

To: Chief Directors: Metro Health Services
Rural Health Services

District Managers: Metro District Substructures
Rural Districts

Director: Forensic Pathology Services
Pharmacy Services

Chief Executive Officers (CEOs): Central Hospitals
Regional and Psychiatric Hospitals
District Hospitals

Executive Directors (Health): Local Authorities/Municipalities, City of Cape Town
South African Military Health Services

Managers: Private Hospitals, private clinics, pharmacies
Department of Correctional Services
Department of Basic Education
Department of Social Development

CIRCULAR H.56/2022

ADVERSE EVENTS FOLLOWING IMMUNISATION (AEFI) SURVEILLANCE: PROCEDURE FOR PROVIDING FEEDBACK ON CAUSALITY ASSESSMENT OF SERIOUS AND SEVERE AEFI CASES

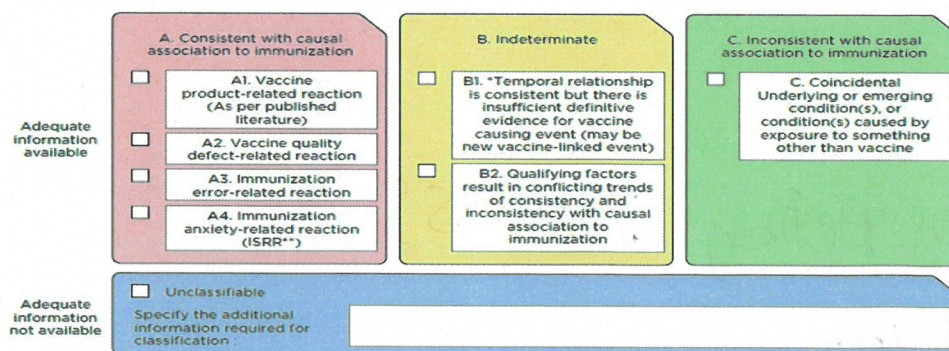
Causality assessment of AEFI is a vital component of AEFI risk assessment, decision making and initiation of action. The National Immunisation Safety Expert Committee (NISEC) reviews serious AEFI cases (according to the World Health Organization's causality assessment methodology) at a national level and establishes whether there is a causal link between immunisation and the adverse event. The outcome of the causality assessment is shared at a national and provincial level for corrective action, and the public to preserve confidence in the immunisation programme. Since January 2021, over 4 800 AEFI cases were reported in South Africa, the majority being minor events.

The pre-requisites for AEFI causality assessment are the following:

- Case investigation completed: with both the case reporting form (CRF) and the case investigation form (CIF) completed.
- Specific diagnosis: there must be a specific "diagnosis" (clinical sign, abnormal laboratory finding, symptom and/or disease) for the case, which is being investigated for a possible association with the vaccine.
- Details and evidence available: details of the case should be available at the time of assessment, including supporting documentation (e.g., clinical notes, laboratory results, autopsy summary/findings etc.)

The classification of cases AEFIs after causality assessment by NISEC is illustrated in the diagramme below.

Fig. 4. Causality assessment classification



*B1 : Potential signal and maybe considered for investigation
** Immunization stress related response

Feedback on the outcomes of causality assessments of severe or serious AEFI cases from the Western Cape was sent to the Provincial Head of Health in January 2022.

- Feedback was received for 28 cases from the Western Cape in this first batch of causality assessment outcomes.
- The feedback provided to the province is shared in the format of a table with the Reference / EPID number, Vaccinee initials, date of birth and a short summary of the outcome of causality assessment. Cases are classified as i) consistent with causal association to immunisation, ii) indeterminant iii) inconsistent with causal association to immunisation, and iv) unclassifiable.
- The province was requested to share the outcomes with the relevant districts, health facilities and vaccinees or relatives (stakeholders), as appropriate. This feedback from NISEC in future will be shared directly to the provincial identified AEFI lead.
- The process, reporting and investigation of AEFI cases has been documented in Circular H72/2021: Vaccine Safety Surveillance: Adverse Events Following Immunisation (AEFI) Monitoring for COVID-19 Vaccination. Kindly refer to this SOP on the investigation process and algorithm for reporting AEFI cases.
- Kindly note that AEFI cases are reported from various types of health facilities (public hospitals, private hospitals, public community health centres, private clinics), health practitioners (general practitioners, specialists), old age homes, forensic pathology services, Department of Correctional Services, private pharmacies, and self-reported via the Medsafety APP / national call centre/ AEFI national email etc. Self-reported severe AEFI cases are requested to seek medical assessment in the public or private sector, and the health practitioner is requested to complete the documentation and submit all supporting documentation.

In the absence of national guidelines and a standard operating procedure, the following process (see attached annexures and algorithm) is recommended and may be updated at a later stage.

- Annexure 1: Interim Guidance and Procedure on the provision of AEFI Causality Assessment Outcome feedback to districts/sub-districts/ sub-structures/health facilities and vaccinee/caregiver in the Western Cape Province
- Annexure 2: Register of AEFI Causality Assessment Outcome Feedback, Western Cape
- Annexure 3: Procedure on feedback of Causality Assessment of serious and severe Adverse Events following on Immunisation (AEFI)

To improve the quality of causality assessment the National Department of Health has requested the following (see attached letter):

- **The formation of a Provincial Review and Investigation Committee** to aid in preliminary causality assessments for review by NISEC.
 - The province is in the process of setting up the committee and clarifying the expectations from NDOH.
- **Ensure capacity at district, sub-district, and facility level to investigate AEFI cases.** AEFI coordinators at district and sub-district level to lead AEFI investigation in their respective areas.
 - District AEFI coordinators are requested to provide the Provincial CDC-EPI unit with the contact details of **sub-district "AEFI coordinators" by the 25th of April 2022**. Please email to: felencia.daniels@westerncape.gov.za ; riana.dippenaar@westerncape.gov.za and charlene.lawrence@westerncape.gov.za
- **Accessing personal information including medical records and laboratory results, autopsy summary or findings.** The NDOH issued a circular (see attached National Vaccination [Programme Circular 1 of 2022, as well as Provincial Circular H05/2022), that included a consent form for the vaccinee/family to complete when AEFI cases are reported.

Yours sincerely.

 Acting CD: ECSS

MS JO ARENDSE

CHIEF DIRECTOR: ECSS

DATE: 20/04/22

Annexure 1: Interim Guidance & Procedure on the provision of AEFI Causality Assessment Outcome feedback to districts/sub-districts/sub-structures/health facilities and vaccinee/caregiver

The district / substructure manager, as the accounting officer is responsible (may delegate to appropriate district official/s e.g., "AEFI coordinator) to provide feedback on the causality assessment outcome to the health facility (public/private), health practitioner (public / private), and vaccinee or family/caregiver of any person that has experienced a severe or serious AEFI.

The delegated district official can further delegate the feedback to the vaccinee or family/caregiver to the health facility manager / medical manager/treating doctor (as they are aware of the case and the context) in the public and private sector. The health facility / medical manager / treating doctor / clinician in public or private sector will decide how to provide feedback (telephonically/written/face to face meeting).

1. All official feedback received from the National Department of Health-NISEC will be provided from the Provincial CDC-EPI office, in the format of a letter to the specific district/substructure, health facility or health practitioner. **For cases reported in the private sector for which outcomes are available, the outcome letter will be sent directly to the private health facility /medical manager /treating doctor to ensure feedback to the vaccinee/care giver/relative (the district and subdistrict/sub-structure public health officials will still be copied in the letter).** The supporting documentation per case submitted to NDOH-NISEC will be included in the communication, for easy reference.
2. The district delegated official (e.g., AEFI coordinator, or medical / clinical manager / quality assurance or clinical governance official), should ensure the outcomes of the causality assessment is shared with the specific health facility/health practitioner and vaccinee, as appropriate.
3. The decision on who provides the feedback to the vaccinee or relative/caregiver should be taken by the district, based on the context of the case and who or which facility reported the case.
 - o **Ideally the health facility/medical/clinical manager of the health facility (public or private) / sub-district / district; or the treating doctor/clinician** in the public and private sector should provide feedback to the vaccinee or the family/caregiver.
 - o **Private sector health practitioners/clinicians or doctors are requested to provide the feedback to clients/cases that had reported an AEFI and was assessed and treated by them.** In certain cases where the treating doctor in the private sector cannot provide the feedback to the vaccinee/family/caregiver, the subdistrict/substructure medical manager/family physicians should assist as appropriate.
 - o **In cases where Forensic Pathology Services reported the case, the treating doctor / medical manager of the health facility is requested to provide feedback to the family/caregiver.**
4. **If further information is required by the official responsible for the feedback of the outcome** to the vaccinee or family/caregiver, **the Provincial Department of Health CDC-EPI can request documentation from the National Department of Health (NDOH) and NISEC, that may assist the official with information that support the outcome.**
5. **Feedback to the vaccinee / family/care giver should be given in a format that is relevant to the specific case** i.e., face-to-face meeting/telephonic etc. in conducted in a manner that includes the principles of client-centredness and patient safety incidence management. If the case / client requests a letter that states the outcome, this should be provided by the level at which the official that provide the outcome is at – i.e., health facility/sub-district/district.
6. All adverse events or AEFI cases (the vaccinee) with outcome "classified as consistent with causal association to immunisation" will be approached by a National Department of Health official with regards to the findings and compensation.
7. If the client / case (vaccinee or family member/care giver) has queries or questions that cannot be answered by the delegated official that gives feedback pertaining to the outcome, this will be forwarded to the provincial level i.e., the Provincial AEFI Review and Investigation Team. The Provincial AEFI team will forward the query to the NDOH for clarity or to assist with resolution.
8. A register or record of the feedback (see Annexure 2) should be kept at district and provincial level on AEFI case feedback that was provided to the health facility/practitioner or vaccinee/family/caregiver. This information may be submitted to the Provincial AEFI office/officials or must be available on request by the Provincial CDC-EPI unit - AEFI team.

Annexure 2: Register of AEFI Causality Assessment Outcome Feedback, Western Cape

District:

Please email completed register to the Provincial CDC-EPI Office

Date of feedback (DD/MM/YYYY)	Reference / EPID Number	Name or initials of case	Contact details of vaccinee/care giver/relative	Name of Health facility/sub-district/substructure	Name of doctor/clinical manager/clinician specialist giving feedback	Manner of feedback (Telephone/ face-to face)	Satisfied / unsatisfied with NISEC outcomes	Comments e.g. any medical support needed
1.								
2.								
3.								
Summary/Comments								

(Indicate EPID number of case; give reasons if case/vaccinee is unsatisfied with the NISEC outcomes, indicate any medical support required)

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Signature of clinician/ doctor/delegated facility official: Date:

Signature of vaccinee/care-giver/relative (if face-to-face meeting): Date:

ANNEXURE 3: PROCEDURE ON FEEDBACK OF CAUSALITY ASSESSMENT OF SERIOUS AND SEVERE ADVERSE EVENTS FOLLOWING IMMUNISATION (AEFI)



NATIONAL IMMUNISATION SAFETY EXPERT COMMITTEE (NISEC)

- Reviews serious and severe AEFI
- Conducts causality assessments (may take several months based on volumes of COVID-19 AEFI cases submitted for assessment)
- Classify cases & communicate outcome with the National Department of Health: EPI, province
- Final outcomes are shared in the format of a table with the reference / EPID number, vaccinee initials, date of birth and a short summary of the outcome of causality assessment. Cases are classified as i) inconsistent with causal association to immunisation, ii) consistent with causal association to immunisation and iii) unclassifiable

National Department of Health

Expanded Programme on Immunisation (EPI):
Email to submit documentation:
 AEFI@health.gov.za

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NATIONAL DEPARTMENT OF HEALTH (NDOH): EPI

- Feedback from NISEC and communicate findings of outcome to the province to ensure implementation of corrective measures in the case of a programme error. Line List or table forwarded the province (Provincial AEFI team)
- Supports the province / district with queries etc.
- May provide additional supporting documentation for final outcomes (causality assessment) of cases, when requested from the province
- Ensure AEFI cases/vaccine recipients classified as “consistent with causal association to immunisation”, are appropriately compensated.

Western Cape DoH CDC-EPI Programme, SPC

Surveillance Officer, EPI Manager, CDC Manager, Director SPC
 021-483-9917/3156
 021-483-4266
 021-483-9964
 082-891-5755
 083-576-7893
 072-356-5146

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PROVINCE

- The official causality assessment outcome received from the NDOH-NISEC will be provided in the format of a letter to the specific district/substructure, copied to the health facility or health practitioner. Supporting documentation for the specific case submitted to NDOH will be included in the communication, for easy reference.
- Requests further information from NDOH on specific case outcomes of causality assessments, if required by the delegated official responsible for the feedback of the outcome to the vaccinee or family/caregiver,
- Support the district/substructures on any further queries or questions that cannot be answered by the delegated official that gives feedback. The Provincial AEFI team might forward the query to the NDOH for clarity or resolution.

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Sonia.botha@westerncape.gov.za
Hillary.goelman@westerncape.gov.za

Provincial AEFI Review and Investigation Team

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DISTRICT (RURAL & METRO DISTRICT HEALTH)

- The district / substructure manager, as the accounting officer is responsible (may delegate to appropriate district official/s e.g., “AEFI coordinator) to provide feedback on the causality assessment outcome to the health facility (public/private), health practitioner (public / private), and vaccinee or family/caregiver of any person that has experienced a severe or serious AEFI.
- Identify the district delegated official/s that should ensure the outcomes of the causality assessment is shared with the specific health facility/health practitioner and vaccinee, as appropriate.
- **The delegated district official (e.g., AEFI coordinator, or medical / clinical manager / quality assurance or clinical governance official), can further delegate the feedback to the vaccinee or family/caregiver to the health facility manager or medical manager / sub-district / substructure (they are aware of the case and context). Private sector reported AEFI cases with causality assessment outcome feedback letters will be sent directly from Provincial CDC-EPI to the private health facility/practitioner to manage.**
- Ideally the health facility/medical/clinical manager of the health facility (public or private) / sub-district / district; or the treating doctor/clinician (public and private) should provide feedback to the vaccinee or the family/caregiver.
- Request further supporting documents from provincial level if official responsible for the feedback of the outcome to the vaccinee or family/caregiver, requires clarification.
- **Keep a register or record of the AEFI case causality assessment feedback**

Rural Health Services (RHS) & Metro Health Services (MHS)

District EPI and Cold Chain/Managers / District Medical Officers, Clinical managers/ Family physicians/ Medical Officer

See contact list in circular H72/2021

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HEALTH FACILITY (PUBLIC, PRIVATE), FORENSIC PATHOLOGY

Facility or Medical Manager / Treating clinician/doctor

DISTRICT OR SUB-DISTRICT/SUBSTRUCTURE

Clinical / Medical Manager/Family Physician may need to provide feedback to vaccinees etc.

- Seen in private sector (private hospitals, GPs, specialists, pharmacies)
- Cases reported by forensics pathology services (deaths at facilities/home)

Principles of providing feedback

- Feedback to the vaccinee/family/caregiver should be given in a format that is relevant to the specific case and context i.e., face-to-face meeting / telephonic / written etc.
- Feedback must be conducted in manner that includes the principles of client-centeredness and patient safety incidence management into account.

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VACCINEE OR FAMILY/CARE-GIVER OF CASE THAT EXPERIENCED AN ADVERSE EVENT

