STANDARD OPERATING PROCEDURE – VACCINATION PROCESS AT VACCINATION SITE

INSTITUTION	National Department of Health		
SECTION	COVID-19 Vaccine_Vaccination Process at Vaccination Site		
OBJECTIVE	- To promote the use of standardised processes during and after the administration of a COVID-19 vaccine to clients across all vaccination sites.		
SCOPE	- On site vaccination process		
COMPILED BY		**ORIGINAL DATE:**	
AUTHORISED BY			
DEFINITIONS	- **Adverse events following immunisation** mean 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. - **Defaced vial** means an empty or spoilt COVID-19 vaccine vial from the label has been intentionally removed or clearly marked after administration to avoid an empty vial being reintroduced into the market and re-used. - **Immunisation station** means the area at a vaccination site where vaccines are administered to clients. - **Marshall** means a person who provides directions to clients, assists with queue marshalling and facilitates the overall flow of processes at a vaccination site. - **Stock Visibility System** means a mobile application and web-based management tool used at health establishments and vaccination sites to capture stock level data for COVID-19 vaccines and related ancillary items. - **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. - **Validation desk** means the area in a vaccination site where clients present themselves for processing prior to administration of a COVID-19 vaccine		
ABBREVIATIONS	- **AEFI:** Adverse Events Following Immunisation - **CRF:** Case Reporting Form - **EVDS:** Electronic Vaccination Data System - **HPRN:** Health Professional Registration Number - **IEC:** Information Education and Communication - **NDoH:** National Department of Health		

	- **PPE:** Personal Protective Equipment - **SVS:** Stock Visibility System
POLICIES, REFERENCES, SOURCE MATERIAL	- Medicines and Related Substances Act 101 of 1965 (the Medicines Act) - Pharmacy Act 53 of 1974 - 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 - National Environmental Management: Waste Act 59 of 2008 - National Environmental Management Act 107 of 1998 - Hazardous Substances Act 15 of 1973
RELATED SOPs	- Enrolment validation of client at vaccination site - Adverse events following immunisation - Waste Management
PRINCIPLES	- COVID-19 vaccines must be administered in accordance with the NDoH vaccine rollout framework relating to allocation and priority groups. - COVID-19 vaccines must also be administered in accordance with all requirements and guidelines of the NDoH. - Each vaccination session should be planned, to ensure that enough vaccinators, vaccines, diluent if applicable, ancillary items, and waste disposal containers are available. - Before the administration of a COVID-19 vaccine, informed consent must be provided by the client - Where access to a COVID-19 vaccine is provided via section 21 of the Medicines Act, informed consent must be in accordance with the conditions attached to the Section 21 authorisation. Note: Provision for recording of informed consent is included in the Electronic Vaccination Data System (EVDS). - Where applicable, provision must be made to facilitate clients receiving a second or subsequent dose of the COVID-19 vaccine administered. - A mechanism must be in place to trace any vaccinee who defaults from receiving a 2nd dose. - After administering a COVID-19 vaccine, the vaccinator must record the details of the vaccine administered on the recipient's vaccine record, plus any other information required using the appropriate reporting tools. - Vaccination sites must report all adverse events following immunisation (AEFI) using the process provided by the NDoH. - The vaccinator must appropriately deface used empty vials after administration to avoid used vials being reintroduced into the market and re-used.

	- Vaccination sites where vaccines are stored on site (primary vaccination sites and fixed outreach sites) must provide stock-on-hand information to the NDoH daily, at the close of the vaccination session, using SVS, using agreed reporting systems and in the correct format. - Vaccination sites must report the number of doses of COVID-19 vaccine and diluents (if required) that were unused, spoiled, expired, or wasted. - If EVDS cannot be used on-site, for any reason (remote areas with no internet access), a paper-based system may be used, and data captured on the EVDS system at the district level. - Vaccine spills should be disinfected with an appropriate antiviral disinfectant (e.g., Biocide). - A three-layered surgical mask must be worn at all times by vaccination personnel and hands must be sanitized with an alcohol-based sanitizer after vaccinating every client. - Cleaning at the vaccination station should be performed frequently at least twice daily with special attention to high touch surfaces. - All vaccination stations must always have an emergency tray or trolley available which complies with the minimum standards in the Standard Treatment Guidelines. - An emergency tray should have a checklist of all the required emergency medicines and suppliers listed and should be checked daily by a vaccinator before commencing a session. - IEC material on COVID appropriate behaviour should be displayed and job aids available at vaccination stations.
FUNCTIONAL ROLES AND RESPONSIBILITIES	- Vaccinator - Administrative staff - Marshall
TOOLS/ MATERIALS/ EQUIPMENT	- PPE - EVDS - Fridges, freezers, cooler boxes - Vaccine Thermometers - Vaccine Vial Monitors - Temperature monitoring charts - Syringes and needles - Sharps safety disposal boxes
SAFETY WARNINGS	- Do not attempt to recap the needle. This practice can lead to needle-stick injuries. - Needle-stick injuries should be avoided as far as possible and dealt with following standard procedures - Strictly adhere to safe waste management protocols for discarding PPE, vaccine vials and other consumables at vaccination site.
MONITORING AND EVALUATION	KPIs - TBD
RECORD KEEPING	COVID-19 vaccine 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. Vaccination process for administration of all vaccines 2. Vaccination process for second or subsequent dose (where applicable)		
1	**Vaccinator process for administration of all vaccines**	
1.1	Confirm the enrolment validation of the client (Refer to *SOP xx: Enrolment validation of client at vaccination site)*	Validation personnel
1.2	Confirm registration of client	Vaccinator
1.3	Complete the COVID-19 vaccine health questionnaire with details obtained from client (Refer to Annexure 1: *COVID-19 Vaccine Health Questionnaire)*	Vaccinator
1.3.1	Counsel the client about the vaccine, dosing interval, possible side effects, adverse event reporting and importance of the follow up dose if applicable.	Vaccinator
1.4	Read the "Informed Consent Form" section (applicable to the vaccine to be administered) on the COVID-19 Vaccination Form to the client	Vaccinator
1.4.1	Check that the client understands and provides informed consent for vaccination based on the specific COVID-19 vaccine to be administered.	Vaccinator
1.4.2	Confirm consent to being vaccinated from the client through the completion and signing of the electronic or paper consent form	Vaccinator
1.4.3	If the client does not provide consent, end the consultation. The client is not eligible for vaccination.	Vaccinator
1.4.4	Schedule a return appointment for the client if applicable - or refer this process to another administrator.	Vaccinator
1.5	Prepare the injection according to the vaccine specific guidelines.	Vaccinator
1.6	Administer the vaccine according to the vaccine specific guidelines.	Vaccinator
1.7	Capture vaccine specific information found on the box, packaging or vial on EVDS, i.e. manufacturer, batch number, expiry date, dose number (i.e. first or second dose)	Vaccinator
1.8	Use a permanent black marker to deface the label on the empty vaccine vial, and empty vial packaging where applicable, before discarding. Alternatively remove the label of the empty vaccine vial, tear it in two and discard the label appropriately.	Vaccinator
1.9	Immediately and safely dispose of the needle, syringe and defaced vial (if empty) in the designated sharp disposal container or safety box.	Vaccinator

1.10	Schedule an appointment for the client for the next dose - or refer this process to another administrator to make the second appointment.	Vaccinator
1.11	Mark vaccination as complete on EVDS or on manual system used where EVDS is not available	Vaccinator
1.11.1	Vaccinee receives a confirmatory SMS (and appointment date for follow up dose).	System generated
1.12	Complete the vaccination card and hand to the vaccinee.	Vaccinator
1.1.4	Request vaccinee to proceed to observation area	Vaccinator
1.13	Direct the vaccinee to the observation area.	Marshall
2	**Vaccination process for second dose (where applicable)**	
2.1	Receive vaccinee from the validation station for the second dose.	Vaccinator
2.2	Check for the vaccinee's eligibility for a second dose, using EVDS or the vaccination card where EVDS is non-functional:.	Vaccinator
2.3	If the vaccinee has received a vaccination before, which dose, which manufacturer and if any AEFI occurred. This is to ensure that repeat or duplicate doses are not given or not crossed between manufacturers.	Vaccinator
2.3.1	If an adverse event following immunisation occurred, but has not yet been reported, complete the CRF (refer to Annexure 1).	Vaccinator
2.3.2	If a severe allergic reaction (e.g., anaphylaxis) occurred with the previous vaccination, the vaccine is contra-indicated and the client should not be vaccinated.	Vaccinator
2.4	Administer the second vaccination as per vaccine specific guidelines.	Vaccinator
2.5	Capture vaccine specific information found on the box, packaging or vial on EVDS, i.e., manufacturer, batch number, expiry date, dose number (second).	Vaccinator
2.6	Use a permanent black marker to deface the label on the empty vaccine vial, and empty vaccine vial packaging where applicable, before discarding. Alternatively remove the label of the empty vaccine vial, tear it in two and discard the label appropriately.	Vaccinator
2.6	Immediately and safely dispose of the needle, syringe and defaced vial (if empty) in the designated sharp disposal container or safety box.	Vaccinator
2.7	Mark vaccination as complete on EVDS or on manual system used (paper cards) where EVDS is not available	Vaccinator
2.7.1	A notification will be sent to the vaccinee's mobile number as a confirmation of vaccination of the second dose.	System generated
2.8	Complete the vaccination card and hand to the vaccinee.	Vaccinator
2.9	Request vaccinee to proceed to designated observation area.	Vaccinator

2.10	Direct vaccinee to designated observation area	Marshall

ANNEXURES	1. COVID-19 Vaccine Health Questionnaire 2. Case reporting form for adverse events following immunization (AEFI)

Commented [SJP1]: Shaidah/Marione – please check annexures

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: COVID-19 Vaccine Health Questionnaire

The client should answer the following questions:

1. **Are you sick today? Y/N**
2. **If Yes, please provide details: _____**

_____

3. **Have you received any vaccinations in the past two weeks? Y/N**
    a. **If Yes, please indicate what vaccine: _____**
4. **Have you received any other COVID-19 vaccine at any time? Y/N**
    a. **If Yes, please provide the date of vaccination: _____**
    b. **Where did you receive the vaccine (e.g which clinic):_____**
5. **Have you been diagnosed with COVID-19 infection in the last 90 days? Y/N**
    a. **If Yes, what date did you test positive: _____**
6. **Do you have a history of an anaphylactic reaction to anything other than a vaccine or injectable medication Y/N**
    a. **If Yes, please describe: _____**
7. **Have you ever had an anaphylactic reaction:**

Reaction	Yes	No
Trouble breathing		
Broke out in hives		
Facial or tongue swelling		
Low blood pressure		
Other severe symptoms after receiving another vaccination or injection (a shot given intravenously, intramuscularly, or subcutaneously)?		

8. **Female vaccine recipients only: Do you suspect that you might be pregnant today? Y/N**
9. **If Yes or unknown, please indicate when you had your last menstrual period. _____**

Annexure 2: Case Reporting Form (CRF)

health — ALL VACCINES including COVID-19

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