order to enforce compliance. The team shall inform the Regional Offices /PHOs/LGUs of activities taken against non-complying hospital/institutions.

J. Provincial/ City/ Municipal Health Offices shall:

1. Provide timely feedback to the Local Chief Executives (governor/city mayor).
2. Provide assistance to the health worker in the form of technical, legal, social, financial assistance among others.
3. Report hospitals and related facilities that fail to comply with the PIDSR reporting requirements to the Regional Offices.
4. Conduct investigation of reported serious and clusters of minor AEFIs within 48 hours and submits report to next higher level.
5. Designate representatives to AEFI investigation team or during RAEFIC case review.
6. Provide or coordinate with other agencies in the provision of assistance to patients with serious AEFIs.
7. Submit and maintain database of all reported AEFI cases.
8. Analyze, interpret and communicate AEFI data.
9. Develop and implement local risk communication plan and strategies.

K. Barangay shall:

1. Shall detect and report AEFIs to next higher level.
2. The midwife/nurse assigned in the area shall institute initial case management and refer to the MHO/CHO.
3. The barangay council shall provide support to the AEFI case including but not limited to transportation, medicines, hospital referral, communication to family and communities.

L. Hospitals shall:

1. Detect and report all AEFI cases to Epidemiology and Surveillance units.
2. Clinically manage AEFI cases.
3. Facilitate case investigation and specimen collection as needed.
4. Provide access of AEFI investigation teams to medical records of AEFI cases.

VIII. REPEALING CLAUSE

Provisions of AO 2010-0017 and other related issuances that are inconsistent or contrary to the provisions of this Order are hereby rescinded or modified accordingly.

IX. EFFECTIVITY

This Order shall take effect immediately with a one year transition period.

JANETTE LORETO-GARIN, MD, MBA-H
Secretary of Health

Philippine Integrated Disease Surveillance and Response

Case Report Form

ADVERSE EVENTS FOLLOWING IMMUNIZATION

Ver. 2015

Name of DRU: _____

Address: _____

Type: ☐RHU ☐CHO ☐Gov't Hospital ☐Private Hospital ☐Clinic ☐Private Laboratory ☐Public Laboratory ☐Seaport/Airport

Patient No.	Patient's Full Name	Age	Sex	Date of Birth	Complete Address	Signs and Symptoms/ Adverse Event	Suspected Vaccine & Dose No. (1st,2nd,3rd)	Lot Batch #/ Expiry date	Date & Time Vaccinated	Name of Vaccinator/ Profession	Date and Time Onset of Illness	Type of AEFI	Outcome
	Indicate First name, Middle name, Last name	Age: Indicate D - days M - months Yr. - years Sex: F - Female M - Male		mm/dd/yy	Specify Street/Purok/ Subdivision, House #, Barangay, Municipality/ City, Province	Indicate signs and symptoms or adverse event experienced by the case	Indicate suspected vaccine and dose number	Indicate Lot Batch # and expiry date suspected vaccine/s	mm/dd/yy	Indicate full name and profession of the vaccinator	mm/dd/yy	Indicate if Serious or Minor AEFI	A - Alive D - Died (specify date) U - Unknown

Case Definition:

- **Adverse event following immunization** is defined as 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.

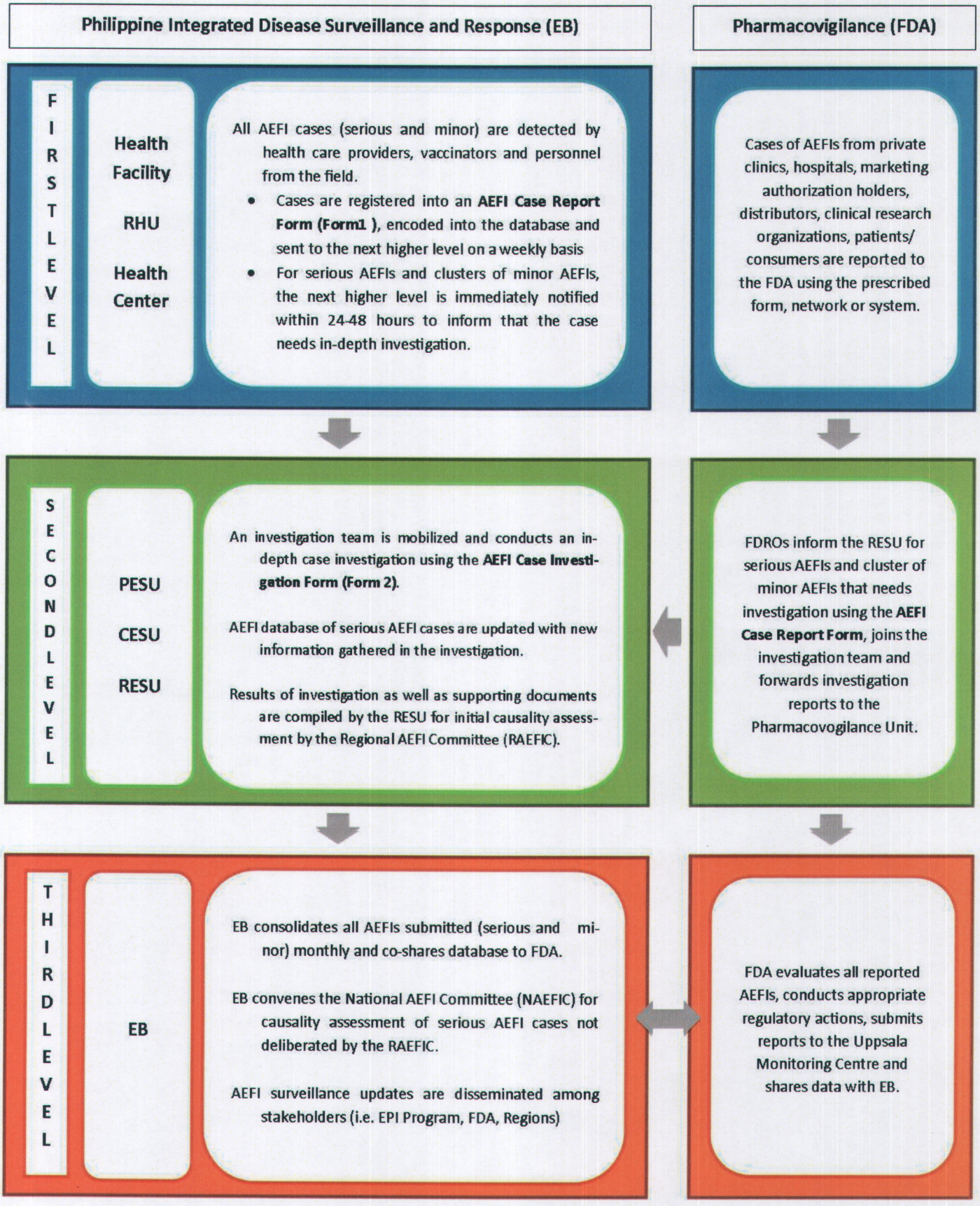
NOTE: *AEFIs to be reported include those that occur within 30 days following vaccination.* ***This form should be completely accomplished by the RHU Nurse/ Hospital staff / DSC of the reporting DRU and submitted to the next higher administrative level every week.***

TYPE of AEFI:

- **Serious AEFI** is defined as an event that is causing a potential risk to the health/life of a recipient leading to hospitalization, disability/incapacity, congenital abnormalities/birth defects or death.
- **Minor AEFI** is an event that is not "serious" and does not pose a potential risk to the health of the recipient. ***Cluster of minor AEFIs*** **should be investigated for causality assessment.** A **cluster** of AEFI is defined as two or more cases of the same or similar events related in time, geography, and/ or vaccine administered. ***(For Serious AEFI and Cluster of Minor AEFIs, a PIDSR AEFI Case Investigation Form and Guide Questions on Investigation should also be filled-out.)***

Annex A. AEFI Case Report Form

Annex B. AEFI Surveillance Flow



Annex C. Adverse Events and Treatments

Adverse 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: ▪ wheezing and shortness of breath due to bronchospasm ▪ one or more skin manifestations, e.g. hives, facial oedema, or generalized oedema. Less severe allergic reactions do not need to be reported. ▪ laryngospasm/laryngeal oedema	Self-limiting; anti-histamines may be helpful.	All
Anaphylaxis	Severe immediate (within 1 hour) allergic reaction leading to circulatory failure with or without bronchospasm and/or laryngospasm/laryngeal oedem	Epinephrine	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 *Mycobacterium bovis* BCG strain. Usually in immunocompromised individuals.	Should be treated with anti-tuberculous regimens including isoniazid and rifampicin.	BCG
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 behaviour 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: ▪ limpness (hypotonic) ▪ reduced responsiveness (hyporesponsive) ▪ pallor or cyanosis – or failure to observe/ recall	The episode is transient and self-limiting, and 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 and local instillation of anti-tuberculous 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 >38oC (rectal) **Afebrile seizures**: if temperature normal	Self-limiting; supportive care; paracetamol and 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 program error.	Critical to recognize and treat early. Urgent transfer to hospital for parenteral antibiotics and fluids.	All
Severe local reaction	Redness and/or swelling centred at the site of injection and one or more of the following: ▪ swelling beyond the nearest joint ▪ pain, redness, and swelling of more than 3 days duration ▪ 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
Thrombo-cytopenia	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 diarrhoea within a few hours of immunization. Often leading to death within 24 to 48 hours. Needs to be reported as possible indicator of program error.	Critical to recognize and treat early. Urgent transfer to hospital for parenteral antibiotics and fluids.	All

Annex D. AEFI Case Investigation Form

Philippine Integrated Disease Surveillance and Response

Case Investigation Form

(Only for Serious AEFI - Death/ Disability/ Hospitalized/ Cluster of Minor AEFI)

FDA

Version 2015

Name of DRU: **Address:**					**Type:** ☐RHU ☐CHO ☐Gov't Hospital ☐Private Hospital ☐Clinic ☐Gov't Laboratory ☐Private Laboratory ☐Airport/Seaport		
I. PATIENT INFORMATION	**EPIID Number**	**Patient's First Name**		**Middle Name**		**Last Name**	
Complete Address:				**District**		**ILHZ**	
Sex: ☐ Male ☐ Female	**Date of Birth:** *MM/ DD/ YYYY*	Age	☐ Days ☐ Months ☐ Years	Height: ____ cm	Weight: ____ kg	Date Admitted/ Seen/Consult :	*MM DD YYYY*
Name of hospital/health facility:				Address :		Admitted? ☐ Yes ☐ No ☐ Unknown	
Date onset of AEFI/ present illness	*MM/ DD/ YYYY* TIME *(hh:min:sec)* ___:___:___ AM / PM			Date next higher level notified	____/____/____	Date of Investigation	____/____/____
Name & Designation of Reporter				Institution:		Contact #/email:	
Name & Designation of Investigator				Institution		Contact #/email:	

II. SUSPECTED VACCINE

Suspected Vaccine/s *(Please indicate Generic and Brand Name)*	Date of Vaccination	Time of Vaccination	Dose No. *(e.g.1st, 2nd, 3rd)*	Site of Injection *(Indicate left or right)*	Batch/ Lot No.	Name of Manufacturer	Expiry Date	Name of Vaccinator	Profession of Vaccinator

Diluent	Date of Reconstitution	Time of Reconstitution	Batch/Lot No.	Expiry Date	Name of Vaccinator

Vaccination Center/Facility:

Vaccination Session: ☐ Routine session ☐ Clinic ☐ Mass Campaign ☐ School – based ☐ Others, _____

III. TYPE OF AEFI:

- ☐ Anaphylactoid reaction (acute hypersensitivity reaction)
- ☐ Anaphylaxis
- ☐ Brachial neuritis
- ☐ Disseminated BCG infection
- ☐ Encephalopathy
- ☐ Hypotonic-Hyporesponsive Episode (HHE)
- ☐ Injection site abscess
- ☐ Intussusception
- ☐ Lymphadenitis
- ☐ Osteitis/ Osteomyelitis
- ☐ Persistent (> 3hours) inconsolable crying
- ☐ Seizures
  - ○ Febrile ○ Afebrile
- ☐ Sepsis
- ☐ Severe local reaction
  - ○ Pain, redness and/or swelling of > 3 days
  - ○ Swelling beyond the nearest joint
- ☐ Thrombocytopenia
- ☐ Toxic Shock Syndrome
- ☐ Others (specify)

_____

_____

_____

Case Definition:

- **Adverse event following immunization** is defined as 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.
- **Serious AEFI** is defined as an event that is causing a potential risk to the health/life of a recipient leading to hospitalization, disability/incapacity, congenital abnormalities/birth defects or death.

AEFI Case Investigation Form

IV. EXAMINATION** DETAILS

Source of Information ☐ Attending physician ☐ Nurse ☐ Midwife ☐ Parent/Guardian ☐ Other _____
Mode of examination ☐ Interview ☐ Medical records ☐ Physical Examination ☐ Verbal autopsy ☐ Laboratory Result ☐ Other _____
If from Verbal autopsy, please mention the source: _____

Name & Designation of person who first examined the patient:	Date & time:

Signs & Symptoms in Chronological Order:

****Instructions – Attach copies of ALL available documents (including case sheet, discharge summary, case notes, lab and autopsy reports) and then complete additional information NOT AVAILABLE in existing documents.**
If patient has taken medical care - Attach copies of all available documents (including case sheet, discharge summary, ***laboratory reports and post mortem reports - if available) and write only information unavailable in the attached documents below.***
If patient has not taken medical care – examine the patient and write down your findings below (use additional sheets if necessary)

Working/Final Diagnosis:

Condition at Investigation: ☐ Alive : oRecovering o Fully recovered oWith Permanent Disability, Specify: _____
☐ Died, Date: ___/___/___

V. Relevant patient information prior to immunization	YES/NO	Remarks
History of allergy		
Pre-existing illness / congenital disorder		
History of hospitalization in last 30 days (indicate the cause)		
Recent history of trauma (indicate date, time and site)		
For adult women • Currently pregnant? (If YES, indicate AOG) • Currently breastfeeding?		
For infants • Natal History • Delivery	☐ Full term ☐ Premature ☐ Postdated ☐ Normal ☐ Caesarian Section ☐ Assisted birth ☐ Any complication, specify	
Was the patient on any concurrent medication for any illness? (If YES, indicate name of drug, indication, doses & date in the remarks)		
Family History of similar event		

Did the patient receive any previous vaccination and experienced the similar event? ☐ NO ☐YES (If YES, complete the table below)

Vaccine	Date of Vaccination	Time of Vaccination	Batch/ Lot No.	Name of Manufacturer	Expiry Date	Name of Vaccinator

AEFI Case Investigation Form

IV. IMMUNIZATION PRACTICES *(Fill up this section by asking and observing immunization practices at the place (s) where concerned vaccine was used)*		
Syringes and Needles Used	**YES/NO/NA***	**Remarks**
Are auto-disable syringes used for immunization?		
If NO, specify the type: ☐ Glass ☐ Disposable ☐ Recycled disposable ☐ Pre-filled syringes		☐ Other _____
Specific key findings/additional observations and comments:		
Reconstitution procedure (complete only if applicable) * Not applicable		
Same reconstitution syringe used for multiple vials of same vaccine?		
Same reconstitution syringe used for reconstituting different vaccines?		
Separate reconstitution syringe for each vaccine vial?		
Separate reconstitution syringe for each vaccination?		
Are the vaccines and diluents used as recommended by the manufacturer		
Specific key findings/additional observations and comments:		
Injection technique of vaccinator (s): (Observe another session in the same locality –same or different place)		
Correct dose and route?		
Time of reconstitution mentioned on the vial (in case of freeze dried vaccines)?		
Non-touch technique followed?		
Contraindication screened prior to vaccination?		
How many AEFI reported from the center that distributed the vaccine in the last 30 days?		
Training received by the vaccinator: (Title)		*If YES, specify date of last training* _____/_____/_____
Specific key findings/additional observations and comments:		

V. COLD CHAIN AND TRANSPORT *(Fill up this section by asking and observing practice)*		
Last vaccine storage point:	**YES/NO**	**Remarks**
Type of vaccine storage: ☐Freezer ☐ Refrigerator ☐ Dry Store ☐ Other, specify:		
Temperature: Body of refrigerator _____ °C Freezer: _____ °C		
Correct procedure of storing vaccines, diluents and syringes followed?		
Any other item (other than vaccines and diluents) in the refrigerator or freezer?		
Partially used reconstituted vaccines in the refrigerator?		
Unusable vaccines in the refrigerator?		
If YES, check all that apply: ☐ expired ☐ no label ☐ VVM Stage 3/4 ☐ Frozen		
Unusable diluents in the storage area?		
If YES, check all that apply: ☐ expired ☐ manufacturer not matched ☐ cracked ☐ dirty ampule		
Specific key findings/additional observations and comments:		
Vaccine transportation:		
Vaccine carrier used: ☐ Polyurethane Foam Insulation ☐ Insulated Plastic Container ☐ Styrofoam ☐ Other, specify		
Vaccine carrier sent to the site on the same day of vaccination?		
Vaccination carrier returned from the site on the same day of vaccination?		
Condition of the vaccine carrier: Was ice-pack used?		
Specific key findings/additional observations and comments:		

AEFI Case Investigation Form

VI. VACCINE DETAILS (Indicate vaccines provided at the site linked to AEFI on the corresponding day)

Number of recipients immunized for each antigen at the session site. Attach record (s) if available	Vaccine Name									
	Total Doses Given									

NOTE: Provide explanation for each YES answers on the following:	YES/NO/#
a) When was the patient immunized? (Tick box below)	
☐ Within the first vaccinations of the session ☐ Within the last vaccinations of the session ☐ Unknown	
☐ Within the first few doses of the vial administered ☐ Within the last doses of the vial administered ☐ Unknown	
b) Was the recommendation for use of this vaccine not followed?	
c) Based on the investigation, does the vaccine (ingredients) administered could have been unsterile?	
d) Based on the investigation, does the vaccine's physical condition (e.g. color, turbidity, foreign substances etc.) was abnormal at the time of administration?	
e) Based on the investigation was there an error in vaccine reconstitution/preparation by the vaccinator (e.g., wrong product, wrong diluent, improper mixing, improper syringe filling etc.)?	
f) Based on the investigation, was there an error in vaccine handling? (e.g. Break in cold chain during transport, storage and/or immunization session etc.)?	
g) Based on the investigation, was the vaccine administered incorrectly (e.g. wrong dose, site or route of administration, wrong needle size, not following good injection practice etc.)?	
h) Number of OTHER recipients immunized from the concerned vaccine vial/ampule	
i) Number of OTHER recipients immunized with the concerned vaccine in the same session:	
j) Number of OTHER recipients immunized with the concerned vaccine having the same batch number in other locations: _____ Specify locations: _____	
k) Is this case a part of a cluster?	
If yes, how many other cases have been detected in the cluster?	
a. Did all the cases in the cluster receive vaccine from the same vial?	
b. If No, Number of vials used in the cluster (enter details separately)	

VII. COMMUNITY INVESTIGATION

Any known similar events reported recently in the locality/community? ☐ YES ☐ NO ☐ UNK

a. If YES, Describe:

b. How many events/episodes?

Of those affected, how many are: Vaccinated _____ Not vaccinated _____ ☐ Unknown

Other significant findings in the community

VIII. CAUSALITY ASSESSMENT ☐ NAEFIC ☐ RAEFIC Date Classified: _____

- ☐ [A1] Vaccine product-related reaction
- ☐ [A2] Vaccine quality defect-related reaction
- ☐ [A3] Immunization error-related reaction
  - ☐ error in vaccine handling
  - ☐ error in vaccine prescribing or non-aherence to recommendations for use
  - ☐ error in administration
  - ☐ Other, specify _____
- ☐ [A4] Immunization anxiety-related reaction
- ☐ [B1] Consistent temporal relationship but insufficient evidence
- ☐ [B2] Conflicting trends of consistency and inconsistency with causality
- ☐ [C1] Co-incidental - Underlying emerging condition (s) or exposure to external factors/something other than vaccine
- ☐ [D] Unclassifiable/Inadequate information