ADVERSE EVENTS FOLLOWING IMMUNIZATION (AEFI) CASE INVESTIGATION FORM

EPIDEMIOLOGY UNIT, MINISTRY OF HEALTH

The MOH should do the investigation personally. Necessary data should be obtained from the parents / patient / hospital by reference to the BHT / physician or from the diagnosis card. Early investigation and return is essential.

A. PARTICULARS OF PATIENT (Please (✓) appropriate box where applicable)

1. Name of patient (IN BLOCK LETTERS) :

2. Residential Address :

3. Date of Birth : ☐☐ / ☐☐ / ☐☐

4. Age	5. Sex	6. Ethnic group	7. RDHS Division	8. MOH area
☐☐/☐☐ y y / m m	☐ 1. Male ☐ 2. Female ☐ 3. Unknown	☐ 1. Sinhalese ☐ 2. Tamil ☐ 3. Moor ☐ 4. Others ☐ 5. Unknown	..... ☐☐	..... ☐☐

B. PRESENT ILLNESS / OUTCOME

09. What is the AEFI reported?	12. Was patient admitted to hospital ?	17. Outcome of the case
..... 10. Date of onset : ☐☐/☐☐/☐☐ d d m m y y 11. Where was the patient treated? ☐ 1. Govt. hospital ☐ 2. Pvt. hosp/practitioner ☐ 3. Other (specify)	1. Yes ☐ 2. No ☐ 3. Unknown ☐ 13. If yes, date of admission : ☐☐/☐☐/☐☐ d d m m y y 14. Name of hospital ..... 15. Ward : ..... 16. BHT No:	1. Cured ☐ 2. Died ☐ 3. Unknown ☐ 18. Date of discharge, transfer or death ☐☐/☐☐/☐☐ d d m m y y 19. If transferred name of hospital .....

C. CLINICAL DATA

(Case definition: An adverse event following immunization is any untoward medical occurrence which follows immunization and which does not necessarily have a causal relationship with the usage of the vaccine)

20. Symptoms and signs	21. Date of onset	22. Laboratory investigations	23. Treatment
☐ 1. Fever ☐ 2. Inconsolable cry ☐ 3. Painful swelling at the injection site ☐ 4. Enlarged tender axillary lymph nodes ☐ 5. Convulsions ☐ 6. Altered sensorium Any other symptoms and signs	☐☐/☐☐/☐☐☐☐ ☐☐/☐☐/☐☐☐☐ ☐☐/☐☐/☐☐☐☐ ☐☐/☐☐/☐☐☐☐ ☐☐/☐☐/☐☐☐☐ ☐☐/☐☐/☐☐☐☐ d d m m yyyy	....	....

D. PAST MEDICAL AND FAMILY HISTORY

		Yes	No	Unknown	If yes (specify) No. and place
24.	Existing congenital disorders	☐	☐	☐	.....
25.	Persisting underlying disease	☐	☐	☐	.....
26.	Previous history of significant illnesses	☐	☐	☐	.....
27.	Family history of similar event	☐	☐	☐	.....
28.	Previous history of similar event	☐	☐	☐	.....

E. OTHER RELEVANT HISTORY

		Yes	No	Specify
(i)	Delays in taking the patient to the hospital	☐	☐	.....
(ii)	Delays in transferring patient to another hospital for specialized treatment	☐	☐	.....
(iii)	Delays in receiving treatment	☐	☐	.....

F. IMMUNIZATION HISTORY

29. Date and time of immunization ☐☐/☐☐/☐☐☐☐ (dd/mm/yy) Time:☐☐.☐☐

30. Place of immunization MOH clinic ☐ Government Hospital ☐
School ☐ Private Clinic ☐ Any other.....

31. Designation of the vaccinator
MOH ☐ PHNS ☐ PHM ☐
RMO ☐ PHI ☐ MO ☐ Others .....

32. Type of vaccine (Pleas ✓ appropriate box)	33. Dose	34. Expiry Date Please indicate the Vaccine No. on the dotted line from the Question 32	34. Batch No.	35. Manufacture	36 Diluents Batch No & Expiry date
☐ BCG ☐ OPV ☐ Penta ☐ MMR ☐ MR ☐ DPT ☐ DT ☐ aTd ☐ TT ☐ Hep B ☐ JE ☐ Influenza ☐ Others (specify)	☐ 1st ☐ 2nd ☐ 3rd ☐ 4th ☐ 5th	Vaccine ..... ☐☐/☐☐/☐☐ Vaccine ..... ☐☐/☐☐/☐☐ Vaccine ..... ☐☐/☐☐/☐☐ Vaccine ..... ☐☐/☐☐/☐☐ Vaccine ..... ☐☐/☐☐/☐☐ d d / m m / y y	....	....	

G. INFORMATION ON COLD CHAIN / STORAGE / VACCINATION TECHNIQUE

37. Vaccine and diluents stored in the	38. Vaccines transported in a	39. Status of the data lodger for 1 month period prior to the date of immunization.	40. Failure to maintain cold chain as indicated in the
☐1. MOH office ☐2. Clinic ☐3. Others ☐Specify	☐ 1. Vaccine flask or vaccine carrier ☐ 2. Cold box ☐ 3. Others (Specify)	Maximum temperature ..... Minimum temperature	40.1 VVM; Stage..... ☐. 40.2 Thermometer at the Main Compartment of refrigerator ☐

At the time of observation of the immunization	Satisfactory	Unsatisfactory	Not observed
41. Maintenance of Cold Chain			
1. Packing of vaccine	☐	☐	☐
2. Maintenance of cold chain in unopened/opened vials during immunization	☐	☐	☐
42. Vaccination procedure			
1. Reconstitution	☐	☐	☐
2. Drawing of vaccine	☐	☐	☐
3. Injection technique	☐	☐	☐
43. Please ✓ the appropriate box Reusable ☐ Disposable ☐ AD syringes ☐			

H. AEFI IN THE CLINIC CENTRE / FIELD

Any history of similar events reported among those vaccinated

44.	At the same clinic session	☐	☐	☐
45.	Using same vaccine at previous clinic sessions at the same clinic centre	☐	☐	☐
46.	Using same vaccine at the other clinic centers	☐	☐	☐
47.	History of similar events reported among those unimmunized (in the Field/Community)	☐	☐	☐

I. CONCLUSION AS TO THE CAUSE OF AEFI

Immunization errors related reaction Event caused by an error in vaccine preparation handling or administration	**Vaccine product related reaction** Event caused by the inherent properties of the vaccine	**Vaccine quality defect related reaction** Event caused due to quality defects of the vaccine product	**Immunization anxiety related reaction** Event from anxiety about or pain from the injection itself rather than the vaccine	**Coincidental events** Event that happens after immunization but not caused by the vaccine – a chance association	**Unknown**
If possible. describe the cause in below given area					

Corrective action taken:……

……

Remarks:……

……

Signature : ..... Name : .....Date : ..... Designation : .....

Please return to: Epidemiology Unit, 231, De Seram Place, Colombo 10. email: epidunit@sltnet.lk Tel : 011-2695112 / 2681548 Fax : 011-2696583