

Format for Investigation of Sudden Unexpected Deaths Following Immunization

Part A	Background information
Part B	Investigation of the sequelae leading to death/Past History of the child
Part C	Investigation of the Hospital Management of the death
Part D	Investigation of the vaccine management and cold chain monitoring of the MOOH
Part E	Autopsy findings
Part F	Causal assessment of the death

Part A Background Information

1. Name of the child:-----

2. Date of Death: -----

3. Details of source of information

	Date	Informant/source
First notification to MOOH		
First notification to RE		
First notification to Epid Unit		

4. Information regarding the death investigators/investigation

Name & Designation Contact No.	Name & Designation Contact No.	Date(s) of investigation

Part B Investigation of the sequelae leading to death/Past History of the child

1. Identification and Related Basic Information

Name, address and contact no. of parent or guardian			
Date of Birth			
Age on the date of immunization			
Sex:			
Ethnic Group			
Gestational Age			
Birth Weight			
Weight at the time of immunization			
RDHS Division			
MOH Area			
Incriminated Vaccines			
Date of immunization		Time	
Time interval between immunization and death			

2. Clinical description/sequelae of the event as described by the mother

2.1 Assessment of the child prior to immunization

2.1.1 Feeding:-----

2.1.2 Activity:-----

2.1.3 Features suggestive of any acute illness (please specify)

2.2 Any Medication within 24 hours prior to immunization: Y/N If yes, please specify.

Drug	Dose/frequency	Last dose given at (time)_

2.3 Assessment of the child during immunization

2.3.1 Details of the immunization procedure

i. Incriminated vaccine/s:-----

ii. Place and time of immunization:-----

iii. Medication simultaneous with immunization: Y/N
If yes please specify

2.3.2 Post immunization observation (Any adverse events noted)

2.3.3 . Assessment of the child during post immunization period

i. Feeding:-----

ii. Activity:-----

iii. Urine output;-----

2.3.4 Description of significant adverse events noted by the mother following immunization

i.-----

ii.-----

2.3.5 Measures taken by the mother/guardian to overcome the above adverse event:

i. Traditional medication: Y/N(if yes please specify)

ii. Treatment at GP/ Govt. Hospital OPD/ Other : Y/N
if yes, please specify

- When was medical advise seek:-----
- medical advise provided/tentative diagnosis:-----
- medication prescribed/dose/frequency/how many doses given/when was last dosage

iii. Any other measures? (Please specify)-----

2.3.6. Out come of the above measures on observed adverse event (please specify)

2.4 Was the child hospitalized? YES /NO

If yes please specify details according to mother/guardian

2.5 Description of the final event according to the mother/guardian

	Date	Time	Person
When the child was last seen alive?			
When was child first seen unresponsive?			
When was child pronounced dead?			

2.5.1 Details of death confirmation:

2.5.2 If child had been asleep during death, please inquire following details

- i. Sleeping place:-----
- ii. Sleeping position-general:-----
- iii. Position child found dead/position during last sleep:-----

- iv. Other people who slept in the same place with the child:-----

3. Antenatal, and birth History

3.1. Antenatal Complications:-----

3.2. Natal period

Place of delivery: -----

Period of gestation:-----

Mode of delivery:-----

(if mode is other than normal vaginal delivery please mention the indication)

Birth weight:-----

Apgar at birth:-----

Any significant finding detected by neonatal examination

Any PBU admissions: Y/N

If yes, please specify details (Indication for admission, duration, management and Follow up visits, outcome of the child) & annex a copy of diagnosis/follow up notes

4. Dietary History

4.1. Duration of exclusive breast feeding:-----

4.2 Details of introduction to weaning foods:-----

4.3 Current diet (brief description):-----

4.4 Any identified food allergies:-----

5. Development History

Highest milestone developed at the time of death:

Gross motor	
Fine motor	
Hearing, Vision	
Social development	

6. Past medical problems of the child

6.1 Hospitalizations

Disease/disorder/Diagnosis	Duration of illness	Institution/Medical Personnel involved

(Please annex copies of diagnosis cards)

6.2. Underlying congenital /acquired diseases or disorders for which child was currently on treatment/follow up

Disease/disorder	Duration of illness	Institution/medical Personnel involved	Management

6.3. Past history of evidence of abuse/ harm/ neglect/ accidental injury/ previous need for child protection.

Injury	Period	Institution/medical Personnel involved	Management

7. Previous immunizations

Vaccine	Date of administration	Batch No.	Adverse events

8. Family History / Social History

8.1. Details of parents

	Mother	Father
Name		
Age		
Educational Level		
Occupation		
Income		
Smoking/alcohol use		

8.2. Details of other siblings

			Number	Age
Number of siblings	Elder	M		
		F		
	Younger	M		
		F		

8.2.1. Any neonatal deaths in the family :(YES/ NO)

If yes please mention details and cause of death

8.2.2. Any infant deaths in the family: (YES/NO)

If yes please mention details and cause of death

8.2.3. Deaths or any other medical problems/hospitalizations among other children:

e. Similar deaths among close genetic relatives: (YES/NO)

Part C	Details of the management of the case at medical institution
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1. Identification and Related Basic Information

Name of the Institution	
Date & time of admission	
Name & Designation of the admitting officer	
Name & Designation of the medical officer in charge of the subsequent follow-up	

2. Clinical description and examination findings as per medical records/by admitting officer and immediate management

3. Details of examination findings and subsequent management as per medical records

3.1. Examination findings

General Examination	
Cardiovascular system	
Respiratory system	
Abdomen	
Central Nervous system	
Pulse Oximeter reading	

3.2. Investigations:

	Investigation	Interpretation
Radiological		
Haematological		
Bio chemical		

3.3 Management

3.3.1 Pharmacological

3.3.2. Non-Pharmacological

3.3.3. Tentative diagnosis/identified problems

3.3.4 Details pertinent to resuscitation of the child

Part D Investigation of vaccine management and cold chain at MOH office

1. Information on vaccine/cold chain and vaccination technique

1. Details of the vaccine

Vaccine	Batch No.	Expiry date	Manufacturer

2 Details of vaccine administration

Anatomical site of immunization	
Needle length and gauge	
Route of Administration, dose	
number of children immunized at same clinic on same day	
number of children immunized with same vaccine at same clinic on same day	
Similar events with other children	

3 Details of cold chain monitoring

Was there a break down in cold chain since the receipt of incriminated stocks of vaccine at the MOH office according to the daily temperature record	
Was there a break down in cold chain since the receipt of incriminated stocks of vaccine at the MOH office according to the temperature data lodger	
Status of the VVM on the stocks of incriminated vaccines	

Part E	Autopsy findings
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1. Description of the autopsy

- 1.1 Autopsy performed: Y/N
- 1.2 Autopsy protocol used: Y/N
- 1.3 Offices involved in autopsy:

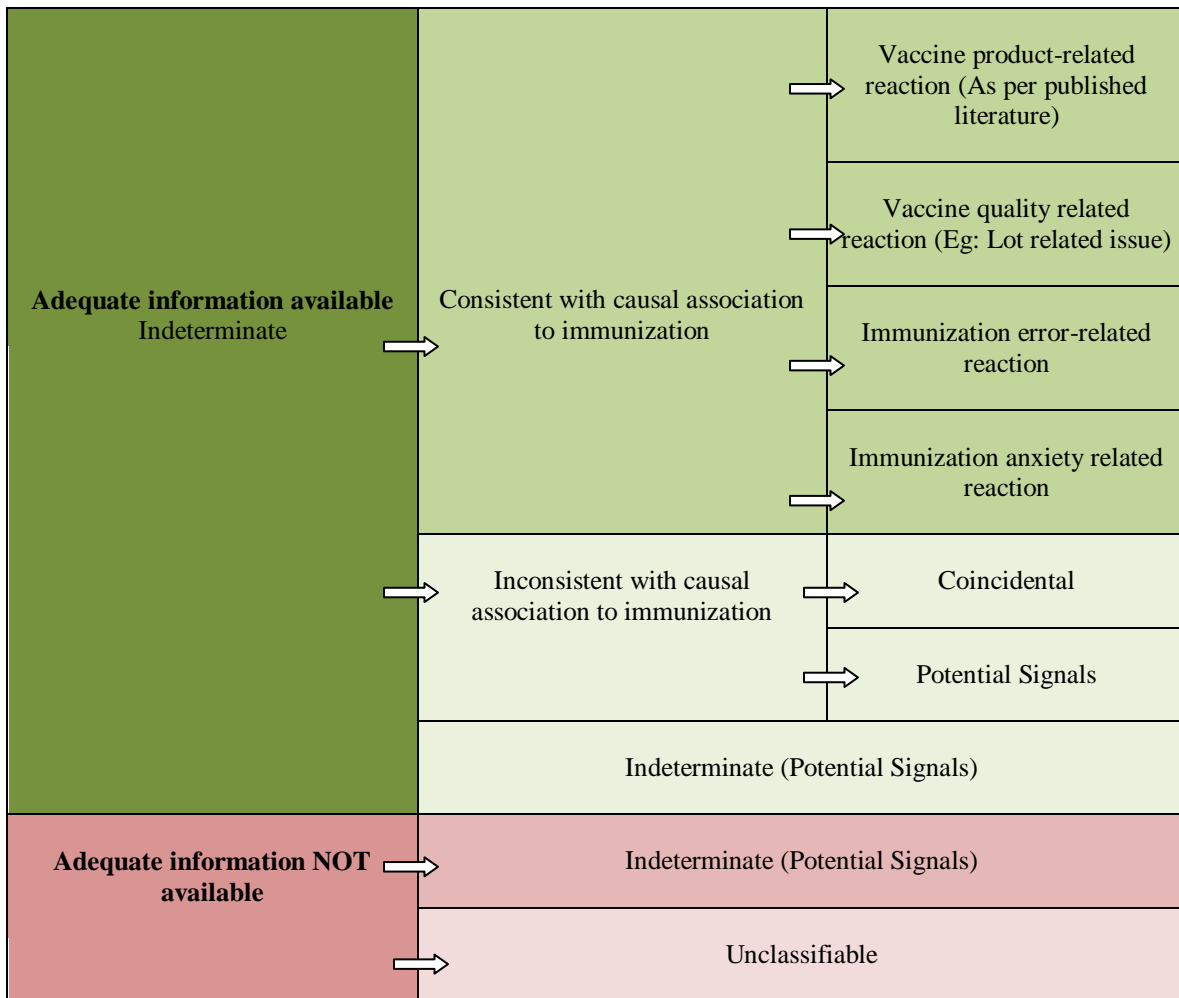
	Name/s	Designation	Institution
Medical officer conducted the autopsy			
Medical officer who conducted the histopathology Examination			
Other officers involved in death investigation(specify)			

1.4. Detailed description of autopsy findings

	Detailed description of autopsy findings
Gross pathology	
Histology	
Toxicology	
Microbiology	
Radiology	
Metabolic screening	
Biochemistry	
Other	

Part F Causality assessment by Expert Committee

Date of causality assessment by expert committee:-----



Conclusion: