

Government of India
Ministry of Health & family Welfare
(Immunization Division)

Standard Operating Procedures for the Ministry of Home affairs in case of Adverse Events following Immunization (AEFI)

The SOP provides a step by step guide to the police and other response agencies in addressing the issues of adverse events following immunization. The Standard Operating Procedures (SOP) is meant to help the investigator in carrying out professional investigation so as to ensure appropriate handling of the vaccine, victim assistance and timely and effective law enforcement:

1. Planning a proper handling of the vaccine and the diluent as an evidence with the assistance of other stakeholders

- The District Immunization Officer/ Medical Officer (PHC) and the police officer investigating the case may be involved in the collection of the vaccine/diluent sample from the site of occurrence of AEFI.
- The vaccine/diluent sample is to be preserved maintaining proper cold chain.

Packing of Samples:

- Separate plastic bags should be used for packing the partially used vaccine vial and diluents.
- The name, age, date of collection, AEFI epidemiology number and point of collection of vaccines/diluents need to be mentioned on the label of the plastic zipper bag. The zipper bag needs to be placed in a vaccine carrier with 4 conditioned ice packs.

Conditioning of ice packs: Icepacks come out of the freezer at -15°C to -25°C . If placed immediately inside carrier, freeze-sensitive vaccines may freeze accidentally.

- Keep at room temperature for a period of time to allow temperature at core of icepack to rise to 0°C (conditioning).
- Take out 4 frozen ice-packs from the freezer and close the door.
- Lay out on a table leaving a 5 cm space all round each icepack.
- Lay out icepacks, preferably in single row
- Check to see if ice inside the icepacks has begun to melt and some condensation or droplets of water appears and listen for sound of water.
- The ice packs need to be changed every 24 hours.

- The vaccine carrier needs to be kept in shade. The vaccine carrier should not be exposed to the sun or heat for a long time.
- The vaccine should not be removed from the vaccine carrier.
- The vaccine should not be frozen.

2. In case of an Adverse Event following immunization victim assistance and appropriate protection, care and attention to be provided to victims and witnesses

- The police officer/inspector and the medical officer/district immunization officer investigating the case shall ensure that all serious AEFI cases are provided immediate assistance (e.g. hospitalization, transport to medical facility).
- If postmortem examination of the case is required, the Department of Health shall provide the necessary assistance.

3. Documentation and transportation of sample to laboratory:

- The completed requisition form sealed with the same official stamp should accompany the samples sent to the laboratory. The official seal will ensure that the samples and details sent to the laboratory are not tampered/ changed during transportation.
- Vaccines and diluents are tested simultaneously; therefore freeze dried vaccine (BCG, Measles and JE) should be accompanied by their respective diluents.

4. Investigation/ Interrogation of the Vaccinator, if needed:

- One of the person who may need to be investigated/interrogated in case of serious AEFI is the vaccinator (ANM, Nurse, MPW, Alternate Vaccinator and others)
- The investigating officer along with the District Immunization officer (DIO)/ Medical Officer (PHC) may probe the vaccinator in order to gather adequate information which may enable the state to perform the casualty assessment. This will help in monitoring the immunization safety, detecting and responding to adverse events following immunization, correcting unsafe immunization practices, reducing the negative impact of the event on health and contributing to the quality of immunization activities.
- The Police while investigating the matter in case of serious AEFI, which had resulted in death, shall always keep the perspective that the event/incident might be just coincidental and/or reaction to the vaccine and it may not be the criminal negligence of the vaccinator and/or other workers for which causality assessment report by an expert, based on detailed lab investigation of the vaccine and associated material, is needed.

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- A copy of various investigations/reports generated on the AEFI, from PHC level to the State level may be collected by the Police Officer/Investigating Officer, from concerned health authorities of the district.