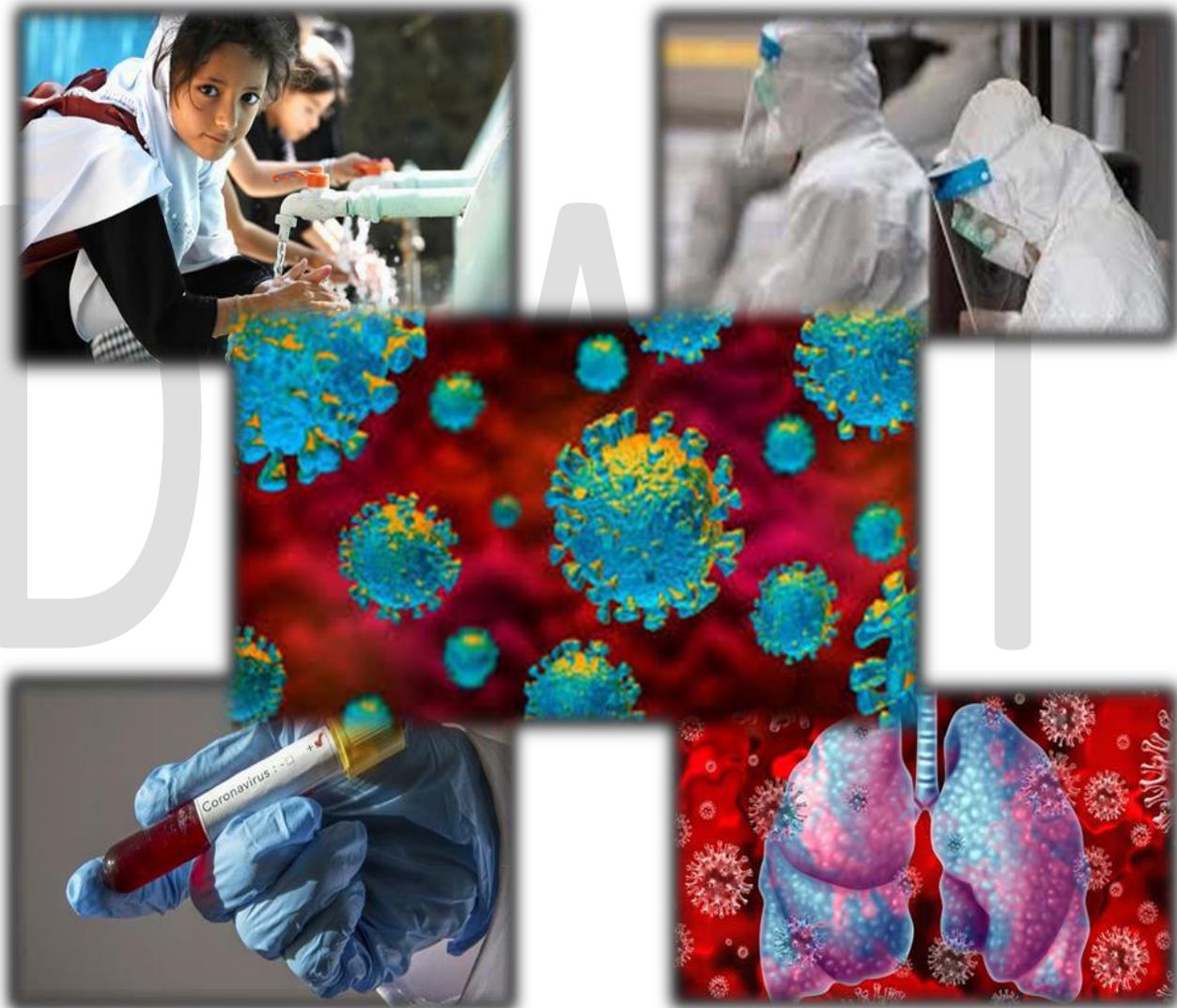




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Guidelines

National Guideline for Surveillance of Adverse Events Following Immunization (AEFI) – COVID-19





Introduction

AEFI is an untoward post-immunization medical incident that can cause public concern. The adverse event may be any unfavorable or unintended sign, abnormal laboratory finding, symptom or disease. Reported adverse events can either be true adverse events resulting from the vaccine or immunization process or coincidental events that are not due to the vaccine or immunization process but are temporally associated with immunization. Therefore, they are required to be investigated in a thorough fashion.

AEFI Surveillance in Context of COVID-19 Vaccines:

The unprecedented rapid development of the COVID-19 vaccines followed by their rapid large-scale use, pose unique challenges in monitoring vaccine safety and mitigating any potential risks through a robust AEFI Surveillance system.

Objectives of AEFI Surveillance:

- Identify problems with vaccine lots or brands leading to vaccine reactions caused by the inherent properties of a vaccine
- Detect, correct and prevent immunization errors caused by errors in vaccine preparation, handling, storage or administration
- Prevent incorrect impression of association arising from coincidental adverse events following immunization, which may have a known or unknown cause unrelated to the immunization
- Reduce the incidence of Injection Reactions caused by anxiety or pain associated with immunization, by educating and reassuring individual vaccinees, parents/guardians and the general public about vaccine safety
- Maintain confidence by properly responding to individuals/parent and community concerns, while increasing awareness (public and professional) about vaccine risks
- Generate new hypotheses about vaccine reactions that are specific to the population of our country/region
- Estimate rates of occurrence of AEFIs in the local population compared with trial and international data, particularly for new vaccines that are being introduced.
- To make decision on further strengthening of existing systems by identifying the gaps.

Classification of AEFI

Table 1. Cause-Specific Categorization of AEFI (CIOMS/WHO 2012)

| Cause-specific type of | Definition |
|-------------------------------------------------------------------------|---------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------|
| Vaccine product-related reaction | An AEFI that is caused or precipitated by a vaccine due to one or more of the inherent properties of the vaccine |
| Vaccine quality defect-related reaction | An AEFI that is caused or precipitated by a vaccine that is due to one or more quality defects of the vaccine product, including its administration device as provided by the manufacturer. |
| Immunization error-related reaction (formerly “programme error”) | An AEFI that is caused by inappropriate vaccine handling, prescribing or administration and thus by its nature is preventable. |
| Immunization anxiety-related reaction | An AEFI arising from anxiety about the immunization. |
| Coincidental event | An AEFI that is caused by something other than the vaccine product, immunization error or immunization anxiety, but a temporal association with immunization exists. |

SECTION 1: Steps of AEFI Surveillance

AEFI Detection and Reporting

Detection

AEFI detection is the recognition of any unusual medical event following vaccination/immunization which can be done by vaccine recipients, parents of immunized children, health care providers and staff in immunization or health care facilities and reporting them to health care provider working within the healthcare system.

Although there is limited data available on potential AEFIs/AESIs that may be linked to COVID-19 vaccine products, following AEFIs may occur:

1. Anaphylaxis
2. Sepsis
3. Generalized rash
4. Fainting
5. Redness at site of injection



6. Fever
7. Headache
8. Pain at Injection site
9. Swelling at injection site

An AEFI focal person (medical doctor trained in handling medical emergencies) will be responsible for medical management of the detected case and for reporting the AEFIs (both minor and major) to district health office. AEFI Focal person will be identified and overseen by Executive Director (ED) or Medical Superintendent (MS) of each designated health facility.

Reporting

Daily Online Reporting:

- Entry of any AEFIs into National Immunization Management System (NIMS) would occur within 30 minutes of Vaccine Administration
- **Responsibility:** Vaccine Administering Staff at Adult Vaccination Counters (National/Provincial Level)

Daily Reports (Hard Copy):

- All Minor and Major AEFIs to be reported on **AEFI Reporting Form (Annex-A)**
- **Responsibility:** Health Facility AEFI Focal Person
- All cases of severe nature to be notified to **District Health Office immediately; minor cases to be reported within 24 hours of occurrence**

Weekly Report (AEFI Surveillance Report)

- A weekly summary of the AEFIs reported during one week will be sent on **HF AEFI Surveillance Report (Annex-B)** will be submitted to DHO and will subsequently be entered into the **EPI-MIS from District Office**

1. Investigation

Major/serious AEFIs are to be investigated without delay, with DHO responsible to undertake all necessary action for investigating the AEFI

It is essential that all Serious AEFIs are investigated particularly:

- Any AEFI that leads to hospitalization
- Any Cluster of AEFIs
- Any AEFI causing significant individual or community concern
- Any death attributed to the vaccine



- **Tool for Investigation:** AEFI Investigation Form (Annex-C)
- **Responsibility:** District AEFI Focal Person and Review Committee
- Reports of Investigation are to be shared with Provincial and National AEFI Review Committees as and when reported

Objectives of investigating AEFI are:

- To confirm diagnosis of a reported AEFI and determine the outcome(s)
- To investigate the link between the vaccine administered and the AEFI
- To determine the contribution of the operational aspects of the programme to the reported AEFI
- To determine whether a reported event was isolated or part of a cluster
- To determine cause(s) of the AEFI so as to provide the best intervention/medical care and take any further action deemed necessary
- To determine whether un-immunized persons are experiencing the same medical event(s)

2. Causality Assessment

Causality of all investigated cases will be reviewed and duly finalized by notified Provincial and National AEFI Review Committees.

3. Data sharing and analysis

- Daily data will be reported through NIMS app and it will be made available for viewing at District Dashboard
- AEFI data (regularly) collected from HF on hard copy of Surveillance Report by **HF staff**
- Uploaded to **EPI-MIS at District level Weekly**
- Data Analysis **at National/Provincial level**
- As the first step of coordination between DRAP and EPI, Federal EPI will share data with DRAP through data entry into **Vigiflow system** for Pharmacovigilance. This practice will be further refined as soon as the pharmacovigilance rules are notified by the Government of Pakistan

Roles and Responsibilities

Keeping in view the vaccine roll out the roles and responsibilities of the respective authorities with oversight authorities have been formulated (Table 2):



| Administrative Level | Responsible Agency for AEFI reporting/management | Oversight |
|-------------------------|--------------------------------------------------------------------------------------------------------------------|-------------------------------------------------------------------|
| 1 National Level | <ul style="list-style-type: none">National AEFI Focal PersonNational Media Focal Person | NCOC and National AEFI Review Committee |
| 2 Provincial Level | <ul style="list-style-type: none">Provincial AEFI Focal PersonProvincial Media Focal Person | Provincial Health Department and Provincial AEFI Review Committee |
| 3 District Level | <ul style="list-style-type: none">District AEFI Focal PersonDistrict Media Focal Person | DHMT/DC/ District Health Authority-CEO |
| 4 Health Facility Level | <ul style="list-style-type: none">Health Facility AEFI Focal Person (Medical Officer) | ED/MS Health Facility |

Vaccine roll out plan

Following activities may be required to be undertaken in chronological order at various stages of vaccine roll-out to ensure a satisfactorily functioning AEFI management and surveillance mechanism. The same system of AEFI surveillance will be required to be adapted by all private sector health facilities to ensure vaccine safety.

Prior to the Vaccine rollout:

1. Trainings of all nursing staff identified for vaccine administration
2. Orientation of hospital staff (Health Facility AEFI Focal Person) on reporting and management of AEFIs and crisis communication management
3. Ensure availability of AEFI kits/ Emergency Medicines at each HF
 - Inj. Adrenaline (1:1000) sol.
 - Inj. Hydrocortisone (100mg) amp.
 - Ringer Lactate/Normal Saline
 - I/V cannula, Drip sets/ Disposable syringes etc.

Day of vaccination

1. Candidate for vaccination will be screened for any contraindications
2. Individuals will be briefly counseled on possible AEFIs by the nurse and whom to contact
3. Vaccinee will be made to wait for 30 minutes after receiving the vaccine
4. Vaccine administering staff will enter data of any minor/major AEFIs occurring within 30 minutes of the event into NIMS



5. If any adverse event is noted, the health facility focal person will fill the AEFI reporting form
6. Daily AEFI data will be reflected on district dashboard for district authorities to timely launch an investigation of AEFI if needed

After the day of vaccination

1. Individuals who have received the vaccine will get an auto-generated message to inquire about any side effects within 24 to 48 hours post vaccination on which they may even reply after 7 days of vaccination (upon which they will be directed to a Health Facility for management)
2. NIMS online portal will be open to citizens for registering complains/AEFIs
3. AEFIs can also be reported to the National Helpline 1166
4. Weekly AEFI data (including zero reports for AEFI caused due to COVID-19 vaccines and other routine vaccines) will be shared with District EPI by District Health Authority for onward submission to the Provincial and Federal Teams accordingly

SECTION 2: Management of AEFIs

The proposed waiting time of 30 minutes at the Health Facility will allow the identification and immediate management of medical emergencies like anaphylaxis, which manifest most frequently within 5 to 30 minutes of vaccine administration. Upon the occurrence of any anaphylactic reactions, vaccine administering staff (nurses/AEFI focal person of the health facility) will administer adrenaline, supply high flow oxygen through nasal prongs or oxygen masks, monitor vitals and initiate reporting protocol by immediately informing the AEFI Focal person for further management of the case.

Health facility AEFI Focal person will be trained and will be responsible for managing all serious AEFIs occurring at the particular Health Facility.

SECTION 3: Crisis Communication

Since AEFIs can occur in any recipient of the vaccine, carefully explaining the possibility of such events before administering the vaccine, which has been made part of the vaccine administration protocol, will help in addressing the crisis, if and when it emerges. For detailed communication response during a crisis, please refer to Covid-19 Vaccination **Risk Communication and Community Engagement Strategy document**.



ANNEX-A



Expanded Programme on Immunization
AEFI Report Form



Name of case: _____ Sex: M F
Date of birth: _____ Age: ____ years ____ months ____ weeks
Father/Husband's name: _____
Village: _____ UC _____ Teshsil/Taluka _____
District: _____ Province: _____

Clinical information

Major complaints (put tick as appropriate):

- | | |
|---------------------------|-----------------------------|
| a) Severe Local Reaction | e) Convulsion |
| b) Injection site abscess | f) Unconsciousness |
| c) Fever | g) Respiratory Distress |
| d) Rash | h) Swelling of body or face |

Type of AEFI: Minor () Serious ()

Is the case hospitalized: i) Others (Pls specify) _____

If Yes, Name and address of the hospital Yes No

Information regarding vaccine and vaccination

Date of vaccination:
Name of vaccine(s) received on this day:
Name of manufacturer & Batch/Lot no. of vaccine(s):
Expiry date of vaccine(s):
Name and address of vaccination center:
Name & designation of person who vaccinated:

*Submit this report to the local health facility in-charge within three days
In case of emergency, report to the local health facility in-charge immediately*

Name and designation of the reporting person Date: ____/____/____



ANNEX-B

WEEKLY VPD/AEFI SURVEILLANCE REPORT, HEALTH FACILITY

Health Facility : _____ Union Council: _____ Tehsil/Taluka: _____
District/Agency: _____ Province/Area: _____ Date of report received in DHO office: ___/___/___
Epi Week No.: _____ Date: From ___/___/___ To ___/___/___ Year: _____ AEFI: _____

| Sr. No | Type of case* | Name of the case | Father's name of the case | Address (House #, street, village, mahalla, UC, Cell Number) | Age | Sex | Date of Onset dd/mm/yy | Total No. of vaccine doses received | Date of last dose received dd/mm/yy | Clinical Presentation of the case |
|--------|---------------|------------------|---------------------------|--------------------------------------------------------------|-----|-----|------------------------|-------------------------------------|-------------------------------------|-----------------------------------|
| 1 | 2 | 3 | 4 | 5 | 6 | 7 | 8 | 9 | 10 | 11 |
| | | | | | | | | | | |
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| | | | | | | | | | | |

* Type of Case Means Major or Minor AEFI

Prepared by: _____ Date: _____ Health Facility In-charge: _____
Name: _____ Name: _____



ANNEX-C



Expanded Programme on
Immunization
AEFI CASE INVESTIGATION FORM

An AEFI case investigation should be initiated within 24 hours of notification of Serious AEFI

| | | | |
|--------------------------------------------------------------------------------------------------------------|-----------------------|--------------------------------------------------------------------|--------------------|
| Investigation ID: PAK _____ / _____ / _____ / AEFI / _____ | | Name of reporting Officer: | |
| Date AEFI reported: | | Designation: Contact | |
| Date investigation started: | | No: | |
| Demographic data of the patient: | | | |
| Name of the case: _____ | | Date of Birth/Age: _____ | |
| CNIC No. _____ | | Sex: <input type="checkbox"/> Male <input type="checkbox"/> Female | |
| Name of Father: _____ | | | |
| Address: House/Street No. _____ | | Village: _____ Union Council: _____ | |
| Tehsil/Taluka/Town: _____ | | District: _____ Province: _____ Contact No: _____ | |
| Place of vaccination: () Govt. health facility () Private health facility () Other (specify) _____ | | | |
| Vaccination in: () Campaign () Routine () Other (specify) _____ | | | |
| Address of vaccination site: | | | |
| Vaccines | | Manufacturer | Lot no./batch no. |
| | | | Expiry Date |
| | | | |
| Most Recent Immunization History: | | | |
| Date and time of vaccination | Vaccine & dose number | Site of administration | Vaccination Center |
| | | | Vaccinated by |
| | | | |
| | | | |
| | | | |



Information about the vaccines and diluents administered to the patient:

- a) In case of multidose vial, was vaccination given:
- within the first few doses of the vial Yes / No
 - Within the last doses of the vial administered Yes / No
 - Unknown Yes / No
- b) Was there an error in prescribing or non-adherence to recommendations for use of this vaccine?
assess Yes/No /Unable to
- Based on your investigation, do you feel that the vaccine (ingredients) administered could
- c) have been unsterile? assess Yes / No / Unable to
- d) Based on your investigation, do you feel that the vaccine's physical condition (e.g. colour, turbidity, foreign substances etc.) was abnormal at the time of administration?
assess Yes/ No / Unable to
- e) Based on your investigation, do you feel that there was an error in vaccine reconstitution/preparation by the vaccinator (e.g. wrong product, wrong diluent, improper mixing, improper syringe filling etc.)? assess Yes /No / Unable to assess
- f) Based on your investigation, do you feel that there was an error in vaccine handling (e.g. break in cold chain during transport, storage and/or immunization session etc.)? assess Yes/No/ Unable to assess
- g) Based on your investigation, do you feel that the vaccine was administered incorrectly (e.g. wrong dose, site or route of administration, wrong needle size, not following good injection practice etc.)? assess Yes /No / Unable to assess
- h) Number immunized from the concerned vaccine vial/ampoule assess Yes/ No / Unable to assess
- i) Number immunized with the concerned vaccine in the same session assess Yes / No / Unable to assess
- j) Number immunized with the concerned vaccine having the same batch number in other locations. Specify locations: assess Yes/ No / Unable to assess



k) Is this case a part of a cluster? Yes / No /
Unable to assess

- i. If yes, how many other cases have been detected in the cluster?
- a. Did all the cases in the cluster receive vaccine from the same vial?
 - b. If no, number of vials used in the cluster (enter details separately)

Suspected vaccine which caused AEFI:

Describe the adverse event in detail:

H/O present illness: (Signs and symptoms in chronological order from the time of vaccination):

Date of onset of AEFI: _____ Time of onset of AEFI:

Date of hospitalization: _____ Time of hospitalization:

Date of death: _____ Time of death:

Autopsy done? () Yes (date) _____ () No

Planned on (date) _____ Time _____

Attach report (if available)

Source of information (all that apply):

Examination by the investigator **Documents** **Verbal Autopsy** **Other**

Name of the person who first examined/treated the patient: _____

Name of other persons treating the patient: _____

Other sources who provided information (specify): _____

If Verbal autopsy, please mention source: _____



| | | | |
|-----------------------------------------------|----------|--------------------------------|------|
| Examination Findings: | | | |
| Pulse | /min | Temp | °F |
| BP | mm of Hg | Heart Rate | /min |
| Resp. Rate | /min | Lungs (wheeze, crepts, ronchi) | |
| Skin change | | Size of skin lesion | cm |
| Cyanosis | | Pupil (reaction to light) | |
| Kernig's sign | | Neck stiffness | |
| Level of Consciousness | | Lymph Node | |
| Jerks | | | |
| Cranial nerve abnormality | | | |
| Other Abnormal Signs (if any): | | | |
| Treatment: | | | |
| Provisional | | | |
| Final | | | |
| Diagnosis: | | | |
| Outcome: | | | |
| <input type="checkbox"/> Died | | | |
| <input type="checkbox"/> Disabled | | | |
| <input type="checkbox"/> Recovering | | | |
| <input type="checkbox"/> Recovered completely | | | |
| <input type="checkbox"/> Unknown | | | |



| Additional information about the patient: (write yes or no, if yes specify) | | |
|-------------------------------------------------------------------------------------------------------------------------------------------------------|-----------------|-----------------------------------------|
| Criteria | Finding | Remarks (If yes provide details) |
| Past history of similar event | Yes / No / Unkn | |
| Adverse event after previous vaccination(s) | Yes / No / Unkn | |
| History of allergy to vaccine, drug or food | Yes / No / Unkn | |
| Pre-existing illness (30 days) / congenital disorder | Yes / No / Unkn | |
| History of hospitalization in last 30 days, with cause | Yes / No / Unkn | |
| Patient currently on concomitant medication? (If yes, name the drug, indication, doses & treatment dates) | Yes / No / Unkn | |
| Family history of any disease (relevant to AEFI) or allergy | Yes / No / Unkn | |
| For adult women | | |
| <ul style="list-style-type: none"> • Currently pregnant? Yes (weeks) _____ / No / Unknown • Currently breastfeeding? Yes / No | | |
| Community investigation: | | |
| No. of cases immunized with suspected vaccine in same session: | | |
| No. of cases of same adverse events found in immunized children/women: | | |
| No of cases of same adverse events found in unimmunized children/women: | | |

| | | |
|--------------------------------------------------------------------------------------------|---|--|
| EPI Management Practice (fill up this section by asking and observing practice): | | |
| Write yes or no where applicable, if yes | | |
| Specify | | |
| <u>EPI store:</u> | | |
| Temp inside ILR (°C) | : | |
| Temp of freezer (°C) | : | |
| Correct procedure of storing vaccines, diluents and syringes followed | : | |
| Any other object (other than EPI vaccines and diluents) in the ILR or freezer | : | |
| Partially used reconstituted vaccines in the ILR | : | |
| Unusable vaccines (expired, no label, VVM stage 3 & 4, Frozen) in the ILR | : | |
| Unusable diluents (expired, manufacturer not matched, cracked, dirty ampoule) in the store | : | |
| <u>Transportation:</u> | | |
| Type of vaccine carrier used | : | |
| Vaccine carrier packed properly | : | |
| Vaccine carrier sent to the EPI site on the same day of vaccination | : | |



Vaccine carrier returned from the EPI site on the same day of vaccination :

Conditioned ice-pack used :

Reconstitution:

Correct procedure followed :

Correct amount of diluent used :

Used separate syringe for each vial :

Matching diluent used :

Injection technique:

Correct dose and route :

Non- touch technique followed :

Vial shaken before each injection :

Contraindication assessed :

How many AEFI reported from vaccination sites of the same worker in the last 30 days? :

Training on EPI received by the vaccinator: (specify the last training including date) :

Laboratory investigation(s) conducted?
Yes No
If yes, mention the tests (attach copy of the reports)

Assessment

| Conclusion about cause of AEFI: tick categories, rank if more than one cause: | | | | |
|----------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------|-----------------------------------------------------------------------------------------------------------------------------|--------------|--------------------|---------|
| Programme error | Vaccine Reaction | Coincidental | Injection Reaction | Unknown |
| <input type="checkbox"/> Non-sterile injection <input type="checkbox"/> Faulty preparation <input type="checkbox"/> Faulty administration <input type="checkbox"/> Faulty transportation <input type="checkbox"/> Faulty vaccine storage <input type="checkbox"/> Other | <input type="checkbox"/> Known reaction <input type="checkbox"/> Vaccine lot problem <input type="checkbox"/> Others: | | | |
| Confidence about conclusion on main cause of AEFI: <input type="checkbox"/> Possible <input type="checkbox"/> Certain <input type="checkbox"/> Probable <input type="checkbox"/> | | | | |



Reason(s) for conclusion:

Corrective Actions

Recommendations:

Additional Notes (attach additional paper):

Investigation Team Details:

- | | | |
|----------------|-------------------|-----------------|
| 1. Name: _____ | Designation _____ | Signature _____ |
| 2. Name: _____ | Designation _____ | Signature _____ |
| 3. Name: _____ | Designation _____ | Signature _____ |
| 4. Name: _____ | Designation _____ | Signature _____ |
| 5. Name: _____ | Designation _____ | Signature _____ |
| 6. Name: _____ | Designation _____ | Signature _____ |



7. Name: _____ Designation _____ Signature _____

Date Investigation Completed: ____ / ____ / ____

Notes:

- 1) Investigation team will submit the filled in AEFI investigation form to EDO (Health) office or equivalent. Attach all medical records e.g. prescription, treatment sheet (if patient is hospitalised), laboratory investigation reports (if any), death certificate & autopsy report (in case of death, if any), photos etc. with the investigation form.
- 2) EDO (Health) or equivalent will send a copy of the investigation report with all attachments to the Provincial and Federal EPI office as soon as it is completed and not later than a week after completion of investigation.
- 3) In case of cluster, use separate investigation form for each case.



Expanded Program
on Immunization
Government of Pakistan



For more information, please contact:

Expanded Program on Immunization, PM National Health Complex, Islamabad

<http://covid.gov.pk/>

<http://nhsrc.gov.pk/>

<https://www.facebook.com/NHSRCOfficial>

<http://www.hsa.edu.pk/>

<https://twitter.com/nhsrcofficial>

<https://www.nih.org.pk/>

<https://www.youtube.com/NHSRC-PK>