

STANDARD OPERATING PROCEDURE – COVID-19 VACCINATION SITE PROCESSES

INSTITUTION	National Department of Health	
SECTION	COVID-19 Vaccination – Site Readiness Assessment	
OBJECTIVE	 To ascertain that a vaccination site conforms to the minimum COVID-19 safety protocols To ensure vaccination sites have proper infection prevention and control practices, To ensure vaccination sites are suitably equipped and comply with applicable legislation, policies and guidelines 	
SCOPE	- Vaccination Site Readiness Assessment	
COMPILED BY	ORIGINAL DATE:	
AUTHORISED BY		
DEFINITIONS		
ABBREVIATIONS	 Vaccinee means a person who is vaccinated with a Covid-19 vaccine. AEFI Adverse Event Following Immunisation EVDS Electronic Vaccine Data System IEC Information, Education and Communication IPC Infection Prevention and Control MFL Master Facility List NDoH National Department of Health 	

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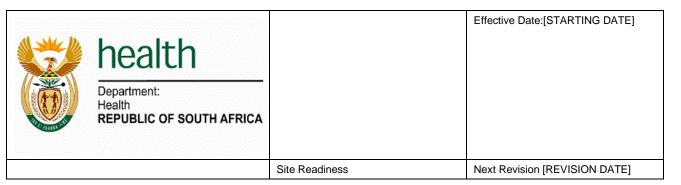
	- PPE Personal Protective Equipment
POLICIES, REFERENCES, SOURCE MATERIAL	 Provincial Drug Supply Management Policy/ Prescript (As applicable) Pharmacy Act 53 of 1974 Medicines and Related Substances Act 101 of 1965 Good Pharmacy Practice rules published in terms of the Pharmacy Act 53 of 1974 Cold chain and Immunisation Operations Manual of 2015 National Environmental Management: Waste Act 59 of 2008 National Environmental Management Act 107 of 1998 Hazardous Substances Act 15 of 1973
RELATED SOPs	 COVID-19 Screening Enrolment Validation Preparation of Cold Chain Equipment Pre vaccination processes / checklist Vaccination Process at Vaccination Site Waste Disposal of COVID-19 Vaccines Waste Disposal of Ancillary Items Storage of COVID-19 Vaccines
PRINCIPLES	 Covid-19 vaccination services must be provided in accordance with all relevant laws, regulations, rules and guidelines, and utilising medicines on the applicable list provided by the National Department of Health. COVID-19 vaccines may not be sold, vaccination sites may not seek reimbursement for any vaccines, syringes, needles, or other ancillary supplies that the government provides without cost to the site. Vaccination sites must be listed on the Master Facility List (MFL) and comply with the minimum requirements as provided in Annexure 1 Vaccination site enrollment. Vaccination sites must hold a permit issued in terms of section 22A (15) of the Medicines and Related Substances Act 101 of 1965 Vaccination sites must comply with the following general requirements. must be easily accessible to clients be arranged in such a way that social distancing can be maintained in both waiting areas and at vaccination stations Vaccination sites must plan immunisation sessions to minimise vaccine wastage Vaccination sites must determine and make readily available the days and times that services will be provided at the site Vaccination sites must designate a separate entry and exit if possible Vaccination site should be sanitised prior to vaccination and cleaned regularly, at least twice daily with special attention to high-touch surfaces, including the screening The number of individuals present at vaccination site must be limited Organising scheduled times for vaccination appointments. Use of outdoor spaces, if possible, and adherence to physical distancing at the health care facility or site; and * For vaccination sessions at health facility, vaccination area and

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	separate spaces depending on the facility).
	 Eligible Vaccinees should pre-register for COVID-19 vaccination through a self-registry on the EVDS platform or walks in at the vaccination site.
	- Vaccine stock must be controlled and to minimise unnecessary wastage
	 Vaccination sites must comply with all requirements defined by the NDoH for disposing of COVID-19 vaccine and diluent, including damaged, expired and/or unused doses.
FUNCTIONAL ROLES AND RESPONSIBILITIES	 Admin Staff District Admin Vaccination site manager
TOOLS/ MATERIALS/ EQUIPMENT	- Site Readiness Checklist
SAFETY WARNINGS	 Adhere to guidance and protocols for IPC measures and use recommended personal protective equipment (PPE) in line with national policy
	 Strictly adhere to safe waste management protocol for discarded PPE and other consumables at session site
MONITORING AND EVALUATION	- TBD
RECORD KEEPING	 All records related to COVID-19 vaccine management must be maintained for a minimum period of five (5) years.

1.1. PROCEDURE:

No	PROCEDURE		RESPONSIBLE
This S	Standard Operating	Procedure (SOP) consists of the following sections:	
	1. Vaccir	ation Site Registration	
	2. Vaccir	ation Site Layout	
	3. Vaccir	ation Team	
	4. IEC M	aterial	
	5. Cold C	chain Maintenance at Site	
	6. Infection	on Prevention and Control Practice	
1	Vaccination S	ite Registration	
1.1	Register vaccina	tion site in accordance with the relevant procedures	District Admin
	Ensure vaccination site is registered on the MFL on the EVDS District Admin		District Admin
2	Vaccination Site Layout		
2.1	Demarcate the s	ite into four stations:	Vaccination Site Manager
	1. COVID	Screening Station	
	2. Enrolm	ent and validation Station	



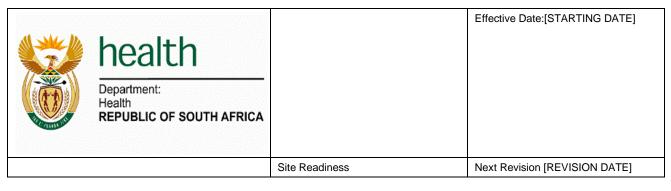
	3. Vaccination Station; and	
	4. Observation Station.	
2.1.1	COVID Screening Station	
	Create designated entry point(s) for the workforce to receive the temperature screens.	Vaccination Site Manager
	Demarcate area to control separation	Vaccination Site Manager
	Display COVID-19 educational health & safety information at entry points	Vaccination Site Manager
	Assist with the orderly flow of people while maintaining all "social distancing"	Vaccination Site Manager
2.1.2	Confirmation of registration on EVDS Station	
	Ventilate the rooms well through open windows and natural ventilation.	Admin staff
	Demarcate access area to ensure proper social distancing	Vaccination Site Manager
	Ensure adequate queue management and crowd control system outside the waiting area	Vaccination Site Manager
	Provide proper access for the differently abled and the elderly	Vaccination Site Manager
	Provide hand washing/ sanitization at entrance	Vaccination Site Manager
2.1.3	Vaccination Station	
	Provide a dedicated room for vaccination with one table and two chairs. Seating arrangement to ensure physical distancing	Vaccination Site Manager
	Provide hand washing/ sanitization at entrance	Vaccination Site Manager
	Provide privacy at the vaccination site, only one person to be processed at a time	Vaccination Site Manager
	Display IEC materials on COVID appropriate behavior	Admin staff
	Obtain all necessary ancillary supplies and consumables as listed below:	Vaccination Site Manager
	Ancillary supplies	
	1. Syringes for vaccination: 1 syringe per dose, depend on vaccine used	
	(Comirnaty [®] 1ml, 0,5ml or 0,3ml syringes) Covid-19 vaccine Janssen (1ml, 2ml)	
	 Needles suitable for intramuscular vaccination: 22gx32mm and 23gx25mm only. 22g for obese patients (1 needle per vial) 	
	3. Syringes for reconstitution- 2ml or 5ml (<i>if required</i>) (1 per vial)	
	4. Needles for reconstitution- 21G (If required) (1 per vial supplied)	
	 Diluent for reconstitution (if required- Sodium Chloride 0.9% injection 2ml (Adcock Ingram Critical Care) (1.8ml per vial) required for Comirnaty[®] 	
	6. Cotton wool balls (2 per number of vaccinees)	
	 A safety box for disposal of used syringes and needles (1 per 100 doses supplied) 	

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	8. Viricidal disinfectant, e.g. Biocide	
	 PPE as outlined in infection control guidelines (3 ply surgical masks for vaccinators and boxes of gloves for emergency use only) 	
	10. Sterile water for irrigation for sites with no running water	
	Handwash and alcohol-based (70%) sanitiser	
	Waste disposal and management	
	1. Healthcare waste risk containers and boxes	
	2. Healthcare waste bags and bins	
	3. Appropriate waste management contract	
	Necessary material for administrative purposes	
	1. Vaccination forms	
	2.Vaccination cards	
	3. Case reporting form (CRF) for reporting AEFI	
2.1.4	Observation Station	
	Provide a room with adequate seating space, drinking water and if possible, toilet facility	Vaccination Site Manager
	Arrange seating arrangement ensuring physical distancing norms	Vaccination Site Manager
	Display IEC materials on COVID appropriate behavior	Vaccination Site Manager
	Ensure emergency trolley is stocked with items as per Site Readiness Checklist	Vaccination Site Manager
		Manager
3	Human Resources	Manager
3	Human Resources Determine the number of Vaccinators at the vaccination	District Admin
3		
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	prominent places at the vaccination site	
5	Cold Chain Management	
	Refer to SOP xx Preparation of Cold Chain Equipment	Vaccination Site Manager
6	Monitor vaccine wastage to identify any avoidable wastage	
	Refer to SOP xx Vaccine Wastage Control	Vaccination Site Manager
7	Infection Prevention and Control Practice	
	Ensure staff and vaccine perform hand hygiene before / after each session using soap and water or with a hand sanitizer that contains 70% alcohol.	Vaccination Site Manager
	Ensure Staff wear proper surgical mask and sanitize hands with an alcohol-based sanitizer after vaccinating every beneficiary	Vaccination Site Manager
	Ensure Staff clean and disinfect environmental surfaces often, including tabletops, chairs, light switches	Vaccination Site Manager



ANNEXURES	Annexure 1: Roles and Responsibilities at Vaccination Site
ANNEAURES	Annexure 2: Site Readiness checklist

2. REVISION DATA

Revision No	Pages	Revision Details	Date	Approved

TRAINING REQUIRED

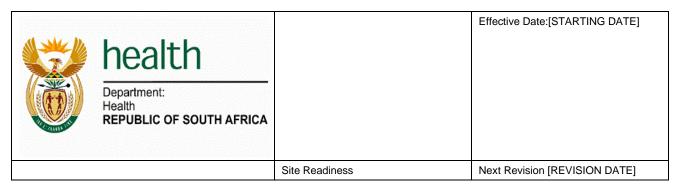
Training to be conducted post SOP sign-off and prior to the effective date as per above

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

Trainees	Type of training

3. SOP AUTHORISED

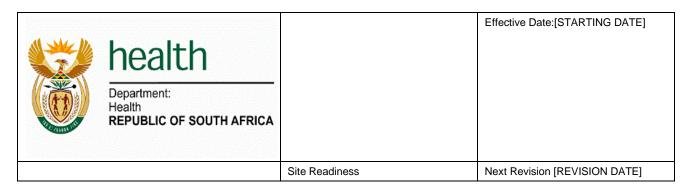
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Checked by			
Approved by			



Annexure 1: Roles and Responsibilities

Roles at the vaccination site	Staff who could fill the role	What the role requires	Resources, tools, and Standard Operating Procedures (SOPs)
Vaccination site manager	Any health care provider (as defined in the Health Act)	Overall management of the vaccination site	All tools used at the vaccination site
Vaccination site scheduling administrator	Administrator	Manage scheduling at the vaccination site and troubleshoot	EVDS scheduling guide
Queue Marshal	Community members and volunteers	Manage and marshal queues	Vaccine Site Conceptual Design Tool
		Troubleshoot when needed	Job-aid for queue marshals
		Provide information to the clients in the queue	
Personnel responsible for COVID-19 screening	Administrative staff and volunteers	Routine COVID-19 screening (temperature, COVID-19 questionnaire, hand sanitising) Confirm registration and refer to relevant queue (Client EVDS code)	SOP - COVID-19 screening process
EVDS admin support personnel	Administrative staff	Confirm proof of registration on EVDS using ID or another suitable document	SOP - Confirmation of registration on EVDS
		Confirm client demographic data on EVDS	EVDS user manual
		Using relevant ID documents	
		Confirm medical aid details (where relevant)	
On-site assisted registration person (if client not registered on EVDS)	Administrative staff	Assist with EVDS registration	EVDS user manual

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Vaccinator	Medical practition dentist, pharmaci professional nurse enrolled nurses, of associate, a para with ATLS, other operating within h scope of practice provide vaccination services. Medical, pharmaci nursing students their clinical trainin supervision.	ist, ist, clinical HCP to on cy, and as part of ing under EVDS *Confirm the id the client *Administer hea questionnaire *Administer inf consent Prepare injection Administer vacci	entity of alth bormed eeded n ne EVDS user m Job aid relatin vaccines in u Chapter 5) Job aid relatin vaccines (structure) Chapter 5) Chapter 5)	ng to different se (see also ng to injection see also
	Pharmacy interns nurse practitioned the supervision o relevant registered professional	rs under Issue vaccinatio f a		forms - sent, health



Annexure 2 Site Readiness Check List

Category	Specific item	Check
	Sufficient designated space for 4 four stations:	
	1. COVID-19 Screening station	
	2. Enrolment and validation station	
	3. Vaccination station	
	4. Observation station	
	Suitable waiting area or space	
	Space is well ventilated If air-conditioned, technical assessment of the air conditioning flow must be done.	
	Temperature must be controlled (for fixed sites)	
	Clean, tidy and not directly exposed to sunlight, rain or dust	
	Functioning of water supply, sanitation, and storm water drainage (stress test sewage system prior to use)	
Premises	Suitable handwashing facilities	
	Suitable ablution facilities (Preferably separate for staff and clients due to the PPE decontamination process)	
	Electrical power points for IT Equipment	
	Adequate lighting Assess the effectiveness of lighting in bad/overcast weather conditions or if site plans to function after dark	
	Back-up electrical power and internet connectivity	
	Evacuation plan in place	
	Security and control of access at sites where medicines (vaccines, ancillaries, emerger medicines) are stored	псу
	1. Designated, lockable space for storage of medicines	
	 Sufficient security to prevent unauthorised access to the place where medicines are kept. 	

	Uses a one-directional flow process.	
	Provides for social distancing and plenty of fresh air in the waiting area and all stations	
Site layout Makes people feel welcome and secure Helps guides clients with clear signage, marshals, or both.	Makes people feel welcome and secure	
	Helps guides clients with clear signage, marshals, or both.	
	Operating hours visible to clients upon entry	

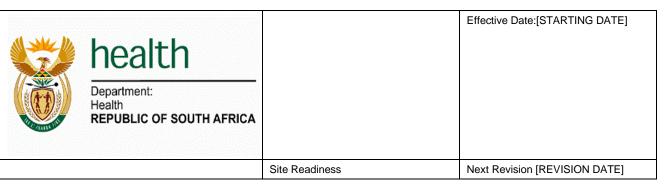
	Furniture	
Equipment	1. Tables	
	2. Chairs	

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Category	Specific item	<u>Check</u>
	3. Desks	
	IT Equipment	
	1. Computer/tablet/laptop for each admin staff	
	2. Computer/tablet/laptop for each vaccinator	
	3. Computers have connectivity and internet access	
	 Android mobile device with SIM card (to receive OTP number and update stock levels on SVS if using the mobile app) 	
	5. 1D Barcode scanner	
	6. 2D Barcode scanner	
	IT equipment set up	
	IT equipment tested	
	COVID-19 Screening equipment	
	1. Clinical thermometers	
	2. COVID-19 screening register	
	Emergency equipment	
	1. Resuscitation equipment	
	2. Trolley	
	Cleaning equipment	
	1. Buckets and cleaning supplies	
	2. Janitor trolleys	

	Equipment	
	1. Suitable freezer at sites storing vaccines that is switched on and functional	
	2. Suitable fridge at sites storing vaccines that is switched on and functional	
Vaccine cold chain	3. Sufficient storage capacity to ensure compliance to vaccine storage requirements	
compliance &	4. WHO PQS continuous temperature monitoring and logging devices	
Equipment	5. Passive containers	
	6. Conditioned ice packs to line the cold box	
	Temperature must be recorded twice daily	
	Contingency plan if cold storage unit fails	

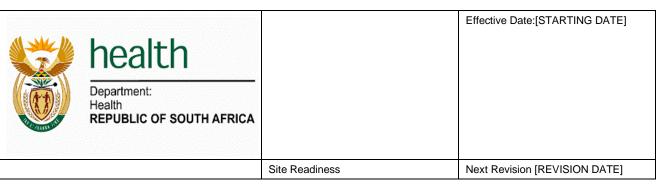
	Vaccinators
	1. Determine number of vaccinators required
Human Resources &	 Vaccinators completed training, competent to provide the service and functioning within his/her scope of practice
Training	3. Vaccination site manager
	4. Vaccine controller at sites storing vaccines
	5. Vaccine champion



Category	Specific item	<u>Check</u>
	Support staff	
	1. Admin staff (note 1 for every 3 vaccinators)	
	2. Queue Marshal/s	
	3. Security	
	All staff involved in the provision of COVID-19 vaccination services are appropriately trained to use relevant reporting tools.	

	Ancillary supplies may vary depending on the type of COVID-19 vaccine. Vaccination sites must maintain an adequate supply of the following ancillary supplies:
	1. Syringes for vaccination: 1ml/2ml (1 syringe per dose)
	 Needles suitable for intramuscular vaccination: 22gx32mm and 23gx25mm only. 22g for Obese patients (1 needle per dose)
	3. Syringes for reconstitution – 2ml or 5ml (<i>if required</i>) (1 per vial)
	4. Needles for reconstitution- 21G (<i>if required</i>) (1 per vial supplied)
	 Diluent for reconstitution (if required - Sodium Chloride 0.9% injection 2 ml (Adcock Ingram Critical Care) (1.8 per vial)
Consumables/	6. Cotton wool balls (2 per number of vaccinees)
Ancillary supplies	7. A safety box for disposal of used syringes and needles (1 per 100 doses supplied)
	8. Viricidal disinfectant, e.g. Biocide
	 PPE as outlined in infection control guidelines (3 ply surgical masks for vaccinators and boxes of gloves for emergency use only)
	10. Sterile water for irrigation for sites with no running water
	Handwash and alcohol-based sanitiser
	Waste disposal and management
	1. Healthcare waste risk containers and boxes
	2. Healthcare waste bags and bins
	3. Appropriate waste management contract

Resources & Tools	Reference guides for vaccination site staff	
	1. Vaccination site guides (COVID-Vaccine Toolkit, SOPs, etc.)	
	2. Job aids	
	Material for administrative purposes	
	1. Vaccination forms	
	2. Vaccination cards	
	3. Case reporting form (CRF) for reporting AEFI	
	4. Case investigation form (CIF) for investigating serious AEFI	
	5. Case investigation forms for adverse events of special interest (AESI)	



Category	Specific item	<u>Check</u>
	Stock cards/bin cards (if not using an electronic stock management system) (for sites where vaccines are stored)	
	Tally sheets or relevant recording form/tool (for temporary mobile outreach services)	
	Information, Educational and Communication material	
	1. Posters	
	2. Hand-outs	
	3. Fact sheets	
	Board with daily tally of vaccinations given against overall target	

Inventory Management	Functional SVS application or bin cards only where no electronic system can be used	
(Primary vaccination sites and temporary outreach sites where vaccines are stored	Tally sheets to be provided to temporary outreach and mobile sites to record daily usage and losses of vaccines and ancillary items	

Emergency Supplies	Adrenalin Injection (1:1000) solution – 2 ampoules	
	Hydrocortisone injection (100 mg) -1 vial	
	Ipratropium bromide 0,5mg, nebulizing solution	
	IV fluids, (Ringer- Lactate solution or normal saline) with drip set	
	Promethazine IM/slow IV (25mg-50mg)	
	Salbutamol 0.5%, solution, nebulizing solution	
	Sodium chloride 0.9%, IV solution	
	Syringes required	
	Needles required	
	AEFI reporting form	