PROCEDURE FOR THE REPORTING OF ADVERSE EVENTS FOLLOWING IMMUNISATION FOR COVID-19 VACCINATION (25/02/2021)

Western Cape Government
Health

CASE DEFINITIONS

Adverse Events Following Immunisation (AEFI)

- Any untoward medical occurrence which follows immunisation and which does not necessarily have a causal relationship with the use of the vaccine. The adverse event may be any unfavourable or unintended sign, abnormal laboratory finding, symptom or disease.

Adverse Events of Special Interest (AESI)

- A pre-specified medically significant event that has the potential to be causally associated with a vaccine product.

AEFI Clusters

- Two or more AEFI cases of the same or similar events related in time or place or geographical setting; and/or vaccine (i.e. the batch/lot, manufacturer, particular facility).

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HEALTH FACILITY / HEALTHCARE WORKER ETC.

REPORT ALL MINOR & SEVERE/SERIOUS AEFI, AESI & CLUSTERS WITHIN 24HRS

- Inform the district and provincial EPI Manager, EPI Disease Surveillance Officer or Information Management Officer, and district/provincial Cold Chain / Pharmacy Manager/clinician/physician. In case of a death, immediately inform the district/provincial EPI Manager / Provincial EPI Disease Surveillance Officer via phone.
- **Obtain an EPID number form either the provincial office (Metro district) or district office (for the specific rural district).**
- Clinically manage minor, serious or severe AEFI, AESI cases and clusters accordingly. Follow the information on the management of anaphylaxis provided in the Field Guide. Contact the clinician/ physician at the referral health facility e.g. tertiary hospital if any advice is required.
- Complete the case report form (CRF) for ALL detected AEFI, AESI cases and clusters. Submit the CRF within 24 hours using the **paper-based/electronic system.** You may be requested to complete the CIF as far as possible.
- Obtain background information and records for serious or severe cases and clusters.

Reporting tools: AEFI CRF Form, AESI CRF Form, Case investigation Form

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DISTRCT

AEFI CASE REPORTING & INVESTIGATION OF SEVERE / SERIOUS AEFI, AESI, & CLUSTERS

- District EPI Manager informs the Provincial CDC-EPI Office / EPI Disease Surveillance Officer of serious/severe AEFIs. Provide and EPID number for all AEFI cases reported.
- The district in liaison with province initiate the case investigation by a multi-disciplinary healthcare team within 48 hours. Conduct a facility visit and use clinical records, vaccine recipient interviews, vaccinator interviews and observations to complete the CIF
- Submit any completed CRF or CIF form and documentation from the health facility, district to the Provincial / District Surveillance Officer or District / Provincial EPI -CDC Manager within 48hrs.
- **Reporting tools: CRF and CIF Forms for AEFI and AESI, and line lists**

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PROVINCE

AEFI CASE REPORTING AND INVESTIGATION OF SEVERE / SERIOUS AEFI, AESI, & CLUSTERS

The Provincial CDC-EPI Office facilitates case investigation and supports the districts as needed.

- Provincial CDC-EPI Surveillance Officer informs National EPI Office / AEFI Coordinator of the serious/severe AEFIs. An EPID number if required on the new forms will be issued either at the provincial / district level
- The Provincial CDC-EPI Surveillance Officer follows up and ensure all CRF, CIF and all documentation (clinical notes, laboratory results, autopsy (verbal, post mortem) etc.) and line lists are submitted to National EPI / AEFI Coordinator.
- **Reporting tools: completed CRF and CIF Forms for AEFI and AESI, and line lists (paper-**

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NATIONAL EPI

- Informs SAHPRA, vaccine supply companies, etc. of the reported AEFI, AESI, and clusters (serious, severe).
- Submit all documentation of case investigations to NISEC for causality assessment
- Support the province/district
- Follow-up feedback from NISEC and communicate findings of outcome to the vaccine recipient and the province to ensure implementation of corrective measures in the case of a programme error.

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NATIONAL IMMUNISATION SAFETY EXPERT COMMITTEE

- Reviews serious and severe AEFI
- Conducts causality assessments that must be completed in 30 days
- Classify cases & communicate outcome with the National Department of Health: EPI, province etc.

Western Cape DoH
CDC-EPI Programme
Surveillance Officer, EPI Manager, CDC Manager
021-483-9917/3156
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Clinician at referral health facility

Rural District Health Services (RDHS) & Metro District Health Services (MDHS)

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

See contact list in circular / memo

National Expanded Programme on Immunisation (EPI):

EPI Manager
012-395-8380
076-690-2138)

AEFI Coordinator

012-395-9461
082-467-1669

Email to submit documentation:
AEFI@health.gov.za

NB! Consult the

- Vaccination Field Guide: COVID-19 Vaccine or Safety Surveillance document
- WHO COVID-19 Vaccines: Safety Surveillance Manual and Healthcare Worker training packages