

COVID-19 Vaccine implementation guide and toolkit

National Department of Health

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Planning for a national vaccination programme will continue over several months, to ensure the most effective implementation possible. As we learn from the experiences of implementation, strategies may need to be adjusted and refined.

This National Implementation Plan for the COVID-19 Vaccination Programme for the people of South Africa may, therefore, be subject to revision over time.

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List of Acronyms

ACSM	Advocacy, communication, and social mobilisation
ADRs	Adverse drug reactions
AEFI	Adverse event following immunisation
AESI	Adverse event of special interest
CDC	Centres for Disease Control and Prevention
CIF	Case investigation form
COVID-19	Coronavirus disease 2019
CRF	Case report form
DoH	Department of Health
EPI	Expanded Programme on Immunisation
EPID	Epidemiological (number)
EVDS	Electronic Vaccination Data System
HIV	Human Immunodeficiency Virus
HCP	Health care professional
ID	Identity document
IEC	Information, education and communication
IPC	Infection prevention and control
NDoH	National Department of Health
NSC	National Surveillance Centre
PPE	Personal protective equipment
PHC	Primary health care
RTCs	Regional training centres
SAHPRA	South African Health Products Regulatory Authority
SARS-CoV-2	Severe Acute Respiratory Syndrome Coronavirus 2
SVS	Stock Visibility System
ToT	Training-of-trainers
WHO	World Health Organisation

List of Definitions

Glossary	Definition
Adverse event	Any untoward medical occurrence that may present after immunisation but which does not necessarily have a causal relationship with the usage of the vaccine
Ancillary items	Medical consumables needed to administer the COVID-19 vaccine; these include syringes, needles, cotton wool balls/swabs, etc.
Civil society	The “third sector” of society, along with government and business, and includes civil society organisations and non-governmental organisations
Clients	The people to be served in the national COVID-19 vaccination programme
Cold chain	The system of transporting and storing vaccines while maintaining the recommended temperature
Cold chain management	The management of medicines that must be stored at refrigerated temperatures from the time of manufacture, through transportation and delivery to health establishments (vaccination sites), until their administration to clients
Cold chain medicines	Medicines that must be stored within the cold chain within a specified temperature range from the time of manufacture, through transportation and delivery to health establishments (vaccination sites), until they are administered
Collaboration	A productive and constructive approach to working in diverse teams and with a range of role players to achieve shared goals
Co-morbidity	One or more medical conditions co-existing with a primary condition. In the context of COVID-19, it refers to existing chronic diseases that could put people at higher risk of complications if they are infected with the coronavirus
Conditioned ice packs	Ice packs that are removed from the freezer and allowed to remain at room temperature until the ice can be heard to “rattle” in the ice pack
COVID-19	The name of the illness caused by the coronavirus, SARS-CoV-2. COVID-19 stands for “coronavirus disease 2019”
COVID-19 vaccination services	The administration of COVID-19 vaccines to eligible populations
Current stock level	The vial count in the main storage location (cold room/freezer/refrigerator) at the close of business daily
Defaced vial	An empty COVID-19 vaccine vial from which the label is intentionally removed or defaced after administration to avoid an empty vial being re-introduced into the market and re-used
Delivery schedule	A schedule defining interval or lead time between vaccine deliveries to primary distribution or vaccination sites
Digital Data Logger (DDL)	A device that continuously monitors and records ultra-low temperatures in freezers and can display and store temperature recordings for a specified period of time

Glossary	Definition
Disposal	The removal of vaccines, ancillary items, used personal protective equipment (PPE) destined for destruction without the intention of retrieval, in compliance with existing legislation
Distribution services	The storage and/or distribution of COVID-19 vaccines, diluents, and ancillary items related to the administration of COVID-19 vaccines
Dose	A quantity of a medicine taken or administered at a particular time
Electronic Vaccination Data System (EVDS)	An electronic system used to capture each vaccination event and provide data to its data analytics platform to monitor and report on vaccinations administered. The EVDS records the journey of the vaccinee who will receive the vaccine from a vaccinator registered on the EVDS at an approved vaccination site registered on the Master Facility List (MFL)
Expiry date	The date up to which a medicine will retain the strength and other properties stated on the label
Fixed outreach service	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.
Herd immunity	When enough people are immune to a disease, either through exposure or vaccination
Health care provider (professional)	A person providing health services in terms of any law, including in terms of the Allied Health Professions Act 63 of 1982, the Health Professions Act 56 of 1974, the Nursing Act 50 of 1978, the Pharmacy Act 53 of 1974, and the Dental Technicians Act 19 of 1979 ¹
Health establishment	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 services ²
IEC material	Information, education, and communications material including but not limited to banners, posters, leaflets about COVID-19 vaccination
Long term power failure	A power failure with a duration of more than 12 hours
Main storage location	The area in a vaccination site where bulk stock (vaccines, ancillary items, and medical equipment) is securely stored
Master Facility List (MFL)	A complete list of all health establishments in the country, both public and private, that comprises a set of administrative identifying information for each facility (signature domain) and basic information on the service capacity of each facility (service domain)
Medium-term power failure	A power failure with a duration of between three and 12 hours

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

² South African National Department of Health. National Health Act 61 of 2003

Glossary	Definition
Mobile outreach service	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.
Mobile team	A vaccination team operating from mobile vehicles to provide outreach services, moving from place to place to provide vaccination services. Vaccines are transported in passive containers. No overnight storage or further distribution of vaccines is allowed.
Morbidity	Suffering from a disease or medical condition
National Vaccine Coordinating Committee	A committee bringing together key government departments, the private sector, and other stakeholders to oversee the implementation of a national vaccine strategy
NDoH National Surveillance Centre (NSC)	The NSC is a web-based performance monitoring and evaluation tool used to provide visibility of stock levels of medicines and personal protective equipment and improve availability across all provinces
Outreach service	A vaccination service linked a health establishment. Outreach services may be provided as a fixed outreach service with cold chain storage (CCS), a temporary outreach service with passive cold chain (PCC), or by a mobile outreach service at multiple points.
Passive containers	Insulated cooler boxes or containers with no active temperature control
Personal Protective Equipment (PPE)	Equipment worn to minimise exposure to hazards that cause serious workplace injuries and illnesses
Pharmacy	Any place wherein or from which any service specially pertaining to the scope of practice of a pharmacist is provided ³
Planning	Making decisions and arranging for something in advance of the event
Primary distribution site	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	A place at a health establishment where vaccination services may be provided
Private sector	The part of the economy that is run by individuals and companies for profit and is not state-controlled. It includes all for-profit businesses not owned or operated by the government
Public sector	Governments and all publicly controlled or publicly funded agencies, enterprises, and other entities that deliver public programmes, goods, and services
Receiving (delivery) site	A health establishment or other vaccination site to which the COVID-19 vaccine may be delivered
Responsible pharmacist	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

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

Glossary	Definition
	Act) and other legislation 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 supervision ⁴
Screening	The process of helping health care workers decide if a client has symptoms of COVID-19 and may need a coronavirus test. It is based on a series of basic questions about the client's health and recent history and may include taking his/her temperature
Section 22A(15) permit	A permit issued in terms of the Medicines and Related Substances Act 101 of 1965 required for a vaccination site to acquire, possess, use and supply COVID-19 vaccines and related medicines, and provide vaccination services
South African Health Products Regulatory Authority (SAHPRA)	The entity established in terms of the Medicines and Related Substances Act 101 of 1965 and responsible for the monitoring, evaluation, regulation, investigation, inspection, registration, and control of medicines (including vaccines), scheduled substances, clinical trials, and medical devices, IVDs, and related matters in the public interest.
Stock (bin) card	A paper-based tool used at vaccination sites to assist in monitoring vaccine usage
Stock issued	The vial count issued out of the main storage location (cold room/freezer/refrigerator) to a vaccination site for use during the day at vaccination stations, or during outreach services
Stock lost	The vial count of any wastage due to for example breakage, expiry, and pilferage
Stock received	The vial count delivered since the last daily update
Stock transferred	The vial count sent to another vaccination site or primary distribution site
Stock Visibility System (SVS)	A mobile application (SVS App) linked to a web management portal (SVS Web) used to monitor the availability of medicines, vaccines, and other health commodities
Supply chain	The flow of goods and services, money, and information between businesses and locations. It includes the efficient movement and storage of raw materials and manufactured goods
Short term power failure	A power failure with a duration of up to three hours
Temperature recording device	A device capable of continuous monitoring of the temperature reached during different stages of movement of a shipment in transit and provides a detailed reading either through a recorder chart or "downloading" the information recorded through a software package
Temporary outreach service	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 session	A period of time arranged for vaccinating clients with the COVID-19 vaccine

⁴ South African National Department of Health. Pharmacy Act 53 of 1974

Glossary	Definition
Vaccination site	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	A designated health care provider trained, competent, and acting within their scope of practice who administers a COVID-19 vaccine to a client
Vaccine champion	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	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)
Vaccinee	A person who is vaccinated with a COVID-19 vaccine
Vaccines	Biological medicines that must be stored under specific temperature conditions, in accordance with the manufacturer's recommendations
Workplace-based vaccination services	Employers may provide vaccinations to employees through their Occupational Health Services. These organisations could provide vaccination services at a primary vaccination site or through outreach services.
World Health Organization (WHO)	The specialised agency of the United Nations responsible for international public health

Chapter 1: Introduction

Message to the reader

Thank you for being part of South Africa's national COVID-19 vaccination programme. This is one of the most important public health interventions of our time. As we start rolling out vaccines, South Africa joins many other nations in an unprecedented global response to the devastating COVID-19 pandemic. Without this programme, COVID-19 will continue to threaten our families and communities; our economy; and our society.

The vaccination of millions of adult South Africans will need government, business, civil society, communities, citizens, and residents to work together. The vaccination programme is led by the Department of Health, but every one of us has an important role to play.

The plan is to ensure the safe and effective implementation of a programme to vaccinate all adults. To do this successfully we need to work together.

People with different skills and expertise are called on to support public health officials in coordinating and delivering the COVID-19 vaccine to our communities.

This guide and toolkit flow from the national vaccination plan. It provides information and tools that will help to support the key elements of the design of the vaccination programme: ensure effective leadership, maximise the speed of the national rollout, ensure fair and efficient access for all, standardise delivery processes to ensure quality, and minimise service delivery transaction times. As a member of the team supporting the COVID-19 vaccination programme in any way - whether at national, provincial, district, or vaccination site level - the information in the toolkit will help guide you. It is anticipated that managers at all levels in both the public and the private sectors, health professionals, administrative and support staff, community health workers and community volunteers will all benefit from using this resource.

What is included?

The guide and toolkit provide guidance for members of the teams that will be on the frontline of South Africa's vaccine rollout.

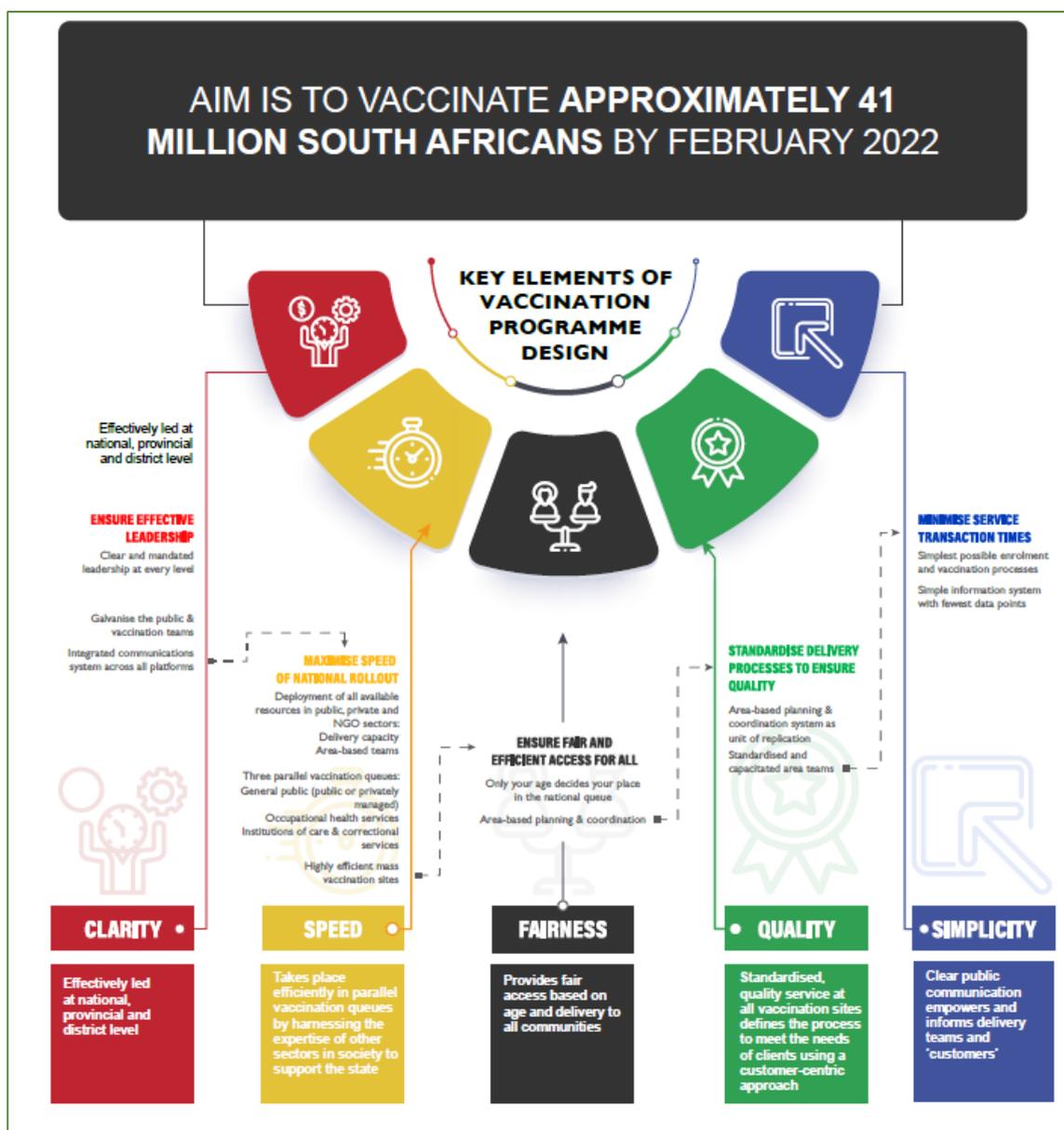
It includes information about the sites at which vaccinations will be provided, the teams that will support the vaccine rollout at various levels, and describes the journey that will be followed by each member of society who will receive the vaccine. It also provides information about the supply chain that will support the availability of vaccines and ancillary items at vaccination sites. This information is supported by Department of Health guidelines, standard operating procedures, job aids, and details of the systems and tools to be used. The content has been developed with input from the various work streams established by the Department to guide the vaccination programme.

This toolkit will not contain every single detail or provide answers to every question. It does, however, let you know where you can find more information.

Depending on your specific role in the team, you may not be required to coordinate all aspects covered in this guide. But each member of the team must have a good understanding of all the systems and processes that need to come together to implement a successful programme.

We are on a learning journey together. There will be problems and challenges to overcome. But, working together, we can ensure the vaccination programme takes off and gathers momentum.

Figure 1: Our shared goal



Structure of the Guide and Toolkit

The document is structured in two parts: (i) an implementation guide and (ii) a compendium of guidelines, tools, and additional information. Links are provided in the implementation guide to the documents included in the compendium. **The implementation guide** contains eight chapters:

- Chapter 1 – Introduction
- Chapter 2 - Vaccine delivery mechanism, site selection, and vaccine introduction
- Chapter 3 – Advocacy, communication and social mobilisation (ASCM) activities
- Chapter 4 – Training health workers for the delivery of COVID-19 vaccination services
- Chapter 5 – Effective vaccine management, cold chain, logistics, and distribution of COVID-19 vaccines in the private and public sector
- Chapter 6 – Planning the client journey, and vaccine administration of COVID-19 Vaccines
- Chapter 7 – Vaccine safety surveillance and reporting
- Chapter 8 - Monitoring and evaluation

PLEASE NOTE: Information included will be updated periodically as the programme unfolds

Chapter 2: Vaccine delivery mechanism, site selection, and vaccine introduction

In this section, the proposed vaccine delivery mechanisms will be described. First, the phased rollout approach is described, followed by national, provincial, and district roles and responsibilities, the composition and functions of an immunisation team, and, lastly, proposed vaccination service delivery platforms.

Phased approach

The South African COVID-19 vaccination programme will follow a population risk-based strategy through a phased approach. During the various phases, different target recipients and delivery strategies will be used. A phased approach is necessary because of the initially limited supply of approved COVID-19 vaccines. The phasing will be determined by the National Department of Health (NDoH) and will be communicated to stakeholders via circulars.

Roles and responsibilities for vaccine introduction – national, provincial, and district

Roles and responsibilities can be differentiated at the national, provincial, and district levels. Throughout the planning and implementation process, the public and private sectors must collaborate to facilitate equitable access of communities to the Covid-19 vaccine.

Table 1: Roles and responsibilities for vaccine introduction

National	Provincial	District
Planning for vaccine introduction		
Provide clear goals, guidelines, and tools	Adapt and implement guidelines and tools to support COVID-19 vaccination services Set goals and develop plans for the province Develop appropriate implementation plans Analysis and synthesis of area-based plans to guide appropriate strategies	Develop district plans based on provincial plans Set vaccination site targets Ensure facility-based micro-planning based on area-based planning
Procurement and distribution of vaccines		
Procure vaccines approved for use by the South African Health Products Regulatory Authority (SAHPRA) Award national contracts for distribution of vaccines to primary distribution sites and primary vaccination sites	Distribution within the province of vaccines and other supplies including infection prevention and control (IPC) supplies, and ancillary supplies	Ensure availability of vaccines and ancillary supplies at vaccination sites Report data relating to vaccines and ancillary supplies
Standards		
Develop criteria, guidelines, and standards for implementation of the	Provide input into criteria, guidelines, and standards for	Implement vaccination services at district level in

National	Provincial	District
vaccination programme in both the public and the private sectors	implementation of the vaccination programme Implement vaccination programme in the province based on criteria, guidelines, and standards Monitor and evaluate the implementation of programme	accordance with criteria, guidelines and standards Supervise vaccination services Monitor and evaluate implementation of the programme in the district
Advocacy, communication, and social mobilisation (ACSM)		
Develop national plan for advocacy, communication, and social mobilisation	Generate demand at provincial level using ACSM	Engage and educate stakeholders and communities Monitor and address vaccine hesitancy with clients
Resources		
Mobilise resources	Plan for, and allocate resources	Utilise resources Manage resources
Cold chain availability and logistics		
Support availability of adequate cold chain equipment and logistics arrangements for vaccine storage and distribution at national level	Provide adequate cold chain equipment and logistics arrangements for vaccine storage, distribution, and administration to the target population Monitor vaccine-related data at the provincial level	Comply with logistical procedures, vaccine storage, and distribution requirements, and administration of the vaccine to the target population
Training		
Making suitable training courses available for personnel involved in the provision of vaccination services	Facilitate the provision of training courses via the Regional Training Centres (RTCs)	Support vaccination site managers to make sure personnel providing vaccination services are trained and competent
Adverse events following immunisation (AEFI) surveillance		
Provide systems, tools, and guidelines to support robust adverse events following immunisation (AEFI) surveillance, AEFI case management, and causality assessment	Monitor provincial vaccine safety surveillance, facilitate causality assessment, and provide provincial AEFI line-list	Report all AEFI and assist with case investigation, allocate epidemiological number (EPID number), and input data into the provincial line-list

Roles for vaccine introduction at the district and area-based level

District COVID-19 vaccination team

The district health manager responsible for COVID-19 vaccine introduction should facilitate the process to establish a **District COVID-19 vaccination team**. District/Metro officials will lead the various work streams within the District COVID-19 vaccination teams. These teams will be supported by the

area-based teams with the goal of successful COVID-19 vaccine introduction and implementation in all sectors.

Summarised in the table below are the recommended roles, time commitment, and functions identified for members of the District COVID-19 vaccination team. These roles can be performed across both the public and the private sector. Depending on the size of the district, some of these roles may be combined.

Table 2: District COVID-19 vaccination team

Role	Time Commitment	Function
1. District Vaccine Team Lead	Should be filled by an individual who is dedicated 100% of the time to the team	Provide effective and inspiring leadership to support successful vaccine roll-out in the district
2. Finance District Lead	Can be filled by an individual with other responsibilities	Provide effective financial management and advice to facilitate compliance with financial processes
3. Communication officer in the District COVID-19 vaccination team	Can be filled by an individual with other responsibilities	Develop a clear communication and support strategy for vaccination teams and the general public
4. Monitoring and Evaluation District Lead	Can be filled by an individual with other responsibilities outside of the team or The role can be taken on by the individual assigned to the role of Vaccine Safety, Surveillance, and Response District Lead	Monitor vaccine roll-out programme planning and implementation, including performance against target, resources, staffing, and activities. Monitor the extent to which national policies to prioritise groups are effectively implemented. Ensure systems for tracing defaulters (where applicable) are in place.
5. Vaccine Safety, Surveillance and Response District Lead	Needs to be filled by an individual who is dedicated 100% of the time to the team	Facilitate the early detection, reporting, notification, investigation and analysis, and feedback of Adverse Events Following Immunisation (AEFIs) and Adverse Events of Special Interest (AESI), to ensure appropriate and timely case management and response. Link with district surveillance officer, ensure allocation of EPID number, facilitate case investigation if required.

Role	Time Commitment	Function
6. Information systems (IT)/ Electronic Vaccination Data System (EVDS)/ Enrolment support District Lead	Needs to be filled by an individual who is dedicated, 100% of the time, to the team	Enhance, augment, and adapt existing IT and information system (IS) infrastructure to support and facilitate the use of EVDS and the Stock Visibility System (SVS) at vaccination sites. Troubleshoot and respond to all EVDS inquiries from end-users. Support effective use and constant flow of data and information in all directions between area-based, district, and provincial vaccine rollout teams.
7. Operational support for EVDS, SVS, and Master Facility List (MFL)	Can be filled by an individual with other responsibilities outside of the team	Operationalise EVDS, SVS and provide support where required
8. Operational Support and Queue Management District Lead	Needs to be filled by an individual who is committed, 100% of the time, to the team	EVDS Vaccination scheduling
a. General Public Enrolment Queue Manager	Can be filled by an individual with other responsibilities outside of the team	EVDS Vaccination scheduling – general public
b. Occupational Health Services enrolment Queue Manager	Can be filled by an individual with other responsibilities outside of the team	EVDS Vaccination scheduling – occupational health (at work)
c. Institutions of Care and Congregate setting enrolment Queue Manager	Can be filled by an individual with other responsibilities outside of the team	EVDS Vaccination scheduling – congregate settings
9. Human Resource Management, Training and Supervision District Lead	Can be filled by an individual with other responsibilities outside of the team	Mobilise and ensure staff are trained, deployed, and support the human resources required for every aspect of successful vaccine rollout
10. Area-based Planning and Coordination District Lead (Site readiness and QI)	Needs to be filled by an individual who is dedicated 100% of the time, to the team	Support the district in area-based planning and coordination and ensure vaccination sites are set up in

Role	Time Commitment	Function
		line with the site typology and vaccine delivery model. Support the districts with service delivery and QI.

The district COVID-19 vaccination team will be supported by an area-based team/s which could be established at ward, sub-district, or district level.

The role of the area-based team

Area-based teams are at the heart of the collaborative approach driving the national vaccination programme. The area-based approach is a different way of thinking about delivery. It uses the different skills of civil society, business, community leaders, and others as part of a team to operate vaccination sites across the country. Without a framework for working together, the various sectors may just ‘do their own thing’ – giving some sectors of society the advantage over others and unnecessarily duplicating efforts. This collaboration is formalised by the establishment of area-based teams working closely with district/metro health officials leading the vaccination programme.

AREA-BASED TEAMS

Create a standardised set of processes that need to be coordinated. This approach comes together in the coordination of a single unit that can be replicated across the community. If the team gets it right in one area, it can be more easily replicated in other areas.

How the area-based team relates to district teams and private sector service providers

To achieve a high level of planning and local coordination with local community leaders and across both public and private sectors, area-based team leaders will be appointed by the vaccine team lead in the district or metro. Area-based team leaders will be health professionals drawn from the public, private or non-government sectors, participating either in a voluntary capacity or remunerated by their employer. There is no additional payment for the services provided by individuals on the area-based team. The role of the team is provided in Table 3 below.

Table 3: Role of the area-based team

Role of area-based team	Team composition	Legal standing and accountability
Facilitate coordinated local planning and implementation	Local public, private and civil society partners, specifically designated (in the case of public officials) or seconded into the team	The area-based team will have no legally delegated responsibilities. They are the vehicle for coordinated local mobilisation
Provide management and technical support to the vaccination team/s		
Engage with communities		

Role of area-based team	Team composition	Legal standing and accountability
Facilitate participation of local providers in provision planning	Public and private service providers	Accountable to their respective employers (government or private) to ensure compliance with applicable legislation, protocols, and standards

The role of the area-based team will thus be to lead local consultation, planning, and coordination. Formal and legal accountability will rest with the district or metro health services official assigned as district vaccine team lead (unless the area lead is a public official delegated that responsibility). In this way, the full expertise available in the area will be harnessed.

Priorities for the area-based team

The area-based team will:

- Plan together to ensure that all adults in the area, 18 years or older, prioritised in accordance with circulars provided by NDoH, are vaccinated by the agreed target date;
- Bring together all the resources needed to help achieve this aim;
- Work with local community leaders, civil society organisations, and influencers to build an understanding of the purpose of vaccination and who needs to get vaccinated first;
- Help ensure that all the necessary management systems come together to enable the programme, by working with members of the district health management office, private providers, and NGO partners.

Table 4: Functions of the area—based team

Role	Time Commitment	Function
1. Environmental Health Provincial Lead (reverse logistics)	Can be filled by an individual with other responsibilities outside of the team	Evaluates the risk management plan, identify challenges and develop interventions
2. Quality Assurance District should be designated official from District Health Services	Needs to be filled by an individual who is committed, 100% of the time, to the team	Audit vaccine delivery units against minimum requirements – assist with supervisory support. Stakeholder engagement
a. Small/Mobile Vaccination Site Quality Assurance Manager	Can be filled by an individual with other responsibilities outside of the team	Evaluate the quality of services provided against the COVID-19 vaccine implementation guide and toolkit, identify challenges and develop interventions. Quality improvement projects based on root cause analyses.

Role	Time Commitment	Function
b. Medium/Large Vaccination Site Quality Assurance Manager	Can be filled by an individual with other responsibilities outside of the team	Evaluate the quality of services provided against the COVID-19 vaccine implementation guide and toolkit, identify challenges and develop interventions Quality improvement projects based on root cause analyses
c. Mass Vaccination Site Quality Assurance Manager	Can be filled by an individual with other responsibilities outside of the team	Evaluate the quality of services provided against the COVID-19 vaccine implementation guide and toolkit, identify challenges and develop interventions. Quality improvement projects based on root cause analyses.

Coordinating COVID-19 vaccinations in a local area

Area-based teams will play an important coordinating role in the effective delivery of vaccinations at a local level. COVID-19 vaccines will not be sold to individuals, as all communities must have equal access to a vaccine, based on their risk of severe disease and death.

Equitable access to vaccines for the eligible population is essential. The community should be well informed on where vaccination services are provided in their area, as well as the processes required to register and receive the vaccine. They should also receive health education to inform their decision to vaccinate.

Practical decision-making is needed to:

- Identify and set up single or multiple vaccination sites in an area,
- Educate and mobilise communities on the vaccine, and
- Overcome any challenges that arise.

Many sites will not have everything they need to execute the plan. Creative problem solving will be required of the team to address issues that arise during the programme. Provincial and district officials should work together with volunteers and people seconded from business and civil society to enable a successful vaccine roll-out.

Vaccination site types

The following principles are applied in the selection and approval of vaccination sites:

- Vaccination site selection will be based on population needs, geospatial planning, and cold chain capacity across the private and public sectors as determined by COVID-19 programme coordinators and supported by area-based teams.

- The provisions of Section 22A (15) of the Medicines and Related Substances Act 101 of 1965 are used to approve organisations such as health establishments wishing to provide vaccination services for the administration of COVID-19 vaccines.
- All health establishments/organisations that wish to provide COVID-19 vaccination services either at or from a primary vaccination site or as a fixed outreach service must submit an application to the Director-General: Health for a permit issued in terms of Section 22A (15) of the Medicines Act. The process to be followed is described in ***Annexure: Standard Operating Procedure for the identification and approval of COVID-19 vaccination sites.***
- Permits are issued subject to certain conditions namely:
 - The health establishment/organisation must comply with the requirements for the provision of Covid-19 vaccination services as determined by the NDoH;
 - Vaccines must only be administered by a health care provider registered and in good standing with the relevant professional council, who has been trained in the administration of COVID-19 vaccines and the management of any related adverse events, is competent to provide such services, and in accordance with his/her scope of practice;
 - COVID-19 vaccination services must only be provided in accordance with all relevant laws, regulations, rules, and guidelines, and utilising medicines recommended by the National Department of Health;
 - Suitable clinical oversight is provided at all vaccination sites.
- The permit holder must ensure compliance with the conditions of the permit and will be held accountable for services provided by the primary vaccination site, as well as for any outreach services provided from the site.
- A permit is valid for two years unless it is withdrawn by the Director-General. A permit may be withdrawn if the holder fails to comply with any condition of the permit.
- Health establishments approved and issued with a COVID-19 vaccination site permit may provide services on-site (primary vaccination site), or offsite as an outreach service at either a fixed outreach site, a temporary outreach site, and/or by a mobile team/s operating from a primary vaccination site.
- Permits may also be issued to an organisation that is not a health establishment to provide vaccination services as a fixed outreach service. Fixed outreach services store COVID-19 vaccines and other medicines required to support the administration of COVID-19 vaccines on-site and must be linked to a health establishment, with a pharmacy registered with the South African Pharmacy Council (SAPC), and which has a responsible pharmacist registered as such. The linked pharmacy will apply for an internal change with the SAPC, which should be approved before vaccines, or other medicines can be stored at the fixed outreach service.
- Fixed outreach services where vaccines are stored, or primary vaccination sites at which vaccines may be stored or distributed must be indicated on the MFL as a distribution site.
- Temporary outreach services and mobile teams which are managed from a primary vaccination site will not be required to hold a permit and are linked to the primary vaccination site as an

outreach service on the MFL. Distribution services may not be provided from a temporary outreach service or by a mobile team.

- It is the responsibility of the permit holder to ensure that vaccinators providing vaccination services are trained, competent, and acting within their scope of practice, to provide vaccination services.
- Permit holders may only acquire, possess, use and supply the vaccines and related medicines recommended by the NDoH as part of COVID-19 vaccination services.

Figure 2 and Table 5 below provide details of the primary vaccination site and the services that are linked to this site. Use the diagram and table to create a common understanding of the various sites, and their features, as well as the services that each type of site can provide.

Figure 2: Vaccination site typology

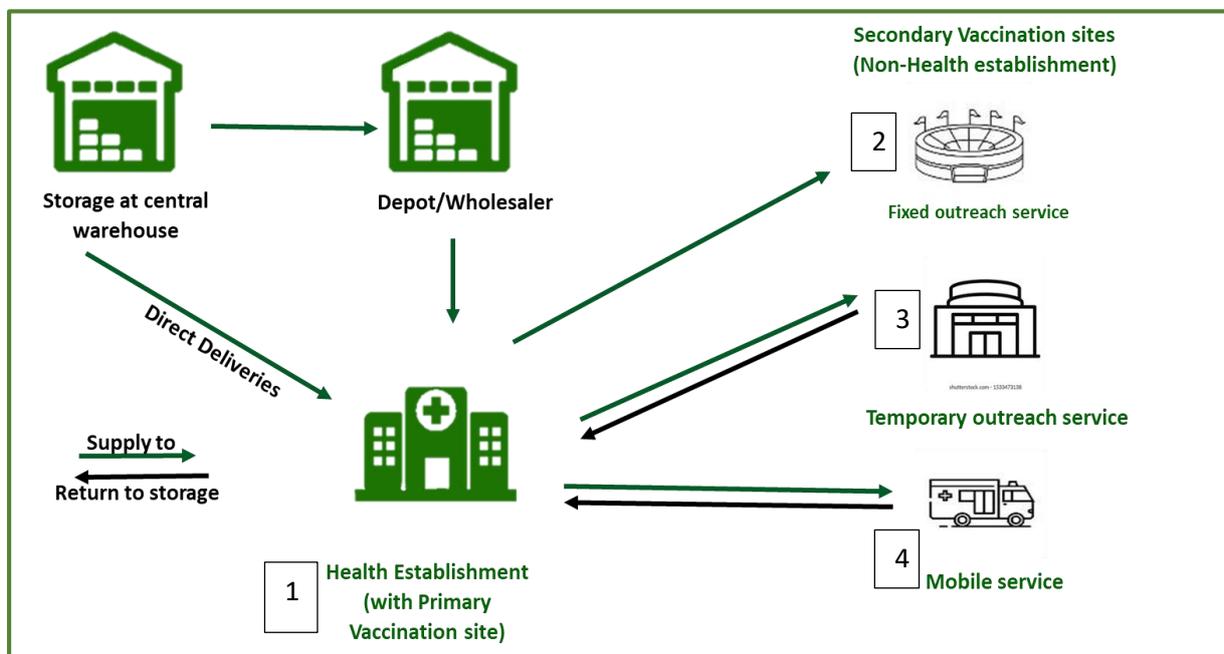


Table 5: Vaccination site typology

1	Primary Vaccination site		
Definition	Primary vaccination site means a place at a health establishment where vaccination services may be provided (Requires a Section 22A(15) permit)		
Registration and permit requirements	<ul style="list-style-type: none"> • Registered on Master Facility (MFL) List (Vaccination and distribution services [if provided] are activated on the MFL) • Listed on EVDS and SVS • Holder of a Section 22A(15) permit issued by the Director-General (DG) of Health in terms of the Medicines Act 		
Ownership	Public or private	Management	Management of that health establishment
Services	<ul style="list-style-type: none"> • Vaccination services (activate on the MFL) • Vaccines stored at the health establishment (activate distribution services on the MFL) • If provide distribution services (activate distribution services on the MFL) • Act as a hub to support outreach services (fixed, outreach and mobile) + health establishments that do not have the capacity to store vaccines 		
Example	<p>Public Sector - Hospitals, community health centres, primary health care clinics, health establishments linked to the Departments of Correctional Services, National Defence and Education</p> <p>Private sector Private hospitals, community pharmacies, general practitioner practices, permanent occupational health clinics and travel clinics (operating in terms of Section 56(6) of the Nursing Act), immunisation clinics, mine hospitals</p>		
Human Resources for vaccine management	<p>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.</p> <p>Vaccine controller means a pharmacist, pharmacist’s assistant, or other healthcare 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 SVS.</p>		

2	Fixed Outreach service		
Definition	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 or organisation providing health services. 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.		
Registration and permit requirements	<ul style="list-style-type: none"> • Register as non-health establishment on MFL • Linked as a service to a health establishment or organisation providing health services on MFL • Stores vaccine and specified medicine - oversight must be provided by a registered pharmacy (pharmacy which has applied for and received approval for an internal change to enable external (off-site) storage at the fixed outreach service) (Activate distribution services on MFL) • Listed on EVDS and SVS • Holder of a Section 22A(15) permit for each site issued by the DG: Health in terms of the Medicines Act 		
Ownership	Public or private or NGO	Management	Health establishment or organisation which operates the site and holds the permit Pharmacy oversees external storage
Services	<ul style="list-style-type: none"> • Provides vaccination services (with EVDS scheduling of appointments) • Has cold chain storage capacity • Does not distribute vaccines 		
Example	Any non- health establishment where vaccines are stored overnight (e.g. mass vaccination site at a private sector venue)		
Human Resources for vaccine management	<p>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.</p> <p>Vaccine controller means a pharmacist, pharmacist’s assistant or other health professional designated to manage the storage and supply of vaccines, the distribution of vaccines to primary vaccination sites, fixed outreach sites and/or the supply of vaccines to temporary and mobile outreach services (where applicable) and the updating of data on SVS.</p>		

3	Temporary Outreach service		
Definition	Temporary outreach service means a place which is not a health establishment 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. (Does not require a Section 22A(15) permit)		
Registration and permit requirements	<ul style="list-style-type: none"> • Linked as a service to a health establishment (primary vaccination site) on MFL • Listed on EVDS • Not listed on SVS • No individual permit; operates in terms of 22A(15) permit issued to health establishment 		
Ownership	Public or private or NGO	Management	Management of the primary vaccination site
Services	<ul style="list-style-type: none"> • Vaccination services provided – EVDS scheduling appointments • Cannot store vaccines overnight • Uses passive cold chain containers (cooler boxes) • Does not distribute vaccines 		
Example	Churches, schools, halls, civic buildings, non-permanent OHS at places of work, congregate settings such as care homes, facilities for older persons		
Human Resources for vaccine management	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.		

4	Mobile Outreach service		
Definition	Mobile outreach service means a vaccination service linked to 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. (Does not require a Section 22A(15) permit)		
Registration and permit requirements	<ul style="list-style-type: none"> • Linked as a service to a health establishment (primary vaccination site) on MFL • Listed on EVDS • Not listed on SVS • No individual permit; operates in terms of 22A(15) permit issued to ‘mother’ health establishment 		
Ownership	Public or private	Management	Management of the primary vaccination site
Services	<ul style="list-style-type: none"> • Vaccination services provided – No appointments • Moves from place to place • Cannot store vaccines overnight • Uses passive cold chain containers • Does not distribute vaccines 		
Example	Mobile teams of vaccinators moving from place to place		
Human Resources for vaccine management	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.		

District COVID-19 vaccination team: Planning for successful vaccine delivery

Vaccination sites are being set up based on factors such as local health establishments, population size and density, and other variables. Area-based teams will play a role in identifying, coordinating, and managing the successful establishment of vaccination sites. Use ***Annexure: Tool for mapping vaccination sites***, to map the distribution sites, primary vaccination sites, and the outreach services (fixed, temporary or mobile) linked to each primary vaccination site.

Micro-planning

A micro-planning exercise is a bottom-up approach to planning. It should generate realistic estimates of the human, financial and material resources needed, based on both the target population and the reality on the ground.

As the number of vaccines required for a local area will not be available all at once, the micro-planning exercise should allow for the different phases of the vaccination programme based on the sequencing described in the National Plan, and the vaccine allocation per phase, which will be approved at a provincial level in the public sector, and at an organisational level or by the organisation in the private sector.

Important information to gather for micro-planning includes:

- The target population, including insured and uninsured persons by district, sub-district, and service delivery site catchment area per vaccination phase.
- Listing and pre-registration of priority groups to be vaccinated in each phase.
- Number of health workers and local volunteers to be members of area-based teams and vaccine delivery units and their respective catchment areas.
- Cold chain equipment and specifications, including existing equipment and functionality, locations, gaps, and possible cold chain infrastructure from the private sector and other sources.
- Required supplies including PPE, vaccine doses, syringes, needles, cotton swabs, safety waste boxes, medical waste boxes, Infection Prevention and Control (IPC) supplies, emergency medicines and emergency tray equipment, monitoring tools, and communication materials.
- Sites for safe and appropriate storage of vaccines and other supplies in the district for distribution.
- Identification of primary vaccination sites and outreach services, how they will be related to each other, and an estimation of how long they will be needed.
- Number of vehicles needed to distribute supplies in the district, as well as for the transport of vaccination teams and supervisors.
- End-to-end waste disposal plans and pickup schedule with the service provider.
- Daily road map for mobile outreach teams and supervisors.
- Strategy for hard-to-reach areas and special populations (including farmworkers and migrants) with suggested solutions and logistical arrangements to reach them.
- A list of traditional and possible new partners (organisations, sectoral offices, businesses) working at a local level, and their potential contributions to the vaccination programme.

Table 6: Summary of the key outputs of micro-planning

Steps	Planning outputs
Identification of the locality and target population	<ul style="list-style-type: none"> • List of districts, sub-districts, and health establishments, public and private • Target population to be vaccinated by locality and by phase of the vaccination roll-out e.g. population over 60 years of age • Defining the catchment areas to guide space needed, cold chain requirements, vaccine logistics, means of transport, and human resources
Identify and classify strategies for each population sub-group by catchment area	<ul style="list-style-type: none"> • Define the catchment area using each strategy to reach the target with the vaccine as per service delivery platform e.g. primary vaccination site, fixed outreach service, temporary outreach service, or mobile service • Identify primary vaccination sites, fixed or temporary outreach services to be managed from a primary vaccination site and areas/sub-groups to be reached using mobile teams • Identify the required number of vaccination teams and supervisors per catchment area
Estimate logistics and supply needs by health establishment/ district	<ul style="list-style-type: none"> • Estimated volume of vaccines and vaccination equipment and supplies, different types of cold chain equipment, IPC supplies, emergency trays, monitoring tools • Number and types of vehicles required; source of vehicles and fuel costs • Printing/availability of monitoring tools, field guides, training materials etc. • Training and micro-planning workshops • Cost of communication and social mobilisation products by type of output (media announcements, communication materials like posters and banners, community dialogue meetings, etc.)
Determine human resources requirements per health facility/ district	<ul style="list-style-type: none"> • Identify the required number of persons (health workers and volunteers) for the vaccination teams, including community mobilisers, marshals, administrative personnel, vaccinators, health educators, data capturers, vaccine champions, vaccine controllers, and waste management personnel • Estimate the cost of field deployment of health workers and volunteers

High-level vaccination site process

The high-level vaccination site activation and deactivation process has seven phases and requires collaboration between the district COVID-19 vaccination implementation team, the area-based team, and the vaccination site manager to plan and coordinate. The seven phases are:

- Site identification
- Site activation
- Site preparation and setup
- Site 'go live'
- Site maintenance
- Site monitoring
- Site deactivation/closure

Site identification

Area-based teams must identify suitable sites to allow for equitable access to vaccinations. Sites must be equipped with:

- Suitable cold chain capacity requirements (primary vaccination sites and fixed outreach services only). NOTE: The vaccine that will be used at the site should also be considered
- Back-up electrical power and Wi-Fi
- Sufficient well-ventilated space and ablution facilities

Sites must also be easy for members of the public to access. Things to consider when choosing a site include:

- How will most people get there?
- Is there a public transport service nearby?
- Is it easy to walk to the site?
- Is there parking nearby?
- Is the site centrally located for most people?
- Is the site easy to access?
- Is the site well-known?
- Is the site able to accommodate people with disabilities?
- Is the site equitably accessible to the community?

If the site will serve a large, sparsely populated area, explore the use of temporary outreach and mobile services, or move the vaccination site to better meet community needs. Very few facilities will meet all the criteria and the optimum site is often the best compromise. This, however, needs to be contrasted against some factors, including the following:

- It is critical to compare the target population for vaccination against the size of the building. As a general statement, clinic and community health centres are often too small to provide adequate space for a logical flow of clients presenting for vaccination.
- A campaign to obtain herd immunity within the population entails vaccinating a substantial component (estimated for South Africa at 67%) of the population, which may take some time

to achieve. Totally taking over a clinic space may compromise the facility's primary care functions and have a negative influence on population health.

- Tents may also be considered. These are normally a cheaper option but have several limitations. For a short-term vaccination drive (1 to 2 days) operating a tented facility on a site may be a solution. However, for longer operation it is not recommended. Challenges include:
 - Vaccines cannot be stored on site
 - Electricity security
 - Climatic conditions, environmental temperature, and wind
 - Ventilation (especially the need for good ventilation)
 - Dust and sand
 - Ground formations not supporting pitching and securing of tents
 - Ground surface and drainage
- In choosing a building to use for a vaccination site (fixed or temporary outreach site) for a medium time frame, it is essential to consider various factors.
 - It is unlikely that the ideal building will be available at all places where a vaccination site is needed. The optimum information is listed for consideration and a compromise may be needed. It is also possible to determine if it may be feasible to make some changes to make the building functional, taking the relatively limited duration of a campaign into account. Safety, however, remains non-negotiable and may override functionality.
 - Often, unused/unoccupied buildings are identified for use. This requires special precautions.
 - What was the building used for in the past and how safe is it to use now?
 - Building structure and safety
 - Functioning of water supply, sanitation, and storm water drainage (stress test sewerage system prior to use)
 - Electricity and safety of installations
 - Environmental safety (surrounding activities and risk, such as factories discharging gasses)
 - Experience has shown that an open-plan hall/hanger facility is more suitable and allows for a more flexible outlay, rather than a building with various smaller rooms.
- Based on the target population, geo-spatial analysis, and socio-economic factors, access to the site by private and public transport needs to be assessed. Road conditions in poor weather conditions need to be appreciated. Access from public transport/taxi routes to the site/building must be taken into account.
- Access control, security, and safety of clients and health care workers must be considered. If needed the local police station must be consulted. (Assess the risk for protest action and confirm the possibility of managing security in a protest action situation)
- Parking for public transport in the close vicinity of the building/site is recommended. Adequate parking for clients utilising private transport must be considered. The surface of the parking area in rainy weather needs to be evaluated.
- Confirm clear entrance and exit possibilities to the building. The aim of a flow plan is a one-directional flow of clients through a structured layout from an accessible and easily identifiable entrance to, preferably, a separate exit. The availability of multiple entrances to accommodate various role players such as a staff entrance, logistical, and delivery entrance

are advantages. Having a separate entrance available for clients coming for a second dose vaccination will also streamline processes.

- Single level floor surface from entrance to exit without any steps is ideal. It must be accepted that aged, disabled, and clients with limited mobility will visit the site. If such a surface is not possible, an alternative entrance or vaccination area for non-mobile clients may be considered. Ideal surface will be non-slip and easy to clean.
- The best precaution against transmitting COVID-19 remains good ventilation. In selecting a building, open windows with natural ventilation remain the ideal. It is essential to contrast the target daily numbers against the space, waiting area, and ventilation to ensure safety. If air-conditioned buildings are used, the assessment of the air conditioning flow requires technical advice.
- Availability of suitable ablutions is often the most limiting factor in utilising an existing building. Preferably separate abluion for staff and clients is needed due to the PPE decontamination process. The total number of people – clients, care workers accompanying clients, children that may come along, and staff – needs to be estimated. The norm used is one toilet per 20 persons. If urinals are available, the norm is one urinal per 25 persons and one toilet per 25 persons. Handwashing facilities are an integral part of abluion facilities, with a ratio of one basin per two toilets.
- Facilities for staff to wash their hands during vaccination are a basic need. Although hand sanitisers can be used, proper hand washing is still recommended. Assessing the availability of handwashing facilities may therefore limit the selection of buildings for vaccination, although loose-standing basins are commercially available for use.
- Adequate lighting is required for vaccination, particularly in areas where vaccinations are mixed and drawn up. The effectiveness of lighting can be measured scientifically but can also be assessed by trial-run actions to ensure adequate lighting is available for the tasks at hand. Recordkeeping and use of computer screens will require shielding from direct sunlight. Assessing the effectiveness of lighting in bad weather conditions/overcast situations must be part of the process. If the facility requires artificial lighting to function during the day or plans to function after dark, emergency power generation may need to be considered due to the risk of power outages.
- As the vaccination process is electronically captured, connectivity in the building or at least in the area is strongly recommended. It is essential to test connectivity and the ability to provide bandwidth. If no connectivity is possible, a paper-based record system can be used but this will delay flow drastically.
- It is important to confirm that Emergency Medical Services are available and will be able to reach the building and evacuate a patient in an emergency. An emergency protocol should be developed and displayed at each vaccination site, including contact details of emergency services/hospitals that should be contacted for insured and uninsured vaccinees.

To support **site identification**, the following tools are available:

- **Annexures: Criteria for selection of sites for ultra-cold chain conditions (-65° to -75°C)**
- **Annexure: Tool for mapping vaccination sites**
- **Annexure: Site Calculator**
 - The “Site Calculator” is a simple tool that can give an indication of the number of vaccinators and sites (small, medium and large) required to vaccinate a known population within a specific amount of time. It is meant to be used early in the process of site selection – when potential/available sites in an area have been identified but have not yet been selected for use.
 - The tool can be used at all levels – area, sub-district, district and provincial. The user only needs to know the population of the area of interest and the potential number of medium sites available in that area. The tool will then calculate the approximate number of vaccinators and sites of small, medium and large size required to vaccinate that population within a given timeframe.
 - The tool can also be adjusted to suit the specific context being planned for by changing the assumed vaccine uptake in the population (reflecting anticipated differences in urban and rural uptake); proportion of insured individuals to be covered by the private sector (reflecting differences across provinces and metros); ratio of hubs to spokes or medium to small sites influenced by density and dispersion in the area, and a number of other factors.
 - It is a flexible tool that is simple to use and meant to assist the area-based planning process, not to prescribe for it.
- **Annexure Additional Capacity Model**
 - The Additional Capacity model serves as a decision-making tool to view current capacity on a sub-district Level, per health establishment in the public/private sector. By utilising this model, the user will be able to determine what additional capacity (vaccination sites or vaccinators) will be needed to vaccinate the remaining population within South Africa within the given mandate.
 - Please navigate to the "Modeling Inputs" tab to view all assumptions.

*Please note that this is information available at this time. It may be updated at any time.

The Head of Department or Provincial Vaccine Lead should sign off on vaccination sites per province. Changes of vaccination sites should be reviewed and approved by the Head of Department or Provincial Vaccine Lead.

Site activation

Master Facility List

Sites must be registered on the National Department of Health MFL and designated as either a site providing vaccination services, distribution services, or both. The MFL is the official list of South African health establishments and includes details about the services at each health establishment. The National Health Act (2003) defines a health establishment as *“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 services”*.

The existing MFL web application is used to manage the master (semi-permanent) dataset of health establishments and their services in the COVID-19 vaccine roll-out. The facility representative can register/update a facility on MFL online at <https://mfl.csir.co.za/>. MFL users (facility representatives and curators) for both the public and private sector have been registered and training has been provided on how to register facilities and manage the semi-permanent data.

The majority of public and private hospitals are already registered on the MFL and, where necessary, semi-permanent facility data should be updated. Other facilities already registered on the MFL include public primary health facilities, correctional service facilities, schools, and community structures identified previously as possible isolation/quarantine sites.

After a self-assessment has been completed by the identified/selected facility or health establishment, and it has been confirmed that the health establishment meets the minimum requirements for the provision of vaccination services, the vaccination site should be activated as a vaccination service – this requires that the facility be registered on the MFL. **(This indicates that the facility can potentially provide vaccination services but will not necessarily be selected as a vaccination site.)** Vaccination site selection will be based on population needs and geo-spatial planning across both the private and public sectors as determined by COVID-19 programme coordinators.

If the facility has the capacity to provide distribution services (defined as ‘the storage and/or distribution of COVID-19 vaccines’) this must also be captured on the MFL.

The MFL also serves as the basis for applying for, and processing Section 22A (15) permits. This permit is issued in terms of the Medicines and Related Substances Act 101 of 1965 by the Director-General of the National Department of Health and enables the facility to acquire, possess, use and supply COVID-19 vaccines.

Health establishments with activated vaccination and/or distribution services on MFL are used as the master data for other systems such as the self-registration system, EVDS, and SVS.

Electronic Vaccination Data System (EVDS)

The EVDS has been adopted as the official system for capturing vaccination events at all vaccination sites. It will be used to record vaccination programme processes, enable data to be collected to monitor the effect of the vaccination programme, design interventions to improve the programme, and monitor coverage, access, and use of the vaccine throughout the country.

The EVDS is a web-based online system that requires internet access. The system is designed with controls to prevent fraud and corruption during the vaccination administration process.

The EVDS records the journey of the vaccinee who will receive the vaccine from a vaccinator registered on the EVDS at an approved vaccination site registered on the MFL on a specific date and time. Paper forms (**Annexure: Vaccination paper based form**) will be available but should only be used in the event of load shedding or the EVDS being offline. The vaccination site manager must ensure that all client information from paper forms is captured on the EVDS as soon as possible.

EVDS
Records the journey of the vaccinee who will receive the vaccine from a vaccinator registered on the EVDS at or from an approved vaccination site on a specific date and time.

The EVDS enables initiation, messaging, coordination, monitoring, and evaluation of the vaccine rollout while collecting essential information to serve as a vaccination record and facilitate vaccine safety surveillance. Appropriate data protection and governance policies are applied to comply with legislative requirements and monitor legitimate, appropriate, and proportionate use and processing of data that may be routinely collected and managed in health information.

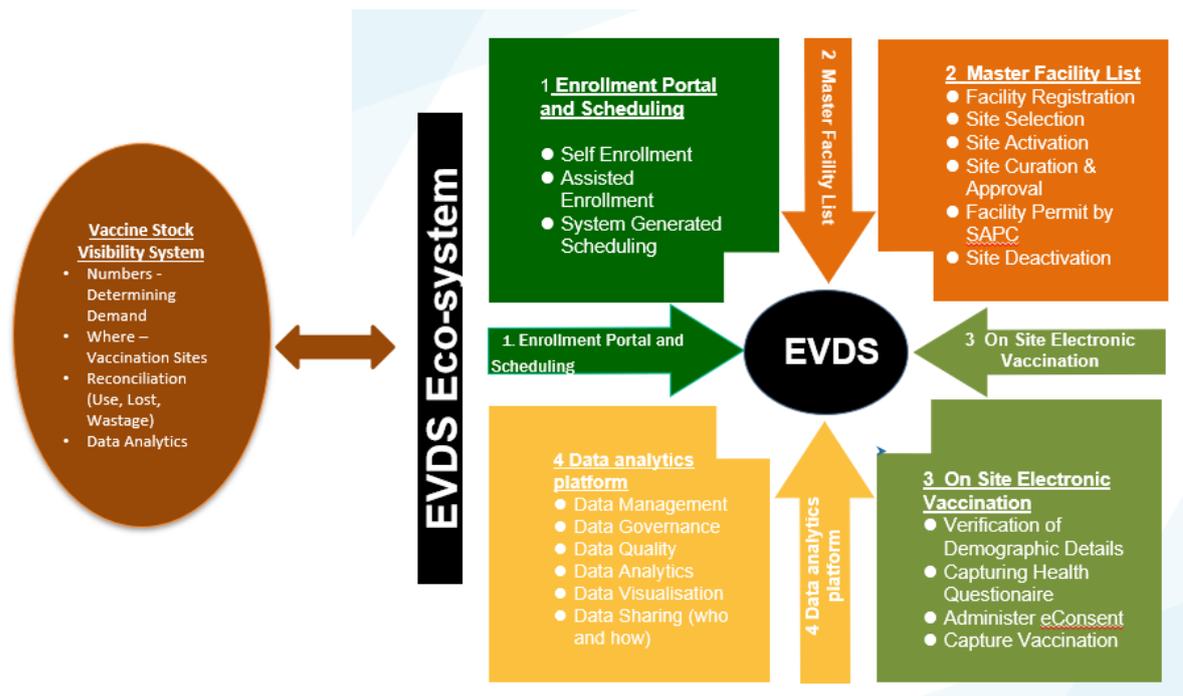
The EVDS assists in both the management and surveillance of the COVID-19 vaccine roll-out by providing and tracking vaccine information - including patient information, such as demographics and number of doses, and details of vaccination sites and vaccinators. The EVDS collects data needed for **monitoring vaccine uptake and coverage, prioritisation, planning, safety monitoring, and vaccine-related studies.**

Summary of EVDS ECOSYSTEM

The EVDS ecosystem consists of the following tools or modules:

- Enrolment Portal and Scheduling
- Master Facility List (MFL)
- On-Site Electronic Vaccination
- Data analytics platform

Figure 3: EVDS ecosystem



There are two types of EVDS users:

- users who are registered to receive a vaccine on the system (EVDS clients or vaccinees); and
- health care providers who are authorised to administer a COVID-19 vaccine (EVDS vaccinators).

EVDS Login:

Given that this system includes personal information about individuals, it is critical to note that the **INDIVIDUAL USER LOGIN DETAILS MAY NOT BE SHARED WITH ANYONE.**

To support **site activation**, the following tools are available:

- **Annexure: Standard Operating Procedure for the identification and approval of COVID-19 vaccination sites**
- **Annexure: MFL User Manual**
- **Annexure: EVDS User Manual**

Site preparation and setup

When preparing a vaccination site, various factors should be considered, including required supplies and challenges which might arise.

Things to be considered include:

- What equipment is available?
- Is more equipment needed?
- What human resources (people) are needed to manage the site?

- What cold chain capacity is available at the site?
- How will the vaccines be delivered/supplied to the site?
- If vaccines are to be stored on-site (in the case of primary vaccination sites and fixed outreach services) how will they be stored safely and in accordance with cold chain and regulatory requirements?
- What items are needed, for example PPE, cleaning supplies, furniture, cold chain equipment, IT equipment, cell phones, stationery, and IEC material?
- Are emergency resuscitation equipment and trolley available?
- What other clinical equipment is needed?
- What is needed for the various stations at the vaccination site (COVID-19 screening, confirmation of client details, vaccination, and observation)?
- How will all needed items be procured/obtained?
- How will the medical waste generated be safely and legally disposed of?
- Are there existing waste management contracts in place? Can these be utilised or extended (if needed)?
- Is connectivity and electricity available to support the IT systems?

To ensure a standard user experience regardless of where vaccination services are provided, the minimum requirements for vaccination sites have been defined. Vaccination services may only be provided at sites that meet the minimum requirements.

To support **site preparation**, the following tools are available:

- ***Annexure: Minimum requirements (criteria) for vaccination sites***
- ***Annexure: Site Preparation Checklist***

Vaccination team

The roles, responsibilities, and resources available to vaccination team members driving the vaccination programme are described in Table 7 below.

A high-level description of what is required, standard operating procedures (SOPs), and job aids, have been included in the toolkit to provide the information needed to get started at the site. Note that the vaccination site manager will have more information, so please be guided by them. If any of the information in the SOPs or jobs aids is not clear, please clarify with your vaccination site manager.

Vaccinators

The vaccinator must complete training on the use of EVDS before registration as a vaccinator on EVDS.

Vaccinators must register for a new account on EVDS, or have a new account created for them. When a vaccinator is registered, they will be linked to their primary vaccination site, although they can be linked to more than one vaccination site or outreach service at a time. The system will allow for traceability on who is capturing the information and at which vaccination site.

The EVDS vaccinator will log onto EVDS using a secure password. This password can be reset if required. Vaccinators are requested not to share their login details with anyone else and should log out before leaving the vaccination site.

Vaccinators are reminded to adhere to the clinical guidelines and the SOPs contained in this toolkit.

Table 7: Roles, responsibilities, and resources available to vaccination team

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	<ul style="list-style-type: none"> • Annexure: EVDS scheduling guide
Queue Marshal	Community members and volunteers	Manage and marshal queues Troubleshoot when needed Provide information to the clients in the queue	<ul style="list-style-type: none"> • Annexure: Vaccine Site Conceptual Design Tool • Annexure: 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)	<ul style="list-style-type: none"> • Annexure: 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)	<ul style="list-style-type: none"> • Annexure: SOP - Confirmation of registration on EVDS • Annexure: EVDS user manual

On-site assisted registration person (if client not registered on EVDS)	Administrative staff	Assist with EVDS registration	<ul style="list-style-type: none"> • <i>Annexure: EVDS user manual</i>
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>	<ul style="list-style-type: none"> • <i>Annexure: SOP - Vaccination process</i> • <i>Annexure: EVDS user manual</i> • <i>Vaccination process (Chapter 6)</i> • <i>Annexure: Job aid relating to injection preparation also Chapter 6</i> • <i>Annexure: Vaccination card</i> • <i>Annexure: Paper-based forms - informed consent, health questionnaire</i>
Observation site personnel	<p>Any health care professional or person with first aid training</p> <p>Designated health care professional to deal with adverse events e.g., medical practitioner, EMS, professional nurse, pharmacist (can also fill another role at vaccination site)</p>	<p>Observe clients' post-vaccination</p> <p>Alert designated health care professional if needed</p> <p>Take appropriate action if there is an adverse event</p> <p>Record adverse event/s</p>	<ul style="list-style-type: none"> • <i>Annexure: SOP Observation of vaccinee following COVID-19 vaccination</i> • <i>Annexure: Job aid: Dealing with adverse events also Chapter 7</i> • <i>Annexure: Adverse event forms, Case reporting form, Case investigation for and AESI form</i>

<p>Vaccine champion</p>	<p>Pharmacist, pharmacist’s assistant, nurse, other designated HCP (could also fill another role)</p>	<p>Manage receipt of vaccines at the vaccination site</p> <p>Manage vaccines and ancillary items at the vaccination site during the vaccination process (including cold chain maintenance)</p>	<ul style="list-style-type: none"> • <i>Annexure: SOP Replenishment of vaccines</i> • <i>Annexure: SOP Procedure to Receive Comirnaty® Vaccine</i> • <i>Annexure: SOP - Procedure to Receive COVID-19 vaccine Janssen®</i> • <i>Annexure: SOP - Storage of Comirnaty® Vaccines</i> • <i>Annexure: SOP - Storage of COVID-19 vaccine Janssen®</i> • <i>Annexure: SOP - Waste Disposal of COVID-19 Ancillary Item</i> • <i>Annexure: SOP - Waste Disposal of COVID-19 vaccines</i> • <i>Annexure: SVS Presentation and job aids</i> • <i>Annexure: SOP - Vaccination Site Closure Procedure</i>
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<p>Designated vaccine controller (At primary vaccination site that provides distribution services)</p>	<p>Pharmacist, pharmacist's assistant</p>	<p>Manage ordering and receipt of vaccines Manage storage of vaccines Manage distribution of vaccines Reporting on SVS</p>	<ul style="list-style-type: none"> • <i>Annexure: SOP - Preparation of cold chain equipment</i> • <i>Annexure: SOP - Replenishment of vaccines</i> • <i>Annexure: SOP - Procedure to receive Comirnaty® Vaccine</i> • <i>Annexure: SOP - Procedure to receive COVID-19 vaccine Janssen®</i> • <i>Annexure: SOP - Storage of Comirnaty® vaccines</i> • <i>SOP - Storage of COVID-19 vaccine Janssen® [Annexure: X]</i> • <i>Annexure: SOP - Distribution of Comirnaty® vaccines to temporary and mobile outreach services</i> • <i>Annexure: SOP - Distribution of COVID-19 vaccine Janssen® to temporary and mobile outreach services</i> • <i>Annexure: SOP - Routine monitoring of vaccine handling</i> • <i>Annexure: SVS presentation and job aids</i> • <i>Annexure: SOP: Waste disposal</i> • <i>Annexure: SOP - Vaccination Site Closure Procedure</i>
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Site layout

The way the site is designed is an important part of making the experience welcoming and less daunting for community members. Think about how people will experience the site when they arrive. Working with team members, design the site and a client journey that:

- Helps guide and reassure people
- Makes people feel welcome and secure
- Uses a one-directional flow process
- Provides for social distancing and plenty of fresh air, especially in the waiting and observation areas
- Helps guide clients with signage, marshals, or both.

The site layout could be tested by having community volunteers move through the stations and adjust if needed.

To support **site layout**, the following tool is available:

- ***Annexure Site readiness checklist***

Site 'go live'

Before a site opens for the first client, mobilise the local community to participate in the process. This means developing a communication strategy to share details, including when and where vaccinations will be given and what individuals need to do to get their vaccinations. If the vaccine being offered requires two doses, build this into the early messaging so that clients are aware they need to visit the vaccination site twice. Explain why it is important to follow through and have both injections for full protection against COVID-19.

Hold a trial run a day or two before the official opening to iron out any snags and unforeseen issues. Consider inviting a few members of the public, who can be ambassadors for the process for the first vaccinations, with a media opportunity and photographs. This will help build others' confidence in the process. Communicate how many people the site expects to vaccinate each day to manage expectations and help prevent surges.

Communicating targets

To boost team morale and show progress, a daily tally of vaccinations given could be listed on a whiteboard or notice board, against an overall target. In some areas we expect sites to be operational for several months. The team on the ground may experience fatigue, and the community may grow anxious. Sharing data that communicates planned vaccinations per day and reports the actual number of vaccinations completed will demonstrate progress, build the team, and highlight when blockages should be addressed.

Site maintenance

The different types of vaccination sites and the process of identifying, activating, preparing a vaccination site for go-live are described above.

Every day a large number of people will spend time at the vaccination site. Regular cleaning, maintenance, and management of wear and tear will be needed so that all members of the public experience the same quality of care and service throughout the rollout. Proactively managing the daily maintenance of the site is an important 'behind-the-scenes' aspect of the successful implementation of the vaccination programme.

The site must be monitored twice daily by the vaccination site manager using the monitoring checklist. The checklist will help the site manager ensure that all the equipment and resources needed to operate successfully are available. The checklist is a guide and should be built on. Add items that you want your site manager to check on twice a day.

Daily checking of the vaccination site

On a daily basis, vaccination site managers must check that the site is ready to receive clients and provide vaccination services.

The vaccination site manager must check that:

- Clear marking of the vaccination site (with banners or posters) and hours of service is in place;
- The site is well ventilated (if natural ventilation is used, open windows and doors);
- Measures are in place to limit the number of individuals to avoid crowding and long waiting times;
- One-way flow through the vaccination site is working with efficient client flow and clear directions to entry and exit points;
- Appropriate IPC measures are being followed with arrangements in place to facilitate physical distancing to enable at least 1-metre distance in all directions between each person;
- Hand-washing stations are functional and soap and/or alcohol-based hand rub dispensers are available and replenished;
- Cleaning and disinfection procedures are followed consistently and correctly according to WHO and NDoH guidance with stations being cleaned and disinfected frequently (at least twice daily) with special attention to high-touch surfaces;
- The various stations (COVID-19 screening, confirmation of client details, vaccination, and observation) are functional and clean, and tidy;
- There is adequate access to IPC supplies and equipment, e.g. PPE, masks, alcohol rub/sanitiser, or handwashing stations with soap and clean water.
- Sufficient ancillary items, emergency tray equipment, and medicines are available and COVID-19 vaccination guidelines are observed at all times. Note: Ancillary supplies may vary depending on the type of COVID-19 vaccine supplied.
- Sufficient cold chain equipment is available. Must include separate passive containers (one for storage of closed vials and one for open vials), conditioned ice packs, and continuous temperature monitoring devices for passive containers;
- All vaccination sites have an emergency tray/s available at all times which complies with the minimum standards as indicated in the NDoH standard treatment guidelines (STGs);
- The required emergency medicines and supplies are available and have been checked daily by a vaccinator before commencing a vaccination session, as outlined in Ideal clinic guidelines.
- Sufficient IEC material is available and displayed to encourage appropriate COVID-19 related behaviour"

Tools for **Site maintenance and daily site preparation:**

- ***Annexure: Site readiness***
- ***Annexure: Twice daily maintenance checklist***
- ***Annexure: SOP - Site Maintenance Daily Activities***
- ***Annexure: Emergency Trolley Check List***

Site monitoring

Conducting supportive supervision: District COVID-19 vaccination team

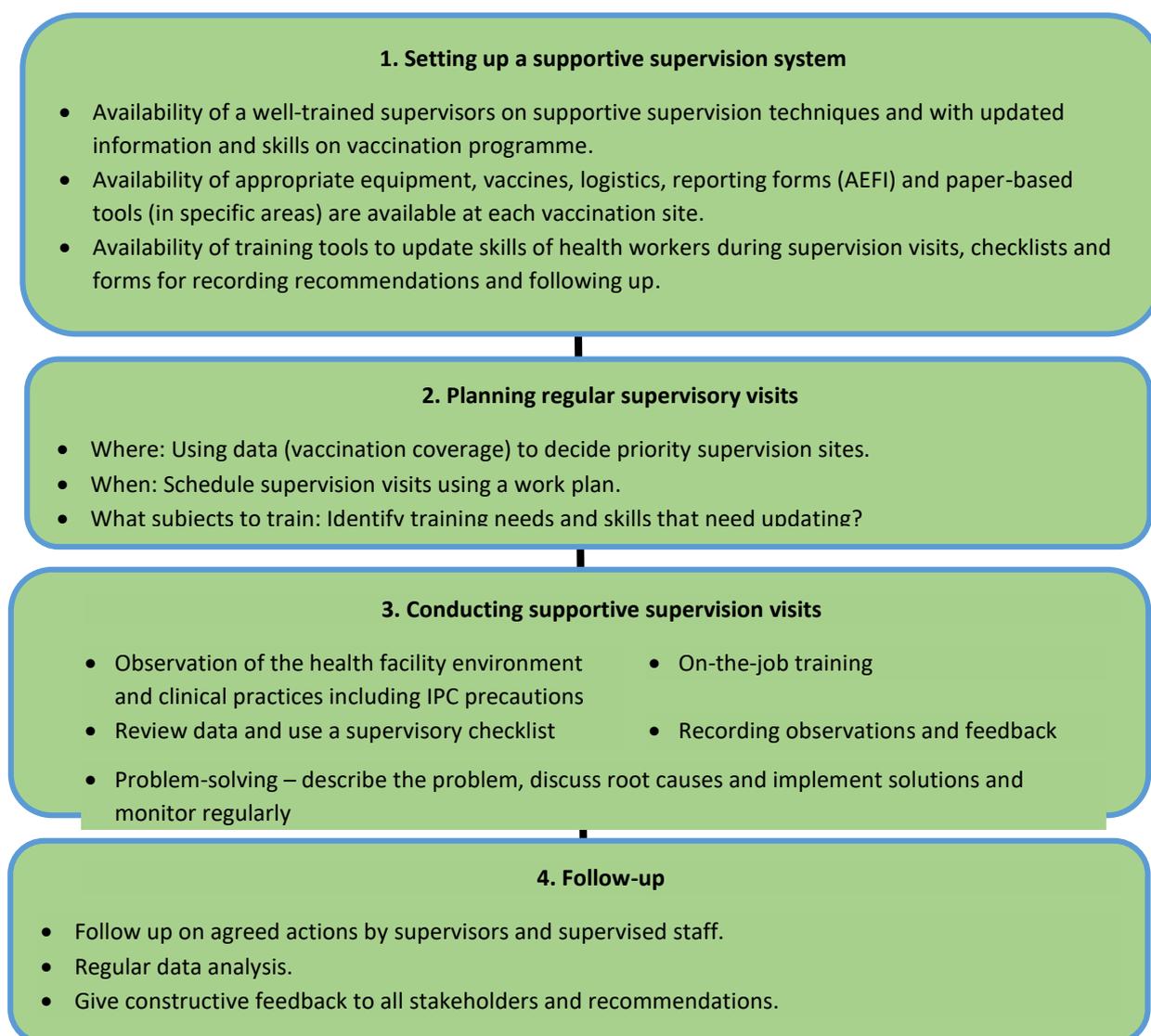
The district COVID-19 vaccine team should conduct supportive supervisory visits -to vaccination sites before and during implementation to identify and address any gaps. Supervision visits should be itemized, scheduled, and budgeted in the micro-plan, and responsibilities assigned. Supportive supervision should focus on identifying challenges, mitigating challenges, improving and/or enhancing the skills of staff to ensure they provide high-quality services.

Supervisors should utilise the site readiness assessment tool and the supervisory checklist to document their findings and discuss findings with the district level in the public and private health sectors, to address any gaps.

Use the supervisory checklist (***Annexure: Supervisory Checklist***) to:

- increase the quality of vaccination services;
- ensure completion of vaccine schedules;
- reduce threats to programme from adverse events (AEFI);
- improve confidence in the COVID-19 vaccine process;
- improve client confidence in the health care system overall.

Figure 4: Process of supportive supervision



Monitoring visits

Area-based teams, observer teams, or other competent authorities will also monitor vaccination sites. This will provide helpful oversight and insights to improve the process. Marshals should be trained to welcome observer teams. Members of these teams should identify themselves to the local site management to observe, without disrupting activities at the site, and should be identifiable through bibs or identity cards.

Observers have an important role to play in a transparent and well-run process and should be welcomed with courtesy at vaccination sites.

Tools for Site monitoring:

- **Annexure: Supervisory check list**

Site closure

Whenever a vaccination site is closed whether permanently or for a period of time, the site should be decommissioned, and the vaccination service deactivated on the MFL and synchronised with the EVDS and SVS (if vaccines were stored on-site). The EVDS scheduling should also be deactivated, and clients redirected to alternate vaccination sites.

Several factors will influence how long a site is active. Communicate with the public ahead of site deactivation to ensure that, as far as possible, all eligible members of the community can receive a COVID-19 vaccination and have returned to the site for their follow-up injection if needed.

Please review this and discuss with your vaccination team lead to clarify points that are unclear. The vaccination site manager should escalate issues to the district or provincial teams if they have questions about the process.

Tools for **Site closure**:

- ***Annexure: MFL User Manual***
- ***Annexure: EVDS User Manual***
- ***Annexure SVS – Un-enrolment Job Aid***

Escalation of site-related issues

All site-related issues should be escalated as follows:

- Phone call:
 - Vaccination Site manager >> District COVID-19 vaccination team lead >> Provincial Vaccine Lead (delegated by the Head of Department to manage the process)
- AND
- Report sent via email:
 - Vaccination Site manager >> District COVID-19 vaccination team lead >> Provincial Vaccine Lead (delegated by the Head of Department to manage the process)

Chapter 3: Advocacy, communication, and social mobilisation (ACSM) activities

The ACSM strategy supports the rollout of COVID-19 vaccines in South Africa through (a) the dissemination of timely, accurate, and transparent information about the vaccine(s); and (b) training health workers to communicate effectively with clients about COVID-19 vaccines, to build trust and increase uptake. The purpose of ACSM is to alleviate public apprehension about the vaccine, promote public confidence, and increase public acceptance and demand for the COVID-19 vaccine.

The overarching goal of the ACSM strategy is to contribute toward national efforts to achieve herd immunity through a phased COVID-19 vaccine rollout strategy throughout South Africa. To achieve this goal, the NDoH and partners will pursue the following specific objectives:

- Facilitate a coordinated effort in communicating about the vaccine;
- Make sure the public receives timely, consistent, and factually correct information on COVID-19 vaccines (availability, safety, timelines) to build and maintain trust, and avoid people being influenced by false or inaccurate information, myths, and misconceptions;
- Generate awareness of the phased approach of the vaccine rollout and understanding of the prioritisation of target groups;
- Reduce vaccine hesitancy and public resistance towards COVID-19 vaccines;
- Mitigate misconceptions about any AEFI that may occur;
- Address perceptions of a low risk of infection amongst specific population groups and build an enabling environment for widespread adoption and maintenance of non-pharmaceutical interventions such as mask-wearing, physical distancing, and other appropriate behaviours to reduce the risk of COVID-19 infection.

Effective communication between health workers and the community

The goal of vaccine safety communication is to empower people to make evidence-informed choices about COVID-19 vaccination. Any communication approach must encourage trust in health authorities and those delivering the vaccine, facilitate access to timely, accurate, and credible information about COVID-19 vaccination safety via trusted channels, and provide people with a means of asking questions and having their concerns addressed.

Social mobilisation and demand creation

Role of communication officer in the District COVID-19 vaccination team

Mobilise stakeholders

Strategies that can be used to mobilise the community include engaging with traditional leaders, leaders of faith-based and other civil society organisations, as well as local businesses to inform their constituencies (people they represent) and employees of the importance and process for getting vaccinated when their turn comes. This approach will allow you to have few discussions that reach many more people.

Responsibilities include – through multiple approaches – encouraging community members to sign up to be vaccinated using the EVDS. Activities will include inviting the community, in a sequence of age bands, to sign up on the EVDS, and wait for an SMS telling them when to come to a vaccination site for their appointment.

Communication will be ongoing as unplanned delays and unexpected events may disrupt the smooth flow of things. Keeping the public updated will be central to building trust with the community. COVID-19 has disrupted everyday life and people want accurate information.

Understand which communication tasks will be the responsibility of the district vaccination team and which will fall to the national and provincial government

Use communication channels available in local community:

-to inform people how to enroll on the EVDS,

-what to bring to the vaccination site (ID documents) on the day of vaccination and

-what to expect when they arrive for vaccination.

Communication media could include posters, radio announcements, using the local and community newspapers, or ideally a combination of these;

Understand communication protocols with the district and provincial health departments so that clear messages are conveyed to the public; and

Liaise closely with vaccination sites to coordinate the start of the vaccination roll-out in the area and facilitate social mobilisation and preparedness.

Role of the health worker in COVID-19 vaccination

First, health workers are the early recipients of the COVID-19 vaccine because of their work exposure and risk of infection, and because they play a critical role in providing essential health services. Second, they will administer the COVID-19 vaccines and share key messages about the vaccine. Health workers are also advocates for the COVID-19 vaccine. They can share their own vaccination experience and are a valued and trusted source of information for the community. Finally, health workers are representatives of the community. They are the bridge between the community and the health system after an AEFI has been reported.

Health care professionals (HCPs), i.e. health workers with a professional qualification in health care, are a significant trusted source of health information to the public. A recent survey found that the vast majority of South Africans trust HCPs the most for medical and health advice. Thus, what HCPs say

and how they interact with clients, can strongly influence vaccine acceptance. This is of absolute importance as we roll out the COVID-19 vaccine.

Tailored COVID-19 vaccine communication for different risk groups

It is very important to tailor messages by risk group. This will help people to understand why they are eligible for vaccination. It will also build trust and confidence in the vaccine. Health workers eligible for vaccination in Phase 1 of the rollout need information about how the COVID-19 vaccine will help protect them from being infected while performing their job. Also, frontline workers need information about how vaccination helps to reduce the risk of COVID-19 transmission to their patients, their own families, neighbours, and the community at large, while they continue to provide essential health services during the pandemic.

People aged 60 years and older need information about COVID-19 affecting older people more adversely and to understand that the vaccine will help protect them from COVID-19 or from becoming severely ill should they get infected. Essential workers need to be informed that, since they encounter many other people in their daily routine, the COVID-19 vaccine will help protect them from being infected while performing their jobs.

Pro-vaccination strategy

The development of an insight-informed pro-vaccination strategy is essential for effectively promoting and maintaining demand for the COVID-19 vaccine. This includes actions to reduce the impact of (a) messaging from the anti-vaccination movement, by campaigning against misinformation with messages highlighting and weighing the protective benefits of vaccination against the loss associated with not being vaccinated; (b) having agreements and plans in place to flag and remove mis/disinformation; (c) building the social norm that vaccination uptake is widespread and accepted, and (d) facilitating the availability of and access to vaccines.

Members of the public receiving COVID-19 vaccinations are entitled to clear and accurate information about the vaccines being used and the strategy to achieve herd immunity. This includes promoting vaccine literacy within the general public and trust in the fairness and efficiency of the vaccine rollout programme. Multiple channels of communication should be used to distribute positive promotional information about COVID-19 vaccination available from the national and provincial communications teams, adapting these to local contexts as relevant.

Area-based teams and teams at vaccination sites will be ambassadors for the process, equipped to answer questions posed by the public. Plain-language descriptions of the vaccines being administered are included below.

- <https://sacoronavirus.co.za/category/tool-kits/>
- <https://sacoronavirus.co.za/2021/02/22/covid-19-vaccine-phased-rollout-plan/>
- <https://www.cdc.gov/coronavirus/2019-ncov/vaccines/toolkits.html>
- <https://www.health.mil/About-MHS/MHS-Toolkits/COVID-19-Vaccine-Toolkit>
- <https://www.usp.org/covid-19/vaccine-handling-toolkit>
- <https://www.cdcfoundation.org/CBOVaccineResources>
- https://en.hesperian.org/hhg/COVID-19_Vaccines

Vaccine hesitancy

Vaccine hesitancy is a delay in acceptance or refusal of vaccines, despite vaccination services being available. Vaccine hesitancy is dynamic and context-specific, varying across time, place, and vaccines.

It ranges from delaying vaccination, to refusing vaccination, despite the availability of vaccination services. It is influenced by confidence (in effectiveness, safety, the system, and policymakers); complacency (i.e. perceived low risk of acquiring a vaccine-preventable disease); and convenience (i.e. availability, accessibility, and appeal of immunisation services).

It is important to understand the difference between vaccine hesitancy and vaccine denial. The term “vaccine denier” refers to someone who not only refuses vaccination, but also refuses to engage with scientific evidence, and will not change their mind no matter how much evidence there is against their beliefs.

Conspiracy theories about COVID-19 started spreading rapidly after the first cases were reported and were widely shared on social media. Anti-vaccine lobbyists adapted these theories to spread misinformation discrediting vaccines.

Effective communication to address vaccine hesitancy

As the public’s most trusted source of vaccination information, HCPs must effectively communicate about the COVID-19 vaccine to maintain the public’s respect and trust and their confidence in vaccination. First, HCPs must plan well and ensure enough time is spent giving personal attention to each client. Second, on arrival at a vaccination site, HCPs must establish rapport with a warm welcome and positive reinforcement for coming to the facility. Third, HCPs must presume that clients will accept the COVID-19 vaccine, as the presumptive approach is more effective than the participatory approach (where clients are asked their opinions). Fourth, if a client is hesitant, the HCP must encourage them to express their ideas and feelings, always showing interest and respect, and responding to all questions they might have, acknowledging any concerns with empathy to increase trust and reduce any COVID-19 vaccine refusal.

In addition, when an adult visits any health establishment, whether it is specifically for the COVID-19 vaccine or another reason, and the HCP notices the person is part of one of the risk groups, the approach should be to first deal with the actual reason they came. HCPs should then use brief presumptive communication, stating that they should get their COVID-19 vaccine today, if they have not already received it. Presumptive communication is always the best approach, in this case, assuming the client would accept the vaccine. Should the client accept vaccination, then he/she should be directed to the vaccination site and, where possible, assisted to register on EVDS. Should the client not accept vaccination because they are vaccine-hesitant, the focus of the HCP should be on counselling, using motivational interviewing techniques. Should the client still decline vaccination, they should be encouraged to consider vaccination and the door should be left open to discuss vaccination again at future visits.

Please refer to the lecture video in [Module 6 of the NDOH training course on COVID-19 vaccination](#), which provides a selection of different scenarios of communicating with different types of vaccine-hesitant clients.

Role of the vaccinator in crisis communication for AEFI

Events such as the publication of new data on COVID-19 vaccines, a temporary vaccine suspension or recall, and AEFI reports in the media, are all potential threats to public confidence in vaccine safety. HCPs must reassure community members that the vaccine is given to protect them from COVID-19 and explain why the vaccination is given, including the benefits of vaccination, safety of the vaccine, common side-effects, and how to take care of any side effects. If a HCP notices that a recently

vaccinated client has fallen seriously ill after vaccination, they must immediately start the appropriate treatment and refer the patient to a health establishment if needed.

They must inform the CDC/District Surveillance officer immediately, over the telephone, and complete and submit the case reporting form for AEFI within 24 hours. HCPs must never speak to the media if approached about a serious illness after vaccination; instead, they must immediately refer the media to the National AEFI coordinator, who will have up-to-date information about what has happened and what needs to be done. When an AEFI has been reported, communication with the affected vaccine recipient (vaccinee) and their family is very important. The HCP must explain to them that when an adverse event occurs following immunisation, it does not mean the vaccine caused the adverse event: adverse events occur in the normal course of life.

They must be reassured that an investigation is being carried out by the government. The HCP should empathise with them, not give incorrect/false information, and inform them when follow-up information will be shared. Should no additional information be available at the agreed time, communication must be maintained, and they must be provided with a new follow-up date and time. As the family is part of a community, the community must also be kept informed as appropriate, and empathy shown.

Chapter 4: Training health workers for the delivery of COVID-19 vaccination services

The NDoH COVID-19 vaccination programme requires training on the specifics of the different COVID-19 vaccines, the phased rollout targeting various groups within the population, AEFI reporting, and communication strategies for building public confidence in these new vaccines.

A large number of health workers, including both HCPs and support staff, are needed to support COVID-19 vaccination efforts nationwide. HCPs and support staff are essential to ensuring the South African population is vaccinated safely as soon as possible. They play critical roles in proper vaccine storage, handling, preparation and administration, disposal, AEFI reporting, and communication. They must receive the training needed to effectively meet the demands of their roles.

Training will be ongoing as new COVID-19 vaccines become available and recommendations relating to COVID-19 vaccines evolve as we learn more about the vaccines and how to optimise the vaccination programme.

Area-based teams will play an important role in making sure that health workers in their area have access to and receive the training they need to fulfil their roles to the best of their ability. Vaccination site managers must also make sure that staff involved in providing vaccination services at vaccination sites are trained and have the needed knowledge and skills to support the provision of a quality vaccination service.

Who needs to be trained?

The overall objective is to train as many HCPs and support staff as possible, with a particular focus on vaccinators. With the issuing of permits in terms of section 22A (15) of the Medicines and Related Substances Act 101 of 1965, new vaccinators could be included in the programme. These include all HCPs who are trained, competent, and who are acting within their scope of practice.

A variety of HCPs and support personnel in both the public and private sectors will be needed to implement the COVID-19 vaccination programme. These include:

- Experienced vaccinators;
- HCPs who have been trained to vaccinate but who have not administered vaccines in the past 12 months or longer;
- Pharmacists and pharmacy support personnel responsible for vaccine logistics and cold chain management;
- Community health workers and volunteers involved in supporting vaccination services;
- Administrative and other support staff involved in supporting vaccination services.

Training is important not only for those who will prepare and administer a vaccine but also for those responsible for other critical functions, including protecting the vaccine cold chain, inputting required data, communicating with vaccine recipients, AEFI management, and reporting.

Method and training approach

The training of health workers is being rolled out in a cascaded fashion, with the first phase of training of master trainers (ToT) completed at the end of January 2021. Training is being cascaded by master trainers through a combination of virtual online and face-to-face training in small groups. The [Knowledge Hub \(https://www.knowledgehub.org.za/form/covid-19-vaccination-training\)](https://www.knowledgehub.org.za/form/covid-19-vaccination-training) will be used

to provide vaccination programme training for master trainers, vaccinators, and other health workers in both the private and public health sector. Modules are updated or added (e.g., on SVS, EVDS, the MedSafety app) as new processes are finalised, or as new information about the vaccines and the programme becomes available.

Training rollout in the public sector is being done in a phased approach in line with the phases of the vaccine rollout plan: hospitals are prioritised, followed by community health centres and primary health clinics (PHCs).

Regional training centres (RTCs) are leading the DoH training efforts in the provinces, with the assistance of other directorates and district support partners. RTCs are tasked with the responsibility of ensuring that standardised training material and content is cascaded at district and sub-district level for training of health workers. The face-to-face training follows the standard ToT approach where more experienced master trainers train, upskill and support other health workers on the contents of the curriculum and other issues that may arise regarding the training. Training progress is being tracked weekly to monitor progress and address any training gaps.

Learning objectives:

The course takes 14 hours to complete and has seven modules:

Table 8: Learning objective for health worker training course

Module	Topic
1	Introduction to COVID-19 vaccination training.
2	Storage, handling, delivery, and waste management of COVID-19 vaccines
3	Organising COVID-19 vaccination sessions
4	Adverse events following immunisation (AEFI) monitoring for COVID-19 vaccination
5	COVID-19 vaccination data management
6	Communication with the community about COVID-19 vaccination
7	Ethical considerations for the COVID-19 vaccination programme

The overall aim of this training is to capacitate health workers by providing key information necessary for rolling out COVID-19 vaccination to South African health workers.

Accessing the course on the Knowledge Hub

Existing Knowledge Hub users must not re-register but self-enrol using their existing username and password to access the course by clicking on “Enrol me” or using this [link: https://www.knowledgehub.org.za/lms/course/view.php?id=66](https://www.knowledgehub.org.za/lms/course/view.php?id=66).

To recover the password or forgotten login details, participants must navigate to the Knowledge Hub and click on the 'Forgot Password' button, to reset their details using the same email address they used during registration. New users can register for the course by following this link: <https://www.knowledgehub.org.za/form/covid-19-vaccination-training>. Login details will be sent within 48 hours.

Private sector health workers and vaccinators should select ‘Other’ from the drop-down list of facility names, which will open a new free text box where the name of the organisation/facility must be typed in.

To facilitate the NDoH process of monitoring and evaluation, participants are requested to provide information as accurately and precisely as possible. Participants must check that personal details and email addresses are captured correctly as this information will be used on the certificate and ongoing communication. Once the registration form is submitted, participants will receive a confirmation email from the Knowledge Hub confirming registration for the course. Check your spam folder if you do not receive it immediately.

The course is CPD-accredited with the Health Professions Council of South Africa (HPCSA) for 14 'Level 1' points (12 general points and 2 ethics points). On completion of the online course, the certificate will be automated by the Knowledge Hub system. For offline face-to-face training:

- In the public sector, certificates will be issued by the relevant RTCs;
- In the private sector and other government departments, certificates should be issued by the designated trainer in line with company/department in-service training protocols;
- Evidence and all accompanying proof of training records should be kept for three years for future auditing purposes.

NDOH approved policies, guidelines, SOPs, job aids that are referred to in the course are available on the [Knowledge Hub eLibrary](https://www.knowledgehub.org.za/e-library) - <https://www.knowledgehub.org.za/e-library>.



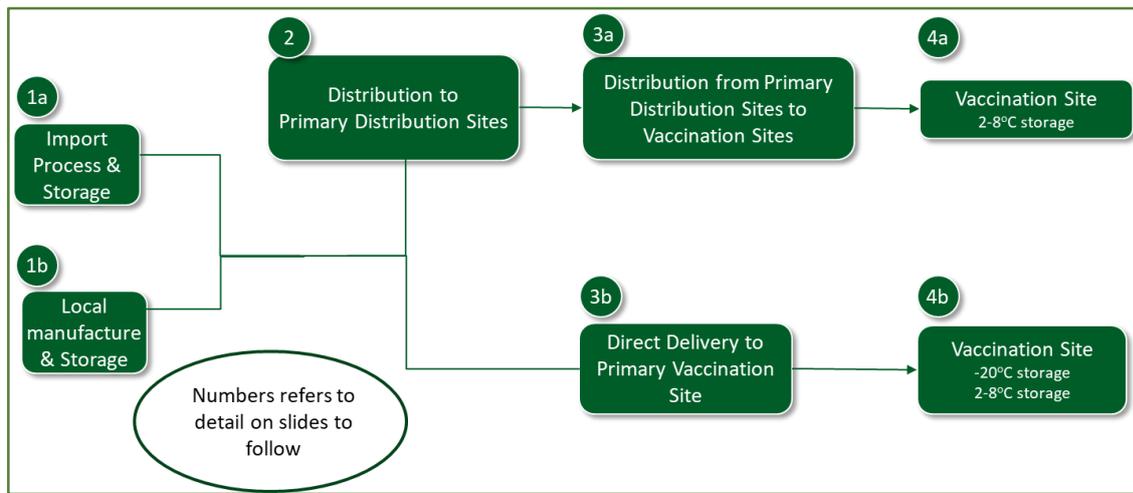
A device and internet connectivity are required to connect to the course. Accessing the course materials and recorded lectures online is free as the Knowledge Hub has been zero-rated.

Chapter 5: Effective vaccine management, cold chain, logistics, and distribution of COVID-19 vaccines in the private and public sector

Overview of vaccine logistics, distribution, and storage

COVID-19 vaccine storage and distribution will be managed at the national level, with decentralisation to provincial depots and other identified distribution sites. The appropriate quantity of vaccines and supplies to be distributed will be determined based on the micro-plan estimates.

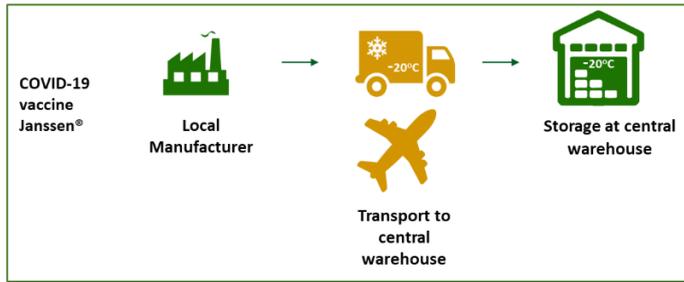
Figure 5: Vaccine distribution process



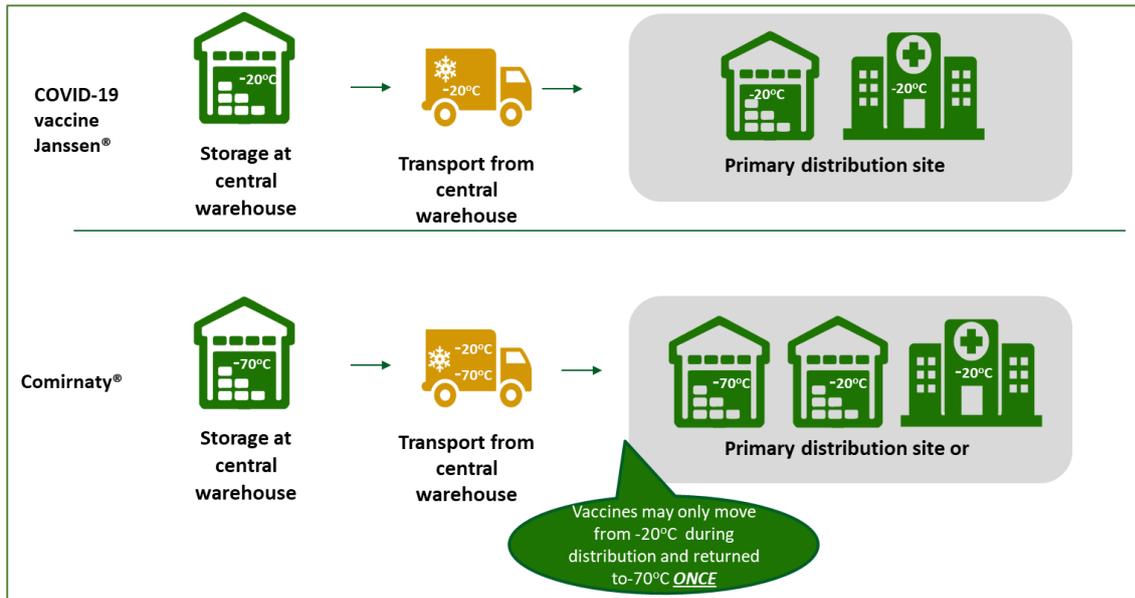
1a: Import process & central storage – all vaccines



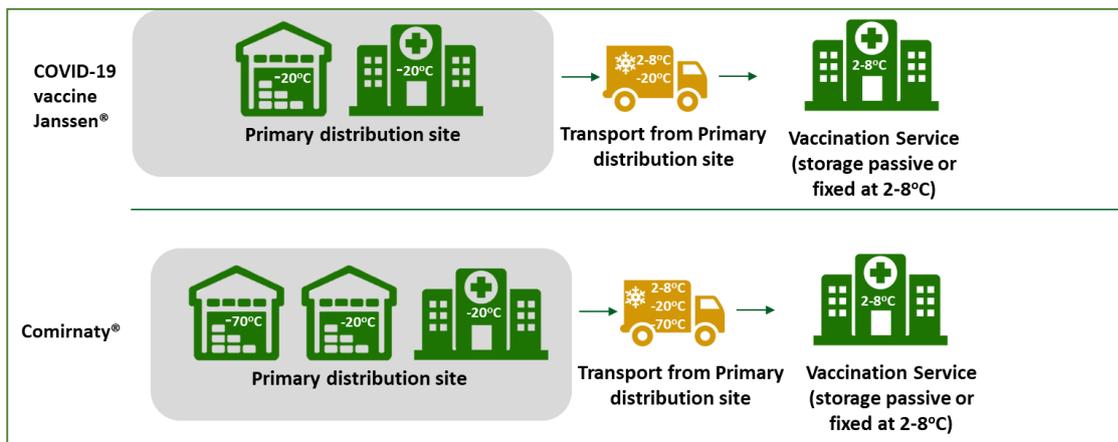
1b: Local manufacture & central storage



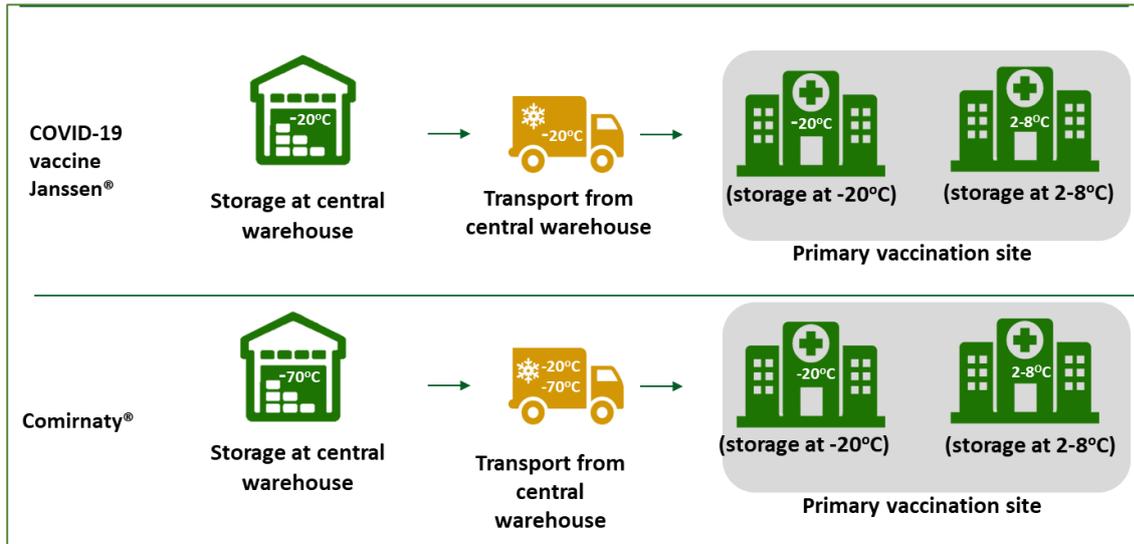
2 Distribution to primary distribution and vaccination sites



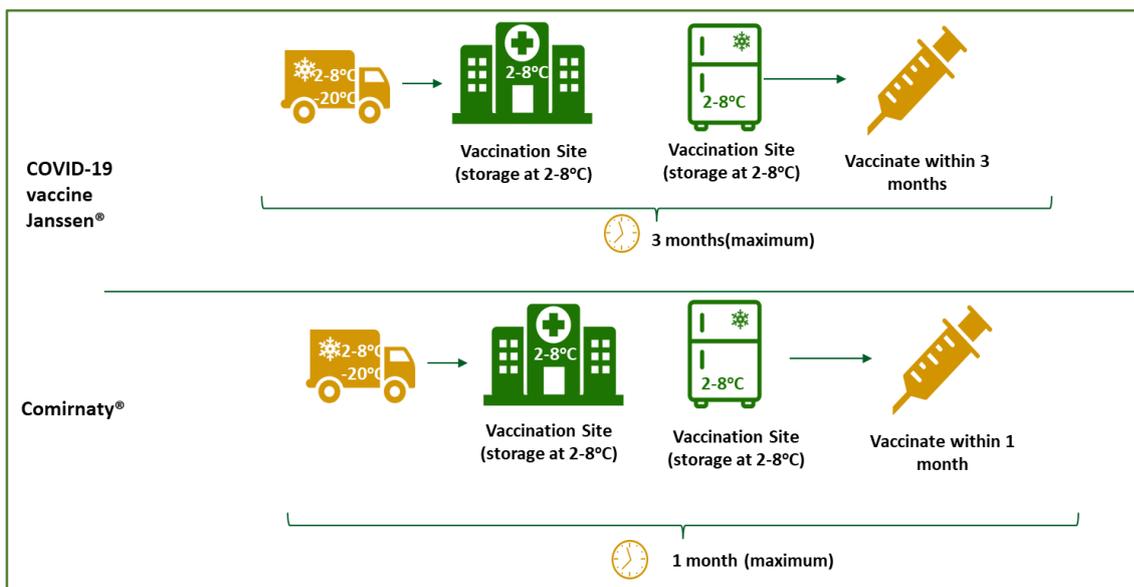
3a: Distribution from primary distribution/vaccination site to outreach services



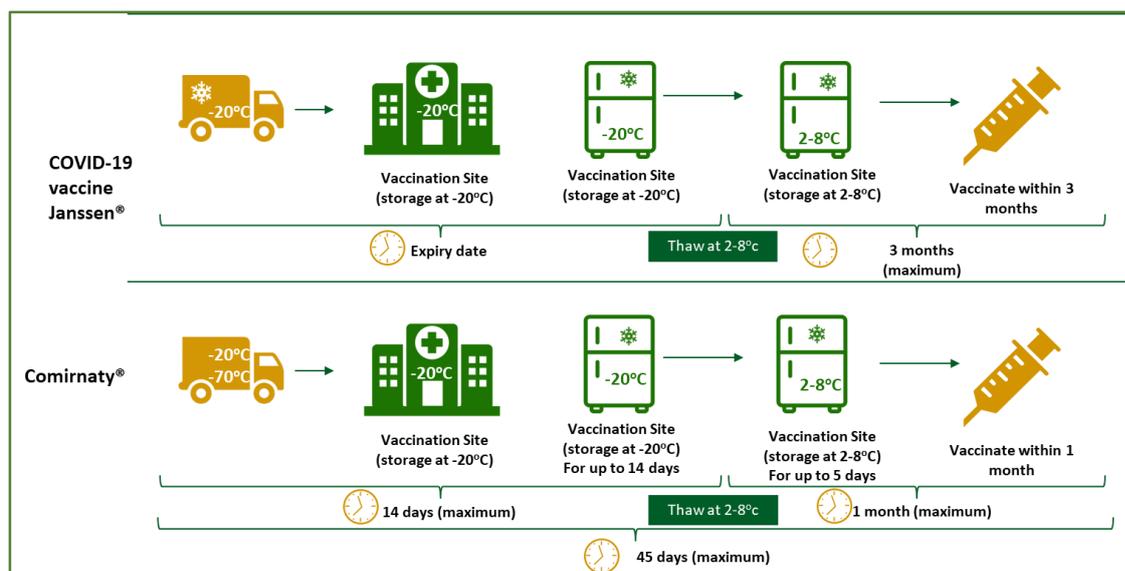
3b: Direct delivery to primary distribution/vaccination site



4a: Primary distribution/vaccination site with 2-8°C storage



4b: Primary distribution/vaccination site with -20°C storage



Distribution quantities will be calculated centrally based on the target population and consumption rate, among other factors. Once the vaccines are ready to be delivered, the receiving facility will be notified to ensure readiness to receive the vaccines. Vaccine security during transportation and delivery processes must be ensured. The vaccines may only be delivered to designated delivery sites (a health establishment or other vaccination site to which the COVID-19 vaccine may be delivered). Vaccines should be stored as per the manufacturer's storage specifications in an access-controlled room.

Stock replenishment throughout the phases

The NDoH has developed a stock replenishment model that will calculate COVID-19 vaccine requirements for both public and private sector vaccination sites. Several basic parameters are necessary to estimate the number of vaccines and ancillary items needed including:

- The target population in the area;
- Details of vaccines included in the national schedule; such as the number of doses and the number of doses per vial; and
- The wastage multiplication factor for vaccines and syringes.

To ensure transparency of recommended orders and encourage collaboration between NDoH, and public and private sector partners, the output of the replenishment model (recommended orders) will be shared with the relevant health establishment/ vaccination/distribution site for approval and sign-off. The replenishment model will be further refined as the programme evolves with a buffer included to accommodate walk-ins.

Receiving COVID-19 vaccines from central distributors

Vaccines will be distributed from a central distributors contracted by the NDoH. The delivery lead time may vary depending on the cold chain capacity at the primary distribution/ vaccination site, the vaccine being distributed, and the size of the target population. Each primary distribution/vaccination

site or organisation coordinating multiple distribution/vaccination sites have to set up an account with the central distributors allocated by the NDoH.

Vaccination and distribution sites receiving the vaccine are required to follow the guidelines for stock receipts from the central distributors and could include the following steps:

1. Stop the temperature recording device, download and save the temperature record for future use
2. Record the temperature on the invoice
3. Check the quantity of the vaccine received
4. Pack away the vaccines immediately
5. Sign the invoice, and return with the signed and stamped copies with the driver
6. Report any discrepancies immediately

Tools for receiving COVID-19 vaccines from central distributors

- ***Annexure: Communiqué from DSV***
- ***Annexure: Communiqué from Biovac***
- ***Annexure: SOP – Procedure to receive Comirnaty® Vaccine***
- ***Annexure: SOP - Procedure to receive COVID-19 vaccine Janssen®***

Effective vaccine management of COVID-19 vaccines

The vaccines discussed in this guide have different presentations, are based on different technologies, and therefore have different storage requirements. All vaccines are light-sensitive, and exposure to sunlight or fluorescent light should be minimised. The properties of the vaccines determine if they are sensitive to heat or sensitive to freezing. Exposure of the vaccines to undesired temperature ranges will result in a loss of potency and can increase the number of adverse events following immunisation (AEFI).

Table 9: Details about the Covid-19 vaccine Janssen® and the Comirnaty® vaccine

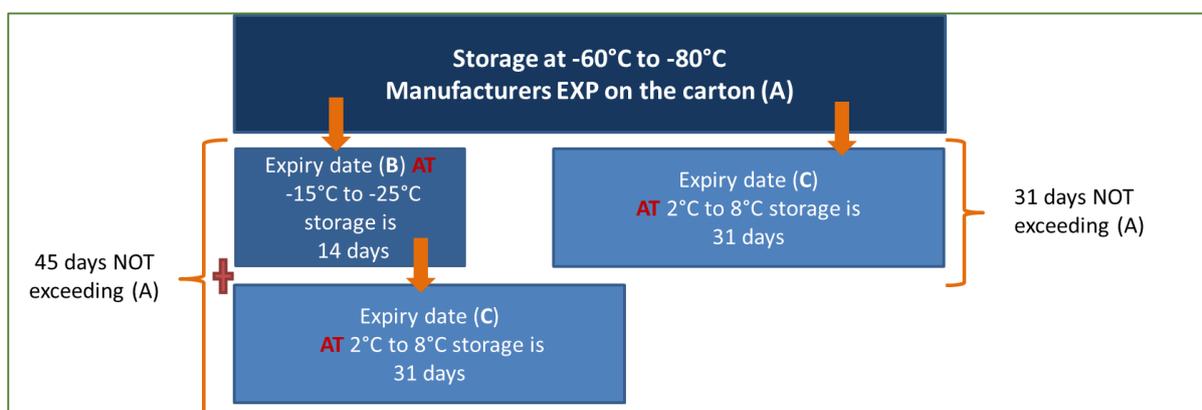
	Janssen Ad26.COVS COVID-19 vaccine	Pfizer-BioNTech COVID-19 Vaccine
Manufacturer	Janssen Vaccines & Prevention B.V.	Pfizer-BioNTech
Trade name	Covid-19 vaccine Janssen®	Comirnaty®
Approved for	Individuals over 18 years of age	Individuals over 16 years of age
Dose	0,5ml	0,3ml
Doses per vial	Vial containing 5 doses.	Vial containing 6 doses

	Janssen Ad26.COVID-19 vaccine	Pfizer-BioNTech COVID-19 Vaccine
Presentation	Liquid suspension for injection Colourless to slightly yellow, clear to very opalescent suspension	The vaccine is a white to off-white frozen dispersion. NOTE: Diluent required - not supplied by Pfizer. Separate diluent must be procured
Diluent required	No	Yes 1,8ml sterile 0,9% Sodium Chloride solution USP, preservative-free Reconstitute with 21g needle and syringe Store the diluent in the fridge at the vaccination site Diluents should NEVER be frozen Ensure that the number of vaccine vials matches the volume of diluent required
Ancillary supplies required – Vaccine administration	1ml or 2ml syringes 22g or 23g needle (28mm, 32mm or 38mm)	0,3ml, 0,5ml or 1ml syringe 22g or 23g needle (28mm, 32mm or 38mm)
Received at distribution site from the central distributor at	Distributed at -25°C to -15°C	Distributed at -60°C to -80°C The original expiry date (A) is applicable for continued storage at -60°C to -80°C
Storage at 1st delivery site - could be a primary distribution site (e.g. depot) or vaccination site (direct delivery)	Store at -25°C to -15°C The expiry date for storage at -25°C to -15°C is printed on the vial and outer carton after "EXP"	Store at -25°C to -15°C The expiry date at -25°C to -15°C is 14 days from the day the vaccine is transferred from -60°C to -80°C storage range The “new” expiry date (B) must be indicated on the outer carton or shipper by the vaccine controller. If the vaccine has not been used by the “new” expiry date (B) the vaccine must move either to 2°C to 8°C

	Janssen Ad26.COVID-19 vaccine	Pfizer-BioNTech COVID-19 Vaccine
		<p>OR</p> <p>The vaccine could be moved back to -60°C to -80°C storage range –This may only be done ONCE</p>
Distribution from primary vaccination site to another vaccination site	<p>Distribution at 2°C to 8°C</p> <p>Once removed from the freezer, the vials should be protected from light, for a single period of up to 3 months, not exceeding the printed expiry date (EXP)</p>	<p>Distribution at 2°C to 8°C</p> <p>Indicate date when the vaccine was transferred from -25°C to -15°C to 2°C to 8°C</p> <p>The “new” expiry date (C) at 2°C to 8°C is 31 days from the day the vaccine is transferred from -60°C to -80°C or -25°C to -15°C storage range.</p> <p>EXPIRY DATES (B) AND (C) MAY NOT EXCEED THE PRINTED EXPIRY DATE (A)-(EXP)</p>
ONCE VACCINE HAS THAWED AT 2 to 8°C IT MAY NEVER BE FROZEN AGAIN		
Thawing	<p>Recommendation: When stored frozen at -25°C to -15°C, a vial should be thawed overnight at 2°C to 8°C</p> <p>Doses for use the next day should be placed in the refrigerator the night before</p> <p>Or refer to the package insert</p>	<p>Recommendation: When stored frozen at -25°C to -15°C, a vial should be thawed overnight at 2°C to 8°C</p> <p>Doses for use the next day should be placed in the refrigerator the night before</p> <p>Or refer to the package insert</p>

	Janssen Ad26.COVID-19 vaccine	Pfizer-BioNTech COVID-19 Vaccine
Storage at 2nd site – vaccination site	<p>Store in a refrigerator at 2°C to 8°C for up to 3 months, not exceeding the original expiry date</p> <p>Upon moving the product to 2°C to 8°C storage, the "new" expiry date must be written on the outer carton and the vaccine should be used or discarded by the updated expiry date.</p> <p>The original expiry date should be made unreadable</p> <p>The vial must be kept in the original package to protect from light and to track the expiry for the different storage conditions, if possible</p>	<p>Store in a refrigerator at 2°C to 8°C for up to 31 days, not exceeding the original expiry date (A)</p> <p>Upon moving the product to 2°C to 8°C storage, the "new" expiry date (C) must be written on the outer carton and the vaccine should be used or discarded by the updated expiry date</p> <p>The original expiry date (A) should be made unreadable</p> <p>The vial must be kept in the original package to protect from light and to track the expiry for the different storage conditions, if possible</p>
Storage After First Puncture of the Vaccine Vial (after opening)	<p>The vaccine should preferably be used immediately after the first puncture of the vial. The product can, however, be stored between 2°C - 8°C for a maximum of 6 hours</p> <p>The vaccine presents as a multi-dose vial with no preservative. Therefore, once a vial is taken out to be used, the date and time should be indicated</p> <p>The vaccine must be discarded 6 hours after opening the vial or at the end of the immunisation session, whichever occurs first</p>	

The transfer of Comirnaty® vaccine between temperature ranges



Basic vaccine principles

- Never expose opened vials to direct heat, light, or sunlight.
- If possible, for opened vials, use a separate passive container with a temperature monitoring device to allow monitoring of temperature during use.
- Never transport or return opened multi-dose vials to the cold chain storage. Discard them.
- The vaccine and diluent should be at the same temperature at the time of reconstitution; therefore, the diluent should be stored in the refrigerator at the vaccination site.
- Diluents should NEVER be frozen.
- Always ensure that the volume of diluent available matches the number of vaccine vials to be used.

Vaccine distribution

- An SOP is available for the packing and transport of vaccines in line with the manufacturer's specifications.
- The vaccine properties should be considered, including the heat and freeze sensitivity of each vaccine.
- The duration of the journey, transport conditions, and temperature profiles of the routes should be known and considered when selecting passive containers and coolant packs.
- The correct type of coolant pack and quantity should be selected.
- Validated passive containers that meet the WHO specifications should be used for vaccine distribution.
- Conditioned ice packs should be used during distribution. NOTE: The use of GEL PACKS is not recommended for lower-level distribution at temperatures between 2-8°C, as this increases the risk of freezing the vaccine.
- During distribution, each passive container should include a continuous temperature monitoring device that meets WHO specifications.
- Maintain temperature records to demonstrate compliance.

Tools for Vaccine Distribution:

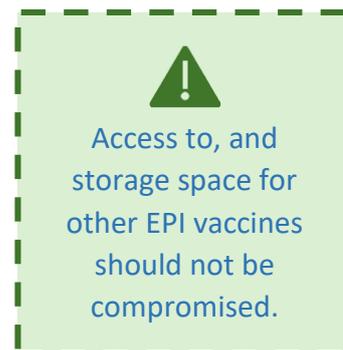
- ***Annexure SOP – Distribution of Comirnaty® Vaccines to temporary and mobile outreach services***
- ***Annexure SOP – Distribution of COVID-19 Vaccines Janssen® to temporary and mobile outreach services***

Vaccine storage

To ensure safe storage of vaccines the following quick tips should be followed for storage between 2-8°C:

- Store the vaccine in a purpose-built vaccine refrigerator. Domestic refrigerators are not considered suitable for vaccine storage due to various reasons, including the short hold-over time during a power failure.
- Ensure that sufficient cold chain capacity is available for all thermolabile medicines stocked, including Expanded Programme on Immunisation (EPI) vaccines and COVID-19 vaccines.
- Products must be stored in a temperature-regulated environment as per the manufacturer's product recommendations.

- Enough refrigerator capacity should be available to allow orderly arrangement and air circulation.
- The refrigerator should be clean.
- WHO-approved/compliant continuous temperature recording devices must be installed.
- Regardless of the system used, the temperature should be monitored physically twice daily.
- The cold storage area or refrigerator must be connected to a standby generator.
- The devices must be connected to an alarm and/or warning system in the event of a power failure or other events that may lead to temperature excursions.



All the above requirements are in line with the Rules relating to Good Pharmacy Practice published in terms of the Pharmacy Act 53 of 1974. All sites that store COVID-19 vaccines must have contingency plans to manage power failures, equipment breakdowns, or cold chain breaches.

Tools for Vaccine Storage:

- ***Annexure SOP – Storage of Comirnaty® Vaccines***
- ***Annexure SOP – Storage of COVID-19 vaccine Janssen®***

Use of Diluents

- Diluents are not interchangeable
- Should not be frozen
- Should be stored at the same temperature as the vaccine at the time of reconstitution

Correct use of diluents

- Only a diluent recommended by the manufacturer should be used
- Diluent presentation must always match vaccine presentation e.g. 1 diluent for 1 vial of vaccine

Correct reconstitution practice

- Reconstituted vaccine must be disposed of after six hours
- Reconstituted vaccine must be stored within the cold chain throughout the immunisation session

Multi-dose vial policy

How to use the Multi-dose policy? A vaccine is safe if:

- The expiry date has not passed; vial should be dated, and time indicated once open
- The vaccines are stored under **appropriate cold chain conditions**
- The vaccine vial septum has **not been submerged in water**
- **Aseptic technique** has been used to withdraw all doses
- **Reconstituted vaccines should be discarded after six hours** or at the end of the immunisation session, whichever occurs first

Handling temperature excursions

There should be concerted efforts to ensure that vaccines are stored and handled within the permissible temperature range. However, if temperature excursions should occur:

- The designated responsible person must be informed and appropriate steps taken to manage the situation
- Actions must comply with manufacturer's documented advice and/or WHO recommendations
- An incident report and root cause analysis investigation must be completed
- Contingency plans must be implemented immediately to prevent loss
- Stock must be moved to an alternative cold storage area
- The moved stock must be segregated and marked "**Do not use until authorised**"
- If removal is not possible, the storage area must be kept closed to maximise temperature control
- Temperature to be monitored on at least an hourly basis
- Check for evidence of exposure (Temperature records)
- If advised that products are safe for use, then mark as "**Use First**" and date
- Create a site report indicating the number of vials suspected/affected and the cause
- If vaccines are confirmed to have been damaged:
 - Complete the relevant waste disposal documentation.
 - Vaccine vials should be discarded in biohazardous waste or a medical waste container, such as those used for expired medicines. Deface the label on each vaccine vial with a black permanent marker or remove the label before disposal in the specified health waste container.

Table 10: Handling temperature excursions

	Covid-19 vaccine Janssen[®]	Comirnaty[®]
Temperature excursions while frozen	If the vaccine has thawed, it may not be frozen again Place the vaccine in 2-8°C, and update the expiry date as discussed	Stability data indicates that the unopened vial is stable for up to: • 24 hours when stored at temperatures from -3 °C to 2 °C
Temperature excursion while in 2-8°C storage in <u>CLOSED</u> vials	The vaccine is stable for a total of 12 hours at 9°C to 25°C . It is not a recommended storage or shipping condition but may guide decisions for use in case of temporary temperature excursions	Stability data indicates that the unopened vial is stable for up to: • a total of 4 hours when stored at temperatures from 8°C to 30°C - this includes 2 hours at up to 30 °C if thawed at room temperature
Temperature excursion in <u>OPEN</u> vials	After the first puncture of the vial, the vaccine can be held at room temperature (maximum of 25°C) for a single period of up to 3 hours	Should be discarded 6 hours after first puncture of the vial. After reconstitution, the vaccine may NOT be frozen again

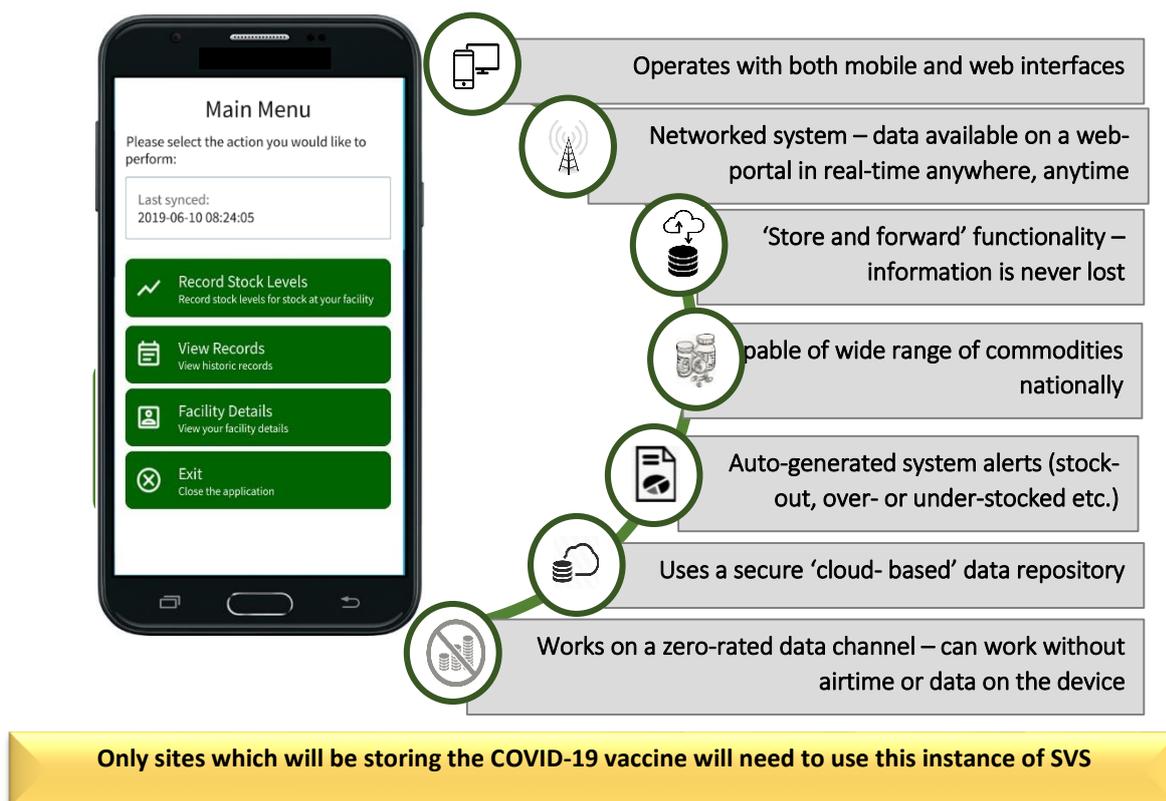
Tools for **managing temperature excursions**:

- **Annexure: SOP – Management of Temperature Excursions with Comirnaty[®] Vaccines**
- **Annexure: SOP – Management of Temperature Excursions with COVID-19 vaccine Janssen[®]**

Stock Visibility System

The NDoH Stock Visibility System (SVS) will be used to monitor the availability of COVID-19 vaccines and other items. This will provide access to the relevant data to inform decision-making and help ensure that stock is replenished in the right quantities and on time. Features of the SVS include:

Figure 6: SVS features



This SVS Covid-19 instance mobile app and web portal are completely separate from the version currently used to monitor the availability of essential medicines, related commodities, and personal protective equipment at public primary health care (PHC) clinics and hospitals. A link to the application can be found here: covid19vaccinesza.app

Primary distribution sites, primary vaccination sites, and fixed outreach services must report vaccine stock levels daily, at the end of the day (closing balance for the day), indicating stock-on-hand, stock lost, stock received, and stock issued. Stock levels for ancillary items and diluent should be submitted weekly by close of business every Friday (closing balance for the week).

Why SVS in the COVID-19 Vaccine Supply Chain?

SVS assists managers at all levels to proactively identify shortages, overstocking and short-dated stock, as well as providing visibility of overall stock levels across the country. Use of SVS will also:

- Support optimised and equitable distribution of vaccines and ancillary items

- Enable access to the relevant vaccine and ancillary item availability data to inform decision-making
- Facilitate rapid turnaround time in data analytics and planning processes
- Allow for ease of reporting and data standardisation.

System overview and enrolment

The application has the following features that allow for end-to-end management of the vaccine and ancillary supplies.

Figure 7: Stock Visibility System



One of two methods can be used to capture data on the SVS:

1. Mobile App Version: Download the app on an Android device using the provided enrollment details. The app can work offline in areas with poor connectivity, then syncs the data across when connectivity is restored. The app works without airtime or data when a Vodacom SIM is used. If another network is used, the app will require data bundles, airtime, or access to Wi-Fi to work.
2. Desktop Web Version: Download the desktop version of the application onto a Windows device using the provided enrollment details. Capture stock levels on your computer which must have network connectivity (e.g. Wi-Fi dongle, fibre, etc.) to work.

Although any device can be used for the mobile app version, the mobile process is zero-rated **only** when using the Vodacom network. The use of different network providers may attract a service fee.

Only ONE person per site that stores or distributes vaccines, can enrol on the device, using either Mobile OR desktop. Thereafter, anyone trained and knowledgeable can submit data. This is to ensure there is only one source of data emanating from each site.

To support use of SVS the following tools are available:

- **Annexure: SVS Covid-19 Mobile App User Guide and Web Overview (Presentation)**
- **Annexure:SVS Job aids and support tools – also available on the COVID-19 web portal (covid19vaccinesza.app under Information Repository)**

Security measures to protect the vaccine

The vaccines must be kept in an access-controlled room, and refrigerators/rooms where the vaccines are stored should be locked. Daily monitoring and stock-taking are required.

In the context of high demand but limited stocks, clear security arrangements must be in place to ensure the safety and integrity of COVID-19 vaccines and ancillary products throughout the supply chain. A plan should be developed to safeguard the security of staff and all sites where vaccines are stored, as well as during transit. Planning for the security of vaccines is the responsibility of the vaccination site manager at a primary vaccination site or fixed outreach sites or the leader of the vaccination team where vaccination services are provided at temporary sites or by mobile teams.

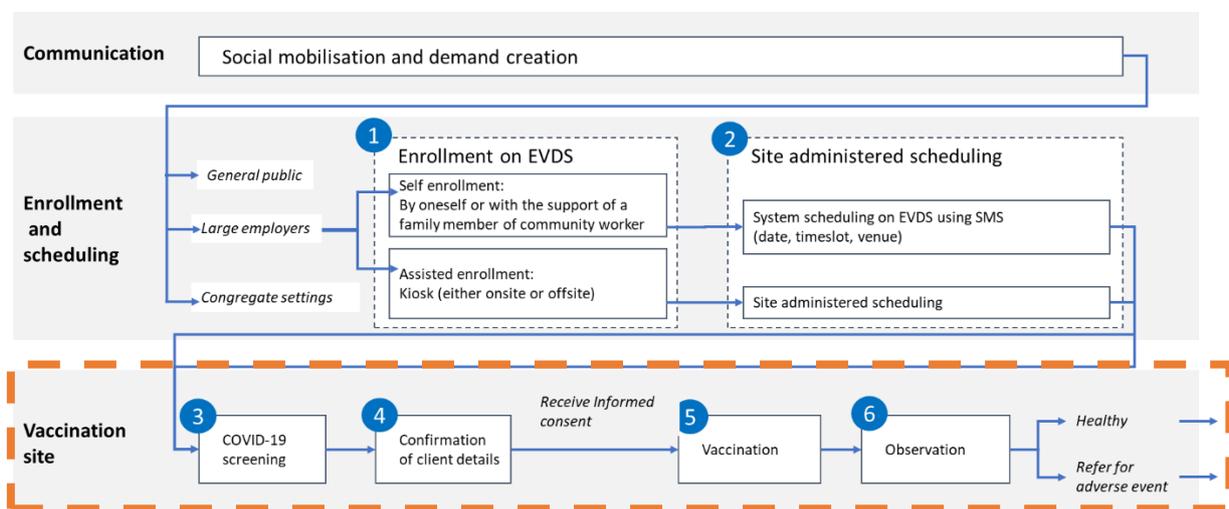
Chapter 6: Planning the client journey, and vaccine administration of COVID-19 Vaccines

The COVID-19 vaccination programme aims to curb death and severe disease, where age is the best proxy of risk until almost half the adult population has been vaccinated. In Phase II, age-based sequencing will start with the population older than 60 years and moving down. Vaccination services will be offered in congregate setting such as old age homes, correctional services, and in care homes. Similarly, in workplaces employees can be vaccinated through occupational health services where this is possible.

Planning and coordinating the client's vaccination journey

All clients, no matter where they live, will follow the same vaccination journey illustrated below. This will ensure that a quality service is delivered to all communities, no matter the setting. Review the diagram below and imagine people moving through this process either in a community hall, a marquee outside a hospital, an occupational health clinic on a mine, a pharmacy, or a large stadium.

Figure 8: High-level Client Journey at a vaccination site



Enrollment and Scheduling (Steps 1 and 2)

Enrollment on EVDS

Everyone who wants to be vaccinated should be enrolled on EVDS. Different options of vaccination enrollment are available including:

- Self-enrollment
- On-site enrollment

To receive a vaccination all clients must enroll on the official Covid-19 vaccination registration portal (refer Figure 9 below). The system will ask them to identify where they live as well as their preferred time and day of the week for vaccination.

Clients who can self-enroll for vaccination on the EVDS should do so, or enroll through assisted registration.

Figure 9: Enrolling on the Electronic Vaccination Data System

The infographic is divided into three vertical columns, each representing a different enrollment method. The background is orange with white text and icons.

- WWW:** Icon of a laptop and smartphone. Text: "Any device with Internet Access". Instruction: "Connect device to the internet and go to: <https://vaccine.enroll.health.gov.za>".
- USSD:** Icon of a mobile phone. Text: "FREE on all South African Mobile Networks". Instruction: "Dial *134*832*IDNumber#. No ID Number? Just dial *134*832#".
- WhatsApp:** Icon of a WhatsApp logo. Text: "Internet access or data required". Instruction: "Send the word REGISTER to 060 012 3456 on Whatsapp".

Below the columns, there is a list of instructions:

- Follow the instructions and enter all the information that is requested.
- You will need your identification number (Passport, Asylum seeker number, RSA ID or refugee number)
- Enter the location where you want to be vaccinated (home or work)
- If you are a member of a medical aid you will need your medical aid provider name and your medical aid number

At the bottom, the hashtag **#IChooseVacciNation** is displayed.

Every vaccination site or outreach service should provide for on-site enrollment on the EVDS. Clients presenting without a vaccination code should be assisted to enroll on EVDS. Depending on the vaccination capacity at the site, these clients should move into the queue for vaccination, or enter the vaccination programme at Step 4 in Figure 8 above.

Being vaccinated with the COVID-19 vaccine is a choice and, therefore, a client may exit the process at any point and may return at a later date to get vaccinated. For example, if a client goes through the screening and confirmation of client details area and, at the point of vaccination, decides not to follow through with the vaccination, they may exit the site, and either chose not to receive the vaccine or, at a later stage (after receiving further information) return for vaccination. Anyone exiting should not be recorded as having received the vaccine. **Vaccinators MUST NOT record vaccination before the vaccine has actually been administered to the client.**

Site administered scheduling

When vaccination sites are activated, clients enrolled on EVDS will receive an SMS, informing them of the date, time, and venue to receive their vaccination. Clients will be asked to bring a form of identification, and proof of medical aid if applicable.

Each site will appoint a **vaccination site scheduling administrator** who will manage the scheduling system at that site.

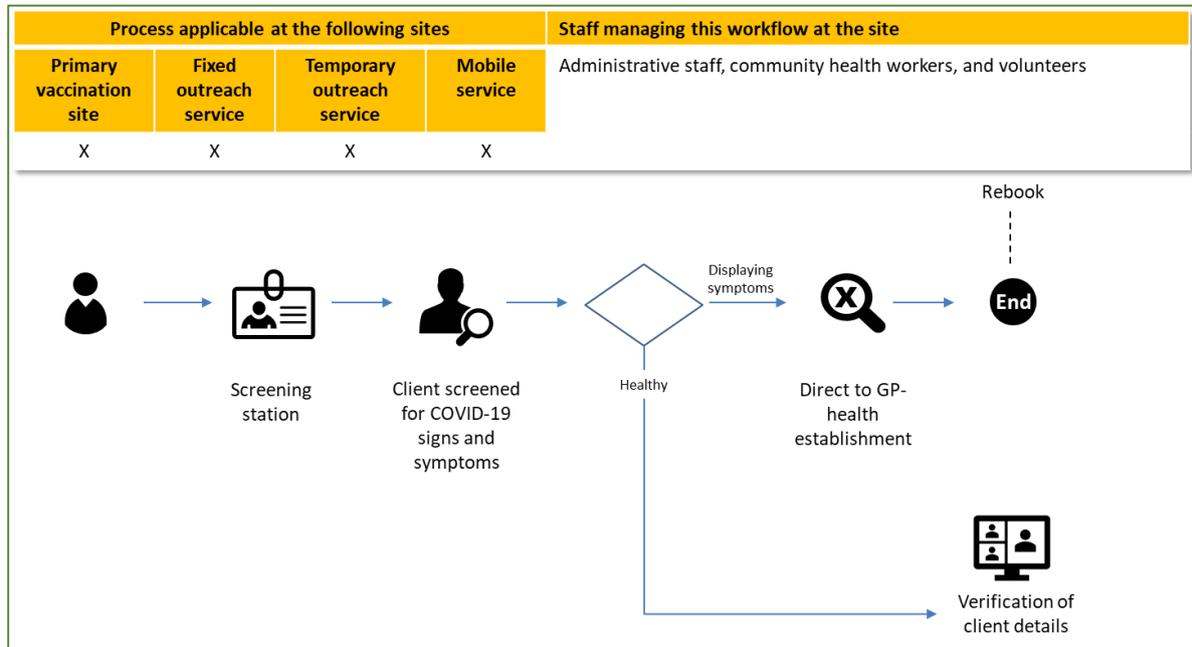
The next four steps of the client journey take place at the vaccination site and are described below.

COVID-19 Screening (Step 3)

On arrival at a vaccination site, all clients and staff working on the site will undergo COVID-19 screening. Clients who are screened and have no symptoms of COVID-19 will then move to a waiting area until marshals direct them to administration desks for confirmation of their details.

Clients with COVID-19 symptoms will be referred for testing, asked to exit the site, and will be rescheduled for another appointment. Site staff should alert the vaccination site manager if a person with COVID-19 symptoms is identified and should request them to consult their health care provider. These clients are welcome to return on a new appointment date if they are well.

Figure 10: COVID-19 screening of clients



To support COVID-19 screening the following tools are available:

- ***Annexure: SOP: COVID-19 screening of client***

Confirmation of client details (Step 4)

Following COVID-19 screening, the client should be directed to the administration desk for confirmation of enrolment on the EVDS or join the assisted enrollment queue to get registered on EVDS. Clients must bring their proof of identification (South African ID, driver's licence, passport, refugee or asylum seeker number, or an affidavit in this regard) to confirm client details. Clients whose details are successfully confirmed remain on-site for vaccination.

- If the client's name or proof of identification number is incorrect, the client should re-enrol with the correct information.
- If the demographic information and medical aid details are incorrect personnel at the site will update details on EVDS.
- Clients without proof of identity may be directed to return to the site with an applicable identity document.

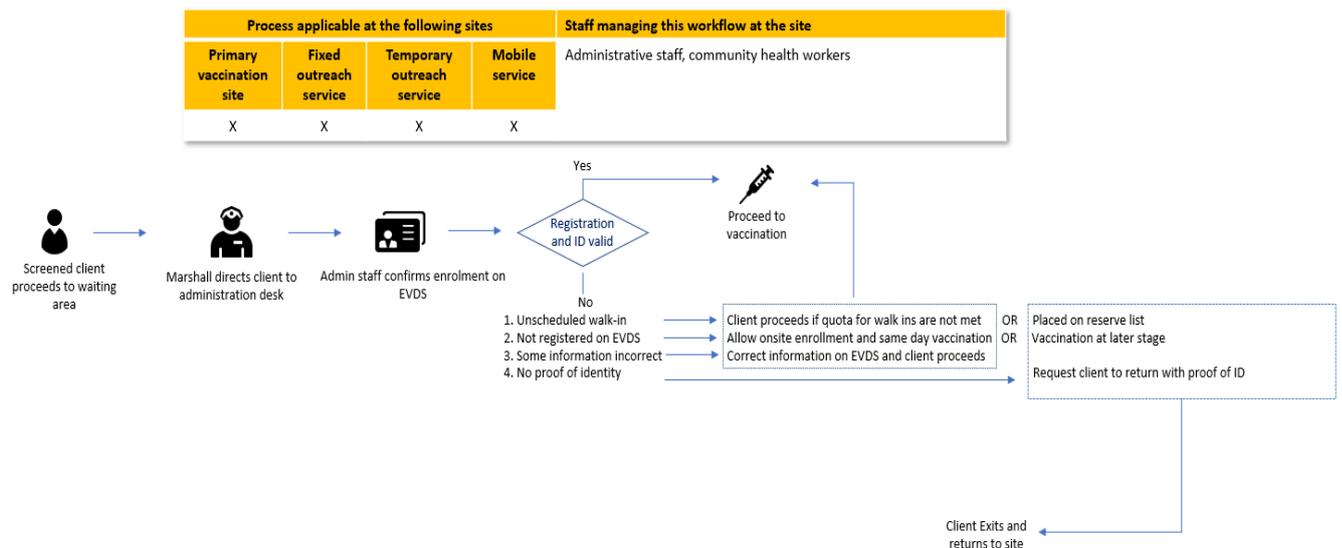
Client enrolled on EVDS but not scheduled (unscheduled walk-in):

- The site should put measures in place to accommodate unscheduled walk-in clients. If the vaccination site capacity does not allow same-day vaccination – advise the client to return on the scheduled appointment date and time.
- Alternatively, unscheduled walk-ins could be added to the reserve list (maintained by the vaccination site) – to be contacted if vaccine doses remain at the end of the day.

Client not enrolled on EVDS (not-enrolled walk-in):

- On-site assisted registration and receive the vaccine on the same day.
- On-site assisted registration and schedule appointment for vaccination – if the vaccination site capacity does not allow same-day vaccination.
- Self-enrollment or off-site assisted registration - receive scheduled appointment for vaccination.
- Alternatively, walk-ins could be added to the reserve list (maintained by the vaccination site) – to be contacted if vaccine doses remain at the end of the day.

Figure 11: Confirmation of client details



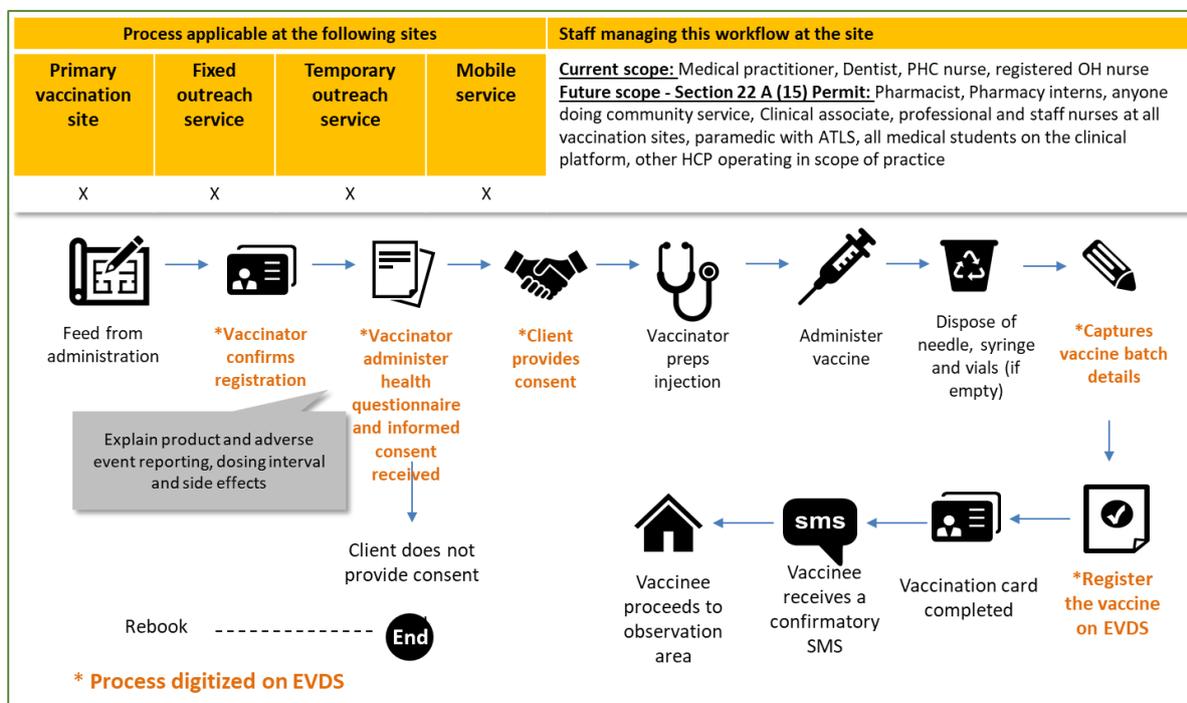
To support **confirmation of client details** the following tools are available:

- **Annexure: SOP: Confirmation of client details X]**
- **Annexure: EVDS User manual**

Administering the vaccine (Step 5)

A number of processes take place during this step (refer to Figure 12 below). EVDS is used to capture details of the vaccine administration process. **NOTE: Vaccinators must only register vaccination on EVDS after the vaccine has been administered.**

Figure 12: Vaccination process

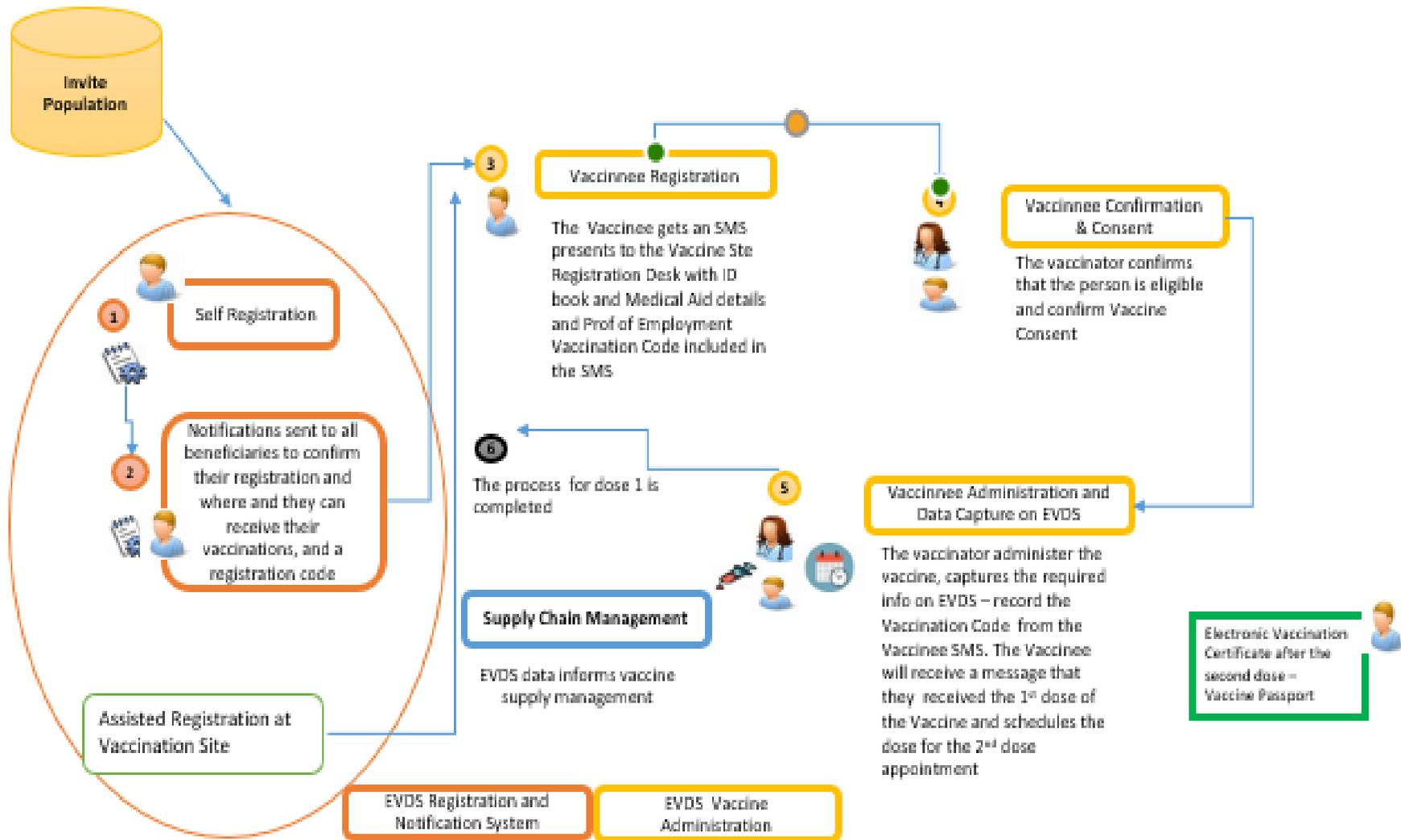


High-level summary of EVDS digitised workflow

The client journey is supported by EVDS as follows

1. Eligible persons are invited to enrol through the self-registration portal which accommodates web-based, WhatsApp, and USSD registration. EVDS sends SMS to the client to confirm enrolment.
2. The client is scheduled to receive the vaccine at an approved vaccination site. EVDS sends client details of the scheduled appointment.
3. At the vaccination site, the client will present with a vaccination code for a scheduled appointment and the details of the client are confirmed.
4. The client provides consent, where after the vaccinator administers the vaccination, records the vaccination on EVDS, and schedules the next appointment.
5. The vaccinator selects vaccine, batch number, expiry date, dose number, while the system records the date and time of dose.
6. An SMS will be sent to the mobile number of the vaccinee to confirm that vaccine was administered and the date of the next appointment (if applicable).
7. A similar process will be followed for the second dose, if appropriate, ensuring that the first and second doses are the same type of vaccine from the same manufacturer.

Figure 13: High-level Summary of the EVDS Workflows



Administer Health questionnaire

A health questionnaire has been included to assist the vaccinator to make clinical decisions related to vaccine selection and identify precautions to consider before vaccination. If the recommended vaccine is not available at the vaccination site, the client should be referred to a vaccination site that has the recommended vaccine.

Table 11: Precautions to consider before vaccination

People with a history of a severe allergic reaction to any component of the vaccine should <u>not be vaccinated</u>. This is the only CONTRA-INDICATION for all COVID-19 vaccines. Always refer to the package insert of the vaccine to be administered for details on vaccine components
Data on COVID-19 vaccination of persons living with autoimmune conditions are limited, they must consult their doctor before being vaccinated.
Pregnant women may be vaccinated when the benefit of vaccinating (e.g., health workers at high risk of exposure and pregnant women with co-morbidities) outweighs the potential vaccine risks. The WHO does not recommend pregnancy testing before the COVID-19 vaccination.
Lactating / breastfeeding women should be offered vaccination if they are part of a risk group. The WHO does not recommend discontinuing breastfeeding after vaccination.
Immunocompromised persons may have a reduced response to any of the COVID-19 vaccines.
Vaccination can be offered to people who have had COVID-19 in the past with an interval of one month since recovering from the infection.
Vaccination can be offered to people who have had COVID-19 monoclonal antibody convalescent plasma treatment in the past with an interval of three months since the treatment.
The COVID-19 vaccines have not been tested when administered simultaneously with other vaccines. A 14-day interval between receiving the COVID-19 vaccine and any other vaccine (e.g., the flu vaccine) is recommended.
For the COVID-19 vaccine Janssen®
Very rare cases of thrombosis and thrombocytopenia have been observed. This includes severe cases of venous thrombosis at unusual sites such as cerebral venous sinus thrombosis, splanchnic vein thrombosis, as well as arterial thrombosis with thrombocytopenia
Health care professionals should be alert to the signs and symptoms of thromboembolism and/or thrombocytopenia. Those vaccinated should be instructed to seek immediate medical attention if they develop symptoms such as shortness of breath, chest pain, leg swelling, or persistent abdominal pain following vaccination. Additionally, anyone with neurological symptoms including severe or persistent headaches or blurred vision after vaccination, or who experiences skin bruising (petechia) beyond the site of vaccination after a few days, should seek prompt medical attention.

Informed Consent

As with other vaccines, COVID-19 vaccines are not 100% effective and may not protect everyone who is vaccinated against COVID-19. For vaccines that require two doses, ensure that clients do not miss the second injection and emphasise that **it is important to complete the vaccination course**. Full protection against COVID-19 requires that recommended doses of the vaccine be given within the proper interval and that different COVID-19 vaccines are NOT used interchangeably.

Everyone receiving health care services in our country has the right to information about the services they get, including the benefits and risks of services and the implications and risks of refusing health care services. Health care providers must, where possible, communicate with citizens in a language they know and in a way that is easy to understand.

Recipients must provide their informed consent for specific health services, including vaccinations. A member of the vaccination team will explain the vaccine used, what happens if the client reacts to the vaccination (has an adverse event), whether an additional vaccine dose is needed at a follow-up visit to the vaccination site, how long between these doses, and possible side effects.

To receive their COVID-19 vaccination, the client must digitally confirm consent or sign a paper consent form, if they agree to be vaccinated. The contents of the consent form may differ depending on the vaccine to be administered to the client. Once they have provided their consent, the vaccine can be administered to the client.

Clients must be reminded that it is still unknown how long vaccinated people will be protected for, and that individuals must continue to wear masks, practise social distancing, and wash their hands often, as well as using hand sanitiser frequently.

Tools for informed consent:

- **Annexure: Health Questionnaire**
- **Annexure: Informed consent – Comirnaty® vaccines**
- **Annexure: Informed consent - COVID-19 Vaccines Janssen®**

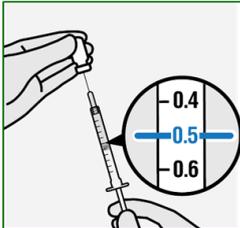
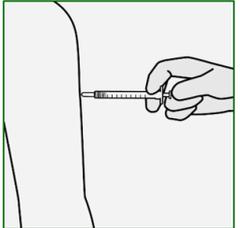
Administration of the vaccination

Vaccinations may be administered by a vaccinator who is a designated health care provider trained, competent, and acting within their scope of practice.

The vaccinator prepares the vaccine. The technique for preparing a COVID-19 vaccine for administration may differ depending on the product used.

Figure 14: Preparing to administer the COVID-19 vaccine Janssen®

Frozen vaccine should be thawed before use as described

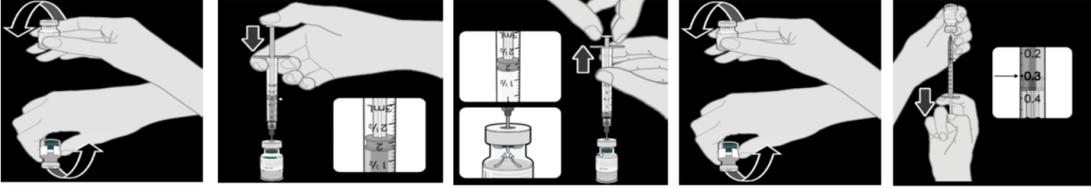
 <p>Swirl the vial gently</p> <ul style="list-style-type: none">• Before administering a dose of vaccine, swirl the vial gently in an upright position for 10 seconds. <p>Do not shake.</p>	  <p>Withdraw 0.5 mL</p> <p>Use a sterile needle and sterile syringe to extract a single-dose of 0.5 mL from the multi-dose vial</p>	 <p>Inject 0.5 mL</p> <p>Administer by intramuscular injection only into the deltoid muscle of the upper arm</p>
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Open vaccine vials should be discarded after 6 hours

- **The COVID-19 vaccine Janssen® is a single dose vaccine**

Figure 15: Preparing to administer Comirnaty® vaccine

Frozen vaccine should be thawed before use as described



Gently invert the undiluted vial 10 times before dilution. Do not shake

The thawed vaccine must be diluted in its original vial with 1.8 mL sodium chloride 9 mg/mL (0.9%) solution for injection, using a 21 gauge or narrower needle and aseptic techniques.

Equalize vial pressure before removing the needle from the vial stopper by withdrawing 1.8 mL air into the empty diluent syringe.

Gently invert the diluted dispersion 10 times. Do not shake.

After dilution, the vial contains 2.25 mL from which 6 doses of 0.3 mL can be extracted.

- Using aseptic technique
- Withdraw 0.3 mL of Comirnaty®.

Indicate the date and time of reconstitution

Open vaccine vials should be discarded after 6 hours

- **The Comirnaty® vaccine requires two doses administered 42 days apart**

Vaccine administration

The vaccinator must:

- Always disinfect his/her hands before starting with this procedure.
- Before opening a vial, read the expiry date on the label and ensure that the vaccine has not expired.
- Clean the rubber stopper of the vial with a cotton swab moistened with clean water, before each withdrawal from the vial.
- Draw up the required dose (see vaccine-specific instructions) using a sterile needle and syringe. Follow the **“one needle, one syringe, one time”** policy.
- Expose the arm completely from shoulder to elbow.
- The injection site is 3-5cm below the acromion process.
- Clean skin with cotton wool moistened with water, not an alcohol swab.
- Administer the required dose of vaccine into the deltoid muscle (upper arm) of the non-dominant arm.
- Inject the vaccine by holding the syringe firmly between thumb and forefinger and inserting the needle into the densest portion of the muscle at a 90° angle.
- Inject the vaccine slowly and remove needle quickly.
- Apply gentle pressure with sterile gauze or cotton ball.

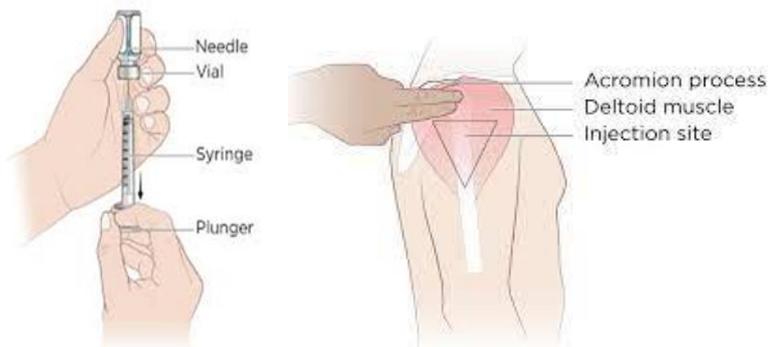
NOTE

- Never prefill syringes with vaccines for use later
- Never leave the needle and syringe in a vial
- Do not soak the cotton balls/swabs in water
- All COVID-19 vaccines must be administered intramuscularly - NOT intravenously or subcutaneously.
- Vaccine spills should be cleaned with an appropriate **antiviral disinfectant**.

- Do not rub the site as this interferes with the absorption of the vaccine.
- Discard needle and syringe as one (without disconnecting or re-capping) into the sharps container.
- Disinfect your hands and make the client comfortable.

Always disinfect your hands before and after the procedure.

Figure 16: Administration of a COVID-19 vaccine



Disposal of needles, syringes, and vials

Dispose of all needles and syringes in a sharps disposal container immediately after they have been used. It is important to handle sharps waste properly to prevent health and environmental hazards.

To ensure safe handling and disposal of sharps containers:

- Do not recap the needles before disposal into the container.
- Do not handle or shake the sharps container more than necessary. Never squeeze, sit, or stand on sharps containers.
- Never fill sharps containers more than $\frac{3}{4}$ full, or above the “full line” of the container as this increases the risk of needle-stick injuries.
- Sharps containers must be sealed when they are $\frac{3}{4}$ full.
- Take extra care when you carry the containers to the collection site. Hold the container with the handle provided.
- Only used vials, needles, and syringes must be discarded in the marked yellow sharps containers.
- Keep used and full sharps containers in a dry, safe place and out of reach of clients and the public until they are collected by a designated waste disposal company.

- **Train everyone who will handle the sharps container to do so safely.**
- **Do not ask untrained staff to handle sharps containers.**

Figure 17: Example of sharps container



Disposal of vials

- Discard all used vaccine vials and the outer carton. The open vaccine vials should be defaced with a permanent marker or the label removed before disposal in the specified health waste container.
- Unused vaccine vials that have been compromised in any way should be recorded and disposed of in the pharmaceuticals waste container. Vaccine vials should be defaced with a permanent marker or the label removed before disposal.

After administering the vaccine

- Record the administered dose on the EVDS and the vaccination card.
- Register vaccination as complete on EVDS.

Return date and reminder system

- Give return date for the second dose (if applicable) based on the vaccine schedule, and record the return date on the vaccination card.
- The vaccinee receives SMS from EVDS confirming vaccination.
- Where applicable, the vaccinee receives an SMS notification from the EVDS, with the scheduled date and time of the second dose.
- The client receives a completed vaccination card.
- The client moves to the observation area.

Tools for administration of the vaccine:

- *Annexure: SOP - Vaccination process at vaccination site*
- *Annexure: Job aid - Preparing to administer Comirnaty® vaccine*
- *Annexure: Job aid - Preparing to administer COVID-19 vaccine Janssen®*
- *Annexure: Job aid – Administration of a COVID-19 vaccine*
- *Annexure: Copy of the Vaccination Card*

Observation (Step 6)

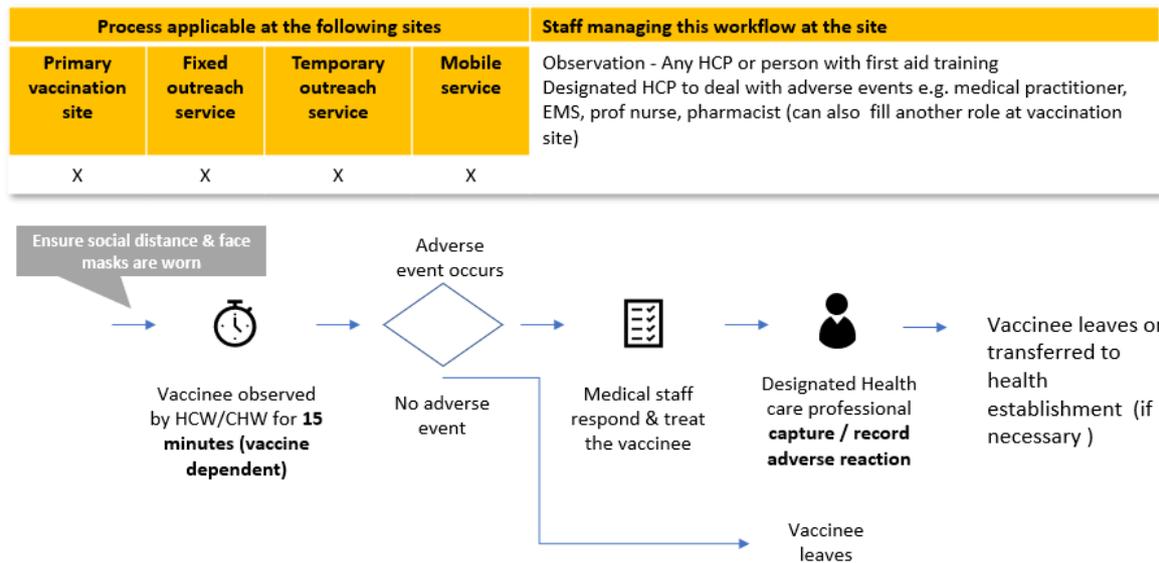
Client observation

After receiving their vaccination, vaccinees are directed to an observation area, where they should remain for at least 15 minutes. This period should be extended to 30 minutes if the vaccinee is considered at risk of anaphylaxis. At this time any health care professional or a person with first aid training is on duty with clients to make sure they are well immediately after vaccination.

Clients must keep a safe social distance and wear face masks. After 15 minutes the clients may leave the vaccination site if they are well.

Every vaccination site has a designated health care professional responsible for client care if an adverse event takes place. These people may also fulfil another role at the vaccination site, for example as a vaccinator or vaccination site manager.

Figure 18: Observation post administration of the vaccine



Adverse event in observation area

If a vaccinee experiences an adverse event, he/she will be attended to on-site or referred for further clinical care. Any adverse event following immunisation (AEFI) must be documented and reported as set out in the section below.

AEFI reporting in both the private and public sector should be done on the MedSafety application or submit a case reporting form to the district office and AEFI@health.gov.za. If required, the National COVID-19 hotline could be contacted for support on 0800 029 999.

For detailed information on reporting of AEFI please refer to Chapter 7.

Management of anaphylaxis

Anaphylaxis is a rare AEFI. It is an acute hypersensitivity reaction with multi-organ system involvement that can present as, or rapidly progress to a severe life-threatening reaction. The estimated incidence is 1 in a million vaccinations or less.

It is therefore important that all vaccination teams have the capability, tools, knowledge, and access to the medicines and equipment needed to manage anaphylaxis should it happen.

Clinical features include:

- Acute onset of signs and symptoms
- Urticaria (hives) or angioedema
- Bronchospasm, wheezing, dyspnoea, chest tightness
- Laryngeal oedema with upper airway obstruction or stridor
- Gastrointestinal symptoms such as nausea, vomiting, diarrhoea
- Hypotension and/or shock
- Dizziness, paraesthesia, syncope, sweating, flushing, dysrhythmias

These symptoms may occur 5 to 30 minutes' post-vaccination. All cases of anaphylaxis should be recorded immediately on an Adverse Event Following Immunisation (AEFI) case reporting form before the vaccinee leaves the vaccination site.

Emergency Procedure in the case of Anaphylaxis

A very severe allergic reaction usually occurs within seconds or minutes after exposure to an allergen but may be delayed for up to 1 hour. The reaction can be short-lived, protracted, or biphasic, i.e. acute with recurrence several hours later. Immediate reactions are usually the most severe and/or life-threatening.

The standard treatment guidelines should be followed to treat anaphylaxis as indicated in the table below:

Table 12: Management of anaphylaxis

<i>Resuscitate (CAB) immediately. – If required</i>	
<i>Place hypotensive or shocked patient in horizontal position. Do NOT sit the patient up.</i>	
<i>Severe anaphylaxis: administer oxygen by facemask at high flow rate of 15 L/min.</i>	
<i>Remove the trigger if possible.</i>	
MEDICAL TREATMENT	
First line priority	Second line priority
Adrenaline (epinephrine) is the mainstay of treatment and should be given immediately. Adrenaline (epinephrine), 1:1000, IM, 0.01 mL/kg as a single dose. <ul style="list-style-type: none">• Adults: 1:1000, IM, 0.5 mg (0.5 mL) as a single dose, into the lateral thigh.• Repeat in 5 minutes if no improvement.	Oxygen, 8-10 L/minute via facemask or up to 100% oxygen, as needed.

AND If hypotension not responding promptly to adrenaline (epinephrine)
Also give Sodium chloride 0.9%, IV: <ul style="list-style-type: none"> Adults: 1000–2000 mL, at the most rapid flow rate possible in the first minutes of treatment. Repeat as needed.
CAUTION: Monitor continuously for clinical response and fluid overload.
AND If wheeze:
Salbutamol 0.5%, solution, nebulised, with high flow oxygen. <ul style="list-style-type: none"> 0.5–1 mL (2.5–5 mg) salbutamol 0.5% solution, in 4 mL of sodium chloride 0.9%.
AND If wheeze:
AND Ipratropium bromide, solution, added to salbutamol solution. Adults: 2 mL (0.5 mg)
AND Hydrocortisone IM/slow IV, immediately. Adults: 200 mg immediately.
AND Promethazine IM/slow IV. Adults: 25–50 mg.
REFERRAL All patients. Note: Adrenaline (epinephrine) administration may have to be repeated due to its short duration of action. Observe closely during transport.

Tools for **observation of vaccinees and management of AEFI**

- **Annexure: SOP – Observation of vaccinee post COVID-19 vaccination**
- **Annexure: SOP – AEFI form**

Disposal of COVID-19 vaccine

Never transport or return opened multi-dose vials used in vaccination to the cold chain storage – discard them

- Put used vaccine vials and unopened vaccine vials that have expired/passed six hours after reconstitution or suffered heat exposure into pharmaceutical waste containers or a biohazard container.
- Open vials posing a risk of cuts may be classified as sharps waste and must be handled as such.
- Label the containers with the infectious substances symbol.
- Seal the containers before transporting them to the treatment site.

Disposal of medical waste

All used masks and other PPE, used cotton wool and gauze, must be disposed of in the medical waste containers suitable for biohazardous material. Similarly, all materials used to decontaminate vaccine spills with disinfectant should be disposed of in medical waste containers.

Medical waste containers must be sealed when they are full. Keep sealed medical waste containers in a dry and safe place, out of reach of children and the public, until they have been safely disposed

of/collected by the approved company. Always segregate waste at generation points and follow the Waste Management and Healthcare Risk Waste disposal protocols.

Tools for **disposal of waste:**

- ***Annexure: SOP – Waste disposal of COVID-19 ancillary items***
- ***Annexure: SOP – Waste disposal of COVID-19 vaccines***

Conclusion of Vaccination Session

Concluding the vaccination session is an integral part of the process and should be done properly. When closing the session any unused open COVID-19 vaccine vials must be dealt with according to the SOP for that specific vaccine. Count the unopened COVID-19 vaccine vials and write down the number on the tally sheet.

If unopened COVID-19 vaccine vials are returned from a temporary outreach site or mobile team, return the vials, vaccine carrier, and coolant packs to the primary vaccination site. The usable unopened vials must be placed back in the cold chain storage and recorded on SVS as stock received.

Calculate on the tally sheet the number of COVID-19 vaccines administered, the number of vials received, opened, discarded, and returned, and submit the tally sheet to the vaccine champion.

Managing problems that arise

As the implementation of the national vaccination programme gets underway, we expect challenges to arise at any level. Managing these is part of your responsibility. Area-based teams should assist in developing approaches and backup plans to manage the following:

Crowd control and unexpected walk-ins

In some areas, community members will likely arrive at vaccination sites without electronic enrollment on the EVDS. A strategy is required to manage large groups. As part of the planning process, document how large groups of people will be managed while allowing the process to continue. Remember, some clients have traveled or walked a distance to reach the site, so all efforts must be made to help them and not turn them away.

Maintaining vaccination records

The EVDS was developed to digitise the recording of vaccinations to ensure accountability and quality of care. More information is available in Chapter 2.

During the COVID-19 vaccination programme, all processes **MUST** be recorded on EVDS. This will ensure a standard user experience and electronic record of the administration of the vaccine to the vaccinee. This electronic record will be the authoritative source for the creation of the content of the vaccination certificate/passport.

The EVDS is a comprehensive system, and therefore no paper-based records are required in the COVID-19 vaccination programme.

Paper-based vaccination forms should only be used in exceptional circumstances when there are challenges with internet connectivity and electricity, but must be avoided as much as possible because of the following limitations:

- Paper-based records could be lost
- Paper-based records influence data quality where paper-based forms are prone to errors during the capturing process, with some paper-based forms being illegible, decreasing the accuracy of health records
- Paper-based forms increase the risk of adverse events following immunisation, as previous vaccination history on EVDS could not be accessed
- Confirmation of details of a vaccinee may not be possible off-line
- Vaccination code cannot be issued off-line
- The vaccination code cannot be verified
- Confirmation of vaccination cannot be issued off-line
- Automated scheduling will not be available off-line - therefore, the return date should be calculated manually
- Reporting gaps may be created if paper-based records are not added to the daily vaccination statistics for a particular vaccination site.

Every site must designate an administrative clerk to back-capture all paper-based vaccination forms within 48 hours (when the use of a paper-based system is not avoidable). It is the responsibility of the vaccination site manager to make sure this is done.

Load shedding

Planning should include the possibility of load shedding or power loss and the availability of backup power sources for cold storage of vaccines and for the use of tablets and laptops that will be used to register vaccinations delivered on the EVDS.

COVID-19 cases

Screening for COVID-19 will take place at all vaccination sites. Should there be a case of COVID-19 among staff or community members at a vaccination site that site, or a portion of it, may need to close for sanitisation and other measures. Plans to manage this situation including the scheduling of clients and communication with the public should be in place at all vaccination sites.

Chapter 7: Vaccine safety surveillance and reporting

Vaccines are extremely safe and effective. However, adverse events may occur sometimes. Surveillance of vaccine safety is therefore very important.

Adverse events following immunisation (AEFI) in the context of COVID-19 vaccine rollout

An **AEFI** is defined as any untoward medical occurrence which

- follows immunisation;
- does not necessarily have a causal relationship with the usage of the vaccine;
- may be any unfavourable symptom about which a vaccinee complains; and/or
- may be an abnormal laboratory finding, sign or disease identified by medical staff.

Implications for COVID-19 vaccination: The same definition will be used to identify, report, and investigate where appropriate, all AEFI with a COVID-19 vaccine. Current vaccine safety surveillance systems will be adapted to ensure the safety of the public is assured and to counter any real or perceived safety concerns.

Adverse events of special interest (AESI) in the context of COVID-19 vaccine rollout

In the context of COVID-19 vaccine introduction, normal vaccine safety surveillance systems will have to be adapted to ensure that post-vaccination safety information is collected and processed, that the safety of the public is not put at risk and to counter any real or perceived safety concerns. With the COVID-19 vaccine introduction, in addition to AEFI monitoring, any adverse events of special interest (AESI) will also be monitored.

An **AESI** is a pre-specified medically significant event:

- that has the potential to be causally associated with a vaccine product;
- that needs to be carefully monitored; and
- confirmed by further special studies.

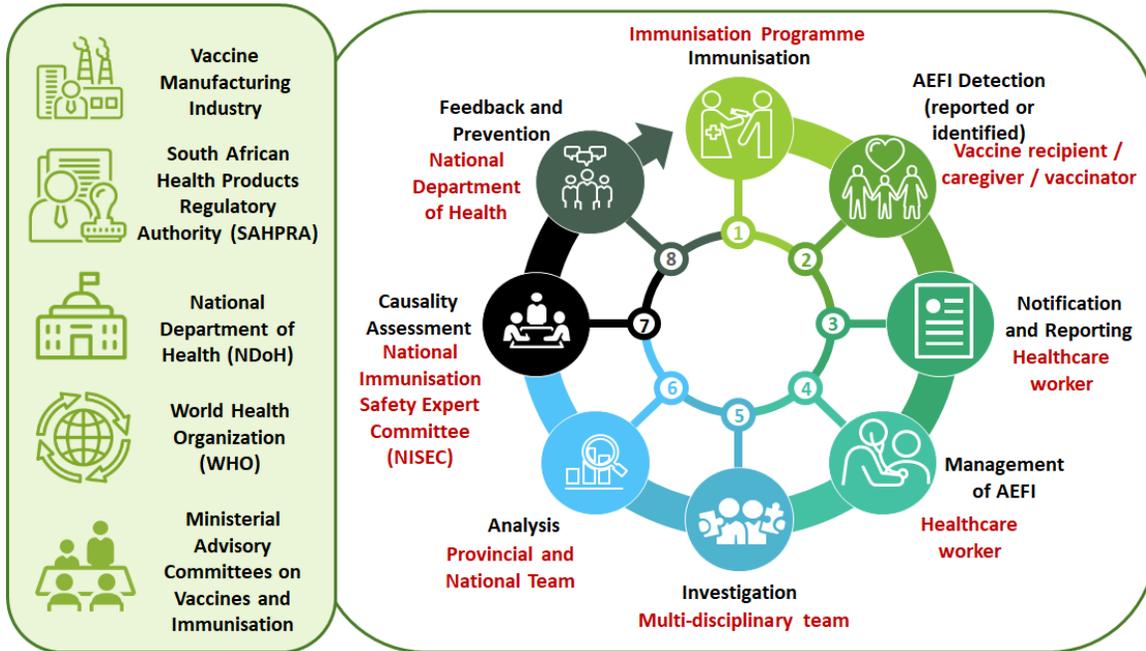
Conditions that are commonly considered as AESI include serious events that have followed other immunisations, for example, the following:

- Guillain-Barré syndrome (GBS)
- Acute disseminated encephalomyelitis (ADEM)
- Anaphylaxis
- Serious events potentially related to novel platforms and adjuvants
- Serious events related to vaccine failure/immunogenicity (vaccine-associated enhanced disease)
- Events that are potentially important for specific populations e.g. HIV infected clients.

The vaccine safety surveillance cycle

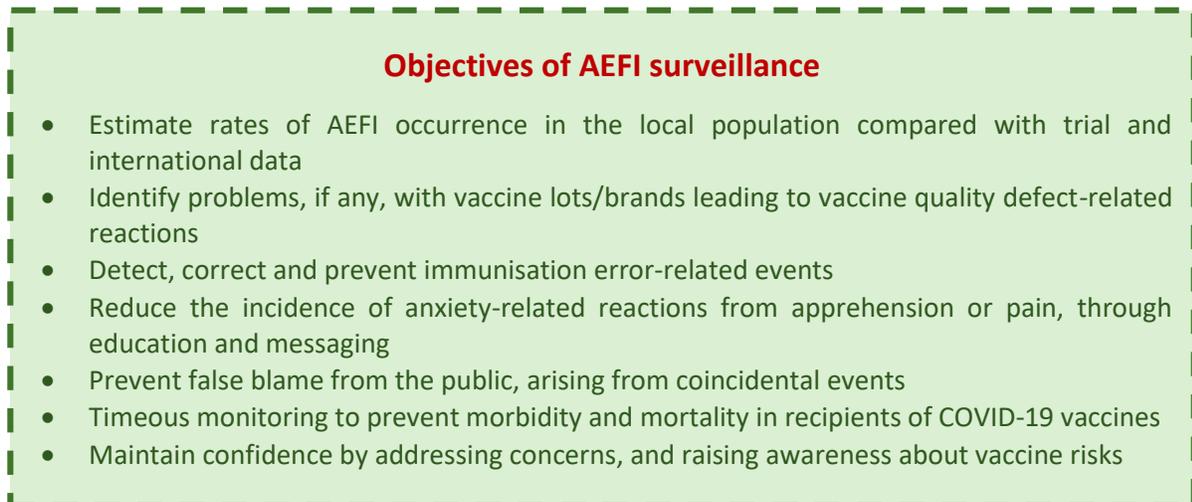
Successful surveillance of AEFI is only possible through the collaborative efforts of various key players and stakeholders. In South Africa, we already have a vaccine safety surveillance system in place within the Expanded Programme on Immunisation (EPI) (refer Figure 19).

Figure 19: AEFI surveillance cycle, key players and stakeholders



The vaccine safety surveillance cycle consists of several key steps to monitor the safety of vaccines, starting at the point where the vaccine is administered within the vaccination programme. The steps that follow thereafter include, identification or detection of an AEFI, notification, and reporting of such an event and the management thereof if necessary. This is followed by the investigation of the adverse event by a multi-disciplinary health care team, analysis of the data collected, causality assessment by an expert committee, and finally communication on the outcome of the causality assessment of the event, including future prevention of any vaccine safety risks. The same process will apply to COVID-19 vaccinations.

Figure 20: Objectives of AEFI surveillance



Categories of AEFI for reporting for COVID-19 vaccines

Figure 21 provides a summary of the different categories of AEFI, with a brief description of each category. Implications for reporting and investigation of AEFI within the context of COVID-19 vaccination are highlighted.

Figure 21: Categories of AEFI and implications for COVID-19 vaccines

<p>Minor reactions</p> <p>Report within 24 hours</p>	<ul style="list-style-type: none"> Do not pose a potential risk Usually occur within a few hours of vaccination Resolve after short period of time Important to inform and assure vaccinees of such events 	<p>Local and systemic reactions can occur as part of the immune response. Other vaccine components can trigger reactions. Reporting of all COVID-19 AEFI is compulsory.</p>
<p>Severe reactions</p> <p>Report within 24 hours Investigate within 48 hours</p>	<ul style="list-style-type: none"> Usually require clinical management Usually do not result in long-term problems Can be disabling but are rarely life threatening Can be vaccine specific reactions to the antigen or another component of the vaccine 	<p>Vaccines are only approved for use when frequency of severe reactions is very rare. Information on rare and very rare AEFI with COVID-19 vaccines is lacking.</p>
<p>Serious event</p> <p>Report within 24 hours Investigate within 48 hours</p>	<p>Any untoward medical occurrence resulting in:</p> <ul style="list-style-type: none"> Death Hospitalisation or prolongation of existing hospitalisation Persistent or significant disability or incapacity Congenital anomaly/birth defect or could be life-threatening 	<p>Information on serious, rare and very rare adverse events following COVID-19 vaccination is lacking.</p>
<p>Cluster</p> <p>Report within 24 hours Investigate within 48 hours</p>	<p>Two or more AEFI cases of the same or similar events related in:</p> <ul style="list-style-type: none"> Time/place/geographical setting; and/or Vaccine (batch/lot, manufacturer, facility) 	<p>Clusters are anticipated when vaccines are administered on massive scale, as with COVID-19. Chances for immunisation errors, immunisation anxiety-related reactions and coincidental events are much higher than with routine immunisation.</p>
<p>Signal</p>	<p>Information arising from</p> <ul style="list-style-type: none"> One/multiple sources (including observations) Suggesting a new potentially causal association, or new aspect of a known association, between vaccine and event/set of related events, either adverse or beneficial Judged to be of sufficient likelihood to justify verification 	<p>Signal detection, verification & response is a key activity in COVID-19 context. Best done by pooling data.</p>

AEFI reporting implications for COVID-19 vaccination: Data about rare and very rare adverse events, as well as adverse events with delayed onset, may still be lacking at the time COVID-19 vaccination services are provided because no clinical trial can be powered to detect these events. Additional information will be needed for which AEFI and AESI surveillance has to be strengthened.

Clinical trial results showed that the **majority of adverse reactions with COVID-19 vaccines were mild to moderate in severity.**



For COVID-19 vaccines, reports on **severe or serious AEFI** must reach SAHPRA within **24 hours** of occurrence through an expedited process. Reports of **minor AEFI** must reach SAHPRA within **7 days**.

Vaccinators will be tasked with the responsibility of providing education to clients on possible adverse events identification and immediate reporting thereof to their health establishment and/or health care provider/s.

Health care providers must report ALL AEFI, whether minor or severe, within **24 hours** of identification of an AEFI, or being notified by the vaccinee about the AEFI. Investigation of severe and serious AEFI must be done within **48 hours** since the AEFI has been identified or the health establishment or vaccination site has been notified thereof.

Causes of AEFI and implications for monitoring COVID-19 vaccine safety

A vaccine reaction is an individual’s response to the inherent properties of the vaccine, even when the vaccine has been prepared, handled, and administered correctly. It must be noted that reported adverse events can either be true adverse events resulting from the vaccine or the vaccination process, or they could be coincidental events that are not due to the vaccine or the vaccination process but are temporally associated with immunisation.

Figure 22: Causes of AEFI and implications for COVID-19

Consistent with causal association to immunisation		Inconsistent with causal association to immunisation
<p>Vaccine product-related reaction</p> <p>Caused or precipitated by a vaccine due to one or more of the inherent properties of the vaccine product</p> <p>Implications for COVID-19</p> <ul style="list-style-type: none"> • Identification of rare and very rare adverse events is not sufficient at the time of COVID-19 vaccine registration • More information will be needed for which AEFI surveillance has to be strengthened 	<p>Vaccine quality defect-related reaction</p> <p>Caused/precipitated by a vaccine, due to one/ more quality defects of the product</p> <p>Implications for COVID-19</p> <ul style="list-style-type: none"> • Knowledge of potential vaccine quality defects might not be sufficient for new vaccine platforms at time of registration • Rapid scaling up of vaccine production poses additional potential risks • Identification of exact substance causing event is needed 	<p>Coincidental event</p> <p>An event that happens after vaccination but is not caused by the vaccine or vaccination process</p> <p>Implications for COVID-19</p> <ul style="list-style-type: none"> • Coincidental events will be of utmost importance for COVID-19 vaccination and one of the reasons for active surveillance of AESI • Because of potential comorbidities in vaccine recipients, it will be challenging to differentiate true coincidental events from COVID-19 vaccine product-related reactions or drug reactions or interactions • Coincidental events can occur in healthy individuals without comorbidities • Knowing population-based incidence (background rates) of pre-specified AESI helps to anticipate and respond to such events
<p>Immunisation error-related reaction</p> <p>Caused by inappropriate vaccine handling, prescribing or administration</p> <p>Implications for COVID-19</p> <ul style="list-style-type: none"> • Vaccines will be administered on massive scale within short time interval; larger number of immunization error-related reactions are anticipated if preparation is insufficient • Staff who are not familiar with immunisation might assist • Multiple vaccines with different specifications for administration, dose and storage, may in be in use 	<p>Immunisation anxiety-related reaction</p> <p>Arising from anxiety about the immunisation and fear of injection</p> <p>Implications for COVID-19</p> <ul style="list-style-type: none"> • Larger number of immunisation anxiety-related reactions are anticipated due to numerous factors including <ul style="list-style-type: none"> ○ older age groups ○ different vaccinating environments ○ novelty of the vaccines and their administration modalities • Example: Vasovagal syncope following vaccination 	

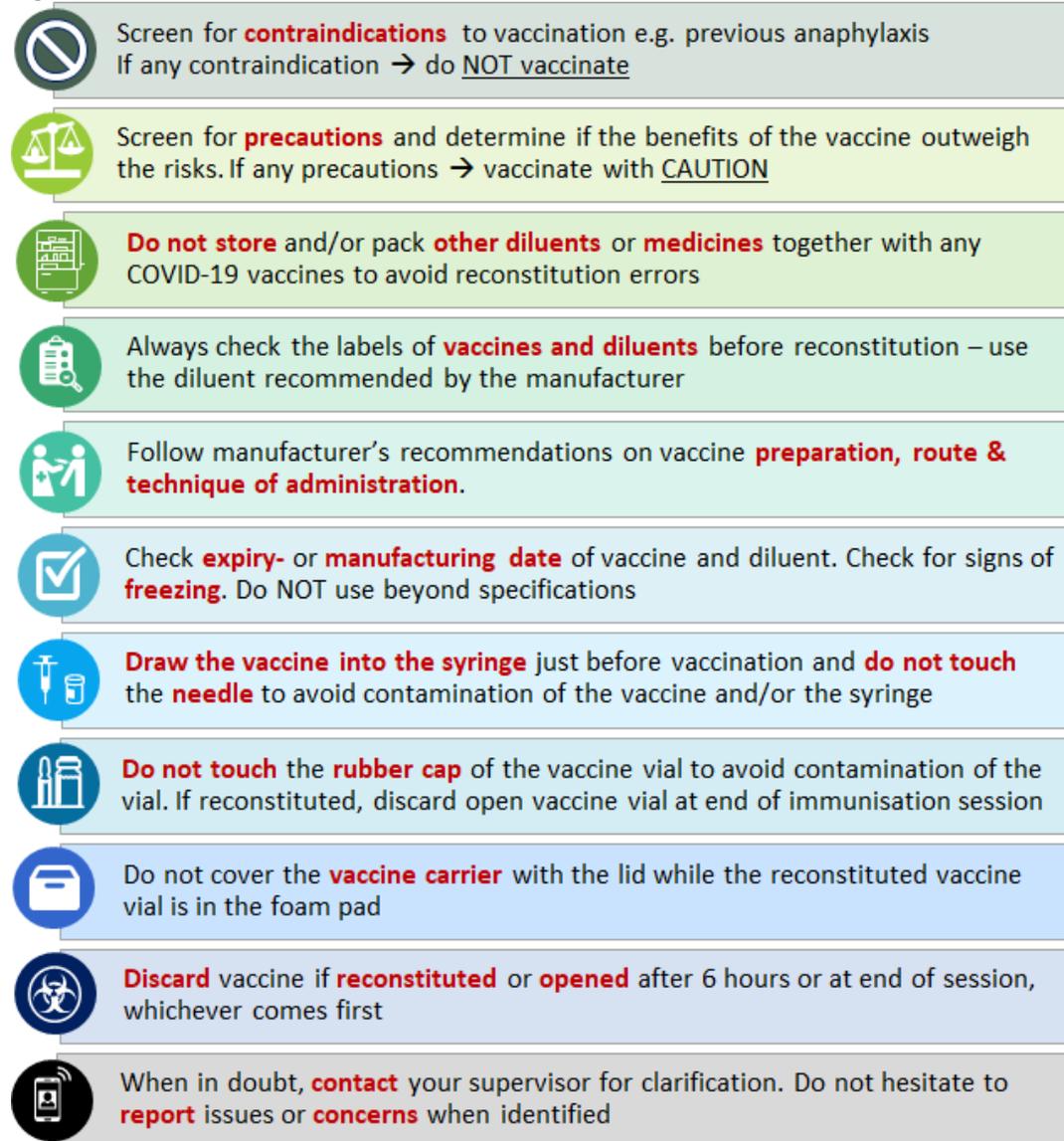
Implications for COVID-19 vaccination: Vaccines will be administered on a massive scale within a short time interval. Hence, a larger number of immunisation error-related reactions are anticipated if preparation and training are insufficient, staff who are not familiar with immunisation might assist, and multiple vaccines with different specifications for storage, dose, administration may be in use. All these factors can introduce human error.

Preventing immunisation programme errors contributing to AEFI

1. Screen the client for any **contraindications** to vaccination. Contraindications are rare characteristics in vaccinees that increase the risk of a serious adverse reaction if the vaccine is given. In the case of contraindication, do NOT vaccinate.
2. Screen for **precautions**, which are events or conditions that should be considered in determining if the benefits of the vaccine outweigh the risks. If so, vaccinate with CAUTION. Refer to Chapter 6 for more information on contraindications and precautions.
3. Vaccination should take place in a controlled setting, with the vaccinee staying at the vaccination site at least 15 minutes after vaccination.

A summary of the most common principles which should be adhered to in practice, to prevent any immunisation error related to AEFI, are outlined in Figure 23.

Figure 23: Prevention of immunisation error related AEFI



Reporting and investigation process for AEFI and AESI

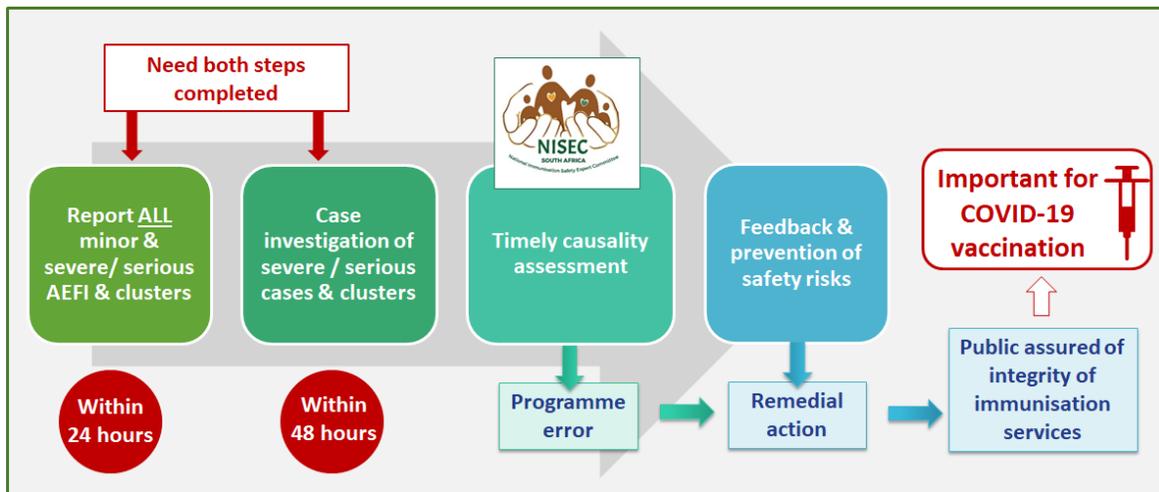
The ultimate goal of timely reporting and investigation of all AEFI and AESI is:

1. Timely **causality assessment** of reported cases should take place **within a maximum of 30 days**.
2. If any programme errors are identified, immediate remedial action can be taken.
3. Preventing any safety risks and effective safety communication, that will assure the public of the integrity of the vaccination services, and create confidence in vaccination, which is essential with COVID-19 vaccination.

Who is responsible for AEFI and AESI reporting?

- All health care workers providing vaccination services have a **professional responsibility** to report any adverse events
- Health care workers providing clinical treatment of AEFI and AESI in health establishments
- Vaccinees
- Researchers conducting clinical trials or field trials.

Figure 24: Goal of reporting and investigation of AEFI



For COVID-19 vaccines, reports on severe or serious AEFI must reach SAHPRA within 24 hours of occurrence through an expedited process. Reports of minor AEFI must reach SAHPRA within seven days. All case reporting forms submitted to the EPI Programme at the NDoH will be submitted to SAHPRA by the National AEFI Coordinator, and the vaccine manufacturer within the stipulated time. Updated reports will be submitted as cases are being investigated and causality assessment completed.

Data collection tools for AEFI and AESI surveillance

Table 14 shows the existing tools used for the reporting, investigation, management, and processing of AEFI data which have been adapted for COVID-19 vaccination, as recommended by the WHO.

All paper-based data collection tools are available as annexures (as indicated in Table 14) and can be downloaded in electronic format from the NICD and SAHPRA websites respectively at <https://www.nicd.ac.za/diseases-a-z-index/adverse-event-following-immunization-aeft/> and <https://www.sahpra.org.za/health-products-vigilance/>.

Table 13: Data collection tools – AEFI and AESI

Tool	Purpose	User
Med Safety App and Annexure: Case reporting form (CRF) for AEFI	To collect basic reports of ALL AEFI cases reported, minor, serious, and severe	All vaccinators and other health care workers who receive notification of AEFI
Annexure: Case reporting form (CRF) for AESI	To collect basic reports of ALL AESI reported, minor, serious, and severe	All vaccinators and other health care workers who receive notification of AESI
Annexure: Case investigation for (CIF) for AEFI and AESI	To collect detailed information when serious and severe AEFI cases, clusters, and AESI are investigated	Multi-disciplinary investigation team
Annexure: AEFI line list	To collate details in the CRF/CIF	District, Province, and National AEFI coordinators
Annexure: AESI line list	To collate details in the CRF/CIF	District, Province, and National AEFI coordinators

IMPORTANT: Electronic reporting through the **Med Safety App** is now the preferred method of reporting ALL AEFI. The Med Safety App is a mobile application available for Android and iOS devices, enabling health care workers and the public to report AEFI for vaccines and suspected adverse drug reactions (ADRs) for medicines.



Download instructions and information videos about the Med Safety App:

- Module 4, Knowledge Hub
- <http://medsafety.sahpra.org.za/>

Questions or challenges experienced with the use of the Med Safety App:

- Email: adr@sahpra.org.za
- Helpline: 012-5010311 (weekdays; office hours)



The case reporting form (CRF) which is available on the Med Safety App, should be completed for ALL AEFI, as the first step in the reporting process. The Med Safety App can also function offline if the user does not have an internet connection. Reports can therefore be created offline and submitted when the user has connectivity. However, the paper-based reporting system can still be used if the reporter experiences difficulties in using the Med Safety App.

For more information on the use of the Med Safety App, refer to the lecture video in Module 4 of the NDoH training course on COVID-19 vaccination, available on the Knowledge Hub.

All AEFI and AESI case reporting, case investigation, clinical records, and other relevant documentation should be submitted to AEFI@health.gov.za.

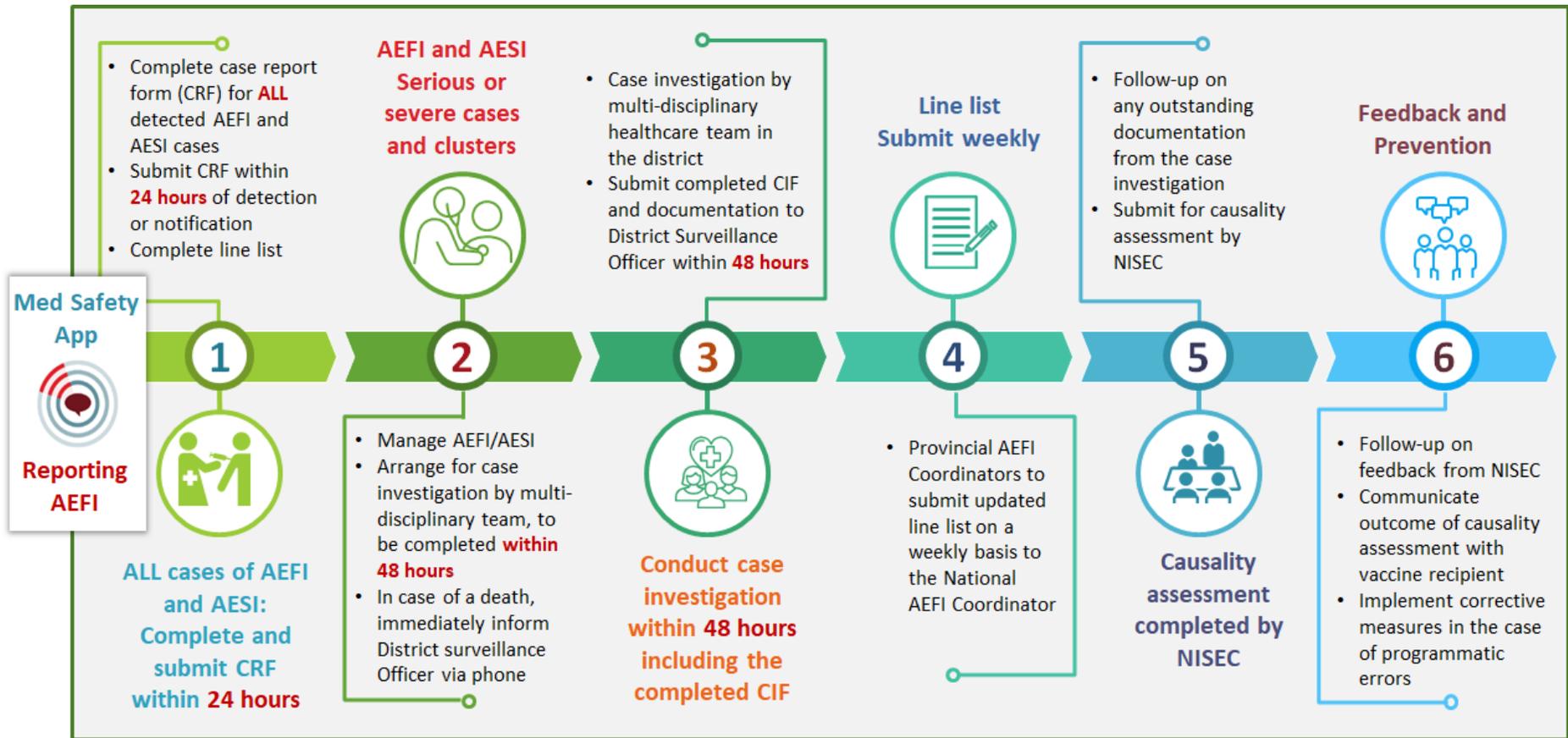
Health care workers must adhere to the stipulated timelines for reporting of ALL AEFI, followed by case investigation of severe and serious cases and clusters. Furthermore, ensure that all forms are accurately completed, and all supporting documents are attached for causality assessment by the National Immunisation Safety Expert Committee (NISEC).



Prerequisites for AEFI causality assessment

- 1. Case investigation completed**
Both the CRF and CIF completed, with case investigation completed.
- 2. Specific diagnosis**
There must be a specific “diagnosis” (clinical signs, abnormal laboratory finding, symptom and/or disease) which is being investigated for, and association with vaccination.
- 3. Details and evidence**
All details of the case should be available at the time of assessment, including supporting documentation (e.g. clinical notes, laboratory results, autopsy report).

Figure 25: Key steps in the reporting process for all AEFI and AESI



Chapter 8: Monitoring and Evaluation

Monitoring the outcomes of the COVID-19 vaccination programme is essential.

Monitoring and evaluation:

Monitoring and Evaluation (M & E) will be aimed at supporting the implementation of the COVID-19 vaccination programme. Several key indicators have been developed to monitor the COVID-19 vaccination programme implementation. Monitoring of progress is crucial to ensure that the set targets are reached within the set time frame.

If it is apparent that the targeted people cannot be reached within the time frame, micro-plans should be revised. Additional manpower may be required, or it may be necessary to extend the period of the vaccination programme.

At the end of the vaccination programme all levels, from sub-district to the district, to province and at the national level, will conduct a similar exercise to determine the coverage reached versus the set target; both in the number of people reached and the percentage. Monitoring data must be used to track performance, progress, challenges, and gaps to inform decision-making and assist managers to take action where problems arise.

Using the monitoring data, managers at various levels should be able to:

- Monitor vaccine availability and stock-outs at the vaccination sites, district, and provincial levels;
- Monitor equity in vaccine distribution and accessibility;
- Monitor performance of different types of vaccines used (disaggregate);
- Integrate and compare public and private sector data;
- Monitor uptake & coverage for the target population in various settings for the different phases;
- Monitor trends of indicators over time;
- Compare performance at provincial, district, and vaccination site levels;
- Monitor adverse events by gender and age

Monitoring data and reports must be used to prompt action for continuous service delivery improvement. Each indicator will consist of data elements (numerator and denominator):

Indicators: EVDS has been designed to calculate the indicators to track and monitor performance and progress made in the implementation of the COVID-19 Vaccination programme. The EVDS will produce dashboards (tables, bar/line graphs) showing performance indicators by various disaggregation (national, provincial, district, facility/vaccination site, age-group, gender, vaccine product, period, etc.).

Numerators: Data for numerators (e.g., number of clients vaccinated) will be captured and/or recorded by the vaccinators in the EVDS. The EVDS will also be linked to the SVS COVID-19 instance to extract data to be used to monitor COVID-19 vaccine stock availability. Data on the number of clients experiencing AEFI will be obtained from the vaccine safety surveillance programme at the NDoH.

Denominators: Data for most of the denominators are obtained from existing information systems. Data on total population by age, gender, or province of residence will be sourced from mid-year population estimates of Statistics South Africa.

The **evaluation** will focus on the effectiveness of the programme and the vaccine itself. It will test the COVID-19 infection rates and death rates following COVID-19 vaccination, and associated factors. The Department will also document lessons learnt and facilitate knowledge exchange among stakeholders and beneficiaries.

The main indicators to measure progress with COVID-19 vaccines are similar to any vaccine introduction:

Vaccine uptake: The number or proportion of people vaccinated with a certain dose of vaccine in a certain time period (e.g., during a month or year); also referred to as % vaccination rate.

Vaccination coverage: The vaccinated proportion of a target population, which is similar to uptake, but considers vaccination in previous time periods. Over time, coverage can be constructed by accounting for uptake in previous time periods (weeks, months, years), depending on the duration of protection of the vaccine. For the year of introduction (2021), uptake and coverage can be used interchangeably.

The indicators have been formulated in accordance with phased vaccine introduction and the target population in each phase. The full list of indicators and description, numerators, denominators, data sources & disaggregation is contained in the National Indicator COVID-19 Vaccination Set as a reference document.

Table 14: High-Level Summary of Indicators

Indicator Category	Indicators	Disaggregation	Data Source
Vaccination Sites	Number of vaccination sites compliant with criteria	Private/public sector, province, and district	MFL
Vaccination Sites	Number of sites approved to provide COVID-19 vaccination services	Private/public sector, province, and district	MFL
Vaccinators	Number of vaccinators allocated per site	Private/public sector, province, and district	EVDS
Vaccinators	Average number of vaccinees vaccinated by each vaccinator/day	Private/public sector, province/district/vaccination site	EVDS
Vaccinators	Number of vaccinators clinically trained on COVID-19 vaccination	Private/public sector	EVDS
COVID-19 Vaccine Supply Chain	Number of vaccines procured	National Department of Health	Supplier contracts and stock received at central stores
COVID-19 Vaccine Supply Chain	Number of vaccine doses distributed/allocated to vaccination sites	Private/public sector, province/district/vaccination site	Stock Visibility System
COVID-19 Vaccine Supply Chain	% vaccination sites reporting vaccine stock out	Private/public sector, province/district/vaccination site	Stock Visibility System

Indicator Category	Indicators	Disaggregation	Data Source
Vaccination Coverage	% of people fully vaccinated against COVID-19	Geographic coverage, age categories, gender, vaccine type, insured/uninsured, private & public vaccination sites	EVDS
Vaccination Coverage	Proportion of the target population fully vaccinated against COVID-19	Geographic coverage, age categories, gender, vaccine type, insured/uninsured, private & public health vaccination sites, beneficiary group	EVDS
Dose uptake	Vaccine dose 1 vaccine uptake rate	Geographic coverage, age categories, gender, vaccine type, private & public health vaccination sites, beneficiary group	EVDS
Drop-out	Dose 1 to 2 Dropout rate (Drop-out refers to persons who received the first dose of a 2-dose vaccine but do not return for their second dose for any reason)	Geographic coverage, age categories, gender, vaccine type, private & public health vaccination sites, beneficiary group	EVDS
Adverse Events Following Immunisation	Number of vaccinated individuals reporting minor to moderate adverse events following vaccination	Geographic coverage, age categories, gender, vaccine type, private & public health vaccination sites, beneficiary group	EVDS & Vaccine AEFI system NDOH & SAHPRA
Adverse Events Following Immunisation	Number of vaccinated individuals reporting adverse events following vaccination	Geographic coverage, age categories, gender, vaccine type, private & public health vaccination sites, beneficiary group	EVDS & Vaccine AEFI system & SAHPRA
Post-vaccination COVID-19 infection	Post-vaccination COVID-19 infection rate	Geographic, cases, admissions, mortality	Data Lake

Tools for Monitoring and Evaluation:

- ***Annexure: COVID-19 Vaccine Dashboard Navigation Guide***

Addendum Frequently asked questions about the vaccination programme

Theme	Question	Response
Client and health care personnel's rights	What are the rights of a client?	<p>The South African Constitution states that everyone has a right to health care and that nobody should be denied emergency medical treatment.</p> <p>A client has a right to participate in decisions that affect his or her personal health and treatment including receiving COVID-19 vaccines.</p> <p>A client must adhere to the rules of the health establishment or other place where vaccination services are provided when receiving treatment or using health services at a health establishment.</p>
	What are my rights as a vaccinator (health care personnel)?	<p>Health care personnel may not be unfairly discriminated against based on their health status.</p> <p>A health care worker may refuse to treat a client who is physically or verbally abusive and who sexually harasses him or her.</p>
Approval of vaccination sites	What are the requirements for registration as a vaccination site?	<p>A health establishment that wishes to provide vaccination services, or a non-health establishment that wishes to provide vaccination services as a fixed outreach service, must register or update details on the Master Facility List (MFL) hosted by the National Department of Health (NDoH). The registration includes selecting services to be provided e.g. vaccination services, outreach services, and/or distribution services. Once the facility is curated and approved on the MFL, an application token for a Section22A(15) vaccination site permit will be sent to the facility representative for completion.</p>
	What requirements/criteria are applied to enable places to qualify as an outreach service (secondary vaccination site). Can vaccines be stored on-site?	<p>A primary vaccination site is a public or private health establishment, registered on the MFL, with vaccination services activated. It is required to hold a permit issued in terms of Section 22A (15) of the Medicines and Related Substances Act 101 of 1965 (the Medicines Act). The site is listed on the Electronic Vaccination Data System (EVDS). A primary vaccination site may act as a vaccination hub and manage the outreach services linked to it.</p> <p>Outreach service is 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 (CCS), a temporary outreach service with passive cold chain (PCC), or by a mobile outreach service at multiple points.</p>

Theme	Question	Response
		<p>Fixed outreach service means a place that is not a health establishment, set up on a semi-permanent basis, and equipped with the required furniture and equipment at which vaccination services are provided. Fixed outreach services store COVID-19 vaccines and other medicines required to support the administration of COVID-19 vaccines on-site. They must be linked to a health establishment, with a pharmacy registered with the South African Pharmacy Council (SAPC). The pharmacy must have a responsible pharmacist registered as such with the SAPC. The linked pharmacy will apply for an internal change with the SAPC, which should be approved before vaccines or other medicines can be stored at the fixed outreach service. It requires a section 22A (15) permit.</p> <p>Temporary outreach service means a place where vaccination services are provided on a temporary basis and is linked to a primary vaccination site. Passive cold-chain containers are used, and vaccines are not stored on-site. The service must be recorded on the MFL, linked to a primary vaccination site. It does not require a section 22A (15) permit – functions under the permit of the primary site.</p> <p>Mobile outreach service means a vaccination service linked to a health establishment with vaccination services (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. No Section 22A (15) permit is required – functions under the permit of the primary site.</p>
	What is meant by a vaccination hub?	A vaccination hub is a primary vaccination site (e.g., at a district hospital) that has been designated to provide vaccination services and is accountable for the vaccination programme in the area e.g., a sub-district. A primary vaccination site acts as a hub and manages outreach services (secondary vaccination sites) linked to it.
	Why must a vaccination site have a Section 22A (15) permit?	Section 22A(5)(f) of the Medicines Act provides that any schedule 2-6 medicines shall not be sold by any person other than a pharmacist and pharmacy personnel (on the prescription of an authorised prescriber in the case of medicines in schedule 3 and higher), a medical practitioner or dentist or a nurse or other health care professional where the medicines that may be sold are provided in the schedules to the Medicines Act. This Act also provides the rules for controlling medicine, such as ordering, prescribing, dispensing, and recording of transactions.

Theme	Question	Response
		<p>Section (22A(15) states that '<i>Notwithstanding anything to the contrary contained in this section, the Director-General may, after consultation with the South African Pharmacy Council as referred to in section 2 of the Pharmacy Act, 1974 (Act No. 53 of 1974), issue a permit to any person or organisation performing a health service, authorising such person or organisation to acquire, possess, use or supply any specified Schedule 1, Schedule 2, Schedule 3, Schedule 4 or Schedule 5 substance, and such permit shall be subject to such conditions as the Director-General may determine.</i>'</p> <p>For COVID-19 vaccination services, the permit is issued to an organisation so that individual vaccinators do not have to be authorised prescribers in terms of the Medicines Act, as well as providing a mechanism of formalising the approval of vaccination services and provision of the required oversight.</p>
Vaccine administration	Who is a vaccinator?	<p>Vaccinator means a person who administers a COVID-19 vaccine to a client.</p> <p>Vaccines must only be administered by a health care provider registered and in good standing with his/her relevant professional council. He/she must have been trained in the administration of COVID-19 vaccines and the management of any related adverse events and be competent to provide such services. The administration of vaccines must form part of the vaccinator's scope of practice.</p> <p>Covid-19 vaccination services must only be provided in accordance with all relevant laws, regulations, rules, and guidelines, and utilising medicines on the applicable list provided by the NDoH.</p>
	Can the vaccine be drawn up by another person other than the vaccinator?	Where COVID-19 vaccines are administered outside of a clinical trial/ implementation study, vaccines may only be drawn by the vaccinator who will administer the vaccine.
Personnel required at vaccination sites	Do all sites require a pharmacist?	<p>According to Section 22A (15) of the Medicines Act, the Director-General may, after consultation with the SAPC issue a permit to any person or <i>organisation</i> performing a health service, authorising such person or organisation to acquire, possess, use or supply medicines subject to conditions decided by the Director-General.</p> <p>Fixed outreach sites (which are not health establishments) are required to be linked to a registered pharmacy with a responsible pharmacist. The off-site storage for vaccines at a fixed outreach site must fall under the control of the responsible pharmacist of the pharmacy to which it is linked.</p>

Theme	Question	Response
	Does my site require a pharmacist's assistant?	Pharmacist's assistants (basic) and pharmacist's assistants (post-basic) are registered with the SAPC. They may, in terms of the Pharmacy Act 53 of 1974 (the Pharmacy Act), practise under the direct supervision of a pharmacist in a pharmacy or under the indirect supervision of a pharmacist in a primary health care clinic. They may fulfil the role of a vaccine controller or a vaccine champion at a vaccination site provided they are functioning in terms of their scope of practice and the requirements relating to supervision.
	What training is required as a vaccinator?	The National Department of Health is providing a 14-hour training course. This course is accredited by the Health Professions Council of South Africa. This training is specific to COVID-19 vaccinations.
Information relating to the vaccine	Do I have a choice as to where I receive the vaccine?	<p>In the case of health care personnel, most hospital personnel will be vaccinated at their place of work with personnel providing health services at the primary health care level being vaccinated either at their place of work or as part of an outreach service. This may differ from province to province.</p> <p>The general public will be advised to use a vaccination site closest to them.</p> <p>Area-based planning will be used and only age will dictate your position in the queue. The planning and scheduling are such that the vaccination journey is designed to offer the same quality regardless of the site or area, thus minimising the need for preference for certain sites and areas.</p>
	Can I select which vaccine I will receive?	South Africa has procured a limited number of different vaccines which provide similar protection. Most clients will receive the vaccine available at the vaccination site where they receive their vaccine. In some cases, it may be necessary to use an alternate vaccine for medical reasons. Advice in this regard will be provided by the vaccinator and the health care personnel providing health care services to the client.
	What if I don't want the vaccine that is being offered?	A client has a right to participate in decisions that affect his/her personal health and treatment. Every client must be informed of the benefits, risks, implications, and obligations associated with the option to either agree or refuse health services. This must be done in a language clearly understood by the client, also bearing in mind their level of literacy.

Theme	Question	Response
	How will patient confidentiality be maintained?	All the client's information, including their health status, treatment or stay in hospital, is strictly confidential. No one may disclose this information unless the user consents in writing and unless ordered by the court. In some cases, non-disclosure of key information may pose a threat to public health.
	How is the vaccine ensured to be safe?	<p>By their nature, no medicine is ever completely risk-free. Great care is, however, taken to make sure medicines are safe for public use. During the various stages of development, manufacturing, and use of medicines, there is continuous evaluation of their safety and efficacy. Before approval is provided to make medicines available for use in a country, medicines are evaluated by the relevant medicine regulatory authority. In South Africa, this function is performed by the South African Health Products Regulatory Authority (SAHPRA).</p> <p>In the case of COVID-19 vaccines, the sale of vaccines may be authorised in terms of Section 21 of the Medicines Act. This type of authorisation enables SAHPRA to approve the sale of unregistered medicines subject to certain conditions. Vaccines may also be registered subject to certain conditions. The vaccines will continuously be monitored by authorities for quality, efficacy, and safety.</p>
	How is my personal information protected?	<p>According to the National Health Act, the person in charge of a health facility in possession of a client's health records must set up control measures to prevent unauthorised access to those records and to the storage facility where records are kept.</p> <p>It is the responsibility of the client to provide the health care personnel with accurate information about his or her health status and to co-operate with health care personnel when using health services.</p>
	What information needs to be captured during the screening process?	<ul style="list-style-type: none"> • Method of identification i.e. SA ID document, passport, asylum seeker, or refugee • Date of birth • Name and surname • Contact number • Physical address • Appointment preference for time • Do you have COVID-19 symptoms? Yes, or No? • If yes, please explain. • Do you have pre-existing conditions and allergies? • Are you a member of a medical aid scheme?

Theme	Question	Response
		<ul style="list-style-type: none"> • Have you ever tested positive or been ill from COVID-19?
	Does the consent differ if it is a vaccine approved via section 21 of the Medicines Act or registered subject to certain conditions?	<p>Authorisation in writing may be given by the SAHPRA for the sale of a specified quantity of an unregistered medicine for a specified period of time subject to certain conditions. SAHPRA may at any time withdraw this authorisation. One of the conditions of this kind of authorisation often relates to clients who receive the medicine being provided with specific information and giving informed consent.</p> <p>In the case of COVID-19 vaccines registered subject to certain conditions, these conditions may also relate to certain information being provided to clients and the obtaining of informed consent.</p>
Waste disposal	How do we manage waste disposal at a site?	<p>Various pieces of legislation describe the precautions to be taken for the prevention of injury, ill-health, or death of persons who may be exposed to unused vaccines, used ancillary items, and personal protective equipment resulting from the provision of vaccination services.</p> <p>The disposal of medicines such as vaccines is prescribed in the General Regulations published in terms of the Medicines Act. Other important pieces of legislation include the Pharmacy Act 53 of 1974 and the Good Pharmacy Practice rules published in terms of the Pharmacy Act 53 of 1974, the National Environmental Management: Waste Act 59 of 2008, National Environmental Management Act 107 of 1998, and the Hazardous Substances Act 15 of 1973).</p>
Management of injuries/ incidents at vaccination sites	How do we manage needle prick injuries or other incidents?	The usual procedure would be followed.
	How do we deal with any incidents or injuries on-site?	<p>Any person may lay a complaint about how he or she was treated at a health establishment and have the complaint investigated.</p> <p>The relevant member of the Executive Council must establish a procedure for the laying of complaints within those areas of the national health system for which they are responsible.</p> <p>The procedures for laying complaints must be displayed by all health establishments.</p>

Theme	Question	Response
		<p>In the case of a private health establishment, allow for the laying of complaints with the head of the relevant establishment.</p> <p>The proper procedure followed at an “ideal clinic” should be followed at all health establishments. An ideal clinic is defined as one with good infrastructure, adequate staff, adequate medicines and supplies, good administrative processes, and sufficient adequate bulk supplies. Applicable clinical policies, protocols, and guidelines are adhered to, and it harnesses partner and stakeholder support.</p>
	How do I report adverse events?	You complete the adverse events following immunisation and adverse events of special interest form. In the case of COVID-19, you fill in the Case Reporting Form for Suspected Adverse Events of Special Interest COVID-19. The form requires details that form part of the investigation following the immunisation and the adverse reaction thereafter. The form and all supporting documents should be emailed within 24-hours to aefi@health.gov.za and copy the District EPI Surveillance Officer.
	What does the section 21 reporting for SAHPRA include?	Medicines accessed through Section 21 do not undergo the scrutiny of a benefit-risk assessment applied to medicine registration submissions or clinical trial applications. Additional reporting requirements are thus imposed by SAHPRA and may differ for each product approved in this manner.
Vaccine storage and distribution	Where can vaccines be stored?	<p>Vaccines may be stored at primary distribution sites, primary vaccination sites, and fixed outreach vaccination sites. Temporary vaccination sites may not store vaccines overnight. For mobile teams operating from a primary vaccination site, vaccines will be carried by vaccination teams. There will be no storage of vaccines on site.</p> <p>Vaccines are thermolabile products and must be stored in a cold room, freezer or refrigerator depending on the product-specific temperature requirements. Detailed requirements are provided in the rules relating to pharmacy practice published in terms of the Pharmacy Act.</p>
	What are the legislative requirements for the storage of vaccines?	The refrigerator, cold room, or freezer must be connected to a standby generator or other emergency power system to ensure an uninterrupted power supply in the event of power failure.

Theme	Question	Response
		<p>The storage area must allow for the orderly arrangement of products, to permit air circulation and proper product rotation.</p> <p>The storage area must be clean and properly maintained to restore factory standards.</p> <p>Recording devices that meet WHO specifications must be installed to monitor and record temperatures.</p> <p>They require controlled temperature storage where they are monitored and recorded at least two times a day.</p> <p>These records must be reviewed regularly.</p>
	<p>What is the legislative requirement for the distribution of vaccines?</p>	<p>For transportation of vaccines to vaccination sites, the route must be planned and assessed beforehand to ensure that delays that may expose vaccines to extreme temperatures are avoided.</p> <p>During transportation within South, Africa temperatures must be monitored strictly due to distance and large geographical areas.</p> <p>Temperature data loggers, refrigeration tags, freezer tags, log tags, or cold chain monitoring cards that meet WHO specifications must monitor the temperature throughout the trip.</p>
	<p>What is the PFMA process to procure ancillary items?</p>	<p>Supply chain procedures should be followed, as should compliance with grant procurement procedures.</p> <p>The Public Finance Management Act (PFMA), 1999 (Act No. 1 of 1999) promotes economy, efficiency, effectiveness, and transparency in the use of state resources and one of its key objectives is to eliminate waste and corruption in the use of public assets.</p>
	<p>How will billing work for private clients?</p>	<p><i>Medical</i> aid schemes are obliged to <i>pay</i> for COVID-19 <i>vaccinations</i> for their clients. Private clients will indicate during registration for vaccinations that they are medical aid scheme members, and the scheme will be billed directly.</p>
	<p>Can I be turned away from a site or refused vaccination?</p>	<p>If a client's details are not verified on the EVDS, they may be enrolled on the system at the vaccination site. If possible the client may receive their vaccination at the site on the same day. If not, they will be asked to return at a later date.</p>