Philippine Integrated Disease Surveillance and Response

Case Investigation Form

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

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.

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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 : ○Recovering ○ Fully recovered ○With 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

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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 _____ ºC Freezer: _____ ºC		
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:		

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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