

**ONLY for Serious and Severe Adverse Events Following Immunisation, Clusters and Adverse Events of Special Interest**

**SECTION A: BASIC DETAILS**

Province: \_\_\_\_\_ EPID No: 

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District: \_\_\_\_\_ Country - Province - District - Year - Case no.

**NB: The EPID number must be IDENTICAL to the number on the CASE REPORTING FORM**

**PATIENT IDENTIFICATION**

**NOTE: In maternal vaccination, if mother and baby / more than one baby are affected, complete separate form for each affected individual**

Vaccine recipient name & surname: \_\_\_\_\_ **Note: Use a separate form for each case in a cluster**

Sex:  M  F  Other

Date of birth: DD/MM/YYYY **OR** Age at onset:  Years  Months  Days

**OR** Age group:  0 - <1 year  1 - 5 years  >5 – 18 years  >18 – 60 years  >60 years

Patient's full residential address with landmarks (Street name, house number, locality, etc.):  
\_\_\_\_\_  
\_\_\_\_\_

Telephone no: \_\_\_\_\_ Mobile no: \_\_\_\_\_ E-mail: \_\_\_\_\_

**INVESTIGATOR'S DETAILS**

Name & surname of reporting officer: \_\_\_\_\_

Designation / Position: \_\_\_\_\_ E-mail: \_\_\_\_\_

Telephone: \_\_\_\_\_ Mobile: \_\_\_\_\_

Date of filling this form: DD/MM/YYYY

Date of investigation: DD/MM/YYYY **This report is:**  First  Interim  Final

**DETAILS OF THE EVENT**

Date of onset of event: DD/MM/YYYY Time of first symptom:  Hr  Min

Date first reported to the health authority: DD/MM/YYYY

Date of hospitalization (if applicable): DD/MM/YYYY Status on the date of investigation:  Died  Disabled  Recovering

Recovered completely

Recovered with complications  Unknown

If died, date of death: DD/MM/YYYY Time of death:  Hr  Min

Autopsy done:  Yes  No **If YES**, date of autopsy: DD/MM/YYYY Attach report (if available)

If **NO**, autopsy planned: Date: DD/MM/YYYY Time  Hr  Min

Autopsy NOT done nor planned. Provide reasons: \_\_\_\_\_  
\_\_\_\_\_

**IMMUNISATION HISTORY**

Name of vaccinator: \_\_\_\_\_ Designation: \_\_\_\_\_

Name of vaccination site: \_\_\_\_\_

Address of vaccination site: \_\_\_\_\_

Place of vaccination:  Govt. health facility  Private health facility  Other (specify) \_\_\_\_\_

Type of site:  Fixed  Mobile  Outreach

Vaccination in:  Campaign  Routine  Other (specify): \_\_\_\_\_

**TRIGGER EVENTS**

**Minor local reactions**

Swelling <5cm  Induration / hardness

Redness  Rash

Other (specify): \_\_\_\_\_  
\_\_\_\_\_  
\_\_\_\_\_

**Minor systemic reactions**

Excessive crying (infant)  Mild fever <38°C

Mild headache  Mild body aches

Mild pain (to touch / on movement, but not interfering with daily activities)  Fainting

Other (specify): \_\_\_\_\_  
\_\_\_\_\_

Patient name & surname: \_\_\_\_\_ EPID Number: \_\_\_\_\_

<p><b>Severe local reactions</b></p> <input type="checkbox"/> Pain, redness and/or swelling >3 days <input type="checkbox"/> Swelling >5cm <input type="checkbox"/> Swelling beyond nearest joint <input type="checkbox"/> Lymphadenitis <input type="checkbox"/> Abscess <input type="checkbox"/> Necrosis at vaccination site <input type="checkbox"/> Other (specify): _____ _____ _____	<p><b>Severe systemic reactions</b></p> <input type="checkbox"/> Hospitalisation <input type="checkbox"/> Fever ≥38°C <input type="checkbox"/> Seizures <input type="checkbox"/> Febrile <input type="checkbox"/> Afebrile <input type="checkbox"/> Toxic shock syndrome <input type="checkbox"/> Other (specify): _____ <b>Foetal adverse reactions in the case of maternal immunisation:</b> <input type="checkbox"/> Decreased FHR variability <input type="checkbox"/> Decreased foetal movement <input type="checkbox"/> Foetal death <input type="checkbox"/> Onset of preterm labour, assessed to be possibly/probably related <input type="checkbox"/> Foetal anomaly assessed to be possibly/probably related (e.g. congenital anomaly feasible with pre-pregnancy or 1 <sup>st</sup> trimester immunisation) <input type="checkbox"/> Foetus affected by maternal immunization (e.g. live vaccine administered to mother)
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**VACCINE INFORMATION (Attach copy of Road to Health Booklet or Vaccination Card)**  
**NOTE: In the case of a foetal adverse event, ALSO record the mother's maternal vaccination details**

Vaccine/s administered (Complete ONLY for alleged vaccine/s administered before the event)								Diluent (Where applicable)		
Vaccine/s given (Use trade names)	Date vaccinated	Time vaccinated	Dose number (1 <sup>st</sup> , 2 <sup>nd</sup> )	Batch/ Lot number	Expiry date / Manufacture date (COVID)	VVM Stage (If applies)	Manufacturer	Batch/ Lot number	Expiry date	Date & time of reconstitution

<b>Consumables used (unless pre-filled)</b>	<b>Needles</b>	Size: _____	Batch: _____	Expiry date: _____
	<b>Syringes</b>	Size: _____	Batch: _____	Expiry date: _____

**SECTION B: RELEVANT PATIENT INFORMATION PRIOR TO IMMUNISATION (Use additional sheet if needed)**  
**NOTE: In the case of a foetus/newborn potentially affected by maternal immunisation, complete questions below for mother. Where questions would apply to the foetus/newborn, please provide additional details in the space provided**

Questions applicable to the VACCINEE	Findings and Remarks *Compulsory to provide explanations			
Any history of similar event?	Yes*	No	Unknown	
Any previous reactions or adverse event after immunisation?	Yes*	No	Unknown	
Any history of allergies? (vaccine, food, drugs)	Yes*	No	Unknown	
Any family history of any allergies?	Yes*	No	Unknown	
Any family history of any disease/s (relevant to AEFI)?	Yes*	No	Unknown	
Pre-existing medical condition/ congenital disorder?	Yes*	No	Unknown	
Pre-existing acute illness (30 days) prior to vaccination?	Yes*	No	Unknown	
Suffering from any medical condition currently?	Yes*	No	Unknown	
History of hospitalisation in last 30 days, with cause?	Yes*	No	Unknown	
Tested COVID-19 positive prior to vaccination? Date?	Yes*	No	Unknown	
Receiving any concomitant medication? <i>If yes, name the drug, indication, doses and treatment dates.</i>	Yes*	No	Unknown	
Receiving any herbal and/or traditional medicines? <i>If yes, name the drug, indication, doses and treatment dates.</i>	Yes*	No	Unknown	

**For adult women:** Currently pregnant:  Yes (weeks) \_\_\_\_\_  No  Unknown  
 Currently breastfeeding:  Yes  No

**For infants:** Gestation:  Full-term  Premature  Post-term Birth weight: \_\_\_\_\_  
 Delivery procedure:  Normal  Caesarean  Assisted (forceps, vacuum, etc.)  
 With complications (Specify): \_\_\_\_\_

Patient name & surname: \_\_\_\_\_ EPID Number: \_\_\_\_\_

**SECTION C: DETAILS OF FIRST EXAMINATION\*\* OF SERIOUS/SEVERE AEFI CASE**

Source of information (Tick (✓) all that apply):  Examination by the investigator  Documents  
 Verbal autopsy (Please mention source): \_\_\_\_\_  
 Other (Specify): \_\_\_\_\_  
 Name & surname of the person who first examined/treated the patient: \_\_\_\_\_  
 Name & surname of other persons treating the patient: \_\_\_\_\_  
 \_\_\_\_\_  
 Other sources who provided information (specify): \_\_\_\_\_  
 \_\_\_\_\_

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

<b>Person completing the clinical details</b>	Name & Surname: _____	Date: <u>DD/MM/YYYY</u>
	Designation: _____	Time: <input type="checkbox"/> <input type="checkbox"/> Hr <input type="checkbox"/> <input type="checkbox"/> Min
	Contact: _____	

**\*\*Instructions: Attach copies of ALL available documents (including case reporting form, discharge summary, case notes, laboratory reports and autopsy reports, prescriptions for concomitant medication) 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). Provide only information not available in the attached documents below.
- **If patient has not received medical care:** Obtain history, examine the patient and record your findings below (add additional sheets if necessary)

\_\_\_\_\_  
 \_\_\_\_\_  
 \_\_\_\_\_  
 \_\_\_\_\_  
 \_\_\_\_\_  
 \_\_\_\_\_  
 \_\_\_\_\_  
 \_\_\_\_\_  
 \_\_\_\_\_  
 \_\_\_\_\_  
 \_\_\_\_\_

Provisional / Final diagnosis at the facility ("valid diagnosis"): \_\_\_\_\_

**SECTION D: DETAILS OF VACCINES PROVIDED AT THE SITE LINKED TO AEFI ON THE CORRESPONDING DAY**

Vaccinees immunised for each antigen at session site. Attach record if available.	Vaccine name						
		Number of vaccinees vaccinated per session					

- a) When was the patient immunised?  
 Within the first vaccinations of the session  Within the last vaccinations of the session  Unknown
- b) In case of multidose vials, when was the vaccine given?  Within the first few doses of the vial administered  Within the last doses of the vial administered  Unknown
- c) Time vial was opened:  Hr  Min

Patient name & surname: \_\_\_\_\_ EPID Number: \_\_\_\_\_

		Findings and Remarks *Compulsory to provide explanations		
d) Was there an error in prescribing or non-adherence to recommendations for use of this vaccine?	Yes*	No		
e) Based on your investigation, do you feel that the vaccine (ingredients) administered could have been unsterile?	Yes*	No	Unable to assess	
f) Based on your investigation, do you feel that the vaccine's physical condition (e.g. color, turbidity, foreign substances etc.) was abnormal at the time of administration?	Yes*	No	Unable to assess	
g) 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.)?	Yes*	No	Unable to assess	
h) 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 immunisation session etc.)?	Yes*	No	Unable to assess	
i) 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.)?	Yes*	No	Unable to assess	
j) Number immunised from the concerned vaccine vial/ampoule				
k) Number immunised with the concerned vaccine in the same session				
l) Number immunised with the concerned vaccine having the same batch number in other locations.	Specify locations:			
m) Could this event be a stress response related to immunisation (e.g. acute stress response, vasovagal reaction, hyperventilation, dissociative neurological symptom reaction etc.)?	Yes*	No	Unable to assess	
n) Is this case a part of a cluster?	Yes*	No	Unknown	
If <b>YES</b> , how many other cases have been detected in the cluster?				
Did all the cases in the cluster receive vaccine from the same vial?	Yes*	No	Unknown	
If <b>NO</b> , number of vials used in the cluster (enter details separately)				

**SECTION E: IMMUNISATION PRACTICES AT THE PLACE(S) WHERE CONCERNED VACCINE WAS USED**  
(Complete this section by asking and/or observing practice)

**Syringes and needles used**

Are AD syringes used for immunisation?  Yes  No  Unknown

If NO, specify the type of syringes used:

Glass  Disposable  Recycled disposable  Other: \_\_\_\_\_

Needle used: \_\_\_\_\_

Specific key findings/additional observations and comments: \_\_\_\_\_

\_\_\_\_\_  
\_\_\_\_\_  
\_\_\_\_\_

**Reconstitution procedure (complete only if applicable, ✓ NA if not applicable)**

**Status**

a) Same reconstitution syringe used for multiple vials of same vaccine?	Yes	No	NA
b) Same reconstitution syringe used for reconstituting different vaccines?	Yes	No	NA
c) Separate reconstitution syringe for each vaccine vial?	Yes	No	NA
d) Separate reconstitution syringe for each vaccination?	Yes	No	NA
e) Are vaccines and diluents used the same as those recommended by the manufacturer?	Yes	No	NA

Specific key findings/additional observations and comments: \_\_\_\_\_  
\_\_\_\_\_  
\_\_\_\_\_

Patient name & surname: \_\_\_\_\_ EPID Number: \_\_\_\_\_

Injection technique of vaccinator(s) (Observe another session in the same locality)	Status		
	Yes	No	NA
a) Correct dose and route?	Yes	No	NA
b) Time of reconstitution mentioned on the vial? (in case of freeze dried vaccines)	Yes	No	NA
c) Non-touch technique followed?	Yes	No	NA
d) Contraindications screened prior to vaccination?	Yes	No	NA
e) How many AEFI were reported from the centre that distributed the vaccine in the last 30 days?	Yes	No	NA
f) Training received by the vaccinator? If Yes, specify date of last training DD / MM / YYYY	Yes	No	NA
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	Findings and Remarks			
	*Compulsory to provide explanations			
a) Is the temperature of the vaccine storage refrigerator monitored?	Yes	No*		
i) If YES, was there any deviation outside of 2–8°C after the vaccine was placed inside?	Yes*	No		
ii) If YES, provide details and evidence of monitoring separately.				
b) Was the <u>incorrect</u> procedure followed for storing vaccines, diluents and syringes followed?	Yes*	No	Unknown	
c) Was any other item (other than vaccines and diluents) in the refrigerator or freezer?	Yes*	No	Unknown	
d) Were any partially used reconstituted vaccines in the refrigerator?	Yes*	No	Unknown	
e) Were any unusable vaccines (expired, no label, VVM at stages 3 or 4, frozen) in the refrigerator?	Yes*	No	Unknown	
f) Were any unusable diluents (expired, manufacturer not matched, cracked, dirty ampoule) in the store?	Yes*	No	Unknown	
Specific key findings/additional observations and comments:				
_____				
_____				
_____				

Vaccine transportation	Findings and Remarks			
	*Compulsory to provide explanations			
a) Specify the type of vaccine carrier used				
b) Was the vaccine carrier sent to the site on the same day as vaccination?	Yes	No*	Unknown	
c) Was the vaccine carrier returned from the site on the same day as vaccination?	Yes	No*	Unknown	
d) Was a conditioned ice-pack used?	Yes	No*	Unknown	
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?

Yes  No  Unknown

If YES, how many events/episodes? \_\_\_\_\_ If YES, please describe:

\_\_\_\_\_

\_\_\_\_\_

\_\_\_\_\_

