



health

Department:
Health
REPUBLIC OF SOUTH AFRICA



MINIMUM STANDARDS FOR COVID-19 VACCINATION SITES AND THE PROVISION OF VACCINATION SERVICES

COVID-19 vaccination sites are located in both public and private sector settings. The standards included in this document apply to all sites involved in the national rollout of COVID-19 vaccines in South Africa. Vaccination sites have been categorized as primary vaccination sites and outreach services. Outreach services may be provided as a fixed outreach service, temporary outreach service or mobile outreach service. These outreach services need to be linked to a facility with a valid permit (primary site) and cannot function on their own.

The National Department of Health (the Department) is providing formal approval of vaccination sites for the national rollout of COVID-19 vaccines. This approach is aimed at facilitating compliance with legislation dealing with the control of medicines, compliance of sites with applicable policies, guidelines and standards, and to enable oversight of services. The provisions of Section 22A(15) of the Medicines and Related Substances Act 101 of 1965 (the Medicines Act) are used to approve a health establishment or non-medical site as a vaccination site. The Director General (DG) of the Department may issue a permit to any organisation performing a health service to acquire, possess, use or supply any specified schedule 1 to 5 substance, subject to conditions determined by the DG. In cases where a permit holder fails to comply with the conditions of a permit, the permit may be suspended, revoked or withdrawn. Private sector providers of vaccination services are also required to sign a sale and distribution agreement with the Department, in order to obtain supplies of the vaccines needed.

This document provides the minimum standards for all vaccination sites and the provision of vaccination services, and is in line with the COVID-19 vaccine implementation guide and toolkit.

Acronyms

AEFI	Adverse Event Following Immunisation
DG	Director General
EVDS	Electronic Vaccination Data System
MFL	Master Facility List
NDoH	National Department of Health
SAPC	South African Pharmacy Council
SOP	Standard Operating Procedure
SVS	Stock Visibility System

Definitions

COVID-19 vaccination services mean the administration of COVID-19 vaccines to eligible populations.

Distribution services means the storage and/or distribution of COVID-19 vaccines, diluents and ancillary items related to the administration of COVID-19 vaccines.

Fixed outreach service means a place, where vaccination services are provided on a semi-permanent basis that is not a health establishment - but which is linked to a health establishment. Fixed outreach services may store COVID-19 vaccines and other medicines required to support the administration of COVID-19 vaccines on-site, in accordance with applicable legislation.

Health establishment means the whole or part of a public or private institution, facility, building or place, whether for profit or not, that is operated or designed to provide inpatient or outpatient treatment, diagnostic or therapeutic interventions, nursing, rehabilitative, palliative, convalescent, preventative or other health services¹.

Master Facility List means a complete list of all health establishments in the country, both public and private, that comprise of a set of administrative identifying information for each facility (signature domain) and basic information on the service capacity of each facility (service domain). For the purposes of the vaccination programme, the MFL also includes non-health sites such as South African Social Security Agency (SASSA) pay-points and community halls that are used for outreach services.

Mobile outreach service means a vaccination service linked to a health establishment with vaccination services, known as a primary vaccination site, where vaccines are administered to clients by a team of vaccinators moving from place to place. Passive cold chain containers are used and vaccines are not stored overnight.

Outreach service means a vaccination service linked to a health establishment with vaccination services, known as a primary vaccination site, at which vaccination services may be provided. Outreach services may be provided as a fixed outreach service with cold chain storage, a temporary outreach service with passive cold chain or by a mobile outreach service at multiple points.

Pharmacy means any place wherein or from which any service specially pertaining to the scope of practice of a pharmacist is provided².

Primary distribution site means a depot, sub-depot, wholesale pharmacy or distributor which stores and distributes vaccines to vaccination sites and does not provide vaccination services to clients.

Primary vaccination site means a place at a health establishment where vaccination services may be provided.

Responsible pharmacist means a natural person who is a pharmacist and who shall be responsible to the council for complying with all the provisions of this Act (Pharmacy Act) and other legislation

¹ South African National Department of Health. National Health Act 61 of 2003

² South African National Department of Health. Pharmacy Act 53 of 1974

applicable to services which specially pertain to the scope of practice of a pharmacist, and the legislation applicable to the pharmacy which is under his or her personal supervision³.

Temporary outreach service means a place where vaccination services are provided on a temporary basis and linked to a primary vaccination site. Passive cold chain containers are used and vaccines are not stored on-site.

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 person who administers a COVID-19 vaccine to a client.

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 COVID-19).

Vaccinee means a person who is vaccinated with a COVID-19 vaccine.

Vaccines means biological medicines that must be stored under specific temperature conditions, in accordance with the manufacturer's recommendations.

Primary vaccination sites and fixed outreach sites (i.e. sites where vaccines are stored overnight) are registered and the status managed on the MFL. These facilities must hold a Section 22A(15) vaccination site permit. Organisations that meet the requirements and agree to comply with defined conditions, as determined by the DG, are approved and issued with a COVID-19 vaccination site permit to provide vaccination services.

³ South African National Department of Health. Pharmacy Act 53 of 1974

STANDARDS FOR COVID-19 VACCINATION SITES AND THE PROVISION OF VACCINATION SERVICES

All health establishments/organisations possessing, using and supplying COVID-19 vaccines and providing vaccination services **must** adhere to the minimum standards provided below. The minimum standards as described are applicable to all vaccination sites which include primary vaccination sites, fixed outreach, temporary outreach and mobile services.

1. Compliance with policies and legislation

- 1.1. The vaccination site complies with all applicable legislation, including but not limited to the Pharmacy Act 53 of 1974 (Pharmacy Act); including rules relating to good pharmacy practice published in terms of the Act; Medicines and Related Substances Act 101 of 1965 (Medicines Act); the Nursing Act 33 of 2005; the Health Professions Act 56 of 1974; and the National Health Act 61 of 2003.
- 1.2. COVID-19 vaccination services are provided in accordance with all relevant laws, regulations, rules, guidelines (including the Cold Chain and Immunisation Operations Manual, 2015) and standard operating procedures (SOPs), and utilising medicines on the applicable list provided by the Department.

2. Section 22A(15) permits and registration on the Master Facility List (MFL), Electronic Vaccination Data System (EVDS), and Stock Visibility System (SVS)

Distribution sites – not providing vaccination services or supporting outreach services (e.g. national distributors, wholesalers or provincial depots):

- 2.1. The distribution site is registered on the MFL and distribution service activated – *Observation on the MFL*
- 2.2. The distribution site is enrolled and active on the SVS COVID-19. *Observation - Last data submission and synching on SVS COVID-19 (device or computer)*

Primary vaccination sites

- 2.3. The vaccination site has a valid permit issued by the DG in terms of Section 22A(15) of the Medicines Act. *Displayed, Observation (Evidence: Copy of Section 22A(15) permit)*
- 2.4. The vaccination site is registered on the MFL and COVID-19 vaccine site activated as a service. – *Observation on the MFL*
- 2.5. Active vaccination site is listed on the EVDS. – *Observation - Site registered and has activated COVID-19 vaccine site on the MFL and is available on EVDS*
- 2.6. If vaccines are stored on site overnight, the vaccination site is enrolled and active on the SVS COVID-19. *Observation - Last data submission and synching on SVS COVID-19 (device or computer)*

Outreach sites (Fixed, temporary and mobile services)

- 2.7. All outreach services (fixed, temporary outreach and mobile services) provided from the primary vaccination site are linked on the MFL as outreach services to the primary

vaccination site that holds a valid section 22A (15) permit. *Observation - Outreach sites linked on MFL and available on EVDS*

- 2.8. If vaccines are stored on site overnight, the vaccination site (fixed outreach service), is enrolled and active on the SVS COVID-19. *Observation - Last data submission and syncing on SVS COVID-19 (device or computer)*
- 2.9. A fixed outreach service site has a valid permit issued by the DG in terms of Section 22A(15) of the Medicines Act. *Displayed, Observation (Evidence: Copy of Section 22A(15) permit)*
- 2.10. An active vaccination site is listed on the EVDS. – *Observation - Site registered and has activated COVID-19 vaccine site on the MFL, and is available on EVDS*
- 2.11. In the case of a fixed outreach site:
 - 2.11.1. the pharmacy providing oversight has valid approval from the South African Pharmacy Council (SAPC) for the external storage area;
 - 2.11.2. the storage area is located within a reasonable geographic location of the pharmacy providing oversight and is in the same province;
 - 2.11.3. the external storage area where vaccines are stored is under the control of a pharmacist;
 - 2.11.4. the name and contact details of the responsible pharmacist of the pharmacy providing oversight is available/displayed at the site.

3. Human Resources

Note: Depending on the size of the vaccination site e.g. a small vaccination site (providing less than 40 vaccinations per day), one or more roles may be performed by the vaccinator.

- 3.1. The vaccination site has a designated **vaccination site manager** who is a registered health care provider. *Observation (Evidence: Proof of registration with applicable statutory council)*
- 3.2. All vaccinators working at the vaccination site are registered and in good standing with the relevant statutory council. *Observation (Evidence: Proof of registration with applicable statutory council)*
- 3.3. All vaccinators are practising in accordance with their scope of practice (see below)

Table 1: Scope of practice of health care providers

Statutory Health Council	Health care providers - scope of practice includes vaccination (Allowed to vaccinate)	Health care providers – in scope under supervision as part of a training programme	Health care providers/workers not allowed to vaccinate
Health Professions Council	Medical practitioners	<ul style="list-style-type: none"> • Medical students (4th, 5th and 6th year*) • Medical interns* *Supervised by a medical practitioner 	Other categories not mentioned
	Clinical associates		
	Dentists	<ul style="list-style-type: none"> • Dental students (4th, 5th and 6th year*) • Dentist interns* *Supervised by a dentist 	Dental assistants Other categories not mentioned

Statutory Health Council	Health care providers - scope of practice includes vaccination (Allowed to vaccinate)	Health care providers – in scope under supervision as part of a training programme	Health care providers/workers not allowed to vaccinate
	Paramedic/EMS personnel with advanced trauma life support (ATLS) (Advanced Life Support Practitioner)		Paramedic/EMS personnel with only BLS Other categories not mentioned
South African Pharmacy Council	Pharmacists	<ul style="list-style-type: none"> Pharmacy interns* Pharmacy students (4th year*) *Supervised by a pharmacist	Pharmacist's assistants (all categories) Other categories not mentioned
South African Nursing Council	<ul style="list-style-type: none"> Registered nurses Clinical nurse practitioners Enrolled nurses/staff nurses 	Nursing students only if in line with their clinical allocation list and for purposes of achieving their clinical requirements	Enrolled nursing assistants
Allied Health Professions Council			All categories
Not registered			Community health workers
NOTE: Health care providers with vaccination as part of their scope of practice may vaccinate whilst performing community service.			

- 3.4. All vaccinators are appropriately trained in the provision of COVID-19 vaccination services. *Observation: (Evidence: Certificate of completion of training provided on the Knowledge Hub)*
- 3.5. All vaccinators are registered on the EVDS and linked to the vaccination site where vaccines are being administered. *Observation: (Evidence: Proof of registration on EVDS for that site).*
- 3.6. Person responsible for managing queues and providing assistance to clients and vaccinees is available. *Interview*
- 3.7. Person responsible for the confirmation of client details and verification on EVDS, and/or to register walk-in clients is available. *Interview*
- 3.8. A designated and competent health care provider is available to deal with adverse events e.g. medical practitioner, EMS, professional nurse, pharmacist. *Interview*
- 3.9. The vaccination site (primary vaccination site and fixed outreach service) has a vaccine champion designated to manage the vaccine supply chain. Such person may be a pharmacist, pharmacist's assistant, vaccination site manager, or a vaccinator. *Interview*
- 3.10. There is a vaccine controller 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 SVS COVID-19 (primary vaccination sites). Such person may be a pharmacist, pharmacist's assistant, vaccination site manager, vaccinator or other person designated to perform this function. *Interview*

- 3.11. Staff involved in the provision of COVID-19 vaccination services are appropriately trained and competent to use the relevant reporting tools including SVS and EVDS. *Observation: (Evidence: Proof in-service training)*
- 3.12. Personnel at the vaccination site have access to all SOPs applicable to the provision of vaccination services at that site. – *Observation: (Evidence: File available at all primary vaccination sites and outreach services) or access to COVID-19 Vaccine implementation guide and toolkit (all sites)*

4. Premises

Note: The requirements for premises and equipment for mobile sites may differ from primary vaccination sites, fixed outreach and temporary outreach sites. Mobile services should be adaptive to the environment without compromising quality of care.

- 4.1. The vaccination site is easily accessible to all clients including persons with disabilities and the elderly. *Observation*
- 4.2. Details relating to when the vaccination site is open for the provision of vaccination services are prominently displayed at the entrance to the vaccination site. *Observation*
- 4.3. The vaccination site is arranged in such a way that social distancing can be maintained in both waiting areas and at all stations at the site. *Observation*
- 4.4. The vaccination site is clean and tidy. *Observation*
- 4.5. The vaccination site is well ventilated. *Observation*
- 4.6. There is access to ablution facilities. *Observation*
- 4.7. The vaccination site has dedicated waiting areas/spaces for the various processes. *Observation*
- 4.8. The vaccination site has sufficient designated spaces for COVID-19 screening, confirmation of details, vaccine administration, and recording processes. *Observation*
- 4.9. The vaccination site has a clearly marked post-vaccination observation area. *Observation*
- 4.10. There is an orderly flow of clients through the vaccination site. *Observation*
- 4.11. All persons at the vaccination site are wearing a mask which covers their mouth and nose. *Observation*
- 4.12. All persons at the site have access to soap and water for the washing of hands and/or access to hand sanitizer. *Observation*
- 4.13. The vaccine storage area is temperature controlled (Primary vaccination site and fixed outreach sites). *Observation*

5. Equipment

- 5.1. The vaccination site has all the necessary equipment and furniture to provide vaccination services including desks, tables, and chairs. *Observation*
- 5.2. The vaccination site has access to an emergency resuscitation trolley in close proximity or has necessary basic equipment on hand for outreach sites and mobile services *Observation*
- 5.3. There is a mechanism of setting up appointments and planning immunisation sessions to minimise vaccine wastage. (excluding mobile sites) – could be onsite, on EVDS or 3rd party scheduling. *Observation*

- 5.4. The vaccination site has a computer/s and/or other device/s available to each vaccinator to report vaccination data using the EVDS. *Observation*
- 5.5. The vaccination site has a computer/s or other device/s available to the vaccine champion, controller and/or vaccination site manager to report vaccination data using the SVS COVID-19. *Observation*
- 5.6. The computer/s and/or other device/s used for EVDS and SVS COVID-19 reporting has appropriate connectivity to submit data. *Observation*
- 5.7. Safety waste disposal boxes and, medical waste disposal boxes are available at the vaccination site. *Observation*

6. Vaccine administration

- 6.1. COVID-19 vaccines are administered in accordance with the NDoH vaccine rollout, associated requirements and guidelines. *Observation*
- 6.2. All personnel and clients accessing the vaccination site undergo COVID-19 screening prior to entering the site. *Observation*
- 6.3. Clients who are not yet registered on the EVDS are assisted to register at the site. *Observation*
- 6.4. The vaccinator should accurately record all vaccinations administered on EVDS. *Observation*
- 6.5. Paper-based records are only used when necessary (e.g. in the case of a connectivity or power related challenges). *Observation*
- 6.6. Paper-based records are captured with-in 24 hours. *Observation*
- 6.7. The vaccines are prepared and administered to the client by the vaccinator. *Observation*
- 6.8. Vaccines (and diluents) are kept at the vaccination site maintaining the cold chain until administration. *Observation*
- 6.9. Appropriate ancillary items (syringes, needles etc.) as outlined in the SOP are used. *Observation*
- 6.10. The correct diluent is used to reconstitute vaccines (as applicable). *Observation*
- 6.11. The time and date is indicated on the vaccine vial once opened. *Observation*
- 6.12. Open vaccine vials are stored in a suitable passive cold chain container with a continuous temperature monitoring device while in use. - *Observation*
- 6.13. Vaccine vials which have been open for more than six (6) hours are discarded. – *Observation*
- 6.14. Any expired vaccines are indicated as such and are stored in a separate or quarantine area prior to disposal. *Observation*
- 6.15. Administration of vaccination is only recorded on EVDS **after** the process is completed. *Observation*
- 6.16. The vaccinator completes all the required details on the vaccination card and provides it to the vaccinee **after** the injection has been administered. *Observation*
- 6.17. After receiving their vaccination, vaccinees are directed to an observation area, where they remain for at least 15 minutes. *Observation*
- 6.18. Vaccinators wash their hands or use a sanitiser after each vaccination. *Observation*
- 6.19. All Medical waste is appropriately discarded as per Health Care Risk Waste (HCRW) regulations. *Observation*
- 6.20. A disaster management and evacuation plan is available (Primary vaccination and Fixed outreach sites). *Review of documentation*

7. Storage of medicines (applicable where vaccines and other medicines are stored on site i.e. primary vaccination sites and fixed outreach services)

- 7.1. There is a designated, lockable space or access to the area where medicines used at the vaccination site is controlled (exclude temporary outreach sites and mobile services). *Observation*
- 7.2. The storage area is kept locked at all times when not in use (exclude temporary outreach sites and mobile services). *Observation*
- 7.3. There is sufficient security to prevent unauthorised access to the place where the medicines are stored. *Observation*
- 7.4. There is appropriate and sufficient cold chain storage capacity to comply with the manufacturer's vaccine storage requirements and accommodate the volume of vaccines stored at the site. *Observation*
- 7.5. A continuous temperature monitoring and logging device/s which meets the WHO PQS specification is used to monitor the vaccine storage temperature – it displays alarms, min/max temperatures, and provides a log of temperature readings in the fridge or passive container used. *Observation*
- 7.6. There is an alternative power source available to maintain the cold storage conditions in the event of a power failure (exclude temporary outreach sites and mobile services). *Observation*
- 7.7. In facilities where alternative power source is not available a purpose built vaccine fridge (holdover time of 48 hours) is recommended. *Observation*
- 7.8. There is a contingency plan in place which includes alternative storage locations if the cold storage unit fails and transport to alternate storage locations is available. *Observation/Displayed*
- 7.9. Suitable passive cold chain containers are available to store vaccines, when not in the cold storage unit to transport vaccines to outreach services as required or to alternate storage area. *Observation*

8. Ancillary supplies

- 8.1. The vaccination site has an adequate supply of:
 - 8.1.1. Medicines required to manage any emergencies which may arise. *Observation*
 - 8.1.2. All ancillary items required to provide vaccination services (including where necessary the diluent needed for a vaccine and depending on vaccine use). *Observation.*

These include -

- Syringes for vaccination: 1ml (Pfizer)/2ml (J&J) (1 syringe per dose)
- Needles suitable for intramuscular vaccination: 22gx32mm and 23gx25mm only. 22g for Obese patients (1 needle per dose)
- Syringes for reconstitution – 2ml or 5ml (**if required**) (1 per vial)
- Needles for reconstitution- 21G (**if required**) (1 per vial)
- Diluent for reconstitution (if required - Sodium Chloride 0.9% injection 2 ml (1.8ml per vial)
- Cotton wool balls (1 per vaccinee)
- A safety box for disposal of used syringes and needles (1 per 100 doses supplied)
- Virucidal disinfectant*

- Personal protective equipment (PPE) as outlined in National IPC Strategic Framework and Implementation Manual (3 ply surgical masks for vaccinators and boxes of gloves for emergency use only)
- Sterile water for irrigation for sites with no running water

**Vaccine spills are cleaned with an appropriate disinfectant (e.g. Biocide).*

- 8.2. The vaccination site procures or has access to all items described in 8.1.1. and 8.1.2 as per SOPs put in place by the relevant province or organisation. - *Observation*

Other supplies – *Observation*

- Case reporting form (CRF) for reporting AEFI
- Case investigation forms for adverse events of special interest (AESI)
- Escalation protocol in the event of anaphylaxis, including SOP displayed
- Stock cards/bin cards (if not using an electronic stock management system) (primary vaccination sites and fixed outreach services)
- Vaccination cards
- Tally sheets or relevant recording form/tool (for temporary and mobile outreach services)

Supplies for treatment of Anaphylaxis

- Adrenaline (epinephrine), 1:1000 ampoules
- Sodium chloride 0.9%, IV 1000ml.
- Salbutamol 0.5% nebulising solution with nebulizer (preferred) or metered dose inhaler
- Ipratropium bromide nebulising solution with nebulizer (preferred) or metered dose inhaler
- Hydrocortisone 200mg IM
- Promethazine IM (25/50mg) ampoule
- Ancillary supplies to administer
- Required equipment

9. Inventory management

- 9.1. The vaccination site (primary vaccination and fixed outreach sites) uses an inventory management system, (electronic stock management system or bin cards) to manage of vaccines and ancillary supplies. (NOTE: SVS COVID-19 is a reporting system not a transactional system). *Observation*
- 9.2. Secondary vaccination sites (temporary outreach sites and mobile services) use tally sheets to record daily usage and losses of vaccines and ancillary supplies. *Observation*
- 9.3. The required data is submitted via SVS COVID-19 as per the defined schedule at primary vaccination and fixed outreach sites (data related to vaccines is submitted daily and data relating to ancillary supplies is submitted weekly). *Observation*

10. Vaccine redistribution

- 10.1. The primary vaccination site has appropriate validated packaging (Passive containers and continuous temperature monitoring devices) to maintain the temperature of vaccines during redistribution at the temperature indicated by the manufacturer. *Observation*
- 10.2. Each active/passive container has a continuous temperature monitoring device that meets the specification of WHO. *Observation*

11. Waste disposal and management

- 11.1. The vaccination site has suitable health care waste and health care risk waste receptacles and containers for the disposal of sharps. *Observation*
- 11.2. There are suitable health care waste and health care risk waste receptacles for the disposal of used vaccine vials and vaccines which cannot be used. *Observation*
- 11.3. The labels of used vaccine vials, and vials which cannot be used are defaced or removed prior to disposal. *Observation*
- 11.4. Appropriate records of any inventory movement must be maintained for audit purposes if need be. *Observation*

12. Billing and financial arrangements

- 12.1. No client is made to pay out of pocket for a COVID-19 vaccine or vaccination service. – *Observation*
- 12.2. The medical aid or Department, whichever is applicable is billed by the service provider only after the vaccine has been administered. *Observation*