

 <p>health Department: Health REPUBLIC OF SOUTH AFRICA</p>		Effective Date:[STARTING DATE]
	Site Readiness	Next Revision [REVISION DATE]

STANDARD OPERATING PROCEDURE – COVID-19 VACCINATION SITE PROCESSES

INSTITUTION	National Department of Health		
SECTION	COVID-19 Vaccination – Site Readiness Assessment		
OBJECTIVE	<ul style="list-style-type: none"> - 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	<ul style="list-style-type: none"> - COVID-19 vaccination services mean the administration of COVID-19 vaccines to eligible populations. - Vaccination 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. - Information Education and Communication (IEC) material includes but is not limited to banners, poster, leaflets about COVID-19 vaccination - Vaccines means biological medicines that must be stored under specific temperature conditions, in accordance with the manufacturer’s recommendations. - Vaccination site means a place where COVID-19 vaccination services are provided to eligible populations and may include a primary vaccination site or a place where fixed or temporary outreach vaccination services are provided. - Vaccine Champion means a person who is designated to manage the vaccine supply chain at a place where vaccines are administered. Such person may be a pharmacist, pharmacist’s assistant or nurse and may also function as the vaccination site manager, or as a vaccinator - Vaccine Controller means a pharmacist or pharmacist’s assistant or other health care professional designated to manage the storage and supply of vaccines, the distribution of vaccines to primary vaccination sites, outreach sites and/or the supply of vaccines to mobile teams (where applicable) and the updating of data on the Stock Visibility System (SVS). - 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	<ul style="list-style-type: none"> - 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 		

 <p>health Department: Health REPUBLIC OF SOUTH AFRICA</p>		Effective Date:[STARTING DATE]
	Site Readiness	Next Revision [REVISION DATE]


	<ul style="list-style-type: none"> - PPE Personal Protective Equipment
POLICIES, REFERENCES, SOURCE MATERIAL	<ul style="list-style-type: none"> - 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	<ul style="list-style-type: none"> - 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	<ul style="list-style-type: none"> - 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. <ul style="list-style-type: none"> - 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 establish and implement a mechanism of setting up appointments to prevent crowding - 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 waiting areas should be separated from curative services (i.e. separate times of the day or

 health Department: Health REPUBLIC OF SOUTH AFRICA		Effective Date:[STARTING DATE]
	Site Readiness	Next Revision [REVISION DATE]


	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 Standard Operating Procedure (SOP) consists of the following sections: <ol style="list-style-type: none"> 1. Vaccination Site Registration 2. Vaccination Site Layout 3. Vaccination Team 4. IEC Material 5. Cold Chain Maintenance at Site 6. Infection Prevention and Control Practice 	
1	Vaccination Site Registration	
1.1	Register vaccination site in accordance with the relevant procedures	District Admin
	Ensure vaccination site is registered on the MFL on the EVDS	District Admin
2	Vaccination Site Layout	
2.1	Demarcate the site into four stations: <ol style="list-style-type: none"> 1. COVID Screening Station 2. Enrolment and validation Station 	Vaccination Site Manager

 health Department: Health REPUBLIC OF SOUTH AFRICA		Effective Date:[STARTING DATE]
	Site Readiness	Next Revision [REVISION DATE]


	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: Ancillary supplies <ol style="list-style-type: none"> 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) 2. Needles suitable for intramuscular vaccination: 22gx32mm and 23gx25mm only. 22g for obese patients (1 needle per vial) 3. Syringes for reconstitution- 2ml or 5ml (if required) (1 per vial) 4. Needles for reconstitution- 21G (if required) (1 per vial supplied) 5. 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) 7. A safety box for disposal of used syringes and needles (1 per 100 doses supplied) 	Vaccination Site Manager

 <p>health Department: Health REPUBLIC OF SOUTH AFRICA</p>		Effective Date:[STARTING DATE]
	Site Readiness	Next Revision [REVISION DATE]

	<ul style="list-style-type: none"> 8. Viricidal disinfectant, e.g. Biocide 9. 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 <p>Handwash and alcohol-based (70%) sanitiser</p> <p>Waste disposal and management</p> <ul style="list-style-type: none"> 1. Healthcare waste risk containers and boxes 2. Healthcare waste bags and bins 3. Appropriate waste management contract <p>Necessary material for administrative purposes</p> <ul style="list-style-type: none"> 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 <i>Site Readiness Checklist</i>	Vaccination Site Manager
3	Human Resources	
	Determine the number of Vaccinators at the vaccination	District Admin
	Ensure all site vaccinators have been properly trained, are competent to provide the service and functioning within their scope of practice	District Admin
	<p>Ensure adequate number of Support Staff</p> <ul style="list-style-type: none"> 1. Admin staff (note 1 for every 3 vaccinators) 2. Queue Marshal/s 3. Security 4. Vaccine site manager 5. Vaccine controller (at sites storing vaccines) 6. Vaccine champion 7. Security 8. Cleaning staff 	District Admin
	Ensure all staff involved in the provision of COVID-19 vaccination services are appropriately trained to use relevant reporting tools.	Vaccination site manager
	Ensure flow of vaccines at Vaccination site as per the roles and responsibilities of team members mentioned above	Vaccination Site Manager
4	IEC Material	
	Ensure an adequate number of IEC materials are printed and displayed at	Vaccination Site Manager

 <p>health Department: Health REPUBLIC OF SOUTH AFRICA</p>		Effective Date:[STARTING DATE]
	Site Readiness	Next Revision [REVISION DATE]

	prominent places at the vaccination site	
5	Cold Chain Management	
	<i>Refer to SOP xx Preparation of Cold Chain Equipment</i>	Vaccination Site Manager
6	Monitor vaccine wastage to identify any avoidable wastage	
	<i>Refer to SOP xx Vaccine Wastage Control</i>	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

 <p>health Department: Health REPUBLIC OF SOUTH AFRICA</p>		Effective Date:[STARTING DATE]
	Site Readiness	Next Revision [REVISION DATE]

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

	Name	Signature	Date
Compiled by			
Checked by			
Approved by			


 <p>health Department: Health REPUBLIC OF SOUTH AFRICA</p>		Effective Date:[STARTING DATE]
	Site Readiness	Next Revision [REVISION DATE]

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 Troubleshoot when needed Provide information to the clients in the queue	Vaccine Site Conceptual Design Tool Job-aid for queue marshals
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 Confirm client demographic data on EVDS Using relevant ID documents Confirm medical aid details (where relevant)	SOP - Confirmation of registration on EVDS EVDS user manual
On-site assisted registration person (if client not registered on EVDS)	Administrative staff	Assist with EVDS registration	EVDS user manual


 <p>health Department: Health REPUBLIC OF SOUTH AFRICA</p>		Effective Date:[STARTING DATE]
	Site Readiness	Next Revision [REVISION DATE]

Vaccinator	<p>Medical practitioner, dentist, pharmacist, professional nurse, enrolled nurses, clinical associate, a paramedic with ATLS, other HCP operating within his/her scope of practice to provide vaccination services.</p> <p>Medical, pharmacy, and nursing students as part of their clinical training under supervision.</p> <p>Pharmacy interns and nurse practitioners under the supervision of a relevant registered professional</p>	<p>*MUST be recorded on EVDS</p> <p>*Confirm the identity of the client</p> <p>*Administer health questionnaire</p> <p>*Administer informed consent</p> <p>Refer client as needed</p> <p>Prepare injection</p> <p>Administer vaccine</p> <p>*Record vaccination details</p> <p>Issue vaccination card</p>	<p>SOP - Vaccination process</p> <p>EVDS user manual</p> <p>Job aid relating to different vaccines in use (see also Chapter 5)</p> <p>Job aid relating to injection preparation (see also Chapter 5)</p> <p>Vaccination card</p> <p>Paper-based forms - informed consent, health questionnaire</p>
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 <p>health Department: Health REPUBLIC OF SOUTH AFRICA</p>		Effective Date:[STARTING DATE]
	Site Readiness	Next Revision [REVISION DATE]

Annexure 2 Site Readiness Check List


Category	Specific item	Check
Premises	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)	
	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, emergency medicines) are stored		
1. Designated, lockable space for storage of medicines		
2. Sufficient security to prevent unauthorised access to the place where medicines are kept.		
Site layout	Uses a one-directional flow process.	
	Provides for social distancing and plenty of fresh air in the waiting area and all stations	
	Makes people feel welcome and secure	
	Helps guides clients with clear signage, marshals, or both.	
	Operating hours visible to clients upon entry	
Equipment	Furniture	
	1. Tables	
	2. Chairs	

 <p>health Department: Health REPUBLIC OF SOUTH AFRICA</p>		Effective Date:[STARTING DATE]
	Site Readiness	Next Revision [REVISION DATE]

Category	Specific item	Check
	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	
	4. 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	

Vaccine cold chain compliance & Equipment	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	
	3. Sufficient storage capacity to ensure compliance to vaccine storage requirements	
	4. WHO PQS continuous temperature monitoring and logging devices	
	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	


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

 health Department: Health REPUBLIC OF SOUTH AFRICA		Effective Date:[STARTING DATE]
	Site Readiness	Next Revision [REVISION DATE]

Category	Specific item	Check
	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.	

Consumables/ Ancillary supplies	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)	
	2. Needles suitable for intramuscular vaccination: 22gx32mm and 23gx25mm only. 22g for Obese patients (1 needle per dose)	
	3. Syringes for reconstitution – 2ml or 5ml (if required) (1 per vial)	
	4. Needles for reconstitution- 21G (if required) (1 per vial supplied)	
	5. Diluent for reconstitution (if required - Sodium Chloride 0.9% injection 2 ml (Adcock Ingram Critical Care) (1.8 per vial)	
	6. Cotton wool balls (2 per number of vaccinees)	
	7. A safety box for disposal of used syringes and needles (1 per 100 doses supplied)	
	8. Viricidal disinfectant, e.g. Biocide	
	9. 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)		

 <p>health Department: Health REPUBLIC OF SOUTH AFRICA</p>		Effective Date:[STARTING DATE]
	Site Readiness	Next Revision [REVISION DATE]

Category	Specific item	Check
	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 <i>(Primary vaccination sites and temporary outreach sites where vaccines are stored)</i>	Functional SVS application or bin cards only where no electronic system can be used	
	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	