STANDARD OPERATING PROCEDURE – OBSERVATION OF VACCINEE FOLLOWING COVID-19 VACCINATION AT VACCINATION SITE

INSTITUTION	National Department of Health		
SECTION	COVID-19 Vaccine: Vaccination Site Procedure		
OBJECTIVE	- To ensure that vaccination sites adhere to the minimum COVID-19 vaccine observation protocols after the administration of the vaccine to a vaccinee. - To outline duties and responsibilities of the personnel at vaccination sites.		
SCOPE	- On site vaccine observation following immunisation		
COMPILED BY		**ORIGINAL DATE:**	
AUTHORISED BY			
DEFINITIONS	- **Adverse event** means any untoward medical occurrence that may present after immunisation, but which does not necessarily have a causal relationship with the usage of the vaccine. - **COVID-19 vaccination services** mean the administration of COVID-19 vaccines to eligible populations. - **Designated health care professional** means a trained health care provider whose scope of practice includes treatment of adverse events following immunisation, e.g. medical practitioner, emergency medical personnel, professional nurse, or pharmacist. - **Observation area** means the area in a vaccination site where clients are observed following the administration of a COVID-19 vaccine. - **Vaccination site** means a place where COVID-19 vaccination services may be provided to eligible populations and may include a primary vaccination site or a place where outreach services (fixed, temporary or mobile) are provided. - **Vaccinator** means a designated health care provider trained, competent and acting within their scope of practice who administers a COVID-19 vaccine to a client. - **Vaccinee** means a person who is vaccinated with a Covid-19 vaccine.		
ABBREVIATIONS	- **AEFI:** Adverse Events Following Immunisation - **AESI:** Adverse Events of Special Interest - **CRF:** Case Reporting Form - **DHP:** Designated health professional - **EMS:** Emergency Medical Services - **IEC:** Information Education and Communication - **NDoH:** National Department of Health - **PPE:** Personal Protective Equipment		
POLICIES, REFERENCES, SOURCE MATERIAL	- Pharmacy Act 53 of 1974 - Medicines and Related Substances Act 101 of 1965 - Good Pharmacy Practice rules published in terms of the Pharmacy Act 53 of 1974 - Nursing Act 33 of 2005 - Health Professions Act 56 of 1974 - National Health Act 61 of 2003		
RELATED SOPs	- Vaccination process at vaccination site - Adverse events following immunisation		

PRINCIPLES	- A three-layered surgical mask must be worn at all times by all vaccination personnel. - Cleaning at the observation station should be performed frequently, at least twice daily with special attention to high touch surfaces. - Limit the number of individuals in the observation area to avoid crowding. - Ensure adequate ventilation in the observation area. For natural ventilation, open windows and doors in indoor spaces. If outdoors, pick a well-ventilated, well-shaded area. - Ensure adequate physical distancing - ensure at least 1 metre distance in all directions between each person. - IEC material on COVID appropriate behaviour should be displayed. - Make available hand-washing stations or alcohol-based hand rub dispensers. - Ensure one-way flow of vaccinees through the observation area. - An emergency trolley must be available at every observation area which complies with the minimum standards in the Standard Treatment Guidelines and should be checked daily by a vaccinator before commencing a session. - A basic anaphylaxis treatment kit must be available and should include all medicines outlined in the applicable NDoH Standard Treatment Guidelines (STGs). This kit must be checked daily by the designated health care professional before commencing a vaccination session.
FUNCTIONAL ROLES AND RESPONSIBILITIES	- Observer - Designated health care professional
TOOLS/ MATERIALS/ EQUIPMENT	- Basic anaphylactic kit - Medical equipment
SAFETY WARNINGS	- If AEFI are not rapidly and effectively dealt with, the confidence in a vaccine can be undermined and ultimately have dramatic consequences for immunisation coverage and disease incidence
MONITORING AND EVALUATION	- The vaccinee must be observed by the HCP or other trained health care worker for 15 minutes after vaccination or 30 minutes after receiving the vaccine if the vaccinee has a history of severe allergic reactions.
RECORD KEEPING	- COVID-19 vaccination records must be kept for a period of five years

1. PROCEDURE:

No	PROCEDURE	RESPONSIBLE
This Standard Operating Procedure (SOP) consists of the following sections: 1. Observation of vaccinee post COVID-19 vaccination. 2. Actions where no adverse events are observed. 3. Actions where adverse events are observed.		
1	**Observation of vaccinee post COVID-19 vaccination**	
1.1	Direct vaccinee to designated observation area if still at vaccination station.	Vaccinator/ Marshall

1.2	Observe vaccinee for any immediate allergic reactions and/or unexpected response for at least15 minutes after receiving the vaccine. Observe vaccinee for at least 30 minutes after receiving the vaccine if vaccinee has a history of severe allergic reactions.	Observation area personnel
1.3	Look for any symptoms requiring attention including but not limited to: - Generalised itch or rash - Swelling of the face, lips or tongue - Difficulty breathing, wheezing or stridor - Abdominal pain, nausea or vomiting - Feeling faint or other signs of anaphylaxis - Collapse, dizziness, feeling faint or BP < 90/60 mmHg	Observation area personnel
2.	**Actions where NO adverse events are observed**	
2.1	Inform the vaccinee that he/she may exit the vaccination site with his/her vaccination card.	Observation area personnel
3.	**Actions where adverse events are observed**	
3.1	Treat vaccinee according to symptoms presented and observed. (*Refer to Annexure 1: Assess and manage immediate symptoms following vaccination)*	Designated health professional Observation area personnel
3.2	Inform vaccination site manager	
3.3	Transfer vaccinee to a health establishment for further management if necessary.	Designated health professional Observation area personnel
3.4	Record adverse reaction on the NDoH CRF for AEFI form or if anaphylaxis, on the NDoH CRF for AEFI form once vaccinee is stable or referred and email to AEFI@health.gov.za within 24 hours. (*Refer to Annexure 2: Case Reporting Form for Adverse Events Following Immunisation)*	Designated health professional Observation area personnel
3.4.1	Report to the primary vaccination site, area-based team lead, district manager and provincial lead within 24 hours by copying them in email sent as per step 3.3.	Vaccination site manager
3.4.2	Report to the safety desk call centre: xxxx xxx xxxx	Vaccination site manager
3.5	Replace all medicines/equipment used and seal the emergency kit.	Designated health professional

ANNEXURES	1. Assess and manage immediate symptoms following vaccination 2. Case Reporting Form for Adverse Events Following Immunisation

2. REVISION DATA

Revision No	Pages	Revision Details	Date	Approved

TRAINING REQUIRED

• Training to be conducted post SOP sign-off and prior to the effective date as per above

• Training to be administered to relevant responsible parties after each SOP revision

Trainees	Type of training

3. SOP AUTHORISED

	Name	Signature	Date
Compiled by			
Checked by			
Approved by			

Annexure 1: Assess and manage immediate symptoms following vaccination

**Attach*

Annexure 2: Case Reporting Form for Adverse Events Following Immunisation

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): _____
_____

ALL VACCINES including COVID-19: AEFI CRF Page 1/2 Case Report Form_AEFI_All vaccines incl COVID-19_20210128

Patient name & surname: _____ EPID Number: _____

Severe local reactions	***Severe systemic reactions***		
☐ Pain, redness and/or swelling >3 days	☐ Hospitalisation	☐ Death	☐ Collapse/ shock-like state
☐ Swelling >5cm	☐ Fever ≥38°C	☐ Thrombocytopenia	☐ Anaphylaxis
☐ Swelling beyond nearest joint	☐ Seizures ☐ Febrile ☐ Afebrile	☐ Encephalopathy	☐ Sepsis
☐ Lymphadenitis	☐ Toxic shock syndrome	☐ Vomiting	☐ Diarrhoea
☐ Abscess	☐ Other (specify): _____		
☐ Necrosis at vaccination site	**Foetal adverse reactions in the case of maternal immunisation:**		
☐ Other (specify):	☐ 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	District Office notified: ☐ Yes ☐ No
Date investigation planned: D D / M M / Y Y Y Y	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