Adverse events following immunization- Reporting Forms

FIRST INFORMATION REPORT FORM

First Information Report

Adverse Events Following Immunization

(To be reported within 48 hrs to the GoI)

State	District
Block	Date of report
Name	
Age (DOB)	Sex: Male/ Female
Mother's / Father's Name	
Complete Address of the case	
Date & time of vaccination	Date & time of onset of symptoms
Complete address of place of vaccination	
Vaccines given	
Batch Number & Expiry date of each vaccine	
Type of reaction	
Date of Death	
Any other comment[1]	

Name of person filling the report

Signature and Designation

PRELIMINARY INVESTIGATION REPORT FORM

PRELIMINARY INVESTIGATION REPORT
Adverse Events Following Immunization

(To be reported within 7 DAYS to the GoI)

State	District
Block	Date of report
Name:	
Age (DOB):	Sex: Male/ Female
Mother's / Father's Name	
Complete Address of the case	
Date & time of vaccination	Date & time of onset of symptoms
Vaccines given	
Complete address of place of vaccination	
Batch Number & Expiry date of each vaccine	
Type of reaction	
Date of Death	
Probable cause of death:	
Probable cause of the AE: Programme error/ Vaccine reaction/ Coincidental/ Unknown	
Further action planned: Yes/ No (if Yes Details)	
Any other comment	

Name of person filling the report

Signature and Designation

DETAILED INVESTIGATION REPORT FORM

DETAILED INVESTIGATION REPORT

Adverse Events Following Immunization (AEFI)

(To be reported within three months)

Adverse event following Immunization or Death after Immunization

Date of Investigation: Case ID No.: IND (AEFI)/_ _ /_ _ _ /_ _ / _ _ _ Use same coding as done for AFP cases

1	Name of child affected (In Block Letters)	
2	Name of Parents	Father's name Mother's name
3	Age and Sex	— —/— —/— — Date of Birth Male/ Female yrsmo days (if know)
4	Full detailed address	
5	Place of immunization	Health facility/ Out reach session site/Field camp/ Hospital/ Maternity home/ Private clinic/ any other place
6	a. Date and time of immunization	
	b. Location of immunization session (Full address)	
7	No. of children immunized at the session	BCG___ DPT1___ DPT2___ DPT3___ DPT B___ OPV1___ OPV2___ OPV3___ OPV B___ HEPB 1___ HEPB 2___ HEPB 3___ MEASLES___ DT___ TT1___ TT2___ TT B___ VIT A___ OTHERS___
8	Date and time of onset of	
9	AEFI Date of Initial report	

9	Type of AEFI	
10	Was the patient admitted to hospital	Yes/ No/ Unknown
11	If Yes, date & Time of admission	
	Name of Hospital	
	Ward no	
	Centralized admission number	
	Outcome	Recovered/ still in hospital/ death/ unknown/ Residual problem
12	SYMPTOMS AND SIGNS	
	a. Time of onset	
	b. Sign of shock present/absent	
	c. Temperature	
	d. Pulse	
	e. Respiration	
	f. Convulsion	
	g. Vomiting	
	h. Diarrhoea	
	i. Altered sensorium	
	j. Rash	
	k. Any other symptoms & sign (pl specify)	
	l. Progress of symptoms and signs with brief history & chain of events (Please attach additional sheet if required or patient records if available)	

	m. Mention whether above sign and symptoms are seen by investigating officer or whether above sign and symptoms are noted from hospital record	
13	Treatment given (attach copy of case sheet, if available)	
14	GROWTH & DEVELOPMENT/PAST/ FAMILY HISTORY (please fill as relevant to case)	
	a. Type of Delivery	Normal delivery/ LSCS/ Assisted birth
	b. Gestation	Full term/Premature/Post dated
	c. Complications during birth	
	d. Birth weight (if possible)	
	e. Present Weight (if possible)	
	f. Present length/ height (if possible)	
	g. Present head circumference (if possible)	
	h. Developmental milestones	Gross motor
		Fine Motor
		Language
		Adaptive & Social
	i. Past illness like allergy, asthma, convulsion etc	
	j. Any previous history of similar event after immunization	Yes/ No/ Unknown
	k. Family history - history of epilepsy, allergy, asthma etc in the family	

	l. Any history of similar event in siblings	Yes/ No/ Unknown
	m. Was the child on any concurrent medication for any illness	Yes/ No/ Unknown If yes: Indication & Dosage
15	INFORMATION ON IMMUNIZATION (IN CASE PROGRAMME ERROR SUSPECTED)	
	a. Name of worker who administered vaccine	
	b. Designation	
	c. Length of service	
	d. Experience	
	e. When did worker receive the last training in immunization	
	f. Name of Health Assistant (Supervisor)	
	g. Designation	
	h. Length of service	
	i. Experience	
	j. When did Health Assistant (Supervisor) receive the last training in immunization	
16	k. Total number of mother and children immunized. Attached detailed list giving name/age/sex/vaccines given	
	l. Any history of similar event reported (among those vaccinated)	a. At same clinic: Yes/ No/ Unknown b. Using same vaccine type at previous clinic sessions: Yes/ No/ Unknown
	If Yes	Specify event Number Place

	m. Any history of similar event reported (among unimmunized)	a. At same clinic session: Yes/ No/ Unknown b. In the field: Yes/ No/ Unknown
	If Yes	Specify event Number Place
	n. At what stage was the index child immunized	a. Within the first few doses of the vial b. Within the last few doses of the vial c. Within the first vaccinations of the clinic session d. Within the last vaccinations of the clinic session e. Unknown
	o. Vaccination technique (observe the relevant vaccinator)	Reconstitution: Satisfactory/ Unsatisfactory/ Not observed
		Drawing of vaccine: Satisfactory/ Unsatisfactory/ Not observed
		Injection technique: Satisfactory/ Unsatisfactory/ Not observed
17	DETAILS OF VACCINE GIVEN PRIOR TO AEFI	
	a. Date of receipt of vaccine of implicated batch by	MoH/ State Regional Store District PHC/CHC/ Urban Health Center Sub center/ Out reach session site
	b. Status of maintenance of cold chain at	State
		Regional store
		District Head Quarter
		PHC/ Urban health post
		Subcenter
		Session Site
	c. Is there a suspicion of breach of cold chain as per records? (If so, when & where?)	

	m. Time of receipt of vaccine at field camp site (immunization session site)	
	n. Maintenance of cold chain during transit from Health Post/ PHC to field camp site	
	o. Name of person collecting vaccine from fixed centre to field camp site	
	p. Vaccines used	BCG/ DPT/ OPV/ Measles/ Hepatitis/ Vit A/ others (specify)
	q. If reconstituted, what diluent was used	
	r. Which type of syringe was used for reconstitution?	Reusable/ Disposable/ AD
	s. Practice of reconstitution	Same syringe used for multiple vials of same vaccine/ Same syringe used for reconstituting different vaccines/ Separate syringe for each vial/ Separate syringe for each vaccine
	t. Is the needle left in reconstituted vaccine vial	Yes/ No/ Not observed
	u. Whether label of vial intact i) Batch No ii) Expiry date iii) Manufactured by	
	v. Date and time when vial opened	
	w. Date of vaccine sent for testing	
	x. Result of sample of vaccine sent for testing	
	y. Is the vaccine collected by FDA or SRA	
	i) Name of the officer	
	ii) Date when vaccine sent for testing	

	iii) Place where vaccine sent for testing	
	iv) Result of vaccine sent for testing	
18	STERLISATION OF SYRINGE AND NEEDLE	
	a. Types of syringes used to vaccinate the child.	Reusable/ Disposable/ AD
	b. Method of sterilization if reusable syringes used	
	c. Name and Designation of person who was responsible for autoclaving/ boiling for 20 minutes	
	d. Date and time of autoclaving/ boiling started	
	e. Date and time of autoclaving/ boiling completed	
	f. Sterilization satisfaction as per records of Signolac strip register	
	g. No of syringes & needles autoclaved	
	h. No of syringes & needles used for the session.	
19	INVESTIGATIONS DONE	
	a. Whether any blood tests were done	
	b. If yes, results of blood tests	
	c. Whether CSF was examined	
	d. If yes, result of CSF tests	