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IMMUNIZATION
TECHNICAL SUPPORT UNIT
Ministry of Health & Family Welfare

SPECIAL INVESTIGATION PROTOCOL FOR SERIOUS AEFIs

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This special investigation protocol is for use of officials nominated by the state or central government to investigate reported serious AEFIs. The report of the special investigation is an addition and not a substitute for regular AEFI investigation recorded and reported in Preliminary and Final Case Investigation Format (PCIF and FCIF) as per the National AEFI Guidelines.

1 INTRODUCTION

The ultimate goal of investigating an AEFI case is to arrive at a probable clinical diagnosis based on the chronology of medical events, detailed medical history and other evidences such as hospital records, post mortem reports, laboratory investigations, etc. A probable diagnosis will help in assessing any possible association with the immunization process (due to the vaccine itself or its handling /administration) when causally classifying the AEFI and to further undertake appropriate action.

This investigation protocol addresses the need for standardized specific processes to be followed while investigating reported AEFI cases. It will help to harness the capacity of investigators who are called in to conduct the investigation at short notice and to systematically investigate the cases according to national AEFI guidelines to reach logical conclusions in each case.

2 OBJECTIVES

The objective of the special investigation protocol is to quickly

1. Document the event and associated epidemiological factors affecting it and the final outcome.
2. Collect evidence from all possible sources to establish a probable clinical diagnosis of the event.
3. Use the probable clinical diagnosis of the event to identify the vaccine(s) administered which could have caused the event and to determine the timing between administration of the vaccine and the onset of the event.
4. Examine the operational aspects of the immunization programme pertaining to the event. Determine whether a reported event was a single incident or one of a cluster.
5. Determine whether similar events are occurring in individuals who have not received the same vaccine
6. Provide recommendations based on findings to prevent recurrence and to improve quality of the immunization programme.

What is the need for a special investigation?

A special investigation may be called for in cases where there is an urgency for information to be gathered and processed quickly for faster decision making and when the state or district requests for support in investigations. Some of the scenarios in which special investigations are called for are:

- Cluster events
- Media reports on AEFIs causing concern in the community
- Serious AEFIs of significant concern reported after new vaccine introduction
- Unusual events (on request of central/state/district)

3 PROTOCOL

3.1 Team formation for special investigation

- The special investigation of reported AEFI cases should be done by a team which comprises of at least one pediatrician/ clinician, an epidemiologist and a program person as well as a representative of the drug regulator.
- The investigating team members should be chosen preferably from amongst the members of the AEFI committee based on their area of expertise, training in AEFI surveillance and their availability at short notice.

- The investigating team will be formed as early as possible, but not later than within two working days of decision to investigate the case.
- The investigating team should preferably visit the district from which the AEFI was reported within 48 hours of team formation.
- The SEPIO and one or two members of the State AEFI Committee will also participate in the investigations conducted by the central team.

3.2 Preparation and planning for investigation

- The expenses of the special investigation team of the state will be met out of funds from Part C PIP under head "Trainings" (C.3) as per norms. The AEFI Secretariat will bear expenses of the central team.
- The State EPI Officer will coordinate with respective district health officials to ensure support during investigation of the AEFI by the team.
- Local health officials (BMO/CMHO/DIO) will be informed in advance by the SEPIO for facilitation of the investigation.

- Local health officials will facilitate interviews with local health workers / officials, affected beneficiaries, other beneficiaries, their relatives and visits to cold chain points, affected community / session site or any other place as requested by the team during the visit.
- For cluster cases – In cluster cases, a lot of documentation in the form of listing of affected beneficiaries, mapping of their location, etc. would be needed. This will require the support of local health officers and workers for preparing maps of area and line listing. Proper planning is needed to ensure arrangement of as many interviews as possible and interactions with patients/ officials/treating physician/community and field observation in available time.
- The investigating team must ask for the following logistics /documents to be collected and kept ready by the state / district to ensure systematic and high quality investigation in the shortest possible time:

Documents/records related to cases under investigation

1. Available filled reports (CRF, PCIF and FCIF)
2. Available records (hospital records, post-mortem reports, laboratory reports, physician notes / OPD / prescription records, etc.) of all affected persons
3. Map of area (village/block/district/state)
4. Newspaper cuttings of media reports, if any
5. Analysis of cases of previously reported AEFI cases from the same area (SEPIO office/AEFI Secretariat)
6. Analysis of similar events reported through IDSP from the same area (SEPIO office)

Logistics (facilitation by district health officials /AEFI secretariat)

1. Blank copies of verbal autopsy forms
2. Instruments for clinical examination such as stethoscopes, weighing machines, hammer, tape, torch, etc.
3. Camera
4. Voice recorder

Others

1. List of telephone numbers of local health official/ worker/ partner organizations
2. Locally used terms for reported event / vaccine /diseases.

3.3 Steps in Investigating AEFIs

AEFI investigation requires a sympathetic approach towards beneficiaries and relatives of deceased child/person. The aim of the investigation and benefits in terms of improving the immunisation system should be properly explained to parents and caregivers.

Efforts should be made to ensure that the community /parents do not link the investigation with issues of compensation.

Investigations should be planned and conducted in such a way as to cover the following:

1. Visit vaccination session site
2. Observe the session for quality of service delivery
3. Visit cold chain point and examine vaccine storage / transportation conditions
4. Collect and assess vaccination cards, due lists, tally sheets and other relevant records
5. Interview related health officers, treating physicians, ANM, ASHA and AWW, etc.
6. Interview patients/parents/caregivers
7. Examine the patient – see, touch and record vitals
8. Conduct epidemiological investigations
9. Collect samples and arrange to send for analysis
10. Conclude investigation
11. Prepare report

1 *Visit to site of immunization*

Try to observe a session site by the same vaccinator. The following observations should be made:

- Logistics arrangement at session site – Inflow and outflow of beneficiaries, waiting / observation area before and after vaccination, adequacy of space (table/chairs, etc.) for recording vaccine details, actual site of administration of vaccine, place for counselling of mothers
- Vaccine handling at the site - cold boxes, condition of ice packs and duration of exposure to ambient temperature.

- The condition of vaccine vial monitor, time and date of opening the vial, whether the vial was opened at the beginning or the end of the session.
- In case vials are being reused as per open vial policy, then look for date and time of opening and previous use of vial.

2 *On site observation*

Assess the service by observing it in action (cold chain management and injection safety practices)

- How vaccines are stored in the cold chain
- Whether other drugs are stored with vaccines/diluents
- Whether there are vials without labels
- Batch numbers and expiry dates of vaccines and diluents
- If any of the opened vials look contaminated
- If possible directly observe the immunization procedures (reconstitution, drawing vaccine in the syringe, injection technique, safe handling of needles and syringes; disposal of opened vials)
- Whether Open Vial Policy is being followed as per guidelines

3 *Cold chain & transport conditions*

Investigate and collect data about the SUSPECT VACCINE(S)

- Shipping conditions from manufacturer to the last storage point.
- Storage point conditions (refrigerator), documentation and transport to vaccination site.

4 *Immunization and other relevant records*

Review patient records for

- Immunization history
- Previous medical history, including prior history of similar reaction or other allergies
- Family history of similar events.

Investigate and collect data about the EVENT to record

- History of the event in chronological order to explore the underlying factors, if any
- Detailed clinical description including sequence of clinical manifestations and response to treatment
- Relevant laboratory tests and other investigations (e.g. X-ray, ECG, etc.) performed and their results

- Details of treatment and outcome

Ask for and examine relevant immunization records such as session site tally sheets, MCTS records & immunization register, vaccine indent form, stock registers and daily distribution registers, etc.)

Request for and examine any available monitoring reports/ tour reports related the particular vaccinator in the past year or two to get an idea of the quality of services provided by the vaccinator.

5 *Interviews with health officials, treating physicians, ANM and ASHA*

Interact with health officials, treating physicians, health workers and other staff to get details regarding patient/s, evolution of the event & subsequent management of patient and event. The objective of the interviews is to establish sequence of events from vaccine administration to occurrence and possible reason for the event.

During the interaction, assess the immunization service by making enquiries related to

- Dosage, person, site and technique
- Vaccine storage distribution and disposal
- Reconstitution procedure
- Time between reconstituting and administration
- Number/ type of immunizations and other medications given (e.g. Vit. A) at the site on the day

- Status of training of staff

In case of deaths in which post mortem has been done, ask for the preliminary post mortem report, if available.

6 *Interview of beneficiaries and caregivers:*

- Confirm immunization history, date and time of vaccination, date and time of event, clinical description of event, chronology of symptoms in order, action taken after occurrence of event and current health status.
- Previous medical history, including prior history of similar reaction or other allergies and family history of similar events
- In case it is possible, try to administer the verbal autopsy format in death cases in which there are no clinical records and post mortem was not done

7 *Examine the patient-see/touch/ record vitals*

- Through clinical examination of patient
- Examination of site of injection
- Assessment for presence of any underlying systemic disorder e.g. congenital heart disease
- Assessment of nutritional status (height, weight and signs of malnutrition)

8 *Epidemiological investigation*

Investigate and collect data about OTHER PERSONS

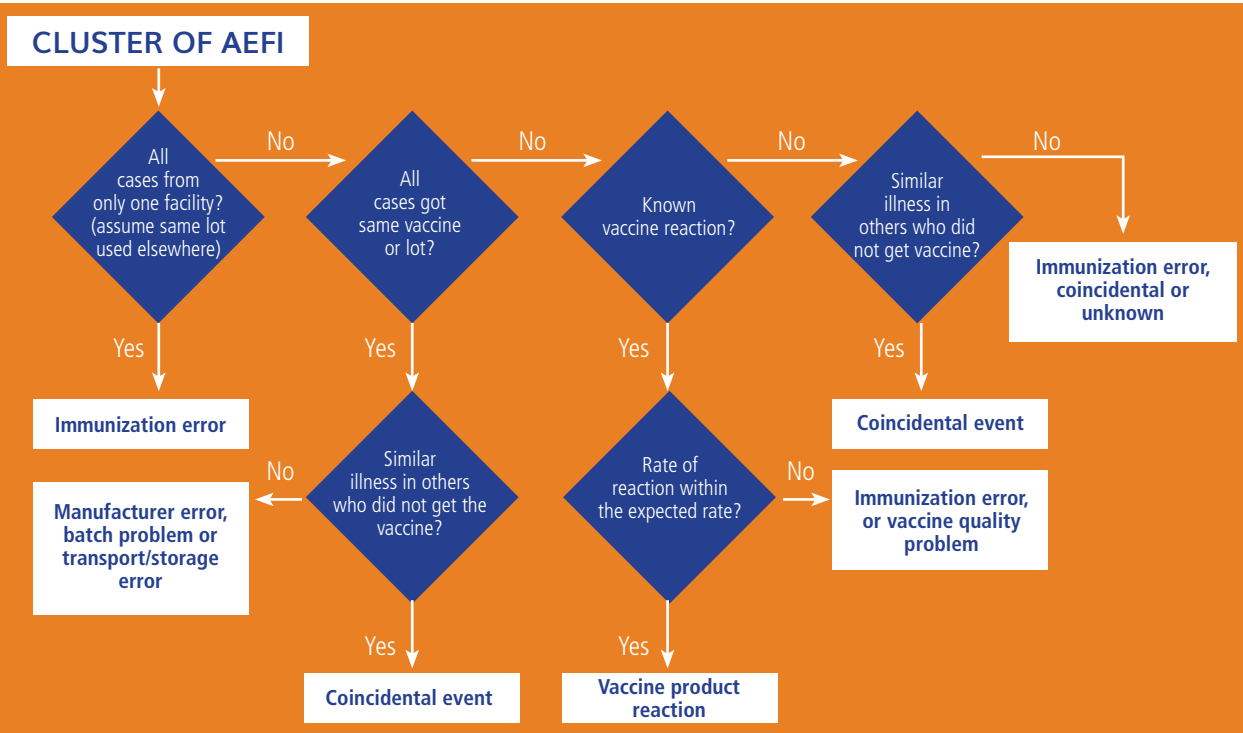
- If others in the community had similar illness: use a case definition , categorize cases and determine the vaccination status of the affected
- Efforts should be made to interview an equal number of beneficiaries from both sexes.
- If possible, try to obtain details of other beneficiaries who received the vaccine from the same distribution point, from the same site and from the same vial

9 *Specimen collection for lab tests when applicable*

Only on clear suspicion, NOT as routine, and never before a working hypothesis has been formulated after discussions, take a decision on which vaccine samples should be sent for testing. Both open and closed vials may be collected and sent under reverse cold chain conditions.

10 *Concluding the investigation*

- Review epidemiological, clinical and laboratory findings and try to arrive at a probable diagnosis of the event
- Narrow down, if possible, to a possible vaccine which may have been related to the event
- Keeping the possible vaccine and the event/diagnosis in mind, formulate a hypothesis on the likely/possible cause(s) of the event
- Test the hypothesis, if possible
- Reach a provisional conclusion on the cause
- Complete AEFI Investigation report
- In case of investigation of clusters, use the following algorithm for help in causally assessing the event:



11 *Preparation of report*

1. All available reports / records, field observations, notes, epidemiological assessment report, photographs, etc. of all the investigators should be collected and compiled before preparation of report.
2. Telephone numbers of patients, relatives, local health worker /officials should be collected during the visit for future references while preparing the report.
3. Emphasis should be to establish linkage, if any, between vaccine and associated event.
4. The objective of the investigation should be to arrive at a clinical diagnosis/ differential diagnosis of the event.
5. Any signal if found associated with vaccine must be mentioned to ensure quality causality assessment classification.
6. Conclusion and specific recommendation should be made in view of improving the AEFI surveillance system and thus quality of immunization programme.

Field checklist to be used for investigation

Field checklist	Yes	No
Interaction with family/vaccine recipient		
Visit to hospital/clinic/ward		
Interaction with treating physician/ health care provider/clinician		
Interaction with vaccinator (health worker)		
Visit to immunization site		
Review of vaccine storage and handling practices		
Visit to community and other vaccination sites in the block/district		
Review of investigation reports such as hospital records, post-mortem reports, blood and urine tests, etc.		

SUBMISSION OF REPORT

The investigation report must be submitted by the state investigation team to the concerned state authority within two days of completion of visit. If more information was asked for, or an awaited report is received, a final investigation report may be submitted not later than two weeks of completion of visit. This final report will be reviewed along with the CRF, PCIF, FCIF and other reports in the next State AEFI Committee meeting for causality assessment.

The central team will submit a preliminary report to the Chairperson, AEFI Investigation Subcommittee and the AEFI Secretariat within two days of completion of visit. The Chair, AEFI Investigation Subcommittee will give the feedback within two days of receiving the preliminary report. Based on the feedback from the Chair of the Investigation Subcommittee, the report will be submitted to the Immunisation Division and to the state, if directed by the Immunisation Division. The final report is to be submitted by the team within two weeks of completion of investigation.

MEDIA AND EXTERNAL COMMUNICATION

The state investigating team must not interact or communicate with the media directly without the consent and knowledge of the relevant authority at the state level.

The central investigating team must not interact or communicate with the media directly without the knowledge and consent of the Chairperson of the National AEFI Committee and/or the Chairperson of the Media Subcommittee.

FORMAT FOR REPORT WRITING

- Background / introduction
- Team composition: Details of team members (names, designations)
- Details of places visited (PHC/CHC, hospital, referral hospital, community, homes of beneficiaries) and persons (name, designation) interviewed
- Case review:
  I. Case summary
  II. Examination of the beneficiary
  III. Patient/ relative narrative
  IV. Details of vaccines used for immunization
  V. Details of any other medication given
  VI. Interviews of health personnel (ANM, cold chain handler, medical officers, DIO, others)
  VII. Sequence of events in chronological order (details with date and time)
- Cold chain examination
- Injection safety & practices examination
- Epidemiological investigation
- Document review: Review of hospital records, post-mortem reports, verbal autopsy formats, lab investigation reports, physician's prescription, review of available records (CRF, PCIF, FCIF)
- Discussion
- Probable clinical diagnosis/ differential diagnosis
- Conclusions
- Recommendations
- Annexures (photographs, maps, etc.)

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