health
Department:
Health
REPUBLIC OF SOUTH AFRICA

CASE INVESTIGATION FORM (CIF) FOR ADVERSE EVENTS FOLLOWING IMMUNISATION (AEFI)

SECTION A: BASIC DETAILS

Province: _____ **EPID No:** S O A - | | | | - | | | | - | | | | - | | | |
District: _____ Country - Province - District - Year - Case no.

NB: THE EPID NUMBER MUST BE IDENTICAL TO THE CASE REPORTING FORM

PATIENT IDENTIFICATION

Patient name & surname: _____ Sex: ☐ M ☐ F

(use a separate form for each case in a cluster)

Date of birth (DD/MM/YYYY):__ __ / __ __ / __ __ __ __ **OR** Age at onset: __ __ years __ __ months __ __ __ days

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

_____

_____

Telephone: _____ 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): __ __ / __ __ / __ __ __ __

DETAILS OF THE EVENT

Date of onset of event (DD/MM/YYYY): __ __ / __ __ / __ __ __ __Time of first symptom (hh/mm): __ __ / __ _

Date of hospitalization (if applicable) (DD/MM/YYYY): __ __ / __ __ / __ __ __ __

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

TRIGGER EVENTS

Adverse event (s): (Tick (✓) all boxes that apply)

Minor reactions

- ☐ Swelling <5cm
- ☐ Redness
- ☐ Rash
- ☐ Excessive crying
- ☐ Fever <38°C
- ☐ Other (specify):

_____

_____

_____

Severe local reactions

- ☐ Pain, redness and/or swelling of more than 3 days duration
- ☐ Swelling >5cm
- ☐ Swelling beyond nearest joint
- ☐ Lymphadenitis
- ☐ Abscess
- ☐ Other (specify):

_____

_____

_____

Systemic reactions

- ☐ Hospitalization
- ☐ Death
- ☐ Anaphylaxis
- ☐ Fever ≥38°C
- ☐ Encephalopathy
- ☐ Collapse / shock-like state
- ☐ Seizures ☐ Febrile ☐ Afebrile
- ☐ Intussusception
- ☐ Diarrhoea
- ☐ Vomiting
- ☐ Toxic shock syndrome
- ☐ Thrombocytopenia
- ☐ Sepsis
- ☐ Other (specify): _____

Severe or Serious Adverse Event: Case to be investigated within 7 days after Reporting; notify provincial and national offices immediately

Status on the date of investigation: ☐ Died ☐ Disabled ☐ Recovering ☐ Recovered completely ☐ Recovered with complications ☐ Unknown

If died, date and time of death (DD/MM/YYYY): __ __ / __ __ / __ __ __ __ (hh/mm): __ __ / __ __

Autopsy done: ☐ Date (DD/MM/YYYY): __ __ / __ __ / __ __ __ __ Attach report (if available)

Autopsy planned: ☐ Date (DD/MM/YYYY): __ __ / __ __ / __ __ __ __ Time (hh/mm):__ __ / __ __

Patient name & surname: _____ EPID Number: _____

Autopsy NOT done: ☐ Reasons for not: _____

_____

_____

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: _____

SECTION B: VACCINE INFORMATION (Please attach a copy of the Road to Heath Booklet (RTHB))

Health facility (or vaccination center) name: _____

Vaccine/s administered *(Complete this section only for alleged vaccines /vaccines that were administered before the event)*								**Diluent** *(Where applicable)*		
***Vaccines given** (Use trade names)	***Date of vaccination**	***Time of vaccination**	**Dose number** (e.g. 1st, 2nd, 3rd)	***Batch/ Lot number**	**Expiry date**	***VVM Stage** (If applies)	***Manufacturer**	***Batch/ Lot number**	**Expiry date**	**Date and time of reconstitution**

SECTION C: RELEVANT PATIENT INFORMATION PRIOR TO IMMUNISATION

	Finding			**Remarks (If yes please specify. Use additional sheet if needed)**
Has the child had any history of similar event?	Yes	No	Unk	
Has the child had any previous reactions after immunisation?	Yes	No	Unk	
Has the child had any history of allergies? (vaccine, food, drugs)	Yes	No	Unk	
Is there a family history of any allergies?	Yes	No	Unk	
Is there a family history of any diseases or allergies?	Yes	No	Unk	
Has the child suffered from any medical condition/ congenital disorder in the past?	Yes	No	Unk	
Is the child suffering from any medical condition currently?	Yes	No	Unk	
Is the child on any medication? ***If yes, name the drug, indication, doses and treatment dates.***	Yes	No	Unk	
Has the child received any herbal and/or traditional medicines? ***If yes, name the drug, indication, doses and treatment dates.***	Yes	No	Unk	

Patient name & surname: _____ EPID Number: _____

For adult women

Currently pregnant: ☐ Yes (weeks) _____ ☐ No ☐ Unknown

Currently breastfeeding: ☐ Yes ☐ No

For infants

The birth was: ☐ Full-term ☐ Pre-term ☐ Post-term Birth weight: _____

Delivery procedure was: ☐ Normal ☐ Caesarean ☐ Assisted (forceps, vacuum, etc.)

☐ With complications (Specify): _____

SECTION D: DETAILS OF FIRST EXAMINATION** OF SERIOUS AEFI CASE

Source of information *(Tick (✓) all that apply*): ☐ Examination by the investigator ☐ Documents

☐ Verbal autopsy (P*lease 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 in chronological order from the time of vaccination:

_____

_____

_____

_____

_____

_____

_____

_____

***Instructions:* Attach copies of ALL available documents (including case reporting form, 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 (add additional sheets if necessary)

_____

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

SECTION E: DETAILS OF VACCINES PROVIDED AT THE SITE LINKED TO AEFI ON THE CORRESPONDING DAY							
Number of children immunised for each antigen at session site. Attach record if available.	Vaccine name						
	Number of children vaccinated per session						

Instructions: Tick (✓) the ☐ and respond to ALL questions below.
*It is compulsory for you to provide explanations for all YES answers separately.

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

	Finding			Remarks
c) Was there an error in prescribing or non-adherence to recommendations for use of this vaccine?	Yes*	No		
d) Based on your investigation, do you feel that the vaccine (ingredients) administered could have been unsterile?	Yes*	No	Unable to assess	
e) 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	
f) 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	
g) 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	
h) 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	

i) Number immunised from the concerned vaccine vial/ampoule				
j) Number immunised with the concerned vaccine in the same session				
k) Number immunised with the concerned vaccine having the same batch number in other locations. Specify locations: _____				
l) Is this case a part of a cluster?	Yes*	No	Unknown	
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?	Yes*	No	Unknown	
b. If no, number of vials used in the cluster (enter details separately)				

SECTION F: 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: _____

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:

_____

_____

SECTION G: COLD CHAIN AND TRANSPORT (Complete this section by asking and/or observing practice)

Last vaccine storage point	**Finding**			**Remarks**
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 of monitoring separately.				
b) Was the correct procedure for storing vaccines, diluents and syringes followed?	Yes	No	Unknown	
c) Was any other item (other than EPI 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	**Finding**			**Remarks**
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 H: 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, describe:

_____

_____

_____

_____

_____

_____

Number of caregivers interviewed: _____

If YES, how many events/episodes? _____

Of those affected, how many are

- Vaccinated: _____
- Not vaccinated: _____
- Unknown: _____

Other comments:

_____

_____

_____

_____

_____

SECTION I: OTHER FINDINGS/OBSERVATIONS/COMMENTS (Use additional sheet if required)

SECTION J: DETAILS OF CASE INVESTIGATION TEAM

Signed off by District EPI Coordinator

Name & surname: _____ Signature: _____
Date (DD/MM/YYYY): __ __ / __ __ / __ __ __ __

Signed off by Appointed District Medical Officer/Specialist

Name & surname: _____ Signature: _____
Date (DD/MM/YYYY): __ __ / __ __ / __ __ __ __