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TO: **DDG: Chief of Operations**

Chief Directors: MHS, RHS, STRATEGY

Directors: EMS, FPS, SPC, HIA, Clinical Service Improvement, Medicine Management, Substructures, Districts

Head of Institutions

Director: City Health

Executive Directors: Local Authorities, South African Military Health Services

Managers: Private Hospitals, private clinics, pharmacies, Department of Correctional Services

Circular H 74. /2022

ADVERSE EVENTS FOLLOWING IMMUNISATION (AEFI) SURVEILLANCE: NATIONAL PROCEDURE FOR REPORTING AND INVESTIGATION OF DEATH OCCURING AFTER COVID-19 VACCINATION

It is expected that deaths could occur post COVID-19 vaccination, and any such deaths should be reported as an AEFI to ensure investigation and causality assessment. Prompt and accurate post-mortem investigations are required for deaths that are suspected to be due to an adverse event following immunisation or are otherwise unexplained to ensure accurate and timely causality assessment by the National Immunisation Expert Committee (NISEC).

According to the National Department of Health, since January 2021, 117 deaths that occurred after vaccination have been causality assessed, with 16 cases classified as unclassifiable due to incomplete information and investigation. To improve investigation and causality assessment, a standard operating procedure (SOP) has been compiled to guide the reporting and investigation of deaths after vaccination, which must be implemented in provinces.

The attached national SOP aims to guide the process of investigating a death which occurred after immunisation, including after COVID-19 vaccination. It specifically outlines how to conduct a preliminary investigation in the case of death of a person after having received a COVID-19 vaccine, for the purpose of conducting a causality assessment.

Kindly find attached the following documents to ensure implementation at all health facilities (including forensic pathology services), and at sub-district, substructure, and district levels.

- National Department of Health Standard Operating Procedure: AEFI Reporting and investigation of death occurring after vaccination, dated 07/03/2022
    - Annexure 1: 2014 WHO Verbal Autopsy Sample Questionnaire
    - Annexure 2: (AEFI) – Pathology report (Absence of Autopsy)
    - Notice of Death / Still birth, DHA-1663 A
    - Case Reporting Form (CRF) for Adverse Events Following Immunisation (AEFI) – ALL VACCINES including COVID-19
    - All Vaccines Including COVID-19: Case Investigation Form (CIF) - AEFI & AESI
- **Annexure 1**: Summary of National Death occurring after COVID-19 Vaccination Standard Operating Procedure: Reporting and Investigation. Kindly note the attached provincial summary of the national SOP contains some minimal changes which is highlighted in red in the annexure.

Complete and comprehensive case investigations are required for deaths occurring after vaccination, and this entails the completion of a CRF, CIF and the submission of supporting documentation (e.g., medical records, clinical notes, laboratory reports, findings of clinical examinations, doctor's summaries, national pathology reports – **Annexure 2**, verbal autopsy, official written Forensic Pathology Services autopsy summary of findings. The investigation requires facilitation with forensic pathology, emergency medical services, sub-district, and district health services, to ensure the submission of all supporting documentation for causality assessment.

Kindly ensure all healthcare workers at health facility level (including forensic pathologists, emergency medical services/paramedics etc.) sub-district/substructure and district public health officials that are part of AEFI investigation teams are acquainted with the content of the circular, to ensure the implementation of the standard operational procedures.

Yours sincerely.

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JO ARENDSE
CHIEF DIRECTOR: ECSS
DATE: 20/05/2022

ANNEXURE 1: SUMMARY OF NATIONAL DEATH OCCURING AFTER COVID-19 VACCINATION STANDARD OPERATING PROCEDURE: REPORTING AND INVESTIGATION

1. DEATH OCCURING AFTER COVID-19 VACCINATION

- Reporting unexplained deaths occurring after vaccination or in persons with a history of COVID-19 vaccination, is important due to the high number of deaths unrelated to vaccination during a pandemic, and because such deaths can cause significant concern among the community. In the case of death being temporally related to COVID-19 vaccination, post-mortem investigations play an essential role in causality assessment.
- Clinicians have a legislative responsibility to accurately report causes of death on the South African death notification form. Adherence to the standard poste-mortem examination, which allows for comprehensive causality assessment of a reported death following vaccination, is imperative, to confirm or rule out causal relationship between vaccination and AEFI.
- In a standard post-mortem examination, it is important to classify the deaths as either due to natural causes or due to unnatural causes. When classifying a death as natural the underlying causes of death, the causal sequence and the contributing causes should be clearly described.

The following deaths should be investigated:

- All suspected deaths that are suspected to be due to an adverse event following immunisation or are otherwise unexplained, occurring within 30 days after vaccination
- A death that occurred beyond 30 days after vaccination where the death may be due to an adverse event such as a deep vein thrombosis (which could occur up to 90 days post vaccination for some vaccines)
- An adverse event with an onset of the reaction within 30 days after vaccination resulting in death after 30 days
- A death which occurred more than 30 days after vaccination where biological plausibility does exist that the vaccine could have contributed to the death.

2. CAUSALITY ASSESSMENT

In South Africa, the basic framework and methodology of the World Health Organization (WHO) is used for causality assessment of all serious and non-serious severe AEFI. Causality assessment is conducted by the National Immunisation Safety Expert Committee (NISEC) for all cases of serious and non-serious severe AEFIs, clusters and adverse events of special interest (AESIs), reported to the National Department of health (NDoH) Expanded Programme on Immunisation (EPI) and the South African Health Products Regulatory Authority (SAHPRA).

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) competed.
- 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.)

Cases are classified after causality assessment by NISEC as i) consistent with causal association to immunisation, ii) indeterminant iii) inconsistent with causal association to immunisation, and iv) unclassifiable. Please refer to the national SOP for more details with regards the classification categories.

3. PROCESS OF CAUSALITY ASSESSMENT OF DEATH OCCURING AFTER VACCINATION

Step 1: Determine the eligibility of the case

- Ascertain that the vaccine was administered before the event occurred
- Obtain detailed and careful clinical history and physical findings from relevant informers
- Have a valid diagnosis for the referred AEFI (adverse or unwanted sign, an outlier laboratory result, a symptom, or a disease)
- If the cause of death is unnatural, an autopsy is mandatory in terms of the Inquest Act (Act 58 of 1959) to identify the exact cause of death.

Step 2: Evaluate the AEFI and define the questions as to whether the COVID-19 vaccine caused e.g., thrombocytopenia, which resulted in death from natural causes.

After these steps above, there are important questions that need to be answered to proceed:

- Is there strong evidence for other causes?
- Is there a known causal association with the vaccine or vaccination?
- Is there strong evidence against a causal association?

Process to follow when death occurs after vaccination

The process that needs to be followed when a death which occurred following COVID-19 vaccination is identified or reported is outline in Table 1, Page 4 of the national SOP. Kindly refer to it, as more detail is contained in it. See Figure 1 below for ease of reference.

Figure 1: Summary of the process to follow when death occurs after vaccination

Identification of death occurring after COVID-19 vaccination

- **Inclusion:** Individuals who die following COVID-19 vaccination, where the death is suspected to be due to an adverse event following immunisation (AEFI), OR any other diagnosis that is an AESI (Adverse Event of Special Interest), OR otherwise unexplained
- **Time onset of death:** No time limit, but in general those who die within 30 days following any vaccination
- Review serious and severe AEFI for causality

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Registering of death

- **Report death to the Registrar of Births and Deaths:** Follow the prescribed process with the DHA-1663 forms completed

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Report death as a serious AEFI

- **Report the death as a serious AEFI:** Immediately within 24 hours) report the death using the Med Safety APP or Complete the AEFI CRF and email to AEFI@health.gov.za or the Provincial CDC-EPI AEFI office
- **Inform District / Provincial AEFI Coordinator:** Immediately (within 24 hours) inform the District/Provincial AEFI Coordinator by phone. See circular H72/2022)

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Request an autopsy

- **General considerations for an autopsy**
  - Preferred and recommended following all deaths suspected to be caused by vaccination
  - Discuss suspected cases of unnatural death with the Forensic Pathologist, regarding possible referral for an autopsy. See further considerations for autopsy on Page 5 of National SOP, all in the provisions of the Inquest Act
- **If death occurring after vaccination is due to natural causes, and a causal association to vaccination is not suspected, at minimum an AEFI Pathology Report (Annexure 2) with immediate cause, underlying cause, contributing factors resulting in the death classified as natural cause MUST be included. If the information is not available (e.g., such as when a person dies at home, without seeking medical treatment) complete the pathology report by conducting a verbal autopsy Annexure 1 of National DOH-SOP). Please note that the Pathology Report information is also contained on Page 4 of the standard notification of death form (BI-1663), the same details can thus be used to complete an AEFI pathology report.**
- **Case triage:** priority for autopsy → anaphylactic events and no readily obvious and plausible explanation for cause of death; If the vaccinee has a positive SARS-CoV-2 swab result → autopsy not required, but a descriptive AEFI pathology report is required.
- **Communication with family or next of kin of deceased**

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Autopsy requirements

- **Information provided to the pathologist:**
  - Documents outlining detailed preclinical and clinical history, including laboratory and radiological findings.
  - If indicated, tissue samples should be collected for in-depth pathologic, virological and genetic testing.
- **Autopsy guidelines:** The extent of the autopsy examination and ancillary investigations must be determined as appropriate for the particular case by the pathologist
- **Ancillary testing:** See testing modalities on page 6 of National SOP

Autopsy not possible

Verbal autopsy

- Conduct a complete verbal autopsy as part of the case investigation, according to standard protocols and guidelines (Annexure 1)
- Document findings and include with AEFI case investigation documents for submission to NISEC.

Case investigation of death as serious AEFI

- **Team**
  - District AEFI team to ensure case investigation commences within 48 hours of the AEFI notification and that the autopsy results are included in the submitted clinical records for causality assessment.
- **Visit to the scene of death**
  - Visit the scene of the death to gather additional evidence if required
  - Samples for microbiology, immunology, histopathology, and virology should be collected according to the instructions given by the relevant laboratories
- **Minimum information to be collected in case of a death post vaccination (see page 7 of National SOP) OR alternatively the CIF could be completed by the pathologist or clinician**
- **Submission of supporting documents:** medical records, clinical notes, laboratory reports, findings of clinical examinations, Annexure 2: National AEFI Pathology, verbal autopsy (Annexure 1 of NDoH SOP), and official FPS post-mortem/autopsy findings/summary,
- **Submit all documentation i.e., CRF, CIF, and supporting documentation to the NDoH EPI to process to NISEC.**

4. LEGISLATIVE REQUIREMENTS FOR CONSIDERATION

- If the cause of death is natural, the medical practitioner should complete a death notification form. If the medical practitioner is uncertain or is of the opinion that the death was due to causes other than natural, he/she shall not issue the above-mentioned form and shall inform a police officer and Forensic Pathology Services.
- In uncertain and unnatural cases, a medical practitioner must submit with the body or as soon as possible, all information pertaining to the deceased that will be relevant for medico-legal examinations.
- The decision to perform a medico-legal post-mortem examination is guided by the provisions of the Inquest Act and the National Health Act.
- **If a definite diagnosis of a natural cause of death not associated with vaccination has been made, no further forensic pathology investigation should be necessary, and the case should not be referred to Forensic Pathology Services.**
- **As a minimum if death occurs within 30 days following vaccination, and it is due to natural causes, and where a causal association to vaccination is not suspected**, the following reports are required:
  - **Pathology report with the immediate cause, underlying cause, contributing factors resulting in the death** classified as natural causes (Annexure 2: AEFI Pathology Report of national SOP) **MUST be included. If the information is not available (e.g., such as when a person dies at home, without seeking medical treatment), then the clinician should complete the pathology report by conducting a verbal autopsy** (use Annexure 1 of the National SOP as a guide). Please note that the required information for the AEFI Pathology Report is also contained on Page 4 of the standard notification of death form (BI-1663), the same details can thus be used to complete an AEFI pathology report.
  - **The AEFI CRF, CIF, and supporting documentation** (e.g., medical records, clinical notes, laboratory reports or findings of clinical examinations, doctor's notes/summary, discharge summaries)

  This will allow for a valid diagnosis to be identified, to consider during causality assessment of AEFI reported as death occurring after vaccination.

5. ROLES AND RESPONSIBILITIES WHEN INVESTIGATING A DEATH OCCURING AFTER VACCINATION

- Kindly refer to Provincial Circular H72/2021 and the national SOP, page 8-9 for more details. The table below highlights some key points and specific roles and responsibilities that must be taken in consideration when investigating a death occurring after vaccination.

Table 1: Specific Roles and Responsibilities related to investigation of a death occurring after vaccination

	Levels of Reporting	Roles and responsibilities
1.	**Vaccinators or health care workers**	• Identification and immediate reporting of all AEFIs presenting at the health facility or establishment (e.g., Forensic Pathology Services) • In the event of a report of death occurring after vaccination, inform the health facility manager immediately. Complete the paper-based CRF or report the case on MedSafety APP. Notify the health facility managers of the case and obtain an EPID number / case reference number generated by the MedSafety APP.
2.	**Health facility/healthcare provider / health facility managers (clinics, primary health care centres, hospitals, forensic pathology services)**	• Immediate reporting of AEFI and AESI cases and clinical management and treatment of the vaccinee presenting to the facility, and appropriate referral to the next level of care of necessary.

		• The treating healthcare professional to submit supporting documentation (medical records, Annexure 2: AEFI Pathology report of National SOP) for severe AEFI cases with non-serious and serious outcomes, including deaths. • In the event of a death occurring after vaccination, alert the district office for further guidance. Complete and submit the CRF (obtain EPID number) or the MedSafety APP reference number to the district/provincial official.
3.	**District / substructure / sub-district AEFI Coordinators (officials responsible for EPI/Communicable Disease Control/infection prevention and control etc.)**	• In the event of death occurring after vaccination, alert the provincial office for further guidance. Submit CRF, CIF and clinical records and supporting documentation (medical records, verbal autopsy and post-mortem results/summaries, Annexure 2: AEFI Pathology Report of national SOP) is obtained to the provincial officials.
4.	**Province/Provincial CDC and EPI (including EPI/VPD Disease Surveillance officials)**	• In the event of death occurring after vaccination alert the Provincial AEFI Committee (including Forensic Pathology Services), and National Department of Health. • In the case of death after vaccination ensure necessary post-mortem examinations completed. • Ensure supporting documents/medical records/verbal autopsy and post-mortem results/summaries / Annexure 2: AEFI Pathology Report of national SOP) is obtained.
5.	**Provincial AEFI Review Committee (including programme officers, EPI, CDC, Pharmacy Services, Communication, Surveillance and specialists)**	• Assists in investigation of AEFI cases (including suspected deaths occurring after 90 days after vaccination) with technical input, when required, along with supporting documents/medical records/verbal autopsy and post-mortem results/summaries/ Annexure 2: AEFI Pathology Report of national SOP) • Submit all documentation i.e., CRF, CIF, and supporting documentation to the NDoH EPI to process to NISEC.
6.	**National Immunisation Safety Expert Committee (NISEC)**	• The NISEC will conduct causality assessment, to determine if there is a causal relationship between the suspected AEFI and the vaccine. • Feedback on the outcome of the causality assessment will be provided to the national and provincial levels, to allow for appropriate corrective actions if necessary.

6. CONTACT NUMBERS AT PROVINCIAL CDC/EPI AND FORENSIC PATHOLOGY SERVICES (FPS)

The following individuals from the CDC-EPI-FPS units may be contacted for specific enquiries. Listed below is also Forensic Pathology Services Managers.

CONTACT	TELEPHONE / CELL	E-MAIL
Provincial Communicable Disease Control (CDC), and Expanded Programme on Immunisation (EPI)		
Ms Charlene A. Lawrence Provincial CDC Coordinator:	021-483-9964 072-356-5146	Charlene.Lawrence@westerncape.gov.za
Ms Sonia Botha Provincial EPI Coordinator	021-483-4266 083-576-7893	Sonia.Botha@westerncape.gov.za
Ms Riana Dippenaar Provincial AEFI Surveillance Manager	021-483-9917 082-891-5755	Riana.Dipenaar@westerncape.gov.za
Ms Felencia Daniels Provincial CDC Administrative Clerk	021-483-3156	Felencia.daniels@westerncape.gov.za
Forensic Pathology Services (FPS		
Ms Vonita Thompson Director: FPS	082-443-3009	Vonita.thompson@westerncape.gov.za
Mr. Sean Fyfe Deputy Director: Garden Route Central Karoo & West Coast	083-650-2379	sean.fyfe@westerncape.gov.za
Mr. Brent Jonker. Deputy Director: Boland Overberg	023-347-6233 083-541-6662	Brent.jonker@westerncape.gov.za
Mr. Kevin Jones Deputy Director: Metro	021-826-5734 083-446-0859	Kevin.jones@westerncape.gov.za
Mr. Carl Gordon Facility Manager: Tygerberg	021-931-4232/3 061-101-3426	Carl.Gordon@westerncape.gov.za
Mr. Wayne Mitten Facility Manager: Salt River / Ops manager OFPI	021-448-4456 071-815-9923	Wayne.mitten@westerncape.gov.za
Dr. J. Verster Head of Forensic Medicine Department: Tygerberg FPS / Stellenbosch University (Forensic Pathologist Expert)	021-931-8043	jverster@sun.ac.za
Prof. Lornaj Martin. Head of Forensic Medicine Department: UCT & Observatory Forensic Pathology Institute	021-447-1496	Lornaj.martin@uct.ac.za
Dr. Gavin Kirk	021-406-6821	gavin.kirk@uct.ac.za

Forensic Pathologist Expert	083-656-4204	

DEATH OCCURRING AFTER COVID-19 VACCINATION

1. Purpose of this document

Although serious and non-serious severe adverse events following immunisation (AEFIs) are rare, those temporally related to vaccine administration could be a major threat to the immunisation programme, as it may result in lack of confidence in vaccines. Hence it is necessary to determine if there is a causal relationship between an AEFI and a particular vaccine, or whether the event happened coincidentally, and independent of vaccination.

This document aims to guide the process of investigating a death which occurred after immunisation including after COVID-19 vaccination. The following deaths should be investigated:

- All deaths occurring within 30 days after vaccination
- A death that occurred beyond 30 days after vaccination where the death may be due to an adverse event such as deep vein thrombosis (which could occur up to 90 days' post vaccination for some vaccines)
- An adverse event with an onset of the reaction within 30 days after vaccination resulting in death after 30 days
- A death which occurred more than 30 days after COVID-19 vaccination where biological plausibility does exist that the vaccine could have contributed to the death.

The document will outline how to conduct a preliminary investigation in the case of death of a person after having received a COVID-19 vaccine, for the purpose of conducting a causality assessment.

2. Causality Assessment

In South Africa, the basic framework of the World Health Organization (WHO) is used for causality assessment of all serious and non-serious severe AEFI.[1] Causality assessment is conducted by the National Immunisation Safety Expert Committee (NISEC) for all cases of serious and non-serious severe AEFIs, clusters and adverse events of special interest (AESIs), reported to the National Department of Health (NDoH) Expanded Programme on Immunisation (EPI) and the South African Health Products Regulatory Authority (SAHPRA). A structured, unbiased, robust, and systematic assessment process, based on the WHO methodology for causality assessment is followed.[1]

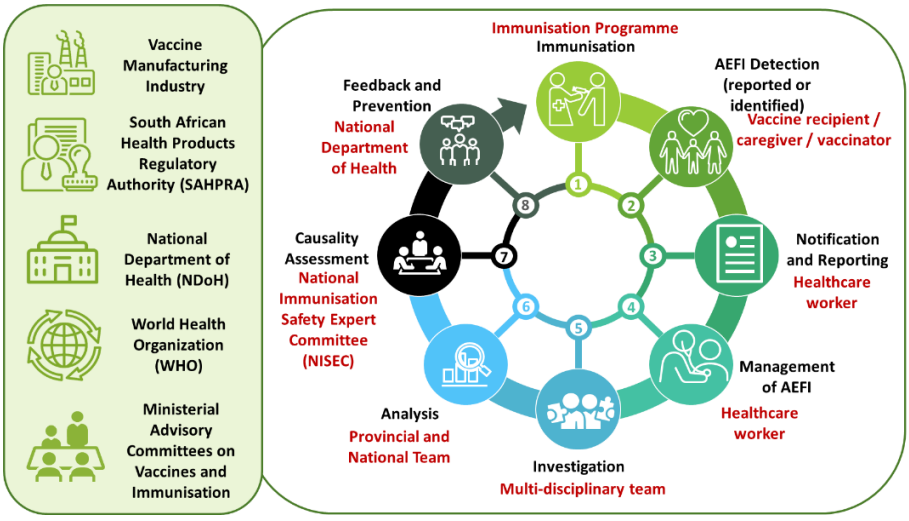

Figure 1 illustrates the vaccine safety surveillance cycle used in South Africa.

2.1. Prerequisites for AEFI causality assessment

2.1.1 Case investigation completed

Case investigation completed, with both the case reporting form (CRF) and the case investigation form (CIF) completed.

2.1.2 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.

2.1.3 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 report).[2]

2.2. Classification of AEFIs after causality assessment by NISEC

2.2.1 Consistent with causal association to immunisation (A)

A1. Vaccine product-related reaction: Caused or precipitated by a vaccine due to one/more of the inherent properties of the vaccine product, even when the vaccine has been prepared, handled and administered correctly.

A2. Vaccine quality defect related: Caused or precipitated by a vaccine, due to one/more quality defects of the product, including its administration device, provided by the manufacturer.

A3. Immunisation error-related reaction: Caused by inappropriate vaccine handling, prescribing or administration.

A4. Immunisation stress-related response: Arising from anxiety about the immunisation and/or fear of needles or an injection.[2]

2.2.2. Indeterminate (B)

B1. A temporal relationship is consistent but there is insufficient definitive evidence of the vaccine causing the event (may be new vaccine-linked event). This could be a potential signal and may be considered for investigation.

B2. Qualifying factors result in conflicting trends of consistency and inconsistency with causal association to immunisation.

2.2.3 Inconsistent with causal association to immunisation (C)

Coincidental event: An event that happens after vaccination but is not caused by the vaccine or vaccination process, because there are underlying or emerging condition(s), or a condition(s) caused by exposure to something other than the vaccine.

2.2.4 Unclassifiable (D)

The case cannot be classified because the information available about the case is inadequate and additional information is required for classification.[2]

3. Death occurring after vaccination

Reporting deaths occurring after COVID-19 vaccination or in persons with a history of COVID-19 vaccination, is important due to the high number of deaths unrelated to vaccination during a pandemic, and because such deaths can cause significant concern among the community. In the case of death being temporally related to COVID-19 vaccination, post-mortem investigations play an essential role in causality assessment. This requires consideration of any possible causal relationship between the COVID-19 vaccine administration and the AEFI, and to exclude any coincidental causes of the AEFI.

Clinicians have a legislative responsibility to accurately report causes of death on the South African death notification form. It is important therefore that a thorough case investigation of a death must be conducted without any delay, to assess the cause of death and identify all relevant risk factors. Adherence to standard post-mortem examination, which allows for a comprehensive causality assessment of a reported death following vaccination, is imperative, to confirm or rule out a causal relationship between vaccination and the AEFI.

In standard post-mortem examinations, it is important to classify a death as either due to natural causes or dues to unnatural causes. When classifying a death as natural the underlying cause of death, the causal sequence and the contributing causes should be clearly described. In the absence of this information, AEFI causality assessment is likely to be indeterminate [3,4]

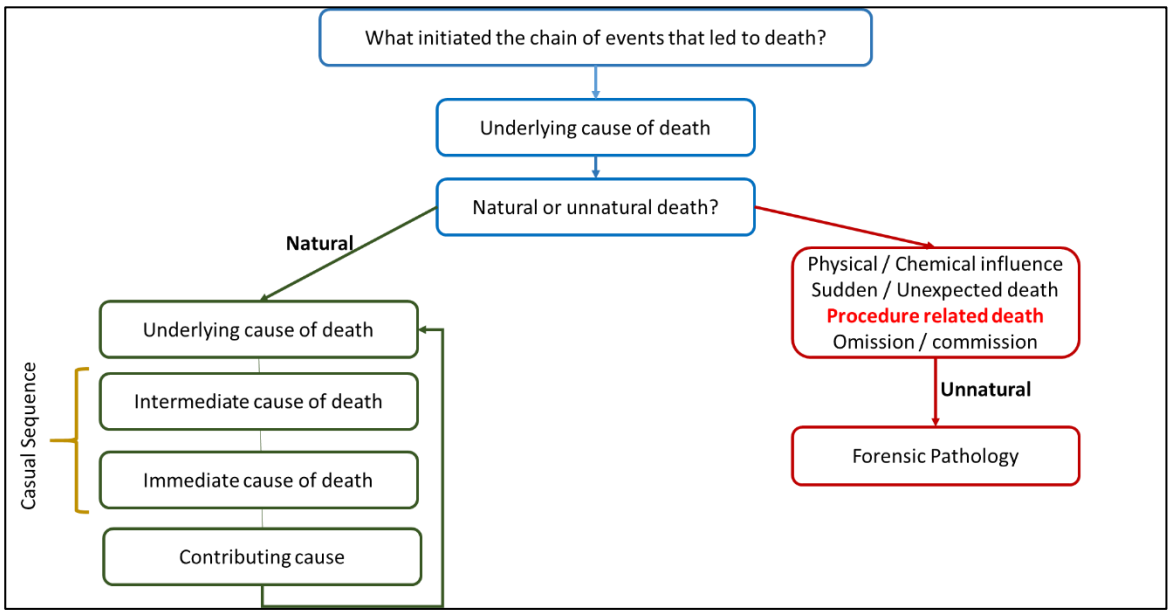

Figure 2: Process for certification of cause of death[4]

- The underlying cause of death is the disease or injury that started the sequence of events leading directly to death or the circumstances of the accident or violence that produced the fatal injury. In the case of a violent death, the form of external violence or accident is antecedent to the injury, although the two events may be almost simultaneous.
- The immediate cause of death is the final disease, injury or complication directly causing the death. It should be noted that the mechanism of death or terminal event (e.g., heart failure, cardiac arrest, respiratory arrest) is not considered to be a valid underlying cause of death and should not be reported on the death certificate without stating the preceding disease or injury.

- Contributing causes of death are other significant conditions contributing to the death, but not part of the direct causal sequence. For example, if a person who is HIV positive dies following complications of surgery for cancer of the cervix, HIV is a contributing cause, but not the underlying or immediate cause of death.[4]

3.1. Causality assessment of death occurring after vaccination

The first step in causality assessment is to determine the 'eligibility' of the case, as it is important to ascertain that the **vaccine is administered before the event occurred.** This can be established by obtaining a very detailed and careful **clinical history and physical findings** plus collecting information from relevant informers. It is also crucial to have **a valid diagnosis for the referred AEFI**, which could be an adverse or unwanted sign, an outlier laboratory result, a symptom, or a disease. If a death occurs after vaccination and the cause of death is considered unnatural, an autopsy should be considered mandatory to identify the exact cause of death.[5]

The next step is to evaluate the AEFI and define the question as to whether the COVID-19 vaccine caused e.g., thrombocytopenia, which resulted in death from natural causes.

After these steps, it is important to proceed answering the following questions: [8]

- **Is there strong evidence for other causes?** To answer this question, it is fundamental to analyse the medical history of the patient, focusing on the clinical examination to confirm the relationship.
- **Is there a known causal association with the vaccine or vaccination?** For this question, it is important to analyse the vaccine product and vaccine quality. Moreover, it is important to exclude immunisation errors and immunisation stress-related responses.
- **Is there strong evidence against a causal association?** At this point, a literature review should be performed in order to exclude the presence of published evidence against a causal association between vaccine administration and the event.
- **Finally, it is important to analyse other qualifying factors for classification** (e.g., pre-existing conditions, event-related to previous vaccinations).

3.2. Process to follow when a death occurs after vaccination

Table 1 outlines the process that needs to be followed when a death which occurred following COVID-19 vaccination is identified or reported.

Table 1: Process to follow when a death occurs after vaccination

Identification of death occurring after COVID-19 vaccination	
Inclusion	Individuals who die following COVID-19 vaccination, irrespective of attribution to vaccination, including any related diagnosis that is an AESI.[6]
Time onset of death	No time limit, but in general those who die within 30 days following any vaccination.
Registering a death	
Report death to the Registrar of Births and Deaths	Follow the prescribed death registration process with the DHA-1663 forms completed[11]

Report death as a serious AEFI	
Report the death as a serious AEFI	Immediately (within 24 hours) report the death using: • Med Safety App OR • Complete the AEFI CRF and email to AEFI@health.gov.za
Inform District/Provincial AEFI Coordinator	Immediately (within 24 hours) inform the District/Provincial AEFI Coordinator by phone.
Request an autopsy	
General considerations for an autopsy	• Preferred and recommended following all deaths suspected to be caused by the vaccine or the vaccination. • Discuss suspected cases of unnatural death with the Forensic Pathologist, regarding possible referral for an autopsy. • If death occurring after vaccination is due to natural causes, and a casual association to vaccination is not suspected, a verbal autopsy[7] (Annexure 1) or AEFI pathology report (Annexure 2) is required with the immediate cause, underlying cause, contributing factors resulting in the death classified as natural causes. This will establish a valid diagnosis, to consider during causality assessment of an AEFI reported as a death occurring after vaccination. If these criteria are met, then an autopsy is not required. • Where the death is sudden and unexplained, the death should be considered under the provisions of the Inquests Act. A medico-legal autopsy is required and in this case, consent from the family is not required. However, the religious and cultural preferences of the family should be considered. • In cases where a medico-legal autopsy is not indicated, but an autopsy is considered necessary, an anatomical autopsy could be sought should this type of resource be available. In these cases, the consent of the next of kin is required. • Decision to conduct the anatomical autopsy should be taken within the legal framework while considering the religious and cultural context. • Autopsy investigations may include the following: radiological examination; histopathological examination; and toxicological and microbiological examinations. • For medico-legal post-mortems performed under the Inquest Act: A post-mortem examination on a body or the remains of a body may only be performed by a medical practitioner who is (a) registered as such with the Health Professions Council of South Africa; and (b) has been appointed by the Head of Department for this purpose, and therefore an authorised person.
Case triage: priorities for autopsy	• Most anaphylactic events attributable to vaccination occur within minutes to hours. Death occurring suddenly post-vaccination (i.e., within 24 hours) → Prioritise for autopsy. • If there is no readily obvious and plausible explanation for the cause of death → Prioritise for autopsy. • A sudden, unexpected and unexplained death requires medico-legal investigation, which may include an autopsy.

	• If there are new onset signs/symptoms not fully explained by underlying conditions → Consider for autopsy • Individuals with suspected COVID-19 → Perform a SARS-CoV-2 swab post-mortem.[8] • If the vaccinee has a positive SARS-CoV-2 swab result →Autopsy not required, but a descriptive AEFI pathology report is required. • If the vaccinee has a positive SARS-CoV-2 swab result, but events resulting in death could be attributed to vaccination → Consider an autopsy. • Post-mortem testing for SARS-CoV-2 should be conducted on all persons who demised at home or outside a health facility.
Communication with family or next of kin of deceased	• Clinician must explain to the family why it is necessary for the autopsy to be conducted. • In the case of suspected COVID-19 infection or where it cannot be ruled out, explain that a diagnosis is required to establish if the deceased was infected with SARS-CoV-2[8].
Autopsy requirements[13]	
Information provided to pathologist	• Documents outlining detailed preclinical and clinical history, including laboratory and radiological findings. • If indicated, tissue samples should be collected for in-depth pathologic, virological and genetic testing.
Autopsy guidelines	The extent of the autopsy examination and ancillary investigations must be determined as appropriate for the particular case by the pathologist. • Collect a nasopharyngeal swab and submit for SARS-CoV-2 PCR as per instructions for all persons who die in the community. Label the sample clearly as 'autopsy specimen'. The NHLS will process these tests at no cost for private patients[8] • Perform full autopsy (preferably including brain and spinal cord). • In addition to nasopharyngeal swab for SARS-CoV-2, perform thorough histologic sampling to evaluate for cause of death, including collection of lung and upper airway tissues if COVID-19 is suspected.[9] • Assess for findings consistent with anaphylaxis, i.e., laryngeal oedema, pulmonary hyperinflation, mucus plugging of airways, tissue eosinophilia. • Examine the vaccine injection site for evidence of inflammation/infection.
Ancillary Testing	• For cases of suspected anaphylaxis, consider testing for serum tryptase levels, and serum IgE levels. • Consider freezing blood or tissue. • Conduct appropriate toxicological analysis based on ante mortem history, symptoms and exposures. • COVID-19 PCR is compulsory for all persons who die in the community. • Routine post-mortem microbiologic and other infectious disease testing, as indicated by gross findings and clinical history. • Request ante mortem laboratory specimens, if available. • Other tests as appropriate for diagnoses under consideration.[10]
Autopsy not possible	

Verbal autopsy	• Conduct a complete verbal autopsy[7] as part of the case investigation, according to standard protocols and guidelines.[6] (Annexure 1) • Document findings and include with case investigation documents for submission to NISEC.
Case investigation of death as a serious AEFI	
Team	District AEFI investigation team should ensure that the case investigation commences within 48 hours of the AEFI notification and that the autopsy results are included in the submitted clinical records for causality assessment.
Visit to the scene of death	• Visit the scene of the death to gather additional evidence if required. • Samples for microbiology, immunology, histopathology and virology should be collected according to the instructions given by the relevant laboratories.
Minimum information to be collected in case of a death post vaccination; Alternatively the CIF could be completed by the pathologist or clinician	• Date and time of vaccination. • What type of vaccine (trade name, manufacturer, dose number, batch number) • Facility where vaccine was administered. • Body site, including right or left, where vaccine was injected. • Date and time of symptom onset. • Specify symptoms experienced (e.g., local reactions, systemic symptoms, cough, sore throat/ILI, rash/urticaria, wheezing, stridor, angioedema, shortness of breath, chest pain). • Any other recent vaccinations. • Describe history of adverse events after other vaccinations. • Specify all current medication taken, including herbal and dietary supplements. • Specify any known allergies. • Specify other comorbidities. • Describe any recent history of COVID-19. • Describe any laboratory testing results and attach relevant documentation. • Describe any other pertinent exposure history (e.g., recent trauma, surgery, hospitalisation, travel, COVID-19 contacts).[10]
Death certification	• Complete relevant documentation described below and share outcome of the pathology report with the AEFI investigation team.

4. Legislative requirements and considerations

If the cause of death is natural, the medical practitioner should complete a death notification certificate Department of Home Affairs (DHA) 1663. A copy of the form should be provided to the next-of-kin or funeral undertakers. If a medical practitioner is uncertain or is of the opinion that the death was due to causes other than natural, he/she shall not issue the above-mentioned form and shall inform a police officer and Forensic Pathology Services.[4]

In uncertain and unnatural cases, a medical practitioner must submit with the body or as soon as possible, all information pertaining to the deceased that will be relevant for medico-legal examinations.

No medical practitioner may perform a post-mortem examination on the body of a deceased person "...who has died of other than natural causes", unless it is specifically done in terms of the Inquests Act

i.e., within the formal framework of medico-legal investigation of death and with the full involvement and notification of the SAPS, where a case should be opened before Forensic Pathology involvement.[4]

The only exception is when a certificate (form BI 1663), confirming exclusively natural causes of death, is issued before a post-mortem examination was performed.[6] Under these circumstances, the post-mortem can only be conducted with the expression of prior consent of the next of kin or where the deceased has consented to such an examined prior to his/her death.[4]

Since an autopsy should only be performed if required as provided for by the Inquests Act, or in cases where resources exist for an anatomical autopsy, the decision to perform a medico-legal post-mortem examination, is guided by the provisions of the Inquests Act and the National Health Act[4]. Therefore, the next of kin should be notified that failure to conduct an autopsy in the event of death as an AEFI, or cases where natural causes are stated on the death certificate without supporting clinical records, could impede their attempt to later claim from the No Fault Compensation Scheme established by the NDoH.

Thus, **as a minimum if death which occurs within 30 days following vaccination, and is due to natural causes, and where a casual association to vaccination is not suspected**, the following reports are required:

1. A **verbal autopsy**; AND
2. **Pathology report** with the **immediate cause, underlying cause, contributing factors resulting in the death** classified as natural causes.

This will allow for a valid diagnosis to be identified, to consider during causality assessment of AEFI reported as death occurring after vaccination.

An AEFI with a serious outcome such as death, will be considered for compensation through the No Fault Compensation Scheme. It is therefore critical that causality assessment be conducted. With causality assessment, the question is asked, as to whether the immediate or intermediate cause of death is causally linked to the use of the vaccine.

5. Specific roles and responsibilities, when investigating a death occurring after vaccination

5.1. Vaccinators or healthcare workers

- Identification and immediate reporting of all AEFIs presenting at the health facility or establishment.
- In the event of a report of death occurring after vaccination, **inform the health facility manager immediately**. Complete the **paper-based CRF or report the case on the Med Safety App**. Notify health facility managers of the case number generated by the Med Safety App.

5.2. Health facility / healthcare provider's / health facility managers (clinics, primary health care centres, hospitals)

- Immediate reporting of AEFI and AESI cases identified by, or reported to, the health facility and/or healthcare providers.
- Clinical management and treatment of the vaccinee presenting to the facility with an AEFI. Appropriate referral to the next level of care if necessary.
- The treating healthcare professional to submit supporting documentation for severe AEFI cases and with non-serious and serious outcomes including death.

- In the event of death occurring after vaccination, **alert the district office** for further guidance. **Submit the CRF or the Med Safety App** reference number to the district official.

5.3. District / sub-structure / sub-district AEFI Coordinators (officials responsible for EPI/ communicable disease control (CDC)/ infection prevention and control (IPC)/ surveillance e.g., facility based programme)

- Overall coordination of the AEFI reporting and investigation process in the district/substructure.
- Monitor the timely submission of CRFs and Med Safety App reports, investigation of serious and non-serious severe cases and subsequent submission of case investigation forms (CIFs).
- Ensure EPID numbers are allocated to all cases, including Med Safety App reports.
- Maintain a District line list of all AEFI cases for submission to the provincial office weekly.
- In the event of death occurring after vaccination, **alert the provincial office** for further guidance. Submit **CRF, CIF and clinical records** and if applicable submit **Med Safety App reference number** to provincial officials.

5.4. Province / Provincial CDC and EPI including vaccine preventable disease surveillance officials

- The province facilitates case investigation and supports the districts as needed.
- Province informs National EPI Office / AEFI Coordinator of the serious/severe AEFIs.
- Paper-based system: An EPID number if required on the new forms will be issued either at the provincial / district level/or a reference number or EPID number will be assigned on the Med Safety APP.
- The responsible official at the provincial level follows up and ensure all CRF, CIF, documentation (clinical notes, laboratory results, autopsy, verbal, post-mortem, etc.) and line lists are submitted to National EPI / AEFI Coordinator and captured on the electronic system.
- In the event of death occurring after vaccination **alert provincial AEFI review committee** and the NDoH, for further guidance. Submit **CRF, CIF and clinical records** and if applicable submit **Med Safety App reference number**.
- In the case of death occurring after vaccination ensure necessary post- mortem examinations completed.

5.5. Provincial AEFI review committee (including programme officers - EPI, CDC, Pharmacy Services, Communication, Surveillance & specialists, and co-opted clinicians or treating medical officer)

- Assist in the investigation of AEFI cases **(including suspected deaths occurring within 90 days after vaccination)** with technical input, when required, along with supporting documents/medical records, verbal autopsy and post-mortem results/summaries.

5.6. National Immunisation Safety Expert Committee (NISEC)

- The NISEC will conduct causality assessment, to determine if there is a causal relationship between the suspected AEFI and the vaccine.
- Feedback on the outcome of the causality assessment will be provided to the national and provincial levels, to allow for appropriate corrective action if necessary. Failure to do this, may undermine confidence in vaccines and the immunisation programme at large.

2014 WHO VERBAL AUTOPSY SAMPLE QUESTIONNAIRE

Death of a person aged 12 years and above

DK= answer means 'don't know'
Ref= answer means 'refused to answer'

World Health Organization

NO.	QUESTIONS AND FILTERS	ANSWER	SKIP
0A100a	Is this a region of high HIV/AIDS prevalence?	YES ☐ NO ☐	
0A100b	Is this a region of high malaria prevalence?	YES ☐ NO ☐	

SECTION 1. INFORMATION ON THE DECEASED

1A100a	What was the first or given name(s) of the deceased? _____		
1A100b	What was the **surname (or family name)** of the deceased? _____		
1A110	What was the sex of the deceased?	MALE ☐ FEMALE ☐	→ 1A200
1A400	Was this a woman who died more than 42 days but less than 1 year after being pregnant or delivering a baby?	YES ☐ NO ☐ DK ☐ Ref. ☐	
1A401	Was this a woman who died more than 42days after being pregnant or delivering a baby?	YES ☐ NO ☐ DK ☐ Ref. ☐	
1A200	Is the date of birth known?	YES ☐ NO ☐ Ref ☐	 → 1A220 → 1A220
1A210	When was the deceased born?	DAY ☐ MONTH ☐ YEAR ☐	
1A220	Is the date of death known?	YES ☐ NO ☐ Ref. ☐	 → AAAA → AAAA
1A230	When did (s)he die?	DAY ☐☐ MONTH ☐☐ YEAR ☐☐	
AAAA	Put adult's age in years	YEARS ☐☐	
1A500	What was her/his citizenship/nationality?	Citizen at birth ☐ Naturalized citizen ☐ Foreign national ☐ DK ☐	
1A510	What was her/his ethnicity? _____		
1A520	What was her/his place of birth? _____		
1A530	What was her/his place of usual residence? (The place where the person lived most of the year) _____		
1A540	What was her/his place of normal residence 1 to 5 years before death? _____		
1A550	Where did death occur? (specify country, province, district, village) _____		

1A560	Where did the deceased die?	Hospital ☐ Other health facility ☐ Home ☐ On route to facility or hospital ☐ Other ☐ DK ☐ Ref. ☐	
1A600	What was her/his marital status?	Single ☐ Married ☐ Life partner ☐ Divorced ☐ Widowed ☐ Too young to be married ☐ DK ☐ Ref. ☐	→ 1A620 → 1A620 → 1A620 → 1A620 → 1A620
1A610	What was the date of marriage?	DAY ☐☐ MONTH ☐☐ YEAR ☐☐	
1A620	What was the name of the father? Surname _____ Name _____		
1A630	What was the name of the mother? Surname _____ Name _____		
1A640	What was her/his highest level of schooling?	No formal education ☐ Primary school ☐ Secondary school ☐ Higher then secondary school ☐ DK ☐ Ref. ☐	
1A650	Was (s)he able to read and write? (select 'yes' also if only one of either reading or writing is know to the respondent)	YES ☐ NO ☐ DK ☐ Ref ☐	
1A660	What was her/his economic activity status in year prior to death?	Mainly unemployed ☐ Mainly employed ☐ Home-maker ☐ Pensioner ☐ Student ☐ Other ☐ DK ☐ Ref. ☐	
1A670	What was her/his occupation, that is, what kind of work does (s)he mainly do? _____		

SECTION 2. Vital Registration and Certification

1A700	Death registration number/certificate _____		
1A710	Date of registration	DAY ☐☐ MONTH ☐☐ YEAR ☐☐	
1A720	Place of registration _____		
1A730	National identification number of deceased _____		
SECTION 3. Information on the respondent and background about interview			
2A100	What is the name of VA respondent? _____		
2A110	What is the respondent's relationship to the deceased?	Parent ☐ Child ☐ Other family member ☐ Friend ☐ Health worker ☐ Public official ☐ Another relationship ☐	
2A115	Did the respondent live with the deceased in the period leading to her/his death?	YES ☐ NO ☐ DK ☐ Ref ☐	
2A120	Name of VA interviewer _____		
2A130	Time at start of interview	hh:mm 24h ____	
2A135	Time at end of interview	hh:mm 24h ____	
2A140	Date of interview	DAY ☐☐ MONTH ☐☐ YEAR ☐☐	
2A150	Did the respondent give consent?	YES ☐ NO ☐	
3A280	During which season did (s)he die?	WET ☐ DRY ☐	
3A300	For how many days was (s)he ill before (s)he died?	DAYS ☐☐	
3A310	Did (s)he die suddenly?	YES ☐ NO ☐ DK ☐ Ref. ☐	

SECTION4 MEDICAL HISTORY ASSOCIATED WITH FINAL ILLNESS.			
3A100	Was there any diagnosis by a physician or health worker of tuberculosis?	YES ☐ NO ☐ DK ☐ Ref. ☐	
3A110	Was there any diagnosis by a physician or health worker of HIV/AIDS?	YES ☐ NO ☐ DK ☐ Ref. ☐	
3A120	Did (s)he have a recent positive test by a physician or health worker for malaria?	YES ☐ NO ☐ DK ☐ Ref. ☐	
3A130	Did (s)he have a recent negative test by a physician or health worker for malaria?	YES ☐ NO ☐ DK ☐ Ref. ☐	
3A135	Was there any diagnosis by a physician or health worker of dengue fever?	YES ☐ NO ☐ DK ☐ Ref. ☐	
3A140	Was there any diagnosis by a physician or health worker of measles?	YES ☐ NO ☐ DK ☐ Ref. ☐	
3A150	Was there any diagnosis by a physician or health worker of high blood pressure?	YES ☐ NO ☐ DK ☐ Ref. ☐	
3A160	Was there any diagnosis by a physician or health worker of heart disease??	YES ☐ NO ☐ DK ☐ Ref. ☐	
3A170	Was there any diagnosis by a physician or health worker of diabetes?	YES ☐ NO ☐ DK ☐ Ref. ☐	
3A180	Was there any diagnosis by a physician or health worker of asthma?	YES ☐ NO ☐ DK ☐ Ref. ☐	
3A190	Was there any diagnosis by a physician or health worker of epilepsy?	YES ☐ NO ☐ DK ☐ Ref. ☐	
3A200	Was there any diagnosis by a physician or health worker of cancer?	YES ☐ NO ☐ DK ☐ Ref. ☐	
3A210	Was there any diagnosis by a physician or health worker of Chronic Obstructive Pulmonary Disease (COPD)?	YES ☐ NO ☐ DK ☐ Ref. ☐	

3A220	Was there any diagnosis by a physician or health worker of dementia?	YES ☐ NO ☐	
		DK ☐ Ref. ☐	
3A230	Was there any diagnosis by a physician or health worker of depression?	YES ☐ NO ☐ DK ☐ Ref. ☐	
3A240	Was there any diagnosis by a physician or health worker of stroke?	YES ☐ NO ☐ DK ☐ Ref. ☐	
3A250	Was there any diagnosis by a physician or health worker of sickle cell disease?	YES ☐ NO ☐ DK ☐ Ref. ☐	
3A260	Was there any diagnosis by a physician or health worker of kidney disease?	YES ☐ NO ☐ DK ☐ Ref. ☐	
3A270	Was there any diagnosis by a physician or health worker of liver disease?	YES ☐ NO ☐ DK ☐ Ref. ☐	

SECTION5. GENERAL SIGNS AND SYMPTOMS ASSOCIATED WITH FINAL ILLNESS			
3B100	Did (s)he have a fever?	YES ☐	
		NO ☐	→ 3B130
		DK ☐	→ 3B130
		Ref. ☐	→ 3B130
3B110	How many days did the fever last?	DAYS ☐☐	
3B115	How severe was the fever?	Mild ☐	
		Moderate ☐	
		Severe ☐	
3B120	Did (s)he have night sweats?	YES ☐	
		NO ☐	
		DK ☐	
		Ref. ☐	
3B130	Did (s)he have a cough?	YES ☐	
		NO ☐	→ 3B180
		DK ☐	→ 3B180
		Ref. ☐	→ 3B180
3B140	For how many days did (s)he have a cough?	DAYS ☐☐	
3B150	Was the cough productive, with sputum?	YES ☐	
		NO ☐	
		DK ☐	
		Ref. ☐	
3B155	Was the cough very severe?	YES ☐	
		NO ☐	
		DK ☐	
		Ref. ☐	
3B160	Did (s)he cough up blood?	YES ☐	
		NO ☐	
		DK ☐	
		Ref. ☐	
3B180	Did (s)he have any breathing problem?	YES ☐	
		NO ☐	
		DK ☐	
		Ref. ☐	
3B190	During the illness that led to death, did (s)he have fast breathing?	YES ☐	
		NO ☐	→ 3B210
		DK ☐	→ 3B210
		Ref. ☐	→ 3B210
3B200	For how many days did the fast breathing last?	DAYS ☐☐	
3B210	Did (s)he have breathlessness?	YES ☐	
		NO ☐	→ 3B242
		DK ☐	→ 3B242
		Ref. ☐	→ 3B242
3B220	For how many weeks did (s)he have breathlessness?	WEEKS ☐☐	
3B230	Was (s)he unable to carry out daily routines due to breathlessness?	YES ☐	
		NO ☐	
		DK ☐	
		Ref. ☐	
3B240	Was (s)he breathless while lying flat?	YES ☐	
		NO ☐	
		DK ☐	
		Ref. ☐	

3B242	During the illness that led to death, did (s)he have difficulty breathing?	YES ☐ NO ☐ DK ☐ Ref. ☐	 → 3B260 → 3B260 → 3B260
3B246	Was the difficulty continuous or on and off?	Continuous ☐ On and off ☐	
3B260	During the illness that led to death did his/her breathing sound like any of the following: Stridor, Grunting, Wheezing	Stridor ☐ Grunting ☐ Wheezing ☐ NO ☐ DK ☐ Ref. ☐	
3B270	Did (s)he have severe chest pain?	YES ☐ NO ☐ DK ☐ Ref. ☐	 → 3B280 → 3B280 → 3B280
3B272	How many days before death did (s)he have severe chest pain?	DAYS ☐☐	
3B274	How many minutes did the pain last?	MINUTES ☐☐	
3B280	Did (s)he have diarrhoea?	YES ☐ NO ☐ DK ☐ Ref. ☐	 → 3B310 → 3B310 → 3B310
3B290	For how many days did (s)he have diarrhoea?	DAYS ☐☐	
3B300	At any time during the final illness was there blood in the stools?	YES ☐ NO ☐ DK ☐ Ref. ☐	 → 3B310 → 3B310 → 3B310
3B305	Was there blood in the stool up until death?	YES ☐ NO ☐ DK ☐ Ref. ☐	
3B310	Did (s)he vomit?	YES ☐ NO ☐ DK ☐ Ref. ☐	 → 3B330 → 3B330 → 3B330
3B315	For how many days before death did (s)he vomit?	DAYS ☐☐	
3B320	Did (s)he vomit blood?	YES ☐ NO ☐ DK ☐ Ref. ☐	
3B325	Was the vomit black?	YES ☐ NO ☐ DK ☐ Ref. ☐	
3B330	Did (s)he have any abdominal problem?	YES ☐ NO ☐ DK ☐ Ref. ☐	
3B340	Did (s)he have severe abdominal pain?	YES ☐ NO ☐ DK ☐ Ref. ☐	 → 3B360 → 3B360 → 3B360
3B350	For how many days before death did (s)he have severe abdominal pain?	DAYS ☐☐	

3B355	Was the pain in the upper or lower abdomen?	Upper abdomen ☐ Lower abdomen ☐	
3B360	Did (s)he have a more than usually protruding abdomen?	YES ☐ NO ☐ DK ☐ Ref. ☐	 → 3B380 → 3B380 → 3B380
3B370	For how many days did (s)he have a more than usually protruding abdomen?	DAYS ☐☐	
3B375	How rapidly did (s)he develop the protruding abdomen?	Rapidly ☐ Slowly ☐	
3B380	Did (s)he have any mass in the abdomen?	YES ☐ NO ☐ DK ☐ Ref. ☐	 → 3B400 → 3B400 → 3B400
3B390	For how many days before death did (s)he have a mass in the abdomen?	DAYS ☐☐	
3B400	Did (s)he have a severe headache?	YES ☐ NO ☐ DK ☐ Ref. ☐	
3B405	Did (s)he have a stiff neck during illness that led to death?	YES ☐ NO ☐ DK ☐ Ref. ☐	 → 3B409 → 3B409 → 3B409
3B407	For how many days before death did (s)he have stiff neck?	DAYS ☐☐	
3B409	Did (s)he have a painful neck during the illness that led to death?	YES ☐ NO ☐ DK ☐ Ref. ☐	 → 3B420 → 3B420 → 3B420
3B410	For how many days before death did (s)he have a painful neck?	DAYS ☐☐	
3B420	Did (s)he have mental confusion?	YES ☐ NO ☐ DK ☐ Ref. ☐	 → 3B440 → 3B440 → 3B440
3B430	For how many months did (s)he have mental confusion?	MONTHS ☐☐	
3B440	Was (s)he unconscious for more than 24 hours before death?	YES ☐ NO ☐ DK ☐ Ref. ☐	 → 3B460 → 3B460 → 3B460
3B450	Did the unconsciousness start suddenly, quickly (at least within a single day)?	YES ☐ NO ☐ DK ☐ Ref. ☐	
3B455	Did the unconsciousness continue until death?	YES ☐ NO ☐ DK ☐ Ref. ☐	
3B460	Did (s)he have convulsions?	YES ☐ NO ☐ DK ☐ Ref. ☐	 → 3B490 → 3B490 → 3B490

3B465	Did (s)he experience any generalized convulsions or fits during the illness that led to death?	YES ☐ NO ☐ DK ☐ Ref. ☐	
3B470	For how many minutes did the convulsions last?	MINUTES ☐☐	
3B480	Did (s)he become unconscious immediately after the convulsion?	YES ☐ NO ☐ DK ☐ Ref. ☐	
3B490	Did (s)he have any urine problems?	YES ☐ NO ☐ DK ☐ Ref. ☐	
3B500	Did (s)he pass no urine at all?	YES ☐ NO ☐ DK ☐ Ref. ☐	
3B510	Did (s)he go to urinate more often than usual?	YES ☐ NO ☐ DK ☐ Ref. ☐	
3B520	During the final illness did (s)he ever pass blood in the urine?	YES ☐ NO ☐ DK ☐ Ref. ☐	
3B530	Did (s)he have any skin problems?	YES ☐ NO ☐ DK ☐ Ref. ☐	
3B535	Did (s)he have sores?	YES ☐ NO ☐ DK ☐ Ref. ☐	 → 3B540 → 3B540 → 3B540
3B537	Did the sores have clear fluid or pus?	YES ☐ NO ☐ DK ☐ Ref. ☐	
3B540	Did (s)he have any ulcers, abscess or sores anywhere except on the feet?	YES ☐ NO ☐ DK ☐ Ref. ☐	
3B542	Did (s)he have an ulcer (pit) on the foot?	YES ☐ NO ☐ DK ☐ Ref. ☐	 → 3B560 → 3B560 → 3B560
3B544	Did the ulcer ooze pus?	YES ☐ NO ☐ DK ☐ Ref. ☐	 → 3B550 → 3B550 → 3B550
3B546	For how many days did the ulcer ooze pus?	DAYS ☐☐	
3B550	Did (s)he have any ulcers, abscess or sores on the feet that were not also on other parts of the body?	YES ☐ NO ☐ DK ☐ Ref. ☐	
3B560	During the illness that led to death, did (s)he have any skin rash?	YES ☐ NO ☐ DK ☐ Ref. ☐	 → 3B596 → 3B596 → 3B596
3B570	For how many days did (s)he have the skin rash?	DAYS ☐☐	

3B575	Where was the rash?	Face ☐ Trunk or abdomen ☐ Extremities ☐ Everywhere ☐	
3B580	Did (s)he have measles rash (use local term)?	YES ☐ NO ☐ DK ☐ Ref. ☐	
3B590	Did (s)he ever have shingles or herpes zoster?	YES ☐ NO ☐ DK ☐ Ref. ☐	
3B596	During the illness that led to death, did (s)he bleed from anywhere?	YES ☐ NO ☐ DK ☐ Ref. ☐	 → 3B610 → 3B610 → 3B610
3B600	Did (s)he bleed from the nose, mouth or anus?	YES ☐ NO ☐ DK ☐ Ref. ☐	
3B610	Did (s)he have noticeable weight loss?	YES ☐ NO ☐ DK ☐ Ref. ☐	 → 3B630 → 3B630 → 3B630
3B620	Was (s)he severely thin or wasted?	YES ☐ NO ☐ DK ☐ Ref. ☐	
3B630	During the illness that led to death, did s/he have a whitish rash inside the mouth or on the tongue?	YES ☐ NO ☐ DK ☐ Ref. ☐	
3B640	Did (s)he have stiffness of the whole body or was unable to open the mouth?	YES ☐ NO ☐ DK ☐ Ref. ☐	
3B650	Did (s)he have puffiness of the face?	YES ☐ NO ☐ DK ☐ Ref. ☐	 → 3B654 → 3B654 → 3B654
3B652	For how many days did (s)he have puffiness of the face?	DAYS ☐☐	
3B654	During the illness that led to death, did (s)he have swelling in the armpits?	YES ☐ NO ☐ DK ☐ Ref. ☐	
3B656	During the illness that led to death, did (s)he have swollen legs or feet?	YES ☐ NO ☐ DK ☐ Ref. ☐	 → 3B660 → 3B660 → 3B660
3B658	How many days did the swelling last?	DAYS ☐☐	
3B660	Did (s)he have both feet swollen?	YES ☐ NO ☐ DK ☐ Ref. ☐	
3B665	Did (s)he have general puffiness all over hi(s)her body?	YES ☐ NO ☐ DK ☐ Ref. ☐	

3B670	Did (s)he have any lumps?	YES ☐ NO ☐ DK ☐ Ref. ☐	
3B680	Did (s)he have any lumps or lesions in the mouth?	YES ☐ NO ☐ DK ☐ Ref. ☐	
3B690	Did (s)he have any lumps on the neck?	YES ☐ NO ☐ DK ☐ Ref. ☐	
3B700	Did (s)he have any lumps on the armpit?	YES ☐ NO ☐ DK ☐ Ref. ☐	
3B710	Did (s)he have any lumps on the groin?	YES ☐ NO ☐ DK ☐ Ref. ☐	
3B720	Did she have any swelling or lump in the breast?	YES ☐ NO ☐ DK ☐ Ref. ☐	
3B722	Did she have any ulcers (pits) in the breast?	YES ☐ NO ☐ DK ☐ Ref. ☐	
3B724	Was (s)he in any way paralysed?	YES ☐ NO ☐ DK ☐ Ref. ☐	 ➞ 3B732 ➞ 3B732 ➞ 3B732
3B730	Did s(he) have paralysis of only one side of the body?	YES ☐ NO ☐ DK ☐ Ref. ☐	
3B731	Which were the limbs or body parts paralysed?	Right side ☐ Left side ☐ Lower part of body ☐ Upper part of body ☐ One leg only ☐ One arm only ☐ Whole body ☐ Other ☐	
3B732	Did (s)he have difficulty swallowing?	YES ☐ NO ☐ DK ☐ Ref. ☐	 ➞ 3B745 ➞ 3B745 ➞ 3B745
3B734	For how many days before death did (s)he have difficulty swallowing?	DAYS ☐☐	
3B740	Was the difficulty with swallowing with solids, liquids, or both?	Solids ☐ Liquids ☐ Both ☐	
3B745	Did (s)he have pain upon swallowing?	YES ☐ NO ☐ DK ☐ Ref. ☐	
3B750	Did (s)he have yellow discoloration of the eyes?	YES ☐ NO ☐ DK ☐ Ref. ☐	 ➞ 3B760 ➞ 3B760 ➞ 3B760

3B755	For how many days did (s)he have the yellow discoloration?	DAYS ☐☐	
3B760	Did her/his hair change in colour to a reddish or yellowish colour?	YES ☐ NO ☐ DK ☐ Ref. ☐	
3B770	Did (s)he look pale (thinning/lack of blood) or have pale palms, eyes or nail beds?	YES ☐ NO ☐ DK ☐ Ref. ☐	
3B780	Did (s)he have sunken eyes?	YES ☐ NO ☐ DK ☐ Ref. ☐	
3B790	Did (s)he drink a lot more water than usual?	YES ☐ NO ☐ DK ☐ Ref. ☐	

CHECK SEX OF THE DECEASED (QUESTION 1A110):

IF FEMALE ☐↓ **IF MALE** ☐→ **JUMP TO SECTION7, No. 3E100**

SECTION 6. SIGNS AND SYMPTOMS ASSOCIATED WITH PREGNANCY AND WOMEN			
3B798	Did she ever have a period or menstruate?	YES ☐ NO ☐ DK ☐ Ref. ☐	 → 3C105 → 3C105 → 3C105
3B800	Did she have excessive vaginal bleeding in between menstrual periods?	YES ☐ NO ☐ DK ☐ Ref. ☐	
3B810	Did her menstrual period stop naturally because of menopause?	YES ☐ NO ☐ DK ☐ Ref. ☐	
3B820	Did she have vaginal bleeding after cessation of menstruation?	YES ☐ NO ☐ DK ☐ Ref. ☐	
3B830	Was there excessive vaginal bleeding in the week prior to death?	YES ☐ NO ☐ DK ☐ Ref. ☐	
3B840	At the time of death was her period overdue?	YES ☐ NO ☐ DK ☐ Ref. ☐	 → 3C105 → 3C105 → 3C105
3B850	For how many weeks had her period been overdue?	WEEKS ☐☐	
3C105	Did she have a sharp pain in her abdomen shortly before death?	YES ☐ NO ☐ DK ☐ Ref. ☐	
3C110	Was she pregnant at the time of death?	YES ☐ NO ☐ DK ☐ Ref. ☐	→ 3C125
3C120	Did she die within 6 weeks of delivery, abortion or miscarriage?	YES ☐ NO ☐ DK ☐ Ref. ☐	 → 3C135
3C125	For how many months was she pregnant?	MONTHS ☐☐	→ 3C200
3C135	**Please confirm**: you said she was NOT pregnant and had NOT recently been pregnant or delivered when she died is that right?	YES ☐ NO ☐ DK ☐ Ref. ☐	→ 3E100
3C200	Did she die within 24 hours after delivery?	YES ☐ NO ☐ DK ☐ Ref. ☐	
3C210	Did she die during labour, and before delivery?	YES ☐ NO ☐ DK ☐ Ref. ☐	
3C212	Did she die after delivering a baby?	YES ☐ NO ☐ DK ☐ Ref. ☐	

3C213	Did she give birth to a live baby within 6 weeks of death?	YES ☐ NO ☐ DK ☐ Ref. ☐	
3C215	Did she die during or after a multiple pregnancy?	YES ☐ NO ☐ DK ☐ Ref. ☐	
3C220	Was she breastfeeding the child in the days before death?	YES ☐ NO ☐ DK ☐ Ref. ☐	
3C230	How many births, including stillbirths, did she/the mother have before this baby?	Number ☐☐	
3C240	Had she had any previous Caesarean section?	YES ☐ NO ☐ DK ☐ Ref. ☐	
3C260	During pregnancy, did she suffer from high blood pressure?	YES ☐ NO ☐ DK ☐ Ref. ☐	
3C270	Did she have foul smelling vaginal discharge during pregnancy or after delivery?	YES ☐ NO ☐ DK ☐ Ref. ☐	
3C280	During the last 3 months of pregnancy, did she suffer from convulsions?	YES ☐ NO ☐ DK ☐ Ref. ☐	
3C290	During the last 3 months of pregnancy did she suffer from blurred vision?	YES ☐ NO ☐ DK ☐ Ref. ☐	
3C310	Did she have excessive bleeding during pregnancy before labour started?	YES ☐ NO ☐ DK ☐ Ref. ☐	 ➡ 3C340 ➡ 3C340 ➡ 3C340
3C320	Was there vaginal bleeding during the first 6 months of pregnancy?	YES ☐ NO ☐ DK ☐ Ref. ☐	
3C330	Was there vaginal bleeding during the last 3 months of pregnancy but before labour started?	YES ☐ NO ☐ DK ☐ Ref. ☐	
3C340	Did she have excessive bleeding during labour or delivery?	YES ☐ NO ☐ DK ☐ Ref. ☐	
3C350	Did she have excessive bleeding after delivery or abortion?	YES ☐ NO ☐ DK ☐ Ref. ☐	
3C360	Was the placenta completely delivered?	YES ☐ NO ☐ DK ☐ Ref. ☐	

3C365	Did she deliver or try to deliver an abnormally positioned baby?	YES ☐ NO ☐ DK ☐ Ref. ☐	
3C370	For how many hours was she in labour?	HOURS ☐☐	
3C380	Did she attempt to terminate the pregnancy?	YES ☐ NO ☐ DK ☐ Ref. ☐	
3C390	Did she recently have a pregnancy that ended in an abortion (spontaneous or induced)?	YES ☐ NO ☐ DK ☐ Ref. ☐	 → 3C400 → 3C400 → 3C400
3C393	Did she die during an abortion?	YES ☐ NO ☐ DK ☐ Ref. ☐	
3C395	Did she die within 6 weeks of having an abortion?	YES ☐ NO ☐ DK ☐ Ref. ☐	
3C400	Where did she give birth?	Hospital ☐ Other health facility ☐ Home ☐ On route to hospital or facility ☐ Other ☐	
3C430	Did she receive professional assistance during the delivery?	YES ☐ NO ☐ DK ☐ Ref. ☐	
3C440	Did she have an operation to remove her uterus shortly before death?	YES ☐ NO ☐ DK ☐ Ref. ☐	
How did the mother deliver her baby?			
3C450	Was the delivery normal vaginal, without forceps or vacuum?	YES ☐ NO ☐ DK ☐ Ref. ☐	→ 3C480
3C460	Was the delivery vaginal, with forceps or vacuum?	YES ☐ NO ☐ DK ☐ Ref. ☐	→ 3C480
3C470	Was the delivery a Caesarean section?	YES ☐ NO ☐ DK ☐ Ref. ☐	

3C480	Was the baby born more than one month early?	YES ☐ NO ☐ DK ☐ Ref. ☐	

SECTION 7. HISTORY OF INJURIES/ACCIDENTS			
3E100	Did (s)he suffer from any injury or accident that led to her/his death?	YES ☐ NO ☐ DK ☐ Ref. ☐	 → 3F100 → 3F100 → 3F100
3E102	Was the injury intentionally inflicted by someone else?	YES ☐ NO ☐ DK ☐ Ref. ☐	 → 3E113 → 3E113 → 3E113
3E104	Was (s)he injured by a firearm?	YES ☐ NO ☐ DK ☐ Ref. ☐	
3E106	Was (s)he stabbed, cut or pierced?	YES ☐ NO ☐ DK ☐ Ref. ☐	
3E108	Was (s)he strangled?	YES ☐ NO ☐ DK ☐ Ref. ☐	
3E111	Was (s)he injured by a blunt force?	YES ☐ NO ☐ DK ☐ Ref. ☐	
3E112	Was (s)he injured by burns?	YES ☐ NO ☐ DK ☐ Ref. ☐	
3E113	Do you think (s)he committed suicide?	YES ☐ NO ☐ DK ☐ Ref. ☐	
3E115	Was it a road traffic accident?	YES ☐ NO ☐ DK ☐ Ref. ☐	 → 3E310 → 3E310 → 3E310
3E120	What was her/his role in the road traffic accident?	Pedestrian ☐ Driver or passenger in car or light vehicle ☐ Driver or passenger in bus or heavy vehicle ☐ Driver or passenger on a motorcycle ☐ Driver or passenger on a pedal cycle ☐	
3E170	What was the counterpart that was hit during the road traffic accident?	Pedestrian ☐ Stationary object ☐ Car or light vehicle ☐	
		Bus or heavy vehicle ☐ Motorcycle ☐ Pedal cycle ☐ Other ☐	

3E310	Was (s)he injured in a fall?	YES ☐ NO ☐ DK ☐ Ref. ☐	
3E320	Did (s)he die of drowning?	YES ☐ NO ☐ DK ☐ Ref. ☐	
3E330	Was (s)he suffering from burns?	YES ☐ NO ☐ DK ☐ Ref. ☐	
3E335	Was (s)he injured by a blunt force?	YES ☐ NO ☐ DK ☐ Ref. ☐	
3E340	Was (s)he injured by a plant/ animal/insect that led to her/his death?	YES ☐ NO ☐ DK ☐ Ref. ☐	 → 3E500 → 3E500 → 3E500
3E400	What was the plant/animal/insect?	Dog ☐ Snake ☐ Insect or Scorpion ☐ Others ☐	
3E500	Was (s)he injured by a force of nature?	YES ☐ NO ☐ DK ☐ Ref. ☐	
3E510	Was there any poisoning?	YES ☐ NO ☐ DK ☐ Ref. ☐	
3E520	Was (s)he subject to violence/assault?	YES ☐ NO ☐ DK ☐ Ref. ☐	
3E530	Was it electrocution?	YES ☐ NO ☐ DK ☐ Ref. ☐	

SECTION 8. RISK FACTORS			
3F100	Did (s)he drink alcohol?	YES ☐ NO ☐ DK ☐ Ref. ☐	
3F110	Did (s)he smoke tobacco (cigarette, cigar, pipe, etc.)?	YES ☐ NO ☐ DK ☐ Ref. ☐	 → 3G110 → 3G110 → 3G110
3F120	What kind of tobacco did (s)he use?	Cigarettes ☐ Pipe ☐ Chewing tobacco ☐ Local form of tobacco ☐ Other ☐	
3F130	How many cigarettes did (s)he smoke daily?	NUMBER ☐☐	
SECTION 9. HEALTH SERVICE UTILISATION			
3G110	Did (s)he receive any treatment for the illness that led to death?	YES ☐ NO ☐ DK ☐ Ref. ☐	 → 3H130 → 3H130 → 3H130
3G120	Did (s)he receive oral rehydration salts?	YES ☐ NO ☐ DK ☐ Ref. ☐	
3G130	Did (s)he receive (or need) intravenous fluids (drip) treatment?	YES ☐ NO ☐ DK ☐ Ref. ☐	
3G140	Did (s)he receive (or need) a blood transfusion?	YES ☐ NO ☐ DK ☐ Ref. ☐	
3G150	Did s/he receive (or need) treatment/food through a tube passed through the nose?	YES ☐ NO ☐ DK ☐ Ref. ☐	
3G160	Did (s)he receive (or need) injectable antibiotics?	YES ☐ NO ☐ DK ☐ Ref. ☐	
3G165	Did (s)he receive (or need) antiretroviral therapy (ART)?	YES ☐ NO ☐ DK ☐ Ref. ☐	
3G170	Did (s)he have (or need) an operation for the illness?	YES ☐ NO ☐ DK ☐ Ref. ☐	 → 3G190 → 3G190 → 3G190
3G180	Did (s)he have the operation within 1 month before death?	YES ☐ NO ☐ DK ☐ Ref. ☐	

3G190	Was (s)he discharged from hospital very ill?	YES ☐ NO ☐ DK ☐ Ref. ☐	
3H130	Was care sought outside the home while (s)he had this illness?	YES ☐ NO ☐ DK ☐ Ref. ☐	 → 3H160 → 3H160 → 3H160
3H140	Where or from whom did you seek care?	Traditional healer ☐ Homeopath ☐ Religious leader ☐ Government hospital ☐ Government health centre or clinic ☐ Private hospital ☐ Community-based practitioner associated with health system ☐ Trained birth attendant ☐ Private physician ☐ Pharmacy ☐	
3H150	Record the name and address of any hospital, health centre or clinic where care was sought	YES ☐ NO ☐ DK ☐ Ref. ☐	
3H160	Did a health care worker tell you the cause of death?	YES ☐ NO ☐ DK ☐ Ref. ☐	 → 3H180 → 3H180 → 3H180
3H170	What did the health care worker say? _____		
3H180	Do you have any health records that belonged to the deceased?	YES ☐ NO ☐ DK ☐ Ref. ☐	 → 4A100 → 4A100 → 4A100
3H190	Can I see the health records?	YES ☐ NO ☐ DK ☐ Ref. ☐	 → 4A100 → 4A100 → 4A100
3H200	Record the date of the most recent (last) visit	DAY ☐☐ MONTH ☐☐ YEAR ☐☐	
3H210	Record the date of the last but one (second last) visit	DAY ☐☐ MONTH ☐☐ YEAR ☐☐	
3H220	Record the date of the last note on the health records	DAY ☐☐ MONTH ☐☐ YEAR ☐☐	
3H230	Record the weight (in kilograms) written at the most recent (last) visit	[KG] ☐☐☐.☐	
3H240	Record the weight (in kilograms) written at the last but one (second last) visit	[KG] ☐☐☐.☐	

3H250	Transcribe the last note on the health records	DAY ☐☐ MONTH ☐☐ YEAR ☐☐	

SECTION 10. Background and context			
4A100	In the final days before death, did s/he travel to a hospital or health facility?	YES ☐ NO ☐ DK ☐ Ref. ☐	 → 4A150 → 4A150 → 4A150
4A110	Did (s)he use motorised transport to get to the hospital or health facility?	YES ☐ NO ☐ DK ☐ Ref. ☐	
4A120	Were there any problems during admission to the hospital or health facility?	YES ☐ NO ☐ DK ☐ Ref. ☐	
4A130	Were there any problems with the way (s)he was treated (medical treatment, procedures, interpersonal attitudes, respect, dignity) in the hospital or health facility?	YES ☐ NO ☐ DK ☐ Ref. ☐	
4A140	Were there any problems getting medications, or diagnostic tests in the hospital or health facility?	YES ☐ NO ☐ DK ☐ Ref. ☐	
4A150	Does it take more than 2 hours to get to the nearest hospital or health facility from the deceased's household?	YES ☐ NO ☐ DK ☐ Ref. ☐	
4A160	In the final days before death, were there any doubts about whether medical care was needed?	YES ☐ NO ☐ DK ☐ Ref. ☐	
4A170	In the final days before death, was traditional medicine used?	YES ☐ NO ☐ DK ☐ Ref. ☐	
4A180	In the final days before death, did anyone use a telephone or cell phone to call for help?	YES ☐ NO ☐ DK ☐ Ref. ☐	
4A190	Over the course of illness, did the total costs of care and treatment prohibit other household payments?	YES ☐ NO ☐ DK ☐ Ref. ☐	

SECTION 11. OPTIONAL OPEN NARRATIVE	
5A100	Narrative Description _____ _____ _____ _____ _____ _____

SECTION 12. DEATH CERTIFICATE				
6H260	Was a death certificate issued?	YES ☐ NO ☐ DK ☐ Ref. ☐	 → END → END → END	
6H270	Can I see the death certificate?	YES ☐ NO ☐ DK ☐ Ref. ☐	 → END → END → END	
6H280	Record the immediate cause of death from the certificate (line 1a) * _____			Duration 1(a)
6H290	Record the first antecedent cause of death from the certificate (line 1b) _____			Duration 1(b)
6H300	Record the second antecedent cause of death from the certificate (line 1c) _____			Duration 1(c)
6H310	Record the third antecedent cause of death from the certificate (line 1d) _____			Duration 1(d)
6H320	Record the contributing cause(s) of death from the certificate (part 2) _____			

Annexure 2: (AEFI) - Pathology report *(Absence of Autopsy)*

Name of the clinician or pathologist (REPORTER)	
Contact details	**Email address:**
	Contact number/s:
Details if admitted at time of death	**Name of facility:**
	Name of treating clinician:
Diagnosis	**On admission:**
	Final diagnoses:
SARS CoV2 swab	**Positive ☐ Negative ☐**
Past medical history ***Note: Include medical history from general practitioner***	
History of allergies	
Concomitant medication ***Note: Include over-the-counter medicines and herbal medicines***	
Presenting complaints and examination findings	

Investigations ***Note: Brief summary of investigation findings; attach all clinical records and documents***	
Management	
Are the presenting complaints suspected to be related to a vaccine?	**Yes** ☐ **No** ☐ **Don't know** ☐
Please consider these factors and add a comment to each. Make a summative decision on relatedness at the end	**Biological plausibility:**
	Association with vaccine:
	Temporal relationship:
NOTE: Sudden, unexpected and unexplained deaths require medico-legal investigation which may include an autopsy	
Other causes ***Note: May include pre-existing conditions, concurrent conditions, other factors e.g. family history, environment, population characteristics, community exposures, or interventions e.g. medication***	
Cause of death ***Note: If the autopsy is not conducted, specify the immediate cause, underlying cause, contributing factors resulting in the death classified as natural causes***	**1. Immediate cause of death:**
	2. Underlying cause of death:
	3. Contributing factors resulting in death:

health
Department: Health
REPUBLIC OF SOUTH AFRICA

ALL VACCINES including COVID-19

CASE REPORTING FORM (CRF) FOR ADVERSE EVENTS FOLLOWING IMMUNISATION (AEFI)

EPID Number: S O A - | | | | - | | | | - | | | | - | | | |

Country - Province - District - Year - Case no

Today's date: D D / M M / Y Y Y Y

All fields in this form are mandatory, unless indicated 'if applicable'. Provide the requested information or tick the appropriate box.

Date received	*Level*	*Signature*
	Private	
	District	
	Province	
	National EPI	
	National SAHPRA	

(For Office use only)

SECTION A: IDENTIFYING INFORMATION

NOTE: In maternal vaccination, if mother and baby / more than one baby are affected, complete separate form for each affected individual

Vaccine recipient name & surname: _____

If child: Caregiver's name & surname: _____

Vaccine recipient's residential address: _____

_____

Mobile no: _____ Telephone no: _____

Email: _____

Sex: ☐ M ☐ F ☐ Other *If applicable:* ☐ Pregnant ☐ Breastfeeding

Date of birth: D D / M M / Y Y Y Y

OR Age at onset: ☐☐ Years ☐☐ Months ☐☐☐ Days

OR Age group: ☐ 0 - <1 year ☐ 1 - 5 years ☐ >5 – 18 years ☐ >18 – 60 years ☐ >60 years

If applicable: Gestation: ☐ Full-term ☐ Premature

Reporter's name & surname:

_____

Designation/Position:

_____

Institution & Department:

_____

_____

Telephone no: _____

Mobile no: _____

E-mail: _____

Date patient notified event to health system:
D D / M M / Y Y Y Y

SECTION B: VACCINE INFORMATION (Please attach a copy of the Road to Health Booklet OR Vaccination Card)

NOTE: In the case of a foetal adverse event, ALSO record the mother's maternal vaccination details

Health facility / vaccination center name: _____ ☐ **DoH** ☐ **Private** ☐ **NGO**

Address / location: _____

Vaccine administered								**Diluent** *(if applicable)*		
Vaccine/s given (Use trade name)	**Date vaccinated**	**Time vaccinated**	**Dose number** (1st, 2nd)	**Batch/ Lot number**	**Expiry date / Manufacture date** (COVID-19)	**VVM Stage** (if applies)	**Manufacturer**	**Batch/ Lot number**	**Expiry date**	**Date & time of reconstitution**

Consumables used (unless pre-filled)	**Needles**	Size: _____ Batch: _____ Expiry date: _____
	Syringes	Size: _____ Batch: _____ Expiry date: _____

SECTION C: TRIGGER EVENTS

Date & time AEFI started: D D / M M / Y Y Y Y ☐☐ Hr ☐☐ Min ***Adverse event (s): (Tick (✓) all boxes that apply)***

Minor local reactions

☐ Swelling <5cm ☐ Induration / hardness
☐ Redness ☐ Rash
☐ Other (specify): _____

_____

Minor systemic reactions

☐ Excessive crying (infant) ☐ Mild fever <38°C
☐ Mild headache ☐ Mild body aches
☐ Mild pain (to touch / on movement, but not interfering with daily activities) ☐ Fainting
☐ Other (specify): _____

_____

Patient name & surname: _____ EPID Number: _____

Severe local reactions

- ☐ Pain, redness and/or swelling >3 days
- ☐ Swelling >5cm
- ☐ Swelling beyond nearest joint
- ☐ Lymphadenitis
- ☐ Abscess
- ☐ Necrosis at vaccination site
- ☐ Other (specify):

_____

_____

Severe systemic reactions

- ☐ Hospitalisation ☐ Death ☐ Collapse/ shock-like state
- ☐ Fever ≥38°C ☐ Thrombocytopenia ☐ Anaphylaxis
- ☐ Seizures ☐ Febrile ☐ Afebrile ☐ Encephalopathy ☐ Sepsis
- ☐ Toxic shock syndrome ☐ Vomiting ☐ Diarrhoea
- ☐ Other (specify): _____

Foetal adverse reactions in the case of maternal immunisation:

- ☐ Decreased FHR variability ☐ Decreased foetal movement ☐ Foetal death
- ☐ Onset of preterm labour, assessed to be possibly/probably related
- ☐ Foetal anomaly assessed to be possibly/probably related (e.g. congenital anomaly feasible with pre-pregnancy or 1st trimester immunisation)
- ☐ Foetus affected by maternal immunization (e.g. live vaccine administered to mother)

NOTE: Severe or serious adverse event ➔ Immediately notify District Office for Case Investigation

Describe vaccine recipient's or caregiver's concern (AEFI signs and symptoms). Use additional sheet if needed

_____

_____

_____

_____

Were there any other similar AEFIs reported in the facility in the past 30 days? ☐ Yes ☐ No (If yes, specify)

_____

_____

SECTION D: PAST MEDICAL HISTORY

Past medical history (including history of previous similar reactions or other allergies), concomitant medication and dates of administration (exclude those used to treat reaction), any other relevant information. Use additional sheet if needed

_____

_____

_____

SECTION E: PRELIMINARY ASSESSMENT AND ACTIONS AT THE TIME OF REPORT

Is this event a serious AEFI? ☐ Yes ☐ No ***If Yes, tick (√) in the appropriate box below***

☐ Death ☐ Hospitalisation ☐ Disability ☐ Life threatening ☐ Congenital anomaly in off-spring of vaccine recipient

Comments: _____

SECTION F: WHAT WAS THE OUTCOME OF THE CASE FOLLOWING THE SUSPECTED AEFI in VACCINEE?

☐ Recovering ☐ Recovered fully (no complications) ☐ Not Recovered ☐ Unknown

☐ Recovered with sequelae; Specify: _____

☐ Died ➔ Date of death: D D / M M / Y Y Y Y ➔ Autopsy: ☐ Yes ☐ No ☐ Unknown

☐ Hospitalisation ➔ Date of admission: D D / M M / Y Y Y Y

➔ Name of hospital: _____ Hospital number: _____

SECTION G: FIRST DECISION MAKING LEVEL TO COMPLETE

Case investigation needed: ☐ Yes ☐ No

Date investigation planned: D D / M M / Y Y Y Y

District Office notified: ☐ Yes ☐ No

If yes, date notified: D D / M M / Y Y Y Y

SECTION H: NATIONAL LEVEL TO COMPLETE

Date report received at National Level: D D / M M / Y Y Y Y **AEFI worldwide unique ID:** _____

Comments: _____

IMPORTANT: Email this form within 24 hours to AEFI@health.gov.za

AND copy the EPI District Surveillance Officer

CONSENT CLAUSE FOR COLLECTION AND PROCESSING OF PERSONAL INFORMATION

By their signature below, the vaccine recipient or relative (in the event of the vaccine recipient being unresponsive or has demised) or caregiver (in the case of a child) hereby provides consent to the collection and processing of their personal information (as set out in this Case Reporting Form) by the National Department of Health and third parties appointed by it (the "Department") for the purposes of investigating and assessing potential adverse events related to a vaccine/s received. The vaccine recipient or relative (in the event of the vaccine recipient being unresponsive or has demised) or caregiver (in the case of a child) acknowledges that this information may be used i) to access all medical and clinical records for the purpose of case investigation, when required; ii) in the generation of statistics; and iii) to make policy decisions relating to vaccine safety and efficacy. This consent may be withdrawn at any time, and the vaccine recipient or relative (in the event of the vaccine recipient being unresponsive or has demised) or caregiver (in the case of a child) may, at any time, object to the collection and processing of their personal information, by contacting the Department (AEFI@heath.gov.za) and the South African Health Products Regulatory Authority (adr@sahpra.org.za).

The Department undertakes to process the personal information contained in this Case Reporting Form, and collected during the process of case investigation in a manner that adheres to the Protection of Personal Information Act. The information will not be stored (in a manner that identifies the vaccine recipient) for any longer than is necessary to achieve the purpose for which the information was collected, unless the Department has a lawful basis to do so. If the vaccine recipient or relative (in the event of the vaccine recipient being unresponsive or has demised) or caregiver (in the case of a child) wishes to access and/or rectify their personal information, they may do so by contacting the Department (AEFI@heath.gov.za).

Vaccine recipient: _____ (Name and Surname)

Signed by the vaccine recipient / relative / caregiver*

_____	_____	_____
Name and Surname	**Signature**	**Date**

*Delete what is not applicable

health
Department: Health
REPUBLIC OF SOUTH AFRICA

ALL VACCINES including COVID-19: CASE INVESTIGATION FORM (CIF)
Adverse Events Following Immunisation (AEFI) AND Adverse Events of Special Interest (AESI)

ONLY for Serious and Severe Adverse Events Following Immunisation, Clusters and Adverse Events of Special Interest

SECTION A: BASIC DETAILS

Province: _____ **EPID No:** S O A - | | | | - | | | | - | | | | - | | | |
District: _____ **Country - Province - District - Year - Case no.**

NB: The EPID number must be IDENTICAL to the number on the CASE REPORTING FORM

PATIENT IDENTIFICATION

NOTE: In maternal vaccination, if mother and baby / more than one baby are affected, complete separate form for each affected individual

Vaccine recipient name & surname: _____ **Note: Use a separate form for each case in a cluster**

Sex: ☐ M ☐ F ☐ Other

Date of birth: D D / M M / Y Y Y Y **OR** Age at onset: ☐☐ Years ☐☐ Months ☐☐☐ Days

OR Age group: ☐ 0 - <1 year ☐ 1 - 5 years ☐ >5 – 18 years ☐ >18 – 60 years ☐ >60 years

Patient's full residential address with landmarks (Street name, house number, locality, etc.):

_____

_____

Telephone no: _____ Mobile no: _____ E-mail: _____

INVESTIGATOR'S DETAILS

Name & surname of reporting officer: _____

Designation / Position: _____ E-mail: _____

Telephone: _____ Mobile: _____

Date of filling this form: D D / M M / Y Y Y Y

Date of investigation: D D / M M / Y Y Y Y _ **This report is:** ☐ First ☐ Interim ☐ Final

DETAILS OF THE EVENT

Date of onset of event: D D / M M / Y Y Y Y Time of first symptom: ☐☐ Hr ☐☐ Min

Date first reported to the health authority: D D / M M / Y Y Y Y

Date of hospitalization (if applicable): D D / M M / Y Y Y Y Status on the date of investigation: ☐ Died ☐ Disabled ☐ Recovering ☐ Recovered completely

☐ Recovered with complications ☐ Unknown

If died, date of death: D D / M M / Y Y Y Y Time of death: ☐☐ Hr ☐☐ Min

Autopsy done: ☐ Yes ☐ No If **YES**, date of autopsy: D D / M M / Y Y Y Y Attach report (if available)

If **NO**, autopsy planned: Date: D D / M M / Y Y Y Y Time ☐☐ Hr ☐☐ Min

Autopsy NOT done nor planned. Provide reasons: _____

_____

IMMUNISATION HISTORY

Name of vaccinator: _____ Designation: _____

Name of vaccination site: _____

Address of vaccination site: _____

Place of vaccination: ☐ Govt. health facility ☐ Private health facility ☐ Other (specify) _____

Type of site: ☐ Fixed ☐ Mobile ☐ Outreach

Vaccination in: ☐ Campaign ☐ Routine ☐ Other (specify): _____

TRIGGER EVENTS

Minor local reactions

☐ Swelling <5cm ☐ Induration / hardness
☐ Redness ☐ Rash
☐ Other (specify): _____

_____

_____

Minor systemic reactions

☐ Excessive crying (infant) ☐ Mild fever <38°C
☐ Mild headache ☐ Mild body aches
☐ Mild pain (to touch / on movement, but not interfering with daily activities) ☐ Fainting
☐ Other (specify): _____

_____

Patient name & surname: _____ EPID Number: _____

Severe local reactions

- ☐ Pain, redness and/or swelling >3 days
- ☐ Swelling >5cm
- ☐ Swelling beyond nearest joint
- ☐ Lymphadenitis
- ☐ Abscess
- ☐ Necrosis at vaccination site
- ☐ Other (specify):

_____
_____
_____

Severe systemic reactions

- ☐ Hospitalisation
- ☐ Death
- ☐ Collapse/ shock-like state
- ☐ Fever ≥38°C
- ☐ Thrombocytopenia
- ☐ Anaphylaxis
- ☐ Seizures ☐ Febrile ☐ Afebrile
- ☐ Encephalopathy
- ☐ Sepsis
- ☐ Toxic shock syndrome
- ☐ Vomiting
- ☐ Diarrhoea
- ☐ Other (specify): _____

Foetal adverse reactions in the case of maternal immunisation:

- ☐ Decreased FHR variability
- ☐ Decreased foetal movement
- ☐ Foetal death
- ☐ Onset of preterm labour, assessed to be possibly/probably related
- ☐ Foetal anomaly assessed to be possibly/probably related (e.g. congenital anomaly feasible with pre-pregnancy or 1st trimester immunisation)
- ☐ Foetus affected by maternal immunization (e.g. live vaccine administered to mother)

VACCINE INFORMATION (Attach copy of Road to Heath Booklet or Vaccination Card)

NOTE: In the case of a foetal adverse event, ALSO record the mother's maternal vaccination details

Vaccine/s administered *(Complete ONLY for alleged vaccine/s administered before the event)*								**Diluent** *(Where applicable)*		
Vaccine/s given (Use trade names)	**Date vaccinated**	**Time vaccinated**	**Dose number (1st, 2nd)**	**Batch/ Lot number**	**Expiry date / Manufacture date (COVID)**	**VVM Stage** (If applies)	**Manufacturer**	**Batch/ Lot number**	**Expiry date**	**Date & time of reconstitution**

Consumables used (unless pre-filled)	**Needles**	Size: _____ Batch: _____ Expiry date: _____
	Syringes	Size: _____ Batch: _____ Expiry date: _____

SECTION B: RELEVANT PATIENT INFORMATION PRIOR TO IMMUNISATION (Use additional sheet if needed)

NOTE: In the case of a foetus/newborn potentially affected by maternal immunisation, complete questions below for mother. Where questions would apply to the foetus/newborn, please provide additional details in the space provided

Questions applicable to the VACCINEE	**Findings and Remarks** *Compulsory to provide explanations			
Any history of similar event?	Yes*	No	Unknown	
Any previous reactions or adverse event after immunisation?	Yes*	No	Unknown	
Any history of allergies? (vaccine, food, drugs)	Yes*	No	Unknown	
Any family history of any allergies?	Yes*	No	Unknown	
Any family history of any disease/s (relevant to AEFI)?	Yes*	No	Unknown	
Pre-existing medical condition/ congenital disorder?	Yes*	No	Unknown	
Pre-existing acute illness (30 days) prior to vaccination?	Yes*	No	Unknown	
Suffering from any medical condition currently?	Yes*	No	Unknown	
History of hospitalisation in last 30 days, with cause?	Yes*	No	Unknown	
Tested COVID-19 positive prior to vaccination? Date?	Yes*	No	Unknown	
Receiving any concomitant medication? ***If yes, name the drug, indication, doses and treatment dates.***	Yes*	No	Unknown	
Receiving any herbal and/or traditional medicines? ***If yes, name the drug, indication, doses and treatment dates.***	Yes*	No	Unknown	

For adult women: Currently pregnant: ☐ Yes (weeks) _____ ☐ No ☐ Unknown
Currently breastfeeding: ☐ Yes ☐ No

For infants: Gestation: ☐ Full-term ☐ Premature ☐ Post-term Birth weight: _____
Delivery procedure: ☐ Normal ☐ Caesarean ☐ Assisted (forceps, vacuum, etc.)
☐ With complications (Specify): _____

Patient name & surname: _____ EPID Number: _____

SECTION C: DETAILS OF FIRST EXAMINATION** OF SERIOUS/SEVERE AEFI CASE

Source of information *(Tick (✓) all that apply)*: ☐ Examination by the investigator ☐ Documents
☐ Verbal autopsy (P*lease mention source):* _____
☐ Other (Specify): _____
Name & surname of the person who first examined/treated the patient: _____
Name & surname of other persons treating the patient: _____
_____
Other sources who provided information (specify): _____
_____
_____

Signs and symptoms of the AEFI in chronological order from the time of vaccination:
_____
_____
_____
_____
_____
_____
_____
_____

Person completing the clinical details	Name & Surname: _____ Designation: _____ Contact: _____	Date: D D / M M / Y Y Y Y Time: ☐☐ Hr ☐☐ Min

***Instructions:* Attach copies of ALL available documents (including case reporting form, discharge summary, case notes, laboratory reports and autopsy reports, prescriptions for concomitant medication) and then complete additional information NOT AVAILABLE in existing documents, i.e.**

- ***If patient has received medical care***: Attach copies of all available documents (including case sheet, discharge summary, laboratory reports and autopsy reports, if available). Provide only information not available in the attached documents below.
- ***If patient has not received medical care:*** Obtain history, examine the patient and record your findings below (add additional sheets if necessary)

_____
_____
_____
_____
_____
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_____
_____
_____
_____

Provisional / Final diagnosis at the facility ("valid diagnosis"): _____

SECTION D: DETAILS OF VACCINES PROVIDED AT THE SITE LINKED TO AEFI ON THE CORRESPONDING DAY

Vaccinees immunised for each antigen at session site. Attach record if available.	Vaccine name						
	Number of vaccinees vaccinated per session						

a) When was the patient immunised?
☐ Within the first vaccinations of the session ☐ Within the last vaccinations of the session ☐ Unknown

b) In case of multidose vials, when was the vaccine given? ☐ Within the first few doses of the vial administered ☐ Within the last doses of the vial administered ☐ Unknown

c) Time vial was opened: ☐☐ Hr ☐☐ Min

Patient name & surname: _____ EPID Number: _____

	Findings and Remarks *Compulsory to provide explanations			
d) Was there an error in prescribing or non-adherence to recommendations for use of this vaccine?	Yes*	No		
e) Based on your investigation, do you feel that the vaccine (ingredients) administered could have been unsterile?	Yes*	No	Unable to assess	
f) Based on your investigation, do you feel that the vaccine's physical condition (e.g. color, turbidity, foreign substances etc.) was abnormal at the time of administration?	Yes*	No	Unable to assess	
g) 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.)?	Yes*	No	Unable to assess	
h) 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 immunisation session etc.)?	Yes*	No	Unable to assess	
i) 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.)?	Yes*	No	Unable to assess	
j) Number immunised from the concerned vaccine vial/ampoule				
k) Number immunised with the concerned vaccine in the same session				
l) Number immunised with the concerned vaccine having the same batch number in other locations.		Specify locations:		
m) Could this event be a stress response related to immunisation (e.g. acute stress response, vasovagal reaction, hyperventilation, dissociative neurological symptom reaction etc.)?	Yes*	No	Unable to assess	
n) Is this case a part of a cluster?	Yes*	No	Unknown	
If **YES**, how many other cases have been detected in the cluster?				
Did all the cases in the cluster receive vaccine from the same vial?	Yes*	No	Unknown	
If **NO**, number of vials used in the cluster (enter details separately)				

SECTION E: IMMUNISATION PRACTICES AT THE PLACE(S) WHERE CONCERNED VACCINE WAS USED

(Complete this section by asking and/or observing practice)

Syringes and needles used

Are AD syringes used for immunisation? ☐ Yes ☐ No ☐ Unknown

If NO, specify the type of syringes used:

☐ Glass ☐ Disposable ☐ Recycled disposable ☐ Other: _____

Needle used: _____

Specific key findings/additional observations and comments: _____

_____

_____

_____

Reconstitution procedure (complete only if applicable, ✓ NA if not applicable)	**Status**		
a) Same reconstitution syringe used for multiple vials of same vaccine?	Yes	No	NA
b) Same reconstitution syringe used for reconstituting different vaccines?	Yes	No	NA
c) Separate reconstitution syringe for each vaccine vial?	Yes	No	NA
d) Separate reconstitution syringe for each vaccination?	Yes	No	NA
e) Are vaccines and diluents used the same as those recommended by the manufacturer?	Yes	No	NA

Specific key findings/additional observations and comments:

_____

_____

_____

Patient name & surname: _____ EPID Number: _____

Injection technique of vaccinator(s) (Observe another session in the same locality)	Status		
a) Correct dose and route?	Yes	No	NA
b) Time of reconstitution mentioned on the vial? (in case of freeze dried vaccines)	Yes	No	NA
c) Non-touch technique followed?	Yes	No	NA
d) Contraindications screened prior to vaccination?	Yes	No	NA
e) How many AEFI were reported from the centre that distributed the vaccine in the last 30 days?	Yes	No	NA
f) Training received by the vaccinator? If Yes, specify date of last training D D / M M / Y Y Y Y	Yes	No	NA

Specific key findings/ additional observations and comments:

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_____

_____

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SECTION F: COLD CHAIN AND TRANSPORT (Complete this section by asking and/or observing practice)

Last vaccine storage point	Findings and Remarks *Compulsory to provide explanations			
a) Is the temperature of the vaccine storage refrigerator monitored?	Yes	No*		
i) If **YES**, was there any deviation outside of 2–8°C after the vaccine was placed inside?	Yes*	No		
ii) If **YES**, provide details and evidence of monitoring separately.				
b) Was the incorrect procedure followed for storing vaccines, diluents and syringes followed?	Yes*	No	Unknown	
c) Was any other item (other than vaccines and diluents) in the refrigerator or freezer?	Yes*	No	Unknown	
d) Were any partially used reconstituted vaccines in the refrigerator?	Yes*	No	Unknown	
e) Were any unusable vaccines (expired, no label, VVM at stages 3 or 4, frozen) in the refrigerator?	Yes*	No	Unknown	
f) Were any unusable diluents (expired, manufacturer not matched, cracked, dirty ampoule) in the store?	Yes*	No	Unknown	

Specific key findings/additional observations and comments:

_____

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_____

Vaccine transportation	Findings and Remarks *Compulsory to provide explanations			
a) Specify the type of vaccine carrier used				
b) Was the vaccine carrier sent to the site on the same day as vaccination?	Yes	No*	Unknown	
c) Was the vaccine carrier returned from the site on the same day as vaccination?	Yes	No*	Unknown	
d) Was a conditioned ice-pack used?	Yes	No*	Unknown	

Specific key findings/additional observations and comments:

_____

_____

_____

SECTION G: COMMUNITY INVESTIGATION (Please visit locality and interview parents/others)

Were any similar events reported within a time period similar to when the adverse event occurred and in the same locality?

☐ Yes ☐ No ☐ Unknown If YES, how many events/episodes? _____ If YES, please describe:

_____

_____

_____

Patient name & surname: _____ EPID Number: _____

Number of caregivers interviewed: _____
Of those affected, how many are:
Vaccinated: _____ Not vaccinated: _____ Unknown: _____
Other comments:
_____
_____
_____
_____

SECTION H: OTHER FINDINGS/OBSERVATIONS/COMMENTS (Use additional sheet if required)

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SECTION I: DETAILS OF CASE INVESTIGATION TEAM

Signed off by District EPI Coordinator: Date: D D / M M / Y Y Y Y

Name & surname: _____ Signature: _____

Signed off by Appointed District Medical Officer/Specialist: Date: D D / M M / Y Y Y Y

Name & surname: _____ Signature: _____

SECTION J: NATIONAL LEVEL TO COMPLETE

Date report received at National Level: D D / M M / Y Y Y Y **AEFI worldwide unique ID:** _____

Comments: _____
_____
_____
_____

IMPORTANT: Email this form, including all supporting documentation, within 48 hours to AEFI@health.gov.za AND copy the District EPI Surveillance Officer

REPUBLIC OF SOUTH AFRICA
DEPARTMENT OF HOME AFFAIRS

DHA-1663 A
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BARCODE

NOTICE OF DEATH / STILL BIRTH

[Births and Deaths Registration Act 51 of 1992]

[Regulations 11 and 14]

To be completed in full and submitted at the Department of Home Affairs' office by the informant or authorised funeral undertaker. The form to be completed in black ink with **BLOCK LETTERS**. Please mark with ☑ the CORRECT box, where required. **All fields are COMPULSORY. Incomplete applications and applications that are not legible may be considered invalid.** (Note: The fingerprints of the deceased, the informant and the undertaker must be taken by the undertaker)

Serial number

A. PARTICULARS OF THE DECEASED

Instructions: Section A to be filled out by **Authorised Medical Practitioner / Professional Nurse,** who is responsible for examining the body to determine the cause of death. The **Informant must** verify, and where necessary, complete in full the personal particulars and other information of the deceased below.

Left thumbprint of deceased

Right thumbprint of deceased

1. Was this a death or a still birth? ☐ 1.1 Death ☐ 1.2 Still birth

2. Identification of the deceased (tick one box):

☐ 2.1 The deceased was identified with an ID document / passport (if foreigner) produced by the family

☐ 2.2 Still born child

☐ 2.3 The features of the deceased do not seem to match the features on the ID document or passport of deceased

☐ 2.4 ID document or passport of the deceased was not presented. The deceased was identified through word of mouth

☐ 2.5 The deceased was already buried prior to the completion of this form

☐ 2.6 The deceased was unidentifiable: ☐ 2.6.1 Burnt ☐ 2.6.2 Decomposed ☐ 2.6.3 Other (specify) _____

☐ 2.6.4 DNA samples retrieved for identification purposes ☐ 2.6.5 Dental records taken for identification purposes

3. Date of Death / still birth Y Y Y Y M M D D

4.1 Place of Death/still birth (City/Town/Village)

4.2 Province of Death/still birth

5. Place of Registration of Death / still birth

6. If death occurred within 24 hours after birth, number of hours alive

7. Home telephone no.

8. Identity No. (Passport No. if foreigner)

9. Age at last birthday if DOB is unknown

10. Date of Birth if there is no ID number Y Y Y Y M M D D

11. Gender ☐ 11.1 Male ☐ 11.2 Female ☐ 11.3 Indeterminable

12. Surname

13. Previous / Maiden Surname

14. Forenames

15. Usual* Residential Address: Street

Town

Province

Postal code

16. Citizenship

16.1 Place of Birth (City / Town / Village) or Country of Birth, if abroad

16.2 Province of Birth

17. Marital Status of the deceased ☐ 17.1 Single ☐ 17.2 Married ☐ 17.3 Widowed ☐ 17.4 Divorced

18. Education level of deceased, (Specify only the highest class completed)

None	Gr R	Gr 1	Gr 2	Gr 3	Gr 4	Gr 5	Gr 6	Gr 7	Gr 8 Form 1	Gr 9 Form 2	Gr 10 Form 3 NTC 1	Gr 11 Form 4 NTC 2	Gr 12 Form 5 NTC 3	Univ Tech	Unknown
(mark with a ☑)															

19. Usual occupation of deceased (type of work done during most of working life)

20. Type of business / industry: (mark with a ☑)

1. Agriculture, hunting, forestry and fishing	2. Mining and quarrying	3. Manufacturing	4. Electricity, gas and water supply	5. Construction	6. Wholesale and retail trade; repair of motor vehicles, motor cycles and personal and household goods; hotels and restaurants	7. Transport, storage and communication	8. Financial intermediation, insurance, real estate and business services	9. Community, social and personal services	10. Private households, extraterritorial organisations, representatives of foreign governments & other activities not adequately defined

21. Was the deceased a regular** smoker five years ago? (mark with a ☑) ☐ 21.1 Yes ☐ 21.2 No ☐ 21.3 Do not know ☐ 21.4 Not applicable (minor)

* Where the deceased lived on most days. **Smoking tobacco on most days.

REPUBLIC OF SOUTH AFRICA
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Serial number

B. CERTIFICATE BY ATTENDING MEDICAL PRACTITIONER / PROFESSIONAL NURSE

Instructions: Section B to be filled out by the same Medical Practitioner / Professional Nurse who completed Section A.

☐ 22.1 I, the undersigned, hereby certify that the deceased named in Section A, to the best of my knowledge and belief, died solely and exclusively due to Natural Causes

☐ 22.2 I, the undersigned, am not in a position to certify that the deceased died exclusively due to Natural Causes

Particulars of the Medical Practitioner / Professional Nurse who filled out the form: 23. HPCSA Registration No.

24. Surname

25. Forenames

26. Name of Health Facility / Practice 27. Facility / Practice No.

28. Business Address: Street

Town Province

Telephone No. (Office) Postal Code

Office stamp of health facility or practice

I, the undersigned, hereby certify that I examined the body of the deceased named in section A and declare that the deceased, to the best of my knowledge and belief, died solely and exclusively due to natural or unnatural causes as indicated on paragraph 22 and in case this is not true, I shall be guilty of an offence and on conviction liable to a fine or to imprisonment for a period not exceeding five years or to both such fine and such imprisonment (Section 31(1)(b) of the Act 51 of 1992.)

Place signed _____

Date signed Y Y Y Y M M D D Signature _____

C. CERTIFICATE BY MEDICAL PRACTITIONER/ FORENSIC PATHOLOGIST

Instructions: Section C to be filled out by Medical Practitioner or Forensic Pathologist, who is conducting medico-legal investigation of death.

29. I, the undersigned, hereby certify that a medico-legal investigation of death has been conducted on the body of the person whose particulars are given in Section A and that the body is no longer required for the purpose of the Inquest Act, 1959 (Act No. 58 of 1959) and the cause of death is:

☐ 30.1 Natural ☐ 30.2 Unnatural ☐ 30.3 Under investigation

31. Date of Post-mortem Y Y Y Y M M D D

32. Name of Medico-legal Mortuary / Mortuary 33. Mortuary No.

34. Mortuary Reference Number of Deceased

35. SAPS Case No. 36. Name of Police Station

Particulars of the Medical Practitioner / Forensic Pathologist who filled out the form: HPCSA Registration No.

37. Surname

38. Forenames

39. Business Address Street

Town Province Postal Code

Telephone No. (Office)

Office stamp of mortuary

I, the undersigned, hereby certify that I examined the body of the deceased named in section A and the deceased, to the best of my knowledge and belief, died solely and exclusively due to natural or unnatural causes as indicated on paragraph 29 and in case this is not true, I shall be guilty of an offence and on conviction liable to a fine or to imprisonment for a period not exceeding five years or to both such fine and such imprisonment (Section 31(1)(b) of the Act 51 of 1992.)

Place signed _____

Date signed Y Y Y Y M M D D Signature _____

D. PARTICULARS OF INFORMANT

Instructions: Section D to be completed by informant. Informant is responsible for certifying the identity of the deceased.

40. Identity No. (Passport No. if foreigner) 41. Date of Birth Y Y Y Y M M D D

42. Citizenship

43. Surname

44. Forenames

45. Residential Address: Street

Town

Province Postal Code

Left thumb print of informant

Telephone No. (Home) Cellphone No.

46. The Deceased is my: ☐ 46.1 Parent ☐ 46.2 Spouse ☐ 46.3 Child ☐ 46.4 Other, Specify _____

I, the undersigned, hereby certify that the identity of the deceased mentioned in section A is to the best of my knowledge and belief true and correct in case it is not true, I shall be guilty of an offence and on conviction liable to a fine or to imprisonment for a period not exceeding five years or to both such fine and such imprisonment (Section 31(1)(b) of the Act 51 of 1992.)

Signature _____ Date signed Y Y Y Y M M D D Place signed _____

REPUBLIC OF SOUTH AFRICA
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Serial number

E. PARTICULARS OF FUNERAL UNDERTAKER

Instructions: Section E to be completed by **Funeral Undertaker**. The undertaker must take his or her finger print, the finger print of the deceased and the informant. **Authorised Funeral Undertaker or Informant** may submit the completed form to the nearest Home Affairs office.

47. Name of Funeral Parlour

48. DHA Designation No. | 49. Company Reg. No.

50. SARS Reg. No. (Income tax reference no.)

Details of Funeral Undertaker or Authorised Representative

51. Identity No. (Passport No. if foreigner)

52. Surname

53. Forenames

54. Business Address
Street
Town
Province | Postal Code

Left thumbprint of funeral undertaker

Telephone No. (Office) | Cellphone No.

55. Date of collection of corpse (Y Y Y Y M M D D) | 56. Date of Cremation (if applicable) (Y Y Y Y M M D D)

57. Place of Burial (City / Town / Village) | Province

58. Date of Burial (Y Y Y Y M M D D) | 59. Grave No. (if available)

Name of person who collected the deceased:

Office stamp of funeral undertaker

60. Identity No. (Passport No. if foreigner)

61. Surname

62. Forenames

Place signed _____

Date signed (Y Y Y Y M M D D) | Signature _____

F. FOR OFFICIAL USE ONLY

Registration of death approved, DHA-1663 received by (particulars of DHA official):

Office stamp of DHA

63. Identity No.

64. Surname

65. Forenames

66. Persal No.

Documents included with this notice:
☐ Copy of the deceased's ID
☐ Copy of ID document of the informant
☐ DHA - 6 (if applicable)
☐ DHA - 1680 (if applicable)

DHA-1663 was submitted by:
☐ Informant
☐ Funeral Undertaker

References

1. World Health Organization. 2019. Causality assessment of an adverse event following immunization (AEFI). Updated user manual for the revised WHO classification. 2nd Edition. https://www.who.int/vaccine_safety/publications/gvs_aefi/en/) (WHO, 2019)
2. World Health Organization. 2015. Global manual on surveillance of adverse events following immunization. Available from: https://www.who.int/vaccine_safety/publications/aefi_surveillance/en/. Accessed 26 October 2021
3. Gold MS, Balakrishnan MR, Amarasinghe A, MacDonald NE. An approach to death as an adverse event following immunization. Vaccine 2016;34:212-217.doi: 10.1016/j.vaccine.2015.
4. Lehola, P. 2012. Statistician-General Statistics South Africa. Cause of Death Certification: A guide for completing the Notice of Death/Stillbirth (DHA-1663)
5. omara C, Sessa F, Ciaccio M, Dieli F, Esposito M, Giammanco GM, Garozzo SF, Giarratano A, Prati D, Rappa F, Salerno M, Tripodo C, Mannucci PM, Zamboni P. COVID-19 Vaccine and Death: Causality Algorithm According to the WHO Eligibility Diagnosis. Diagnostics. 2021; 11(6):955. https://doi.org/10.3390/diagnostics11060955
6. World Health Organization. 2020. Covid-19 vaccines: safety surveillance manual. Geneva: World Health Organization.
7. World Health Organization. 2015. Verbal autopsy standards: ascertaining and attributing causes of death. Available at http://www.who.int/healthinfo/statistics/verbalautopsystandards/en/ [Accessed 26 October 2021)
8. NDoH. Guidelines on Post Mortem Testing for Natural Deaths. October 2020. https://www.nicd.ac.za/wp-content/uploads/2020/10/Guidelines-on-Post-Mortem-Testing-for-Natural-Deaths_2020_Final_signed_20201013.pdf
9. Carpenito L, D'Ercole M, Porta F, Di Blasi E, Doi P, Fagara GR, et al. The autopsy at the time of SARS-CoV-2: protocol and lessons. Ann Diagn Pathol. 2020;48:151562. doi: 10.1016/j.anndiagpath.2020.151562
10. National Health Act, 2003. Chapter 8 (Act G1 0f 2003).
11. Births and deaths Registration Act 51 of 1992.
12. Center for disease control, USA. 2020. https://www.thename.org/assets/docs/NAME%20Autopsy%20Protocol%20for%20Deaths%20after%20COVID-19%20vaccination.pdf (Accessed 26 October 2021)

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Dr Cloete
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Dear Dr. Cloete

REPORTING AND INVESTIGATION OF DEATH OCCURING AFTER VACCINATION

Surveillance of adverse events following immunisation (AEFI) is essential to safeguard public confidence in vaccines used in the South African vaccination programme and the expanded programme on immunisation (EPI). The National Immunisation Expert Committee (NISEC) monitors vaccine safety related events though causality assessment of all serious or severe AEFI.

It is expected that deaths could occur in the vaccinated population, and any such deaths should be reported as an AEFI to ensure investigation and causality assessment. Prompt and accurate post mortem investigations are required to ensure accurate and timely causality assessment by NISEC. Since January 2021, 117 deaths that occurred after vaccination have been causality assessed, with 16 cases classified as unclassifiable due to incomplete information and investigation.

To address this challenge and improve investigation, a standard operating procedure (SOP) has been compiled to guide the reporting and investigation of deaths occurring after vaccination. Your department is requested to review and implement the SOP. Any questions regarding the SOP, or issues related to implementation thereof, should be referred to Ms Marione Schonfeldt (marione.schonfeldt@health.gov.za).

Kind regards

DR SSS BUTHELEZI
DIRECTOR-GENERAL: HEALTH
DATE: 07/03/22