AEFI INVESTIGATION FORM

(Only for Serious Adverse Events Following Immunization Death / Disability / Hospitalization / Cluster)

Section A : Basic details

Province/State: District: Case ID: **541306**

Place of vaccination:
Vaccination in:

Address of vaccination site:

Name of Reporting Officer	
Designation / Position:	
Telephone # landline (with code)	
Mobile	
e-mail:	
Date of investigation	
Date of filling this form	
This report is:	

Patient Name : Sex:
Date of birth:
OR Age at onset: years months days
OR Age group:
Patient's full address with landmarks (Street name, house number, locality, phone number etc.):

Name of vaccines/diluent received by patient	Date of vaccination	Time of vaccination	Dose (e.g. 1st, 2nd, etc.)	Batch/Lot number	Expiry date

Type of site : Other:
Date of first/key symptom: Time of first symptom (hh/mm):
Date of hospitalization:
Date first reported to the health authority:
Status on the date of investigation:
If died, date and time of death: (hh/mm):
Autopsy done?:

Section B : Relevant patient information prior to immunization

Criteria	Finding	Remarks (If yes provide details)
Past history of similar event		
Adverse event after previous vaccination(s)		
History of allergy to vaccine, drug or food		
Pre-existing illness (30 days) / congenital disorder		
History of hospitalization in last 30 days, with cause		
Patient currently on concomitant medication? If yes, name the drug, indication, doses & treatment dates)		
Family history of any disease (relevant to AEFI) or allergy		

For Adult women
Currently pregnant? :
Currently breastfeeding? :

For infants
The birth was :
Birth weight :
Delivery procedure was :

Section C : Details of first examination** of serious AEFI case

Source of information :

If from verbal autopsy, please mention source:

Name of the person who first examined/treated the patient:

Name of other persons treating the patient:

Other sources who provided information (specify):

Signs and symptoms in chronological order from the time of vaccination:

Name and contact information of person completing these clinical details	**Designation**	**Date/time**

****Instructions – Attach copies of ALL available documents (including case sheet, discharge summary, case notes, laboratory reports and autopsy reports) and then complete additional information NOT AVAILABLE in existing documents, i.e.**

- **If patient has received medical care -**
  Attach copies of all available documents (including case sheet, discharge summary, laboratory reports and autopsy reports, if available) and write only the information that is not available in the attached documents below
- **If patient has not received medical care –**
  obtain history, examine the patient and write down your findings below (addadditional sheets if necessary)

Section D : Details of vaccines provided at the site linked to AEFI on the corresponding day

Number immunized for each antigen at session site. Attach record if available.	Vaccine name									
	Number of doses									

a) When was the patient immunized?

In case of multidose vials, was the vaccine given

b) Was there an error in prescribing or non-adherence to recommendations for use of this vaccine?	
c) Based on your investigation, do you feel that the vaccine (ingredients) administered could have been unsterile?	
d) Based on your investigation, do you feel that the vaccine's physical condition (e.g. colour, turbidity, foreign substances etc.) was abnormal at the time of administration?	
e) Based on your investigation, do you feel that there was an error in vaccine reconstitution/preparation by the vaccinator (e.g. wrong product, wrong diluent, improper mixing, improper syringe filling etc.)?	
f) Based on your investigation, do you feel that there was an error in vaccine handling (e.g. break in cold chain during transport, storage and/or immunization session etc.)?	
g) Based on your investigation, do you feel that the vaccine was administered incorrectly (e.g. wrong dose, site or route of administration, wrong needle size, not following good injection practice etc.)?	
h) Number immunized from the concerned vaccine vialampoule	
i) Number immunized with the concerned vaccine in the same session	
j) Number immunized with the concerned vaccine having the same batch number in other locations. Specify locations:	
k) Is this case a part of a cluster?	
i. 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)	

***It is compulsory for you to provide explanations for these answers separately**

Section E : Immunization practices at the place(s) where concerned vaccine was used (Complete this section by asking and/or observing practice)

Are AD syringes used for immunization? :

If no, specify the type of syringes used:

Specific key findings/additional observations and comments:

Reconstitution: (complete only if applicable, √ NA if not applicable)

Reconstitution procedure (√)	**Status**
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 the same as those recommended by the manufacturer?	

Specific key findings/additional observations and comments:

Section F : Cold chain and transport
(Complete this section by asking and/or observing practice)

Last vaccine storage point	**Status**
Is the temperature of the vaccine storage refrigerator monitored?	
If “yes”, was there any deviation outside of 2-8° C after the vaccine was placed inside?	
If “yes”, provide details of monitoring separately	
Was the correct procedure for storing vaccines, diluents and syringes followed?	
Was any other item (other than EPI vaccines and diluents) in the refrigerator or freezer?	
Were any partially used reconstituted vaccines in the refrigerator?	
Were any unusable vaccines (expired, no label,	

VVM at stages 3 or 4, frozen) in the refrigerator?	
Were any unusable diluents (expired, manufacturer not matched, cracked, dirty ampoule) in the store?	

Specific key findings/additional observations and comments:

Vaccine transportation	**Status**
Type of vaccine carrier used	
Was the vaccine carrier sent to the site on the same day as vaccination?	
Was the vaccine carrier returned from the site on the same day as vaccination?	
Was a conditioned ice-pack used?	

Specific key findings/additional observations and comments:

Section G - Community investigation (Please visit locality and interview parents/others)

Were any similar events reported within a time period similar to when the adverse event occurred and in the same locality?

If yes, describe:

If yes, how many events/episodes?

Of those effected, how many are
Vaccinated :
Not Vaccinated :
Unknown :

Other comments:

Section H - Other findings/observations/comments

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