



To:	<p>Chief Directors:</p> <p>District Managers:</p> <p>Director:</p> <p>Chief Executive Officers (CEOs): Executive Directors (Health):</p> <p>Managers:</p>	<p>Metro Health Services (MHS)</p> <p>Rural Health Services (RHS)</p> <p>Metro Health Services Substructures</p> <p>Rural Districts</p> <p>Forensic Pathology Services</p> <p>Emergency Medical Services</p> <p>Pharmacy Services</p> <p>Communications</p> <p>Central Hospitals, Regional and District Hospitals</p> <p>Local Authorities/Municipalities, City of Cape Town</p> <p>South African Military Health Services</p> <p>Private Hospitals, Private Clinics, Pharmacies</p> <p>General Practitioners</p> <p>National Health Laboratory Services</p> <p>Private Laboratories</p>
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CIRCULAR H167/2022

ADVERSE EVENTS FOLLOWING IMMUNISATION (AEFI) SURVEILLANCE: REFERRAL PATHWAYS FOR SERIOUS AND SEVERE AEFI CASES FOR CLINICAL INPUT ON CAUSALITY

Circular H72/2021, H05/2022, H56/2022 and H74/2022 pertaining to AEFI surveillance refers. See attached national letter with regards to causality assessment and urgent referrals of cases.

1. BACKGROUND

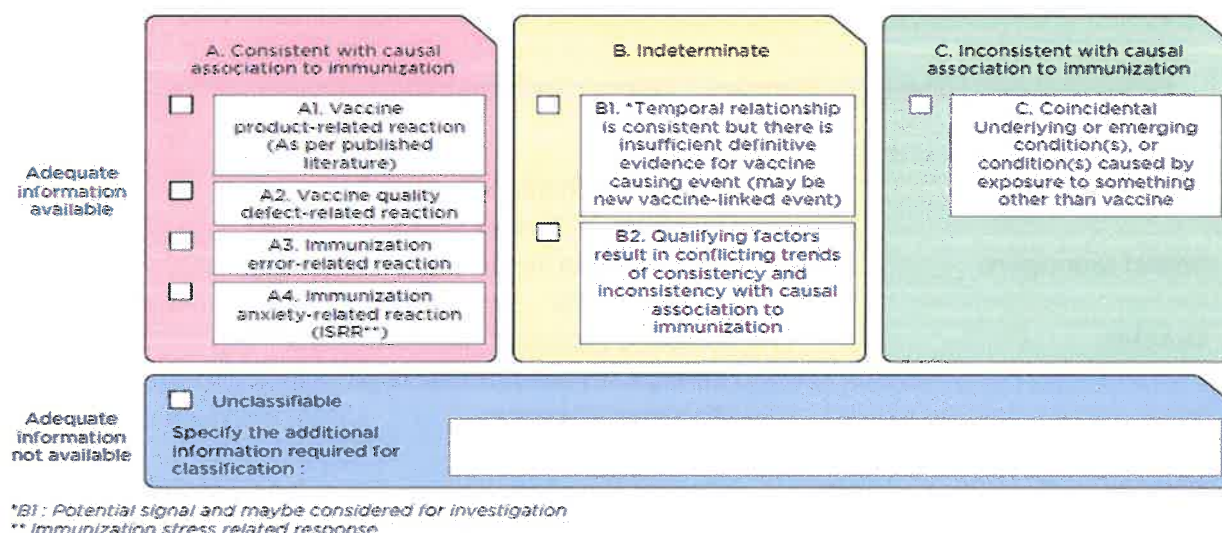
Causality assessment of AEFI is a vital component of AEFI risk assessment, decision making and initiation of action. The National Immunisation Safety Expert Committee (NISEC) reviews serious AEFI cases (according to the World Health Organization’s causality assessment methodology) at a national level and establishes whether there is a causal link between immunisation and the adverse event.

The quality of causality assessment depends on the availability of accurate and complete clinical records. 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 diagram below.

Fig. 4. Causality assessment classification



As per the Directions on the establishment of a COVID-19 vaccine injury no-fault compensation scheme issued in terms of the Disaster Management Act, 2002 (Act no. 57 of 2002), the following points should be noted: "The Department assessor/s seized with collection of the evidence required by NISEC in the determination of causality may investigate any matter that they may deem necessary for the performance of their functions."

2. CHALLENGES AND PROPOSED RECOMMENDATIONS WITH REGARDS TO THE CAUSALITY ASSESSMENT PROCESS

The below mentioned challenges were highlighted by the National Department of Health and have been stipulated in the attached national letter. These challenges have been experienced in provinces in the case investigation and causality assessment process; and needs to be addressed.

Challenges	Recommendations
1. During the causality assessment process by the provincial AEFI committee or NISEC, additional consultation with specific specialists or additional diagnostic procedures may be required to determine the final diagnosis. Without a final diagnosis, causality assessment is not possible.	➤ To facilitate the case investigation process and ensure timely causality assessment of reported AEFIs, it is recommended that these referrals or requests be considered as urgent, and steps put in place to ensure that the vaccinee consults as soon as possible at the most convenient facility.
2. After causality assessment either by the provincial AEFI review committee or NISEC, specific recommendations relating to further medical treatment of vaccinees may be advised for provincial consideration.	➤ Develop an immediate referral pathway to an appropriate health care facility as recommended by the provincial AEFI review committee or NISEC.
3. Accessing clinical notes, reports, and tests from private hospitals and private healthcare providers.	➤ Send communication to private hospitals and private health care providers, requesting their cooperation in finalising outstanding AEFI investigations.

Points 3 and 4 below addresses the recommendations from the National Department of Health at the provincial level; and need to be implemented within the provincial health system, to ensure timely and quality causality assessment.

- **We request buy-in and consensus of all hospitals and role-players/stakeholders e.g., medical records and Heads of clinical specialities (e.g., neurology, radiology, rheumatology, audiology, medical records etc.) that these severe and serious AEFI cases that have undergone or are in the process of causality assessment – be considered as priority.** This will lessen the to-and-fro and the client can be assisted as a matter of relative urgency.
- We especially request all tertiary / academic (as well as regional, specialised hospitals – hospital services) to inform the different departments/specialities within their institutions to prioritise these cases for further clinical input for causality assessment.

3. ACCESSING OF SUPPORTIVE DOCUMENTATION (CLINICAL NOTES, REPORTS, TESTS ETC.)

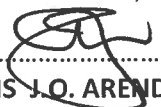
The accessing of personal information including medical records and laboratory results, autopsy summary or findings was highlighted in the NDOH issued circular, which was followed by Provincial Circular H05/2022, that included a consent form for the vaccinee/family to complete when AEFI cases are reported and being investigated. The Provincial AEFI lead's office follows up with practitioners in both the public and private sector to ensure supporting documentation is obtained for submission the review committees.

We continue to emphasise and urge all healthcare providers and practitioners to submit requested documentation, to ensure timely submission and causal assessment of severe and serious AEFI cases.

4. ADDITIONAL AEFI CASE CONSULTATIONS / DIAGNOSTIC PROCEDURES – PROCEDURES FOR URGENT REFERRALS

- 4.1 **Reported serious and severe AEFI cases that require urgent referral to specific specialists/ diagnostic procedures during the process of case investigation, and during and after causality assessment must be prioritised within the existing health referral pathways (i.e., with referral letter) and geographical areas within the health system.**
- 4.2 Patient assessment and investigation will be triaged according to standard criteria and will be further escalated as required in consultation with relevant role-players.
- 4.3 **Serious and severe AEFI cases that during case investigation and management / treatment requires immediate referral to the appropriate healthcare facility, must be initiated by the treating doctor/clinician/physician → referral facility speciality for the appropriate consultation and diagnostic procedures to establish a specific diagnosis.**
 - The treating doctor/clinician/physician must indicate to the referral facility speciality (e.g., neurology, rheumatology etc.) and appointment departments that the case/patient is reported as a severe or serious AEFI and requires an urgent consultation without delay.
- 4.4 **Serious and severe AEFI cases that during and after causality assessment require immediate referral for additional consultation with specific specialists or additional diagnostic procedures to determine the final diagnosis – these requests (differential diagnosis, committee feedback, additional information required) by the provincial review committee or NISEC will be communicated to the treating doctor/clinician by the Provincial CDC-EPI office.**
 - The treating doctor/clinician/physician must initiate the referral to the appropriate health facility / speciality / appointment departments; and must indicate the urgency of consultation.
 - The Provincial CDC-EPI unit will also engage with the appropriate specialists/department/discipline and the health facility management.
- 4.5 **The referral facility and specialists must ensure that cases are prioritised for appointments for assessment and diagnostic procedures, and ensure that all clinical notes, reports, and tests are submitted to the Provincial CDC-EPI for submission to the National Department of Health and committees responsible for causality assessment.**
- 4.6 Annexure 1 can be used by the Provincial AEFI Leads' Office (CDC-EPI) and the referring/treating doctor/clinician/physician – if required; and in line with provincial referral pathways.

Yours sincerely.


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MS J.O. ARENDSE
CHIEF DIRECTOR: ECSS

DATE: 29 Nov 2022
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ANNEXURE 1: ADVERSE EVENT FOLLOWING IMMUNISATION (AEFI) SURVEILLANCE: URGENT REFERRAL AND REQUEST FOR ADDITIONAL CONSULTATION AND DIAGNOSTIC PROCEDURES FORM			
1. Patient / case details			
AEFI EPID number (SOA-WCP-CAT-21-XXX)			
Surname		Name	
ID Number		Date of birth DD / MM / YYYY	
Age (years)		Gender	Male <input type="checkbox"/> Female <input type="checkbox"/>
Folder Number			
Facility where patient normally goes for medical care	Hospital <input type="checkbox"/> CHC <input type="checkbox"/> Clinic <input type="checkbox"/> Name: _____		
2. Referral Institutions details (patient refer to)			
Name of institution		Tel no.	
Level of care	District <input type="checkbox"/> Regional <input type="checkbox"/> Tertiary/academic <input type="checkbox"/> CHC <input type="checkbox"/> PHC <input type="checkbox"/>		
Provincial DOH – Urgent referral request			
Department:	ECSS, Service Priorities Coordination, CDC-EPI – AEFI Provincial Lead Office		
Name and surname	Ms Charlene A. Lawrence, Ms Riana Dippenaar		
Email:	Charlene.lawrence@westerncape.gov.za Riana.dippenaar@westerncape.gov.za	Tel:	021-830-3727 021-815-8664
3. Referring health practitioners' details			
Name & Surname		Date DD / MM / YYYY	
Institution		Department	
4. Referral details (attach any feedback or recommendations)			
Current / Differential Diagnosis			
Current management (attach details of necessary)			
Reasons for urgent referral			
Provincial review committee or NISEC feedback			
Additional information required e.g., investigations, treatments, diagnostic procedures			
Kindly forward the referral practitioners' report / feedback to the treating doctor and the provincial CDC-EPI Office			



**DIRECTOR GENERAL
HEALTH
REPUBLIC OF SOUTH AFRICA**

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PROVINCIAL SUPPORT FOR ADVERSE EVENTS FOLLOWING IMMUNISATION INVESTIGATION

The National Immunisation Safety Expert Committee (NISEC), reviews serious Adverse Events Following Immunisation (AEFI) at national level and require quality AEFI investigation for causality assessment. Causality assessment of AEFI is thus a vital component of AEFI risk assessment, decision making and the initiation of action.

The quality of causality assessment depends on the availability of accurate and complete clinical records. During causality assessment, either by the provincial adverse event review committee or NISEC, additional consultation with specific specialists or additional diagnostic procedures may be required to determine the final diagnosis. Without a final diagnosis, causality assessment is not possible. To facilitate the case investigation process and ensure timely causality assessment of reported AEFIs, it is recommended that these referrals or requests be considered as urgent and steps put in place to ensure that the vaccinee consults as soon as possible at the most convenient facility.

Furthermore, after causality assessment either by the provincial AEFI review committee or the NISEC, specific recommendations relating to further medical treatment of vaccinees may be advised for provincial consideration. During provincial engagements the AEFI provincial leads have indicated a challenge with accessing clinical notes, reports and test from private hospitals and private health care providers.

PROVINCIAL SUPPORT FOR ADVERSE EVENTS FOLLOWING IMMUNISATION INVESTIGATION

As per the Directions on the establishment of a COVID-19 vaccine injury no-fault compensation scheme: issued in terms of the Disaster Management Act, 2002 (Act no. 57 of 2002), the following points should be noted: "The Department assessor/s seized with collection of the evidence required by NISEC in the determination of causality may investigate any matter that they may deem necessary for the performance of their functions."

It is against this background that the Cluster: Child, Youth and School Health recommends each province to:

- Develop an immediate referral pathway to an appropriate health care facility as recommended by the provincial AEFI review committee or the NISEC.
- Send communication to private hospitals and private health care providers, requesting their cooperation in finalising outstanding AEFI investigations.

Kind regards



DR SSS BUTHELEZI
DIRECTOR-GENERAL: HEALTH

DATE: 11/10/2022