NATIONAL HEALTH MISSION
राष्ट्रीय स्वास्थ्य मिशन

ITSU
IMMUNIZATION
TECHNICAL SUPPORT UNIT
Ministry of Health & Family Welfare

Special Investigation Protocol for Serious AEFIs

Disclaimer

This special protocol is developed for the use of trained members of AEFI committees and AEFI secretariat and it is not substitute for standardised case investigation Form (i.e.PCIF,FCIF) used by reporting district.

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 evidence such as laboratory investigations. 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.

THE REQUIREMENT

The field investigation may be necessary in the following scenarios:

- Cluster events
- Requested by state government or MOHFW/AEFI secretariat
- Media reports on AEFIs causing concern in the community
- Serious AEFIs reported after new vaccine introduction of significant concern

OBJECTIVES

The objective of the special investigating protocol is to

- Document the event and associated epidemiological factors affecting it and the final outcome.
- Collect evidence from all possible sources to establish a probable clinical diagnosis of the event.
- 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.
- 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.
- Determine whether similar events are occurring in individuals who have not received the same vaccine
- Provide recommendations based on findings to prevent recurrence and to improve quality of the immunization programme.

SPECIAL INVESTIGATION PROTOCOL

Request received for Special Investigation

Timeline-2 working days (facilitator -AEFI secretariat)

Team Formation

Members

- Pediatrician
- Epidemiologist
- Program Person

2 workoing days (facilitator AEFI secretariat)

Visit to reporting district

State AEFI Committee member may be invited to join facilitators-SEPIO/AEFI secertariat

Steps in Investigation

01. Visit to site of immunization
02. Assess the service by observing it in action
03. Cold chain and transport conditions
04. Immunization and other relevant records
05. Health official,Treating physicians ,ANM, ASHA interviews
06. Patient /& parents interview
07. Examine the patient-see/touch/record vitals
08. Epidemiological investigation-
09. Collection of samples
10. Concluding the investigation
11. Preparation of report

Preparation of report

PREPARATION & PLANNING FOR INVESTIGATION

- Local health official (BMO/CMHO/DIO)will be informed

Documents & Records

- Available reports (FIR /PIR/DIR) or New reporting formats CIF/PCIF/FCIF)
- Available records (Hospital, Lab, PM, Prescriptions, Notes)
- Map of area (village/block/district/state)
- Media reports
- Analysis of previous AEFI cases from the same area (SEPIO office/AEFI secretariat)
- Analysis similar events reported through IDSP from the same area(SEPIO office)

Logistics

- Blank verbal autopsy forms.
- Clinical examination material for ex. Stethoscope, weighing machine, hammer, tape, Torch etc.)
- Camera
- Voice recorder

Other

- Telephone number of local health official/worker /partner organisations
- Understanding the commonly used terms for reported event/vaccine /diseases

Submission of report

2days

Subcommittee chair

Preliminary report to Immunisation Division/State if directed directed by immunization division

Final Report in 2 weeks

PROTOCOL

Team formation

- The 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.
- The investigating team members should be chosen from amongst the members of the AEFI committee based on their area of expertise and their availability at short notice.
- The AEFI Secretariat will co-ordinate the process to decide the team formation.
- The investigating team will be formed as early as possible, but not later than within two working days of requisition received from the Immunization Division, MOHFW / AEFI Secretariat.
- The investigating team should preferably visit the district from which the AEFI was reported within 48 hours of receiving the request from the Immunization Division/AEFI Secretariat.
- Efforts should be made to include state AEFI committee members in the team from concerned state (facilitation by SEPIO/AEFI Secretariat).

Preparation and planning for investigation

- The AEFI Secretariat will contact the State EPI Officer who will coordinate with respective district health officials to ensure support during investigation of the AEFI by the team.
- The AEFI Secretariat will arrange for and bear the cost of travel and boarding as per its norms
- 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 case of cluster cases, a lot of documentation in the form of listing of affected beneficiaries, mapping of their location, etc. would be needed. This will be 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.
- 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**
    i. Available filled reports (CRF, PCIF and FCIF)
    ii. Available records (hospital records, post-mortem reports, laboratory reports, physician notes / OPD / prescription records, etc.) of all affected persons
    iii. Map of area (village/block/district/state)
    iv. Newspaper cuttings of media reports
    v. Analysis of cases of previously reported AEFI cases from the same area (SEPIO office/AEFI secretariat)
    vi. Analysis of similar events reported through IDSP from the same area(SEPIO office)
  - **Logistics (facilitation by district health officials /AEFI secretariat)**
    i. Blank copies of verbal autopsy forms
    ii. Accessories for clinical examination such as stethoscopes, weighing machines, hammer, tape, torch, etc.

iii. Camera

iv. Voice recorder

- **Others**

  i. List of telephone numbers of local health official/ worker/ partner organizations

  ii. Locally used terms for reported event / vaccine /diseases.

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 to the vaccination session site
2. Observing the session for quality of service delivery
3. Visit to the cold chain point and examining vaccine transportation conditions
4. Collecting and assessing vaccination cards, due lists, tally sheets and other relevant records
5. Interviewing related health officers, treating physicians, ANM, ASHA and AWW, etc.
6. Interviewing patients and/ or parents
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

VISIT TO SITE OF IMMUNIZATION

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 date and time of opening and previous use of vial.

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

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.

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
    i. History of the event in chronological order to explore the underlying factors, if any

ii. Detailed clinical description including sequence of clinical manifestations and response to treatment

iii. Relevant laboratory tests and other investigations (e.g. X-ray, ECG, etc.) performed and their results

iv. Details of treatment and outcome

- Relevant immunization records such as session site tally sheets, MCTS records & immunization register, vaccine indent form, stock registers and daily distribution registers, etc.)

INTERVIEWS WITH HEALTH OFFICIALS, TREATING PHYSICIANS, ANM AND ASHA

Details regarding patient/s, event & subsequent management of patient and event

Establish sequence of events from vaccine administration to occurrence and possible reason for the event

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

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 AEFI and current health status.
- Previous medical history, including prior history of similar reaction or other allergies and family history of similar events

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)

EPIDEMIOLOGICAL INVESTIGATION

Investigate and collect data about OTHER PERSONS

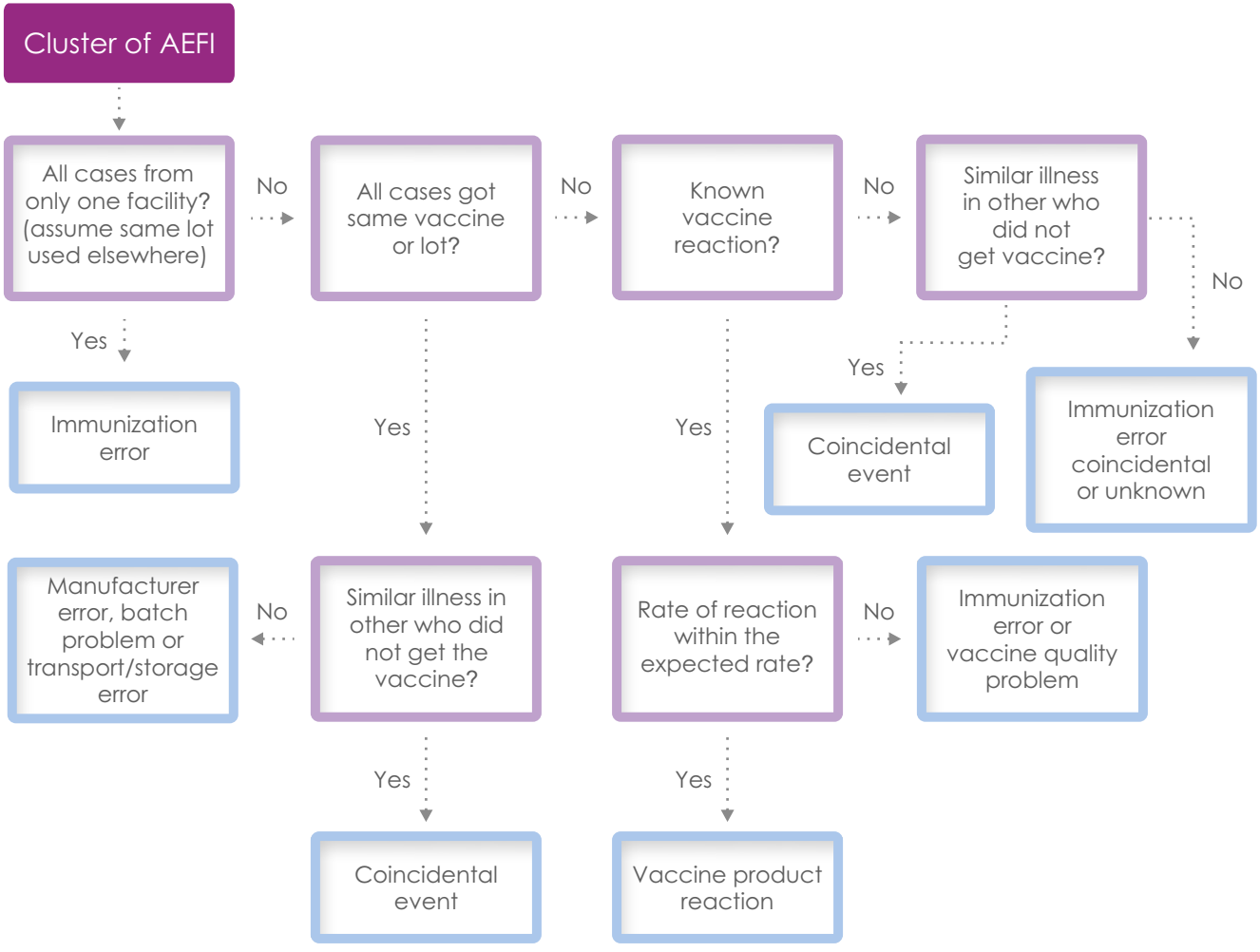
- If others in the community had similar illness: use a case definition , categorize cases and determine the vaccination status of the affected
- Efforts should be made to interview an equal number of beneficiaries from both sexes.
- If possible, try to obtain details of other beneficiaries who received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

SPECIMEN COLLECTION FOR LAB TESTS WHEN APPLICABLE

Only on clear suspicion, NOT as routine, and never before a working hypothesis has been formulated. *Both open and closed vials may be collected and sent under reverse cold chain conditions.*

CONCLUDING THE INVESTIGATION

- Review epidemiological, clinical and laboratory findings
- 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:


Cluster of AEFI
All cases from only one facility? (assume same lot used elsewhere)
No
All cases got same vaccine or lot?
No
Known vaccine reaction?
No
Similar illness in other who did not get vaccine?
No
Yes
Immunization error
Yes
Yes
Coincidental event
Immunization error coincidental or unknown
Manufacturer error, batch problem or transport/storage error
No
Similar illness in other who did not get the vaccine?
Rate of reaction within the expected rate?
No
Immunization error or vaccine quality problem
Yes
Coincidental event
Yes
Vaccine product reaction

PREPARATION OF REPORT

- All the available reports/ records, field observations, notes, epidemiological assessment report, photographs, etc. of all the investigators should be collected and compiled before preparation of report
- Telephone number of patients, relatives, local health worker /officials should be collected during the visit for future references while preparing report.
- Emphasis should be to establish linkage, if any, between vaccine and associated event.
- The objective of the investigation should be to arrive at a clinical diagnosis/ differential diagnosis of the event.
- Any signal if found associated with vaccine must be mentioned to ensure quality causality assessment classification.
- 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/case	☐	☐
■ 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 preliminary report must be submitted to the Chair of the AEFI Investigation Subcommittee and the AEFI Secretariat within two days of completion of visit. The Chair, AEFI Investigation Subcommittee will give the feedback within 2 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 investigating team must not interact or communicate with the media directly without the consent and knowledge of 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:
    - Case Summary
    - Examination of the beneficiary
    - Patient/ relative narrative
    - Details of vaccines used for immunization
    - Details of any other medication given
    - Interviews of health personnel (ANM, cold chain handler, medical officers, DIO, others)
    - 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, 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.)

NOTES

NOTES

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