Version 1

COVID-19 Vaccine Implementation Guide and Toolkit

health

Department:
Health
REPUBLIC OF SOUTH AFRICA

2030 NDP

The roll-out of the COVID-19 vaccination programme will continue over an extended period of time. As we learn from the experiences of implementation, strategies and approaches may need to be adjusted and refined. This COVID-19 Vaccine Implementation Guide and Toolkit may, therefore, be subject to revision.

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This implementation guide and toolkit supports the South African COVID-19 vaccination programme. The implementation guide was developed under the guidance of the National Department of Health's Child, Youth and School Health Cluster with significant engagement, participation and support of all relevant clinical and support programmes. Robust engagement and contributions of provincial and district representatives further enriched the guide and toolkit.

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- World Health Organisation (WHO)
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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 provider
ID	Identity document
IEC	Information, education and communication
IPC	Infection prevention and control
ISSR	Immunisation stress-related response
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
USSD	Unstructured supplementary service data
WHO	World Health Organisation

List of Definitions

Glossary	Definition
Adverse event following immunisation	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 or swabs, etc.
Civil society	The "third sector" of society, along with government and business, includes civil society 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 managed within a specified temperature range 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 in 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
Disposal	The removal of vaccines, ancillary items, used personal protective equipment (PPE) destined for destruction without the intention of retrieval, in compliance with applicable 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 received the vaccine from a vaccinator registered on the EVDS at an approved vaccination site registered on the Master Facility List

Glossary	Definition
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
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
National Surveillance Centre (NSC)	A web-based performance monitoring and evaluation tool used by the National Department of Health (NDoH) to provide visibility of stock levels of medicines and personal protective equipment and improve availability across all provinces

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

[2] IBID

Glossary	Definition
National Immunisation Safety Expert Committee (NISEC)	Independent ministerial advisory committee responsible for casuality assessment of all severe and serious adverse events following immunisation
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	Receiving (delivery) site means a place to which COVID-19 vaccines are delivered by a distributor contracted by the National Department of Health. A delivery site could be a primary distribution site, a primary vaccination site or a fixed outreach service.
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 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	A process to identify a client with 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

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

[4] Ibid

Glossary	Definition
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
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 provider 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 or specified communities 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

Key to icons used

Objective or goal

Annexure

Important infomation

URLs

Critical

EVDS

Requires authorisation or sign off

MFL

Provincial

Observer teams

Area-based teams

District teams

Vaccination site managers

Vaccinators

Vaccine scheduler

Covid-19 screening officer

Onsite assisted registration person

Site/queue marshal

Vaccine champion

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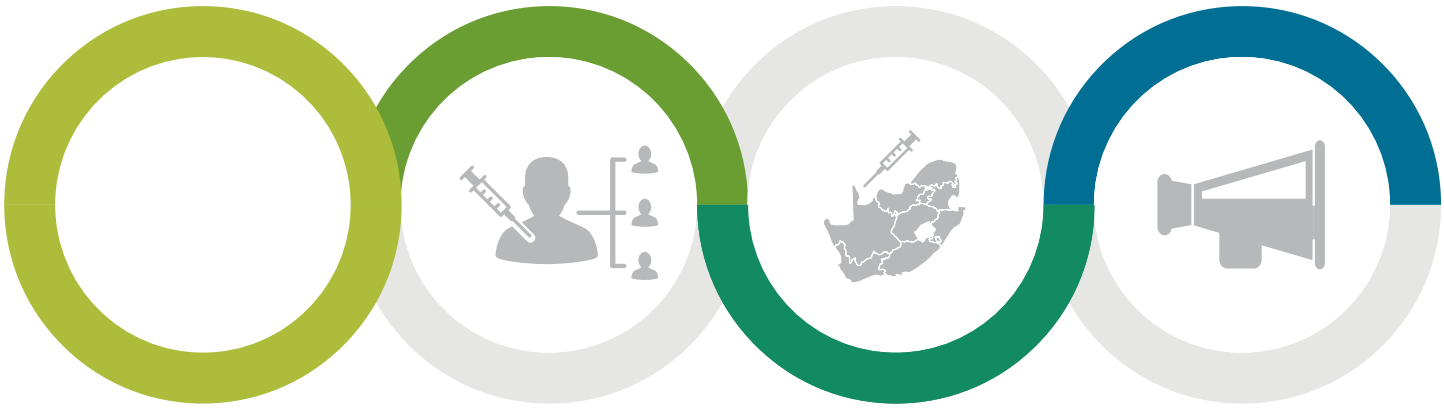

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Message to the reader

You are part of one of the most important public health interventions of our time!

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. 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 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 the eligible population. 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.

Guide purpose

This guide and toolkit flow from the National Vaccination Plan. It provides information and tools that will help support the key elements of the design of the Vaccination Programme to:

- **ensure effective leadership**
- **maximise the speed of the national rollout**
- **ensure fair and efficient access for all**
- **standardise delivery processes to ensure quality**
- **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 providers, administrative and support staff, community health workers and community volunteers will all benefit from using this resource.

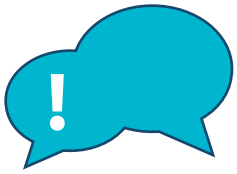
TAKE NOTE

Information in this guide will be updated as the programme unfolds.

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 where vaccinations are provided, the teams that support the vaccine rollout at various levels, and describes the journey that will be followed by each member of society who receives the vaccine. It also provides information about the supply chain that supports the availability of vaccines and ancillary items at vaccination sites.



The toolkit will not contain every single detail or provide answers to every question. But it does let you know where you can find more information.

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.

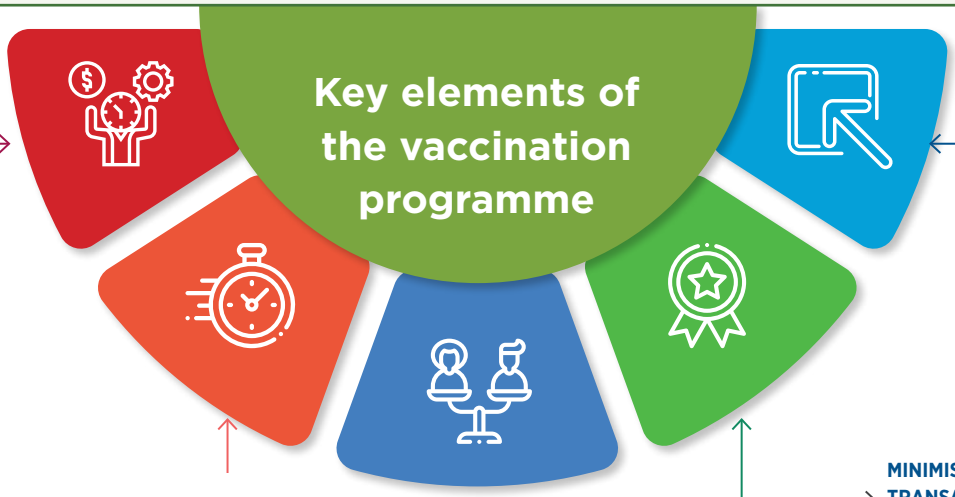
Depending on your specific role in the team, you may not be required to coordinate all aspects covered in this guide. But each member of the team must have a good understanding of all the systems and processes that need to come together to implement a successful programme.

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

1

OUR SHARED GOAL
VACCINATING SOUTH AFRICANS

Key elements of the vaccination programme



ENSURE EFFECTIVE LEADERSHIP

- Clear and mandated leadership at every level
- Galvanise public & private vaccination teams
- Integrated communication systems across all platforms

MAXIMISE SPEED OF NATIONAL ROLLOUT

- Deployment of all available resources in public, private and NGO sectors
- Three parallel vaccination queues
- General public (public or privately managed) Occupational health services
- Institutions of care & correctional services
- Highly efficient mass vaccination sites

ENSURE FAIR AND EFFICIENT ACCESS FOR ALL

- Only your age decides your place in the national queue
- Area-based planning & coordination

STANDARDISE DELIVERY PROCESSES TO ENSURE QUALITY

- Area-based planning & coordination system as unit of replication

MINIMISE SERVICE TRANSACTION TIMES

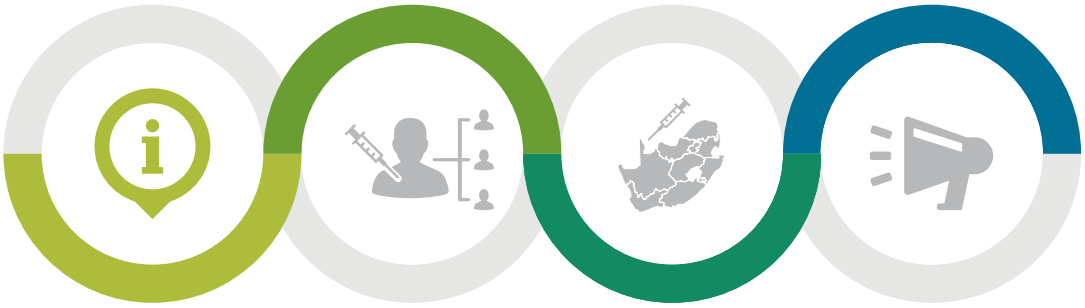
- Simple enrolment and vaccination processes
- Simple information system with fewest data points

Clarity	Speed	Fairness	Quality	Simplicity
Effectively lead at national, provincial and district level	Takes place efficiently in parallel vaccination queues by harnessing the expertise of other sectors	Provides fair access based on age and delivery to all communities	Standardised quality service at all vaccination sites defines the process to meet the needs of clients using a client-centric approach	Clear public communication empowers and informs delivery teams and clients

Structure of the Guide and Toolkit

This document is structured in two parts:

- **Implementation Guide** and
- **Compendium of guidelines, tools, and additional information**. Links are provided in the implementation guide to the documents included in the compendium.



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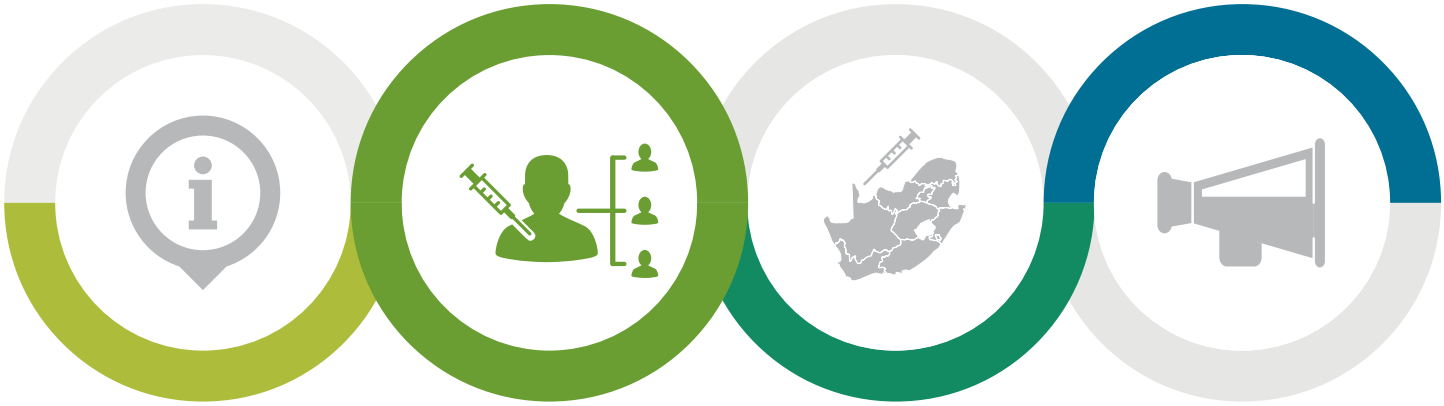

CHAPTER 2

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Chapter purpose

Chapter 2 covers the proposed vaccine delivery mechanisms:

1. The phased rollout approach
2. Sector roles and responsibilities
3. Coordination of vaccination sites
4. Planning of vaccination services

The contents of this chapter will be useful for

Provincial teams

District teams

Area-based teams

Vaccination site managers

Phased approach

The South African COVID-19 vaccination programme follows 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 was necessary because of the initially limited supply of approved COVID-19 vaccines.

The phasing determined by the National Department of Health (NDoH) and will be communicated to stakeholders via circulars.

Sector roles and responsibilities for vaccine introduction

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 of different sectors

PLANNING FOR VACCINE INTRODUCTION

National

- Provide clear goals, guidelines, and tools

Provincial

- Adapt and implement guidelines and tools to support COVID-19 vaccination services
- Set goals and develop plans for the province
- Analysis and synthesis of area-based plans to guide appropriate strategies

District

- 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

National

- Procure vaccines approved for use by the South African Health Products Regulatory Authority (SAHPRA)
- Award national contracts for the warehousing and distribution of vaccines to primary distribution sites and primary vaccination sites
- Process vaccine orders

Provincial

- Ordering and distribution within the province of vaccines and other supplies
- Plan provincial allocation to sites
- Place orders for vaccines and ancillary supplies

District

- Ensure availability of vaccines and ancillary supplies at vaccination sites
- Report data relating to vaccines and ancillary supplies

2

STANDARDS

National

- Develop criteria, guidelines, and standards for implementation of the vaccination programme in both the public and the private sectors

Provincial

- Provide input into criteria, guidelines, and standards for implementation of the vaccination programme
- Implement vaccination programme in the province based on criteria, guidelines, and standards
- Monitor and evaluate implementation of the programme

District

- Implement vaccination services at district level in accordance with criteria, guidelines and standards
- Supervise vaccination services
- Monitor and evaluate implementation of the programme in the district

ADVOCACY, COMMUNICATION, AND SOCIAL MOBILISATION

National

Develop national plan for advocacy, communication, and social mobilisation (ACSM)

Provincial

- Generate demand at provincial level using ACSM

District

- Engage and educate stakeholders and communities
- Monitor and address vaccine hesitancy with clients

RESOURCES

National

- Mobilise resources

Provincial

- Plan for, and allocate resources

District

- Utilise resources
- Manage resources

COLD CHAIN AVAILABILITY AND LOGISTICS

National

- Support availability of adequate cold chain equipment and logistics arrangements for vaccine storage and distribution at national level

Provincial

- 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

District

- Comply with logistical procedures, vaccine storage, and distribution requirements, and administration of the vaccine to the target population

TRAINING

National

- Make suitable training courses available for personnel involved in the provision of vaccination services, through the Knowledge hub in-line with the Human Resource and Development strategy of NDOH

Provincial

- Facilitate the provision of training courses via the Regional Training Centres (RTCs)

District

- Support vaccination site managers to make sure personnel providing vaccination services are trained and competent

ADVERSE EVENTS FOLLOWING IMMUNISATION SURVEILLANCE

National

- Provide systems, tools, and guidelines to support robust adverse events following immunisation (AEFI) surveillance, AEFI case management, and causality assessment

Provincial

- Monitor provincial vaccine safety surveillance, facilitate causality assessment, and provide provincial AEFI line-list

District

- Report all AEFI and assist with case investigation, allocate epidemiological number (EPID number), and input data into the provincial line-list

2

The district and area-based level

Establishing a District COVID-19 Vaccination Team

Key information

The district health manager responsible for COVID-19 vaccine introduction should facilitate the process of **establishing a District COVID-19 Vaccination Team.**

It is recommended that district or metro officials 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.

District COVID-19 Vaccination Team roles, time commitments and functions (for public and private sector)*

Role	Time Commitment	Function
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
Finance District Lead	Can be filled by an individual with other responsibilities	Provide effective financial management and advice to facilitate compliance with financial processes
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
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 vaccination 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 (second dose where applicable) are in place

 Role	 Time Commitment	 Function
Vaccine Safety, Surveillance and Response District Lead	Should 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 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
Information systems (IT)/ Electronic Vaccination Data System (EVDS)/ Enrolment support District Lead	Should 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 and SVS 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
Supply chain lead	Can be filled by an individual with pharmaceutical experience with other responsibilities outside the team	Coordinate, manage and monitor vaccines, ancillary supplies and waste disposal in the vaccination programme
Operational support for EVDS, SVS, and Master Facility List (MFL)	Can be filled by an individual with other responsibilities outside of the tea	Operationalise EVDS, SVS and provide support where required
Operational Support and Queue Management District Lead	Should be filled by an individual who is committed, 100% of the time, to the team	EVDS Vaccination scheduling for all vaccination sites
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
Area-based Planning and Coordination District Lead (Site readiness and quality improvement)	Should 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 line with the site typology and vaccine delivery model Support the districts with service delivery and quality improvement

2

Establishing area-based teams

Key information

The District COVID-19 Vaccination Team should be supported by area-based teams which can be established at ward, sub-district, or district level.

Aim: Implement **a standardised set of processes in a defined area**. The **coordination of a single unit** can be **replicated across the community**.

If the team gets this right in one area, it can be more easily replicated in other areas.

Area-based teams are at the heart of the collaborative approach driving the National Vaccination Programme.

The area-based approach is a new way of thinking about service 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 'do their own thing', giving some sectors of society an advantage over others and unnecessarily duplicating efforts.

FORMALISED COLLABORATION

The framework establishes area-based teams which work closely with district and metro health officials who are leading the vaccination programme.

Area-based team leaders

Area-based team leaders will be health care providers 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 area-based team

Facilitate coordinated **local planning** and **implementation**

Engage with **communities**

Provide **management** and **technical support** to the vaccination teams

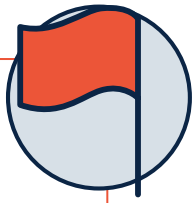
Facilitate **participation of local providers** in provision planning

Composed of:

- Local public, private and civil society partners, specifically designated (in the case of public officials) or seconded into the team
- Public and private service providers

Legal standing and accountability:

- 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)
- Accountable to their respective employers to ensure compliance with applicable legislation, protocols, and standards



Priorities for the area-based team

- **Plan together** to ensure that the eligible population, 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 the phasing of the vaccination roll-out
- Help **ensure that all the necessary management systems come together** by working with members of the district health management office, private providers, and NGO partners.

ASK YOURSELF

Have you been able to make use of all the expertise available in the area?

2

Coordinating COVID-19 vaccination sites in a local area

Key information

APPROVAL AND SIGN OFF OF SITES

The Head of Department or Provincial Vaccine Lead must 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.

District vaccination teams will play an important coordinating role in the effective delivery of vaccinations at a local level. Practical decision-making is needed to:

- ☐ **Identify and set up vaccination sites, and outreach and mobile services in an area**
- ☐ **Educate and mobilise communities to create demand for the vaccine**
- ☐ **Overcome the challenges that may arise**

COVID-19 vaccines may not be sold to individuals, as **all communities must have equal access to a vaccine**

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

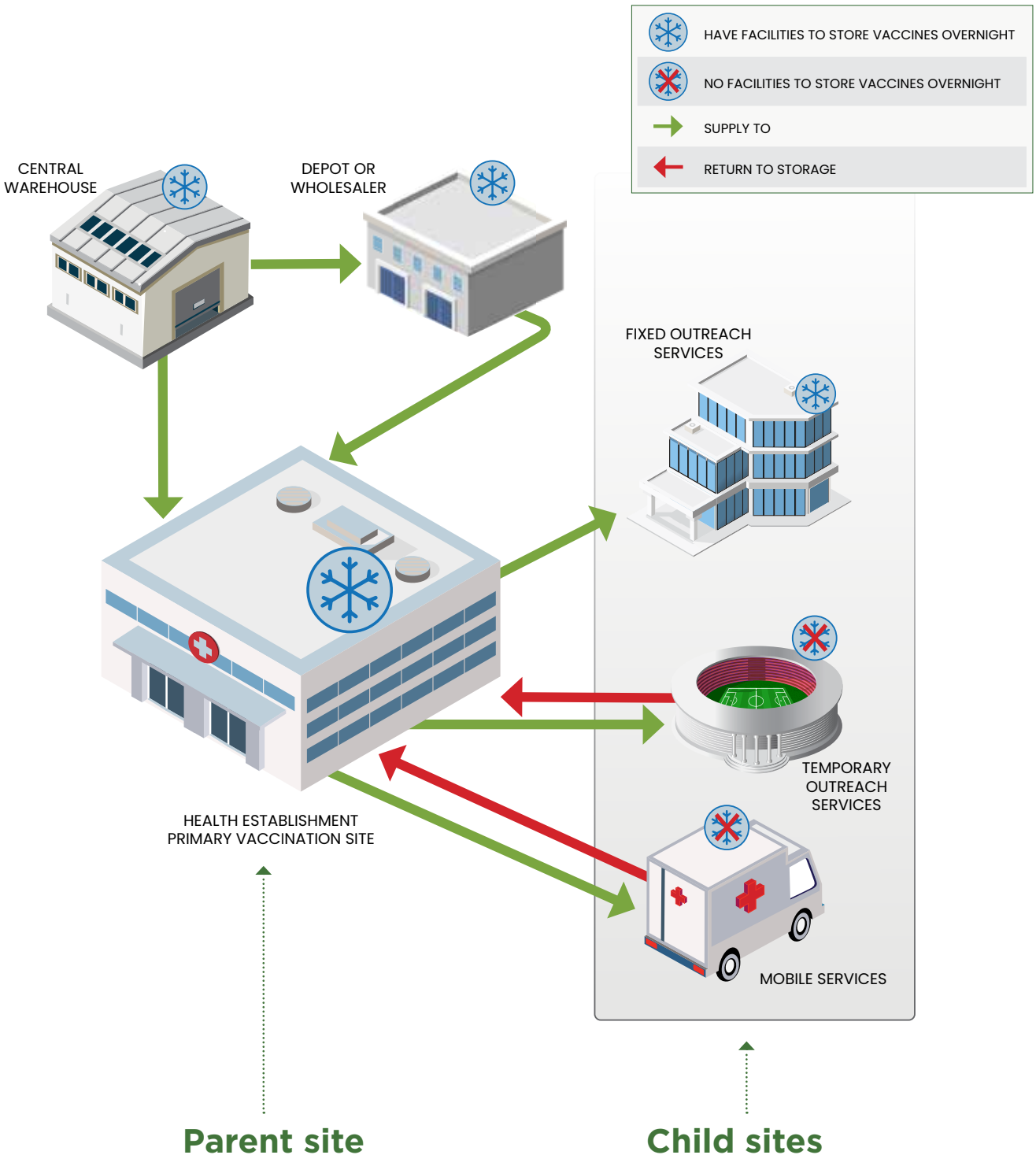
Types of vaccination sites

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

Private & public sector consider:

- Population needs
- Geospatial planning
- Cold chain capacity

DIFFERENT TYPES OF VACCINATION SITES



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General principles for potential vaccination sites

ANNEXURE:

Standard Operating Procedure for the identification, application for, and approval of COVID-19 vaccination sites

SUMMARY

Section 22A(15) of the *Medicines and Related Substances Act,* 101 of 1965 (known as **the Medicines Act** for short) is the legislation that governs which establishments can provide vaccination services.

The Director-General: Health approves the health and other organisations that can provide COVID-19 vaccination services. Applications for a permit (valid for two years) should be submitted online to the NDoH.

A COVID-19 Vaccination Services Permit requires:

- the health establishment to **comply with NDoH the legal and regulatory requirements of the NDoH**
- vaccines to be administered by **health care providers registered and in good standing with their professional council and who are trained** in giving vaccines and managing possible AEFIs
- only the **approved medicines (COVID-19 vaccines Janssen® and Comirnaty®)** to be administered **in accordance with the relevant regulations**
- the fixed outreach service to be **specified on the permit and be overseen by a pharmacy**

The permit holder is responsible for ensuring the permit requirements are met and adhered to. Non-compliance can result in closure of the site and a breach of the sales agreement.

These are the specific details you should familiarise yourself with

- The provisions of section 22A(15) of the Medicines and Related Substances Act 101 of 1965 (the Medicines Act) are used to approve organisations including health establishments, that wish to provide vaccination services for the administration of COVID-19 vaccines
- All organisations or health establishments 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 (refer Annexure: Standard Operating Procedure for the identification, application for, and approval of COVID-19 vaccination sites)
- Permits are issued subject to certain conditions:
    - the health establishment 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 on the applicable list (COVID-19 vaccine Janssen® and Comirnaty® vaccine) provided by the NDoH
    - in the case of a fixed outreach service, COVID-19 vaccination services are only provided at the non-medical site specified on the permit and with the necessary oversight provided by a pharmacy
- 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
- 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 (COVID-19 vaccine Janssen® and Comirnaty® vaccine) and related medicines (required for treatment of anaphylaxis) recommended by the NDoH as part of COVID-19 vaccination services
- All sites at which COVID-19 vaccines are stored are required to report on the NDoH Stock Visibility System (SVS)
- A permit is valid for two years unless it is withdrawn by the Director-General. A permit may be withdrawn, revoked or suspended by the Director-General in terms of regulation 26(7)(c) of the General Regulations published in terms of the Medicines Act, if the holder fails to comply with any condition of the permit
- Non-compliance to the conditions of the permit could result in closure of the vaccination site (primary vaccination site and/or outreach services), and could result in breach of the sales and distribution agreement

2

Primary vaccination sites

A health establishment needs a permit to provide vaccination services

A primary vaccination site...

- ☐ is a place at a health establishment where vaccination services may be provided
- ☐ has the facilities to store vaccines overnight
- ☐ requires a section 22A(15) permit issued by the Director General: Health in terms of the Medicines Act

Ownership may be...

- ☐ public
- ☐ private

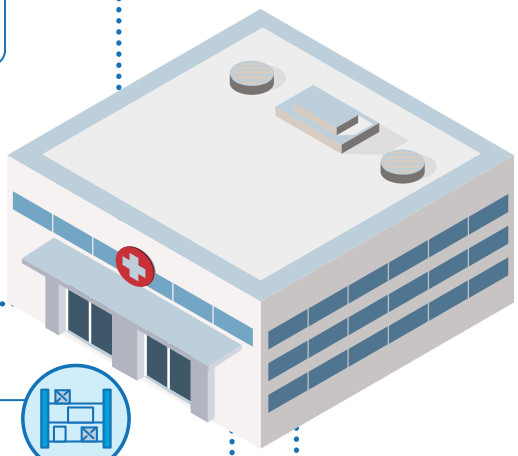
Registration and permit requirements

Registered on MFL as a facility (Vaccine site and distribution site [if applicable] are activated under services at facility)

- ☐ 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

How is the site **managed?**

- ☐ Managed by the organisational structure of the health establishment



What services can you expect of the site?

- A primary vaccination site acts as a hub or 'mother', to support outreach services (fixed, outreach and mobile) and other health establishments that do not have capacity to store vaccines overnight
- Distribution services may be provided from a primary vaccination site to another primary vaccination site and/or to an outreach service

REMEMBER:

Vaccine services, and distribution services **must be activated on the MFL.**

The **human resources** required for vaccine management

A vaccine champion manages the vaccine supply chain at a place where vaccines are administered

A vaccine controller manages the storage, supply and distribution of vaccines, and the updating of data on SVS

Some **examples** of a primary vaccination sites

- **Public Sector** - Hospitals, community health centres, primary health care clinics, health establishments linked to the Departments of Correctional Services, National Defence and Education
- **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

PRINCIPLES

- Primary vaccination sites may provide outreach services as a **fixed outreach service, temporary outreach** or **mobile outreach service.**

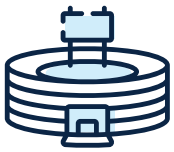
- Vaccination services may also be provided from a **primary vaccination site at another health establishment** such as a temporary or mobile services. This situation would apply for example, where a temporary outreach service is provided at a small health establishment e.g. a **clinic or general practitioner's practice**, which does not have suitable cold chain capacity to store vaccines on-site or where the target population is small.

- In some cases, a primary vaccination site that holds a permit may not provide vaccination services on-site, however, **vaccination service should remain active on the Master Facility List (MFL),** while the **EVDS scheduling should be disabled.** Temporary or mobile services will continue to operate from the primary vaccination site.

Outreach services

FIXED OUTREACH SERVICES

TEMPORARY OUTREACH SERVICES



MOBILE SERVICES

Primary vaccination site or another health establishment

CLINIC OR GENERAL PRACTITIONER'S PRACTICE

Primary site not providing vaccination services on-site

REMAIN ACTIVE ON THE MASTER FACILITY LIST

DISABLE EVDS SCHEDULING

2

Fixed outreach services

A permit may be issued to a health establishment to provide vaccination services at a site which is not a health establishment **(a non-medical site)**

A fixed outreach service...

- ☐ **is a place, where vaccination services are provided on a semi-permanent basis**
- ☐ **is not a health establishment but is linked to a health establishment or organisation providing health 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**

Ownership may be...

- ☐ **public**
- ☐ **private**
- ☐ **NGO**

Registration and permit requirements

Registered as a facility on the MFL (Type: Fixed outreach site & Vaccine site activated under facility services

- ☐ Linked as a fixed outreach service by a health establishment or organisation providing health services on MFL
- ☐ Oversight must be provided by a registered pharmacy (which has applied for and received approval for an internal change to enable external (off-site) storage at the fixed outreach service)
- ☐ 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

How is the site **managed?**

- **Health establishment or organisation which operates the site** and holds the permit
- **Vaccination site manager**
- **Pharmacy** oversees external storage

What **services** can you expect of the site?

- **Vaccination services** (with EVDS scheduling of appointments)
- **Cold chain storage** capacity
- Does **not** distribute vaccines

REMEMBER:

Vaccine services, distribution services **must be activated on the MFL.**

The **human resources** required for vaccine management

A vaccine champion manages the vaccine supply chain at a place where vaccines are administered

A vaccine controller manages the storage, supply and distribution of vaccines, and the updating of data on SVS

Some **examples** of a fixed outreach service

- Any **non-health establishment** where vaccines are stored overnight (e.g. mass vaccination site at a private sector venue)

Fixed outreach services: *Principles*

PERMIT REQUIREMENTS

- The **permit is issued to the health establishment** to provide vaccination services at a non-medical site e.g. Hospital X/Stadium Y (NOTE: the permit is not issued to the site at which vaccination services will be provided). The health establishment must hold a separate permit for each non-medical site at which fixed outreach services will be provided.
- The **permit holder is responsible to ensure that the necessary professional support and oversight,** including access to emergency services is available.
- If the site where a fixed outreach service will be provided is not a health establishment, the facility must be registered on the MFL as a non-medical site. In cases where the fixed outreach service is coordinated by a provincial Department of Health (DOH), e.g. a public sector mass vaccination site e.g. at a Civic Centre, the site should be registered as a non-health site and the semi-permanent data thereof managed by the provincial DOH.
- In the case of large venues, fixed outreach services may be provided at different locations within the same venue (e.g. Hall A, Hall C etc.) by different health establishments/service providers, with a separate permit required for each one.

PHARMACY OVERSEES EXTERNAL STORAGE

- Where vaccines and other medicines are stored at a site which is a non-medical site (fixed outreach service), oversight must be provided by a pharmacy registered with the SAPC with a responsible pharmacist registered as such.
- Only COVID-19 vaccines and the medicines needed to manage anaphylaxis which may occur at the site, may be stored at a fixed outreach site. Such storage must be done in accordance with the provisions of Rule 1.8 of the Rules relating to good pharmacy practice published in terms of section 35A of the Pharmacy Act 53 of 1974 (Minimum Standards specifically relating to a storage area for pharmaceuticals outside the physical premises of a pharmacy).
- In terms of Rule 1.8.1 'Any storage area, which is not physically an integral part of the premises of a pharmacy, must constitute part of a pharmacy licensed by the Department of Health and recorded with Council (SAPC). Such a storage area must fall under the authority of the responsible pharmacist of the pharmacy of which it forms a part, and be operated in compliance with Good Pharmacy Practice. Thus, such a storage area cannot exist/operate independently of a pharmacy.
- The responsible pharmacist of a pharmacy that provides oversight of an off-site (external) storage area at a fixed outreach service, must submit an application for an internal change to the licence of that pharmacy for each external storage area (*Application for the approval of pharmacy premises – internal changes in terms of the Pharmacy Act 53 of 1974*).
- The number of external storage areas that may be supervised by a pharmacy and the supervision thereof is determined by the SAPC. The SAPC has resolved that:
  - a pharmacy may supervise up to five external storage areas at fixed outreach services;
  - each external storage area must be under the control of a pharmacist;
  - each storage area must be located within a reasonable geographic location of the pharmacy providing oversight and be within the same province;
  - approval will be granted for external storage areas at fixed outreach sites for a period not exceeding nine months.

SERVICES

- A fixed outreach service **may not** provide temporary or mobile outreach services.
- A fixed outreach service **may** operate as a delivery site.
- Distribution services **may not**, however, be provided to other outreach services from a fixed outreach service.

2

Temporary and mobile outreach service

Temporary outreach service...

- ☐ **Is not a health establishment but provides vaccination services on a temporary basis - is linked to a primary vaccination site**
- ☐ **can be rendered by roving teams from the health establishment with a vaccination service at the specific outreach point e.g. at an old age home, community hall**
- ☐ **uses passive cold chain containers, and vaccines are not stored on-site**

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 and from within a mobile clinic.**
- ☐ **uses passive cold chain containers, and vaccines are not stored overnight**

Ownership may be...

- ☐ **public**
- ☐ **private**
- ☐ **NGO**

Registration and permit requirements

- ☐ Registered as a facility on the MFL
- ☐ Linked as a temporary outreach service by a health establishment (primary vaccination site) on MFL
- ☐ Listed on EVDS
- ☐ Not listed on SVS
- ☐ No individual permit required; operates in terms of 22A(15) permit issued to primary vaccination site

How is the site **managed**?

- Managed by the primary vaccination site

What **services** can you expect of the site?

- Vaccination services provided
- **Temporary outreach services:** EVDS scheduling appointments
- **Mobile outreach services:** No appointments, moves from place to place
- Cannot store vaccines overnight
- Uses passive cold chain containers (cooler boxes)
- Does not distribute vaccines

Human resources required for vaccine management

A vaccine champion manages the vaccine supply chain at a place where vaccines are administered

Some **examples** of temporary and mobile outreach services

- **Temporary outreach sites** include churches, schools, halls, civic buildings, non-permanent OHS at places of work, congregate settings such as care homes, facilities for older persons or other pop-up sites
- **Mobile outreach services** include teams of vaccinators moving from place to place

No individual permit required. Operates in terms of section 22A(15) permit issued to primary vaccination site

Temporary and mobile outreach services: *Principles*

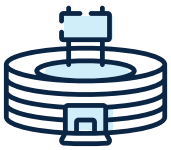
- Temporary and mobile outreach sites are not required to hold their own permit, but operate under the **permit issued to the primary (parent) site** from which they operate.

Permit holder

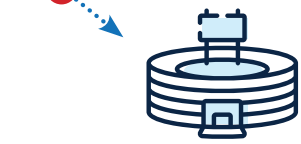
PERMIT ISSUED TO THE PARENT SITE

- Temporary and mobile outreach sites may **not** provide **services** from another outreach (child) site.

Other outreach (child) sites



TEMPORARY OUTREACH SITE



TEMPORARY OUTREACH SITE

- Temporary and mobile outreach sites may **not** provide **distribution** services.

Distribution

MAY NOT PROVIDE DISTRIBUTION SERVICES

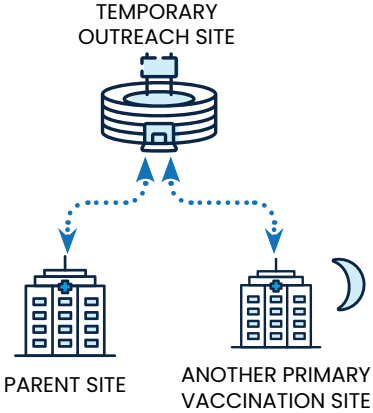
- Although some mobile units are listed on the MFL as health establishments, these units will **not store COVID-19 vaccines** overnight and are linked to a primary vaccination site as a mobile outreach service.

Vaccine storage

MAY NOT STORE VACCINES ON-SITE

- In some cases, vaccines may be stored overnight at **different primary vaccination sites**, as the outreach service may provide vaccination services at different locations and over weekends.

Overnight storage



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Distribution services

What you need to know about distribution services

Pharmacies that hold a licence issued in terms of section 22C(1)(b) of the Medicines Act (manufacturing and wholesale pharmacies) may provide distribution services, but do not require a section 22A(15) permit. These pharmacies may **not** provide vaccination services or support any outreach services

Community and institutional (public and private) pharmacies may provide distribution services. If such pharmacies do not provide vaccination services or support any outreach services, they do not require a section 22A(15) permit but are still required to report on SVS

Employees of an organisation providing distribution services who do not hold a section 22A(15) permit may be vaccinated on-site as part of a **workplace based vaccination programme**, by a provider, who holds a section 22A(15) permit

Primary vaccination sites where vaccines are stored, or from which they may be distributed **must be indicated on the MFL as a distribution site**

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

Vaccination sites are set up based on factors such as local health establishments, population size and density, and other variables.

District teams will play a role in identifying, coordinating, and managing the successful establishment of vaccination sites.

Micro-planning

Key information

A micro-planning exercise is a bottom-up approach to planning. Based on the target population and reality on the ground it should generate realistic estimates of the resources needed, these include:

- ☐ Human resources
- ☐ Financial resources
- ☐ Material resources

WHY IT IS IMPORTANT TO MICROPLAN

As the number of vaccines required for a local area may not be available all at once, it is necessary to have a planning process that will **allow for different phases of the vaccination programme, and take into account the number and type of vaccines available.**

Plan for

- Different phases of vaccination
- Different types of vaccines
- Different quantities of vaccines

2

Key information

NB INFORMATION TO COLLECT WHEN MICRO-PLANNING

- ☐ **The target population**: insured and uninsured persons by district, sub-district, and service delivery site catchment area per vaccination phase
- ☐ Target vaccination **group for each phase**
- ☐ **Number of health workers and local volunteers** available
- ☐ **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
- ☐ Identify how **primary vaccination sites and outreach services**, will be related to each other
- ☐ **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
- ☐ **The traditional and possible new partners** working at a local level, and their potential contributions to the vaccination programme

Planning outputs

STEP 1

Identification of the **locality and target population**

- **Potential vaccination sites:** lists of districts, sub-districts, and public and private health establishments
- **Identity of target population for vaccination:** by locality and phase of the vaccination roll-out (e.g. where they are and which target group)
- **Catchment areas:** space needed, cold chain requirements, vaccine logistics, means of transport, and human resources

STEP 2

Identify and **classify strategies for each population sub-group** by catchment area

- **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 services
- **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

STEP 3

Estimate logistics and supply needs by district and health establishment

- **Training and micro-plan:** for the district and each health establishment
- **Supplies:** estimated volume of vaccines and vaccination equipment and supplies, different types of cold chain equipment, IPC supplies, emergency trays, monitoring tools
- **Vehicles:** number and types of vehicles required, source of vehicles and fuel costs
- **Printed materials:** availability of monitoring tools, field guides, training materials etc.
- **Information, education and communication (IEC):** cost of communication and social mobilisation products by type of output (media announcements, IEC materials, community dialogue meetings, etc.)

STEP 4

Determine human resource requirements per health facility or district

- **Number of health workers and volunteers required for the vaccination teams:** including community mobilisers, marshals, administrative personnel, vaccinators, health educators, data capturers, vaccine champions, vaccine controllers, and waste management personnel
- **Estimated costs:** for field deployment of health workers and volunteers

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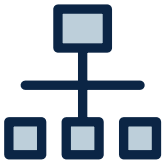
Key messages

Throughout the planning and implementation process, the **public and private sectors must collaborate** to facilitate equitable access of communities to the COVID-19 vaccine



District COVID-19 vaccination teams could be supported by area-based teams to enable successful implementation in all sectors. Area-based teams can be established at ward, sub-district, or district level

All organisations and health establishments that wish to provide COVID-19 vaccination services either at, or from a primary vaccination site, or as a fixed outreach service **must hold a permit issued by the Director General of the NDoH** in terms of section 22A(15) of the Medicines Act

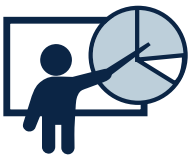
In the case of a fixed outreach service, COVID-19 **vaccination services may only be provided at the non-medical site specified on the permit** and with the necessary **oversight provided by a pharmacy**

Permits are issued subject to conditions, including compliance with requirements for the provision of COVID-19 vaccination services determined by the NDoH

The permit holder must ensure compliance with the conditions of the permit and **is accountable** for services provided by the primary vaccination site, as well as for outreach services provided from the site

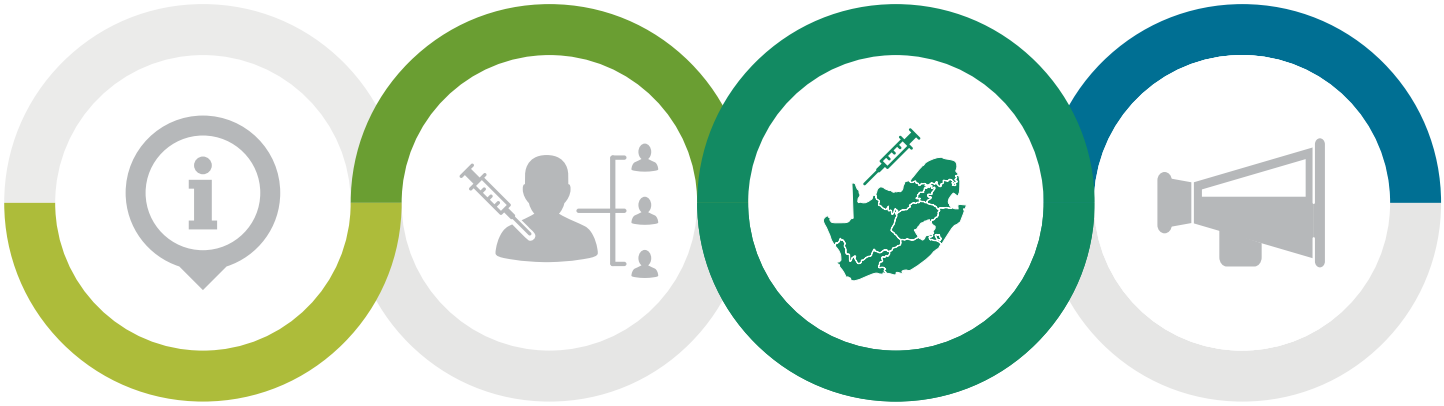
All sites at which COVID-19 vaccines are stored are required to report on the NDoH **Stock Visibility System (SVS)**

A permit may be withdrawn, revoked or suspended by the Director-General



Micro-planning should be conducted and allow for different phases of the vaccination programme and the number and type of vaccines available

Key steps in micro-planning include **identification of the locality and target population**, **identifying strategies to reach each population sub-group**, and **estimation of the human resources, supply needs and logistics required**



CHAPTER 3

Vaccination site set up and management

Chapter 5

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

Chapter 6

Effective vaccine management, cold chain, logistics, and distribution of COVID-19 vaccines

Chapter 7

Planning the client journey, and administration of COVID-19 Vaccines

Chapter 8

Vaccine safety surveillance

Chapter 9
Monitoring & Evaluation

3

Chapter purpose

Chapter 3 describes the different phases of

1. Vaccination site set up
2. Maintenance and monitoring
3. Closure

The contents of this chapter will be useful for:

Provincial teams

District teams

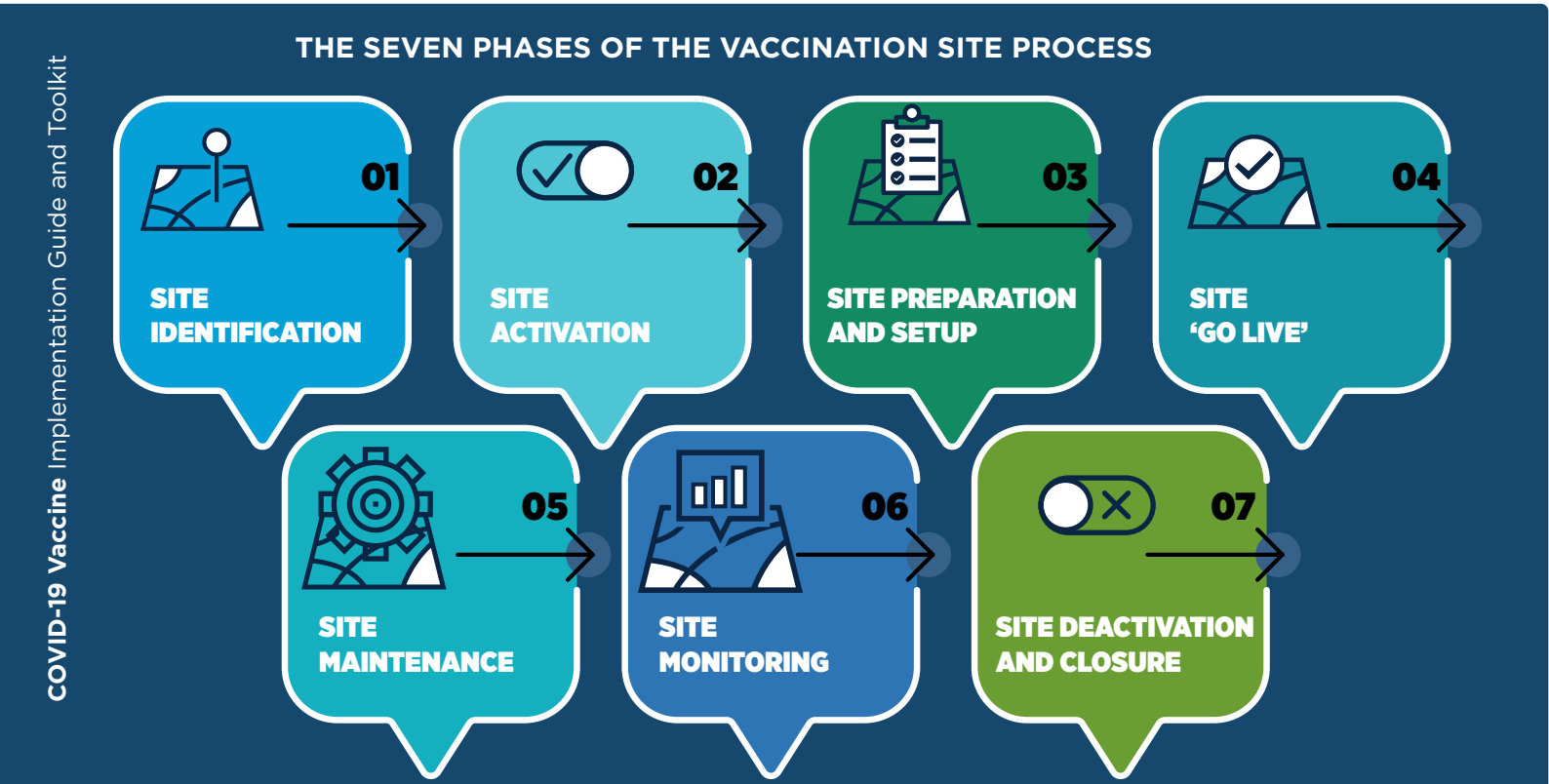
Area-based teams

Vaccination site managers

Vaccinators

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.



SITE IDENTIFICATION

District teams must identify suitable sites to allow for equitable access to vaccinations by all members of society.

The following is a list of the main factors to consider.

Sites must be **equally easy for all members** of the community to access
Is it easy to find and get there?
Are there steps? Is it centrally located?
What happens if it rains?

ACCESS AND ACCESSIBILITY

- ☐ Is the site well-known?
- ☐ Is the site centrally located for most people?
- ☐ How will most people be able to get there?
- ☐ Is there a public transport service nearby?
- ☐ Is there parking if peope use private transport?
- ☐ Is the road accessible if there's lots of rain?
- ☐ Can Emergency Medical Services access the site and evacuate a patient in an emergency?
- ☐ Is the site able to accommodate people who are older or living with disabilities?
- ☐ Can all members of the community access the site with equal ease?

Remember that older people, those who live with disabilities, and clients with limited mobility need to access the site. A single, level, non-slip floor surface from entrance to exit without any steps is ideal. If such a surface is not possible, an alternative entrance or vaccination area should be considered.

3

Site suitability

Although you may need to compromise on some factors, **safety isn't one of them**

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 will often be the best compromise, if so, you will need to consider these important factors:

SIZE

Is it big enough for logical flow of peope?

Compare the target population for vaccination against the size of the building. Clinics and community health centres are often too small to provide adequate space for a logical flow of clients presenting for vaccination

PRIMARY CARE FUNCTIONS

Will using this site compromise service delivery?

Don't compromise the facility's primary care functions. Taking over a small health establishment may have a negative influence on service delivery

TENTS

Is this a short-term vaccination drive?

Tents may be an option but have several limitations. For a short-term vaccination drive operating a tented facility on a site may be a solution. However, for longer operation it is not recommended:

- Vaccines cannot be stored on-site
- Electricity supply might not be secure
- Climatic conditions might be unsuitable (cold and windy)
- Good ventilation is necessary
- Dust and sand might be a hazard
- The ground might not be level, or could be too hard and rocky to pitch or secure a tent
- Drainage might not be good if it rains

BUILDING

Have you considered all the factors when choosing an outreach site for a medium timeframe?

Although you may need to compromise on some things, **safety remains non-negotiable** and may override functionality

It may be feasible to make some changes to make the building functional, but the limited duration of a campaign must be taken into account

Special precautions are required if an unused or unoccupied building is identified for use

- Past use and current safety
- Safety of the structure
- Functioning water supply, sanitation, and storm water drainage (stress test the sewerage system prior to use)
- Safety and reliability of electrical installations
- Environmental safety (what are the surrounding activities and their risks, such as factories discharging gasses)
- Experience has shown that an open-plan hall or hanger facility is the most suitable and allows for a more flexible outlay, rather than a building with various smaller rooms

Risk and security assessment

Clients and health care workers must be kept safe. There are a range of risk factors to consider to keep them safe from infection, and security risks.

Assess security, and safety risks for clients and health care workers

Availability of **suitable ablutions is often the most limiting factor** in finding a suitable building

20 people per toilet, and **one basin per two toilets** is the standard

PROTEST ACTION	It may be necessary to **consult the local police station** as you plan how to assess this risk and how to manage security in a protest action situation
AN IDEAL FLOW PLAN	**A one-directional flow of clients through a structured layout** from an accessible and easily identifiable entrance to a separate exit is ideal if possible. Multiple entrances for staff and deliveries will be an advantage Having a separate entrance available for clients coming to the facility for a second dose vaccination will also streamline processes
VENTILATION	**The best precaution against transmitting COVID-19 remains good ventilation**. In selecting a building, open windows with natural ventilation are 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, assessment of the air conditioning flow requires technical advice
EMERGENCY PLAN	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. The plan should include contact details of emergency services and hospitals for both insured and uninsured clients

Ablution facilities

CLIENTS *Is there access to suitable ablution facilities?*	Estimate the expected number of people; clients (and those accompanying them), care workers, children who may come along, and staff **The standard 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 ablution facilities, with a ratio of one basin per two toilets**
STAFF *Have you assessed the number of basins?*	Because of the PPE decontamination process **it is preferable to have ablution facilities for staff which are separate from those for clients.** One toilet per 20 persons, (or 25 if urinals are available) is the standard to aim for **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 limit the selection of buildings for vaccination, although loose-standing basins are commercially available for use**

3

Lighting, cold chain and connectivity

Adequate **lighting**, the **cold chain requirements** and **connectivity** are all important factors

LIGHTING *Is there enough light to see what you're doing?*	**Adequate lighting is required particularly in areas where vaccinations are mixed and drawn up** Record keeping and use of computer screens will require shielding from direct sunlight While the effectiveness of lighting can be measured scientifically it can also be assessed by trial-run actions to see if it is adequate. Take the weather into account - if it's overcast this can make a difference **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**
COLD CHAIN *What make of vaccine is being administered?*	**The vaccine type that will be used at the site must be considered** Suitable cold chain capacity will be necessary at primary vaccination sites and fixed outreach services
WIFI *Can you connect, or is a paper based record system required?*	As the vaccination process is electronically captured, **WiFi and phone connectivity in the building or at least in the area is strongly recommended**. Test the connectivity to make sure there is band width. If it's not possible to have connectivity, a paper-based record system will have to be used, but this will delay client flow drastically

Key information

AUTHORISATION

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

The Master Facility List

The National Department of Health MFL is the official list of South African health establishments and includes details about the services provided at each health establishment. This existing web-based application is used to manage the master (semi-permanent) dataset of health establishments and their services in the COVID-19 vaccine roll-out.

Before being activated as a vaccination service, a facility must be registered on the MFL.

A health establishment is defined 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"

National Health Act (2003)

FIRST

The identified or selected facility or health establishment should complete a self-assessment, and ensure they are registered on the MFL.

Facility representatives and curators can register new facilities, or update existing ones online at **www.mfl.csir.co.za**.

Public and private sector facility representatives have been trained to register new or update existing facilities on the MFL

NEXT

The facility must be designated as either

- a site providing vaccination services; or
- a site providing vaccine distribution services; or
- a site that provides both services.

IN ADDITION

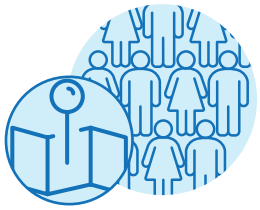
If the facility has the capacity to provide distribution services (**'the storage and/or distribution of COVID-19 vaccines'**) this must also be activated on the MFL.

VACCINATION SITE ACTIVATION

Once the above have been done, **and it is confirmed that the health establishment meets the minimum requirements**, the site can be activated as a vaccination site. This is ultimately based on population needs and geo-spatial planning across both the private and public sectors.

While this process indicates if the facility can potentially provide vaccination services it does not mean that it will definitely be selected as a vaccination site

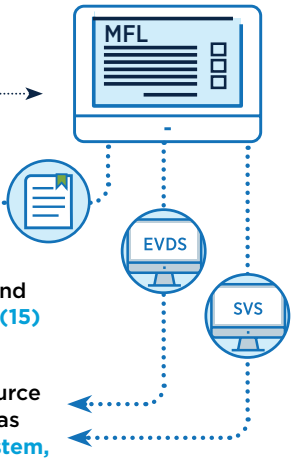
SELECTING AND RECORDING VACCINATION SITES



COVID-19 programme coordinators determine the population needs and geospatial planning outcomes

www.mfl.csir.co.za

Facility representatives and curators manage the MFL web app



In addition the MFL serves as the:

- basis for applying for, and processing section 22A(15) permits.
- and the master data source for other systems such as the self-registration system, EVDS, and SVS.

3

The Electronic Vaccination Data System

The EVDS has been adopted as the official system for capturing vaccination events at all vaccination sites.

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

It is used to

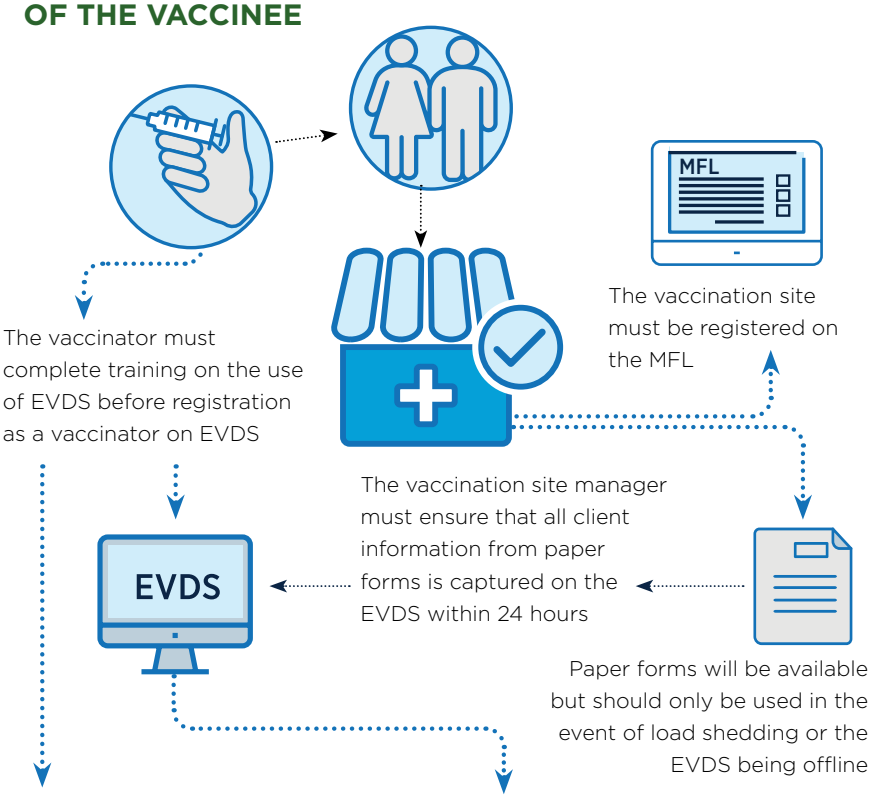
- **record processes**
- **enable data to be collected**
- **monitor coverage, access, and use**

of the vaccine throughout the country

THE VACCINEE RECEIVES THE VACCINE

- **on a specific date and time**
- **at an approved vaccination site**
- **from a vaccinator registered on the EVDS**

RECORDING THE JOURNEY OF THE VACCINEE



ANNEXURE:

Vaccination paper based form

When a vaccinator is registered, they will be **linked to their primary vaccination site.** Vaccinators can be **linked to more than one vaccination site or outreach service** at a time.

The system allows for **traceability** on who is capturing the information and at which vaccination site. The 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.**

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.

It provides and tracks vaccine information, including

- patient information, such as demographics and number of doses
- details of vaccination sites and vaccinators
- data needed for monitoring vaccine uptake and coverage, prioritisation, planning, safety monitoring, and vaccine-related studies

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**

THE EVDS ECOSYSTEM CONSISTS OF THE FOLLOWING TOOLS OR MODULES

- ☐ Enrolment Portal and Scheduling
- ☐ MFL
- ☐ On-Site Electronic Vaccination
- ☐ Data analytics platform

There are different types of users of the EVDS including administrators, vaccinators and schedulers. For more information on the EVDS please access the applicable user manual.

EVDS ECOSYSTEM – summary

ANNEXURES:

Standard Operating Procedure for the identification, application for, and approval of COVID-19 vaccination sites

MFL User Manual

EVDS User Manual

3

SITE PREPARATION AND SETUP

When preparing a vaccination site, various factors should be considered, from what supplies are required, to the challenges which might arise.

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

THINGS TO BE CONSIDERED

- ☐ What equipment is available?
- ☐ Is more equipment needed?
- ☐ What human resources 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, administration, 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?

ANNEXURE:

Minimum standards for covid-19 vaccination sites and the provision of vaccination services

Vaccination team

The roles, responsibilities, and resources available to vaccination team members driving the vaccination programme are described in the table below. Standard operating procedures (SOPs), and job aids, have been included in the toolkit to provide the information needed to get started at the site.

Table 7: Roles and responsibilities at the vaccination site

Vaccination site manager

Who could fill the role?

Any health care provider (as defined in the Health Act)

What the role requires?

Overall management of the vaccination site

Relevant resources

All tools used at the vaccination site

Queue Marshall

Who could fill the role?

Community members and volunteers

What the role requires?

- Manage and marshal queues
- Troubleshoot when needed
- Provide information to the clients in the queue

Relevant resources

Job-aid for queue marshals

Vaccination site scheduling administrator

Who could fill the role?

Administrator

What the role requires?

Manage scheduling at the vaccination site and troubleshoot

Relevant resources

EVDS scheduling guide

EVDS admin support personnel

Who could fill the role?

Administrative staff

What the role requires?

- Confirm proof of registration on EVDS using ID or another suitable document
- Confirm client demographic data on EVDS using relevant ID document/s
- Confirm medical aid details (where relevant)

Relevant resources

- SOP - Confirmation of registration on EVDS
- EVDS user manual

Vaccinator

Who could fill the role?

- 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.
- Medical, pharmacy, and nursing students as part of their clinical training under supervision.

What the role requires?

- MUST be on EVDS
- Confirm the identity of the client
- Administer health questionnaire
- Administer informed consent
- Refer client as needed
- Prepare injection
- Administer vaccine
- Record vaccination details
- Issue vaccination card

Relevant resources

- SOP - Vaccination process
- EVDS user manual
- Vaccination process (Chapter 7)
- Job Aid Injection Preparation_ Comirnaty Vaccine
- Job Aid Injection Preparation_Janssen Vaccine_20122021Vaccination card
- Paper-based forms: informed consent, health questionnaire

3

Observation site personnel

Who could fill the role?

Any health care provider or person with first aid training

Designated health care provider to deal with adverse events e.g., medical practitioner, EMS, professional nurse, pharmacist (can also fill another role at vaccination site)

What the role requires?

- Observe clients post-vaccination
- Alert designated health care provider if needed
- Take appropriate action if there is an adverse event
- Record adverse event/s

Relevant resources

- SOP Observation of vaccinee following COVID-19 vaccination
- Job aid: Dealing with adverse events (Chapter 8)
- Adverse event forms: Case reporting form, Case investigation form and AESI form

Personnel responsible for COVID-19 screening

Who could fill the role?

Administrative staff and volunteers

What the role requires?

Routine COVID-19 screening (temperature, COVID-19 questionnaire, hand sanitising) Confirm registration and refer to relevant queue (Client EVDS code)

Relevant resources

SOP - COVID-19 screening process

On-site assisted registration person
(if client not registered on EVDS)

Who could fill the role?

Administrative staff

What the role requires?

Assist with EVDS registration

Relevant resources

EVDS user manual

Vaccine champion

Who could fill the role?

Pharmacist, pharmacist's assistant, nurse, other designated HCP (could also fill another role)

What the role requires?

- Manage receipt of vaccines at the vaccination site
- Manage vaccines and ancillary items at the vaccination site during the vaccination process (including cold chain maintenance)

Relevant resources

- SOP Replenishment of vaccines
- SOP Procedure to receive Comirnaty® vaccine
- SOP - Procedure to receive COVID-19 vaccine Janssen®
- SOP - Storage of Comirnaty® vaccines
- SOP - Storage of COVID-19 vaccine Janssen®
- SOP - Waste disposal of COVID-19 ancillary item
- SOP - Waste disposal of COVID-19 vaccines
- SVS Presentation and job aids
- SOP - Vaccination site closure procedure

Vaccine controller
(At primary vaccination site that provides distribution services)

Who could fill the role?

Pharmacist, pharmacist's assistant

What the role requires?

- Manage ordering and receipt of vaccines
- Manage storage of vaccines
- Manage distribution of vaccines
- Reporting on SVS

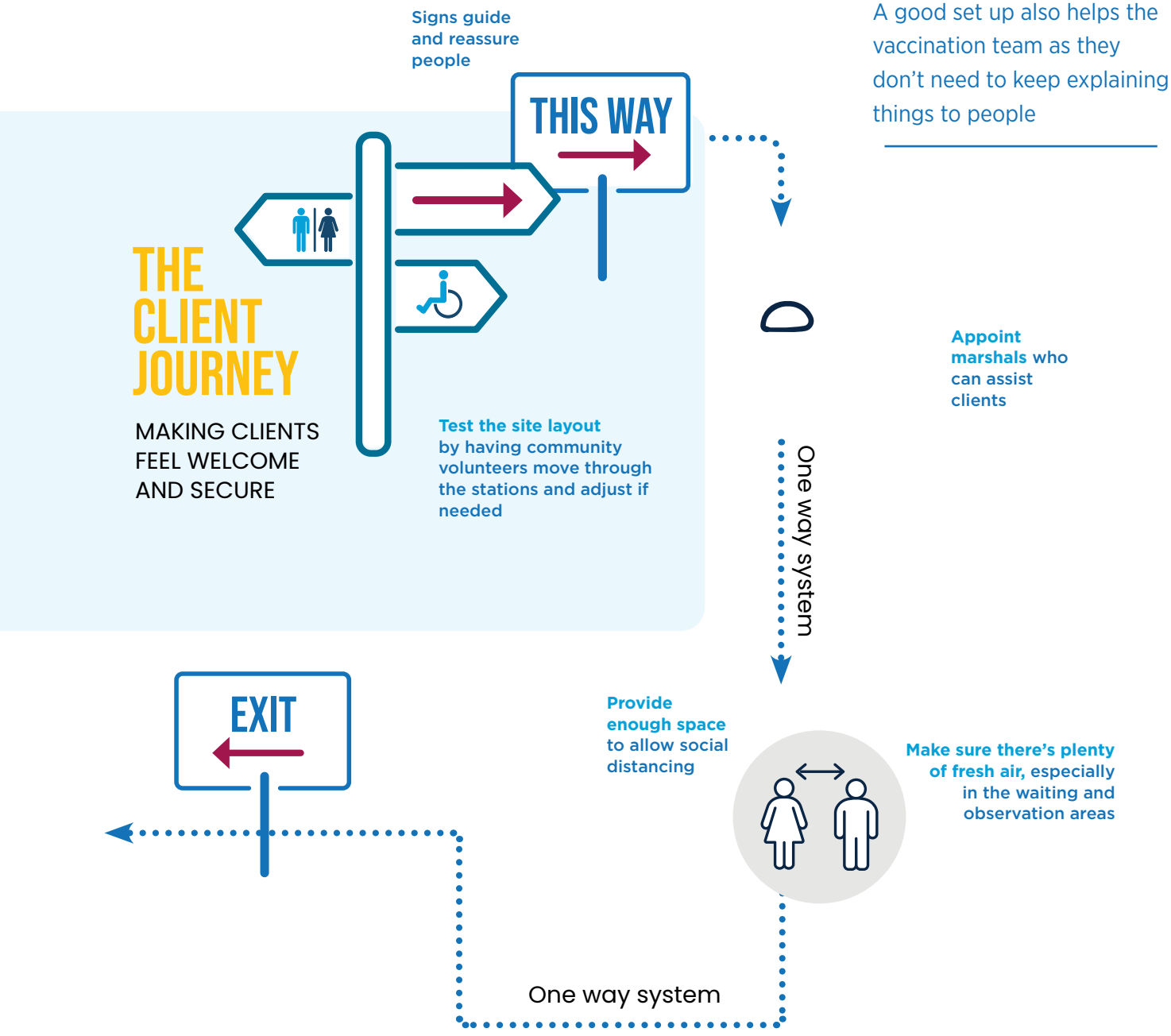
Relevant resources

- SOP - Preparation of cold chain equipment
- SOP - Replenishment of vaccines
- SOP - Procedure to receive Comirnaty® vaccine
- SOP - Procedure to receive COVID-19 vaccine Janssen®
- SOP - Storage of Comirnaty® vaccines
- SOP - Storage of COVID-19 vaccine Janssen®
- SOP - Distribution of Comirnaty® vaccines to temporary and mobile outreach services
- SOP - Distribution of COVID-19 vaccine Janssen® to temporary and mobile outreach services
- SOP - Routine monitoring of vaccine handling
- SVS training material
- Waste Disposal of COVID-19 Vaccines
- Waste Disposal of COVID-19 Ancillary Items
- SOP - Vaccination site closure procedure

Site layout

The way the site is designed is an important part of making the experience welcoming and less daunting for clients.

Design the site as a team and set it up **in a way that people know what to expect and what to do**. A good set up also helps the vaccination team as they don't need to keep explaining things to people



3

SITE ‘GO LIVE’

Before a site opens for the first client, mobilise the local community to participate in the process.

Inviting **members of the public to be ambassadors for the vaccination process**, with a media opportunity, **will help build others’ confidence**

DEVELOP A COMMUNICATION STRATEGY THAT INCLUDES:

- ☐ **when vaccinations will be given**
- ☐ **where vaccinations will be given**
- ☐ **what individuals need to do to get their vaccinations**
- ☐ **if the vaccine being offered requires two doses, building this into the early messaging so that clients are aware they need to visit the vaccination site twice.**

Hold a trial run a day or two before the official opening to iron out any snags and unforeseen issues. Communicate how many people the site expects to vaccinate each day to manage expectations and help prevent surges.

ANNEXURE:

Site “Go live” presentation

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, sites will 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

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 roll-out.

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

The site checklist is a guide

Add any other items that the site manager should check

CHECK THAT THE VACCINATION SITE:

- ☐ is clearly marked and the banners or posters, with hours of service, are in place
- ☐ is well ventilated (if natural ventilation is used, open windows and doors)
- ☐ has measures in place to limit the number of individuals to avoid crowding and long waiting times
- ☐ has a one-way flow that is working efficiently, and has clear directions to entry and exit points
- ☐ has appropriate IPC measures that are being followed with arrangements in place to facilitate physical distancing to enable at least 1-metre distance in all directions between each person
- ☐ has hand-washing stations which are functional and with soap and/or alcohol-based hand rub dispensers
- ☐ has cleaning and disinfection procedures that are followed consistently and correctly according to WHO and NDoH guidance, with stations being cleaned and disinfected frequently with special attention to high-touch surfaces

3

ANNEXURES:

Twice daily maintenance checklist

SOP - Site Maintenance Daily Activities

Emergency Trolley Check List

- ☐ The various stations (COVID-19 screening, administration, vaccination, and observation) are functional, 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 the Emergency Trolley Checklist
- ☐ Sufficient IEC material is available and displayed to encourage appropriate COVID-19 related behaviour

SITE MONITORING

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 itemised, scheduled, and budgeted in the micro-plan, and responsibilities assigned.

Supervisors should utilise the site readiness assessment tool and the supervisory checklist to document their findings and discuss findings at the district level in the case of public sector sites and with the relevant organisation in the case of private sector sites, to address any gaps.

Supportive supervision should **focus on identifying challenges, mitigating challenges, improving and/or enhancing the skills of staff** to ensure they provide high-quality services

USE THE SUPERVISORY CHECKLIST TO:

- ☐ increase the quality of vaccination services
- ☐ reduce the risk of adverse events (AEFI)
- ☐ improve confidence in the COVID-19 vaccine process
- ☐ improve client confidence in the health care system overall

ANNEXURE:

Supervisory checklist

THE SUPPORTIVE SUPERVISION PROCESS

Vaccination sites need the following:

- ☐ **Supervisors who are well trained** on supportive supervision techniques, and have updated information and skills on vaccination programme
- ☐ Appropriate **equipment, vaccines, logistics, and AEFI reporting forms**
- ☐ **Training tools** to update skills of health workers during supervision visits, checklists and forms for recording recommendations and following up

Planning regular supervisory visits:

Where: Use data (vaccination coverage) to identify priority supervision sites

When: Schedule supervision visits using a work plan

What: Identify needs and skills that need updating to decide on the subjects for training?

What to do during supportive supervision visits:

- ☐ **Observe** the vaccination site and clinical practices including IPC precautions
- ☐ **Train** members of the team 'on the job'
- ☐ **Record** observations and collect feedback
- ☐ **Review data** and use a supervisory checklist
- ☐ **Problem solve**

Additional actions:

- ☐ **Agree what needs to be done** by supervisors and supervised staff
- ☐ **Conduct regular data analysis**
- ☐ **Give feedback** to all stakeholders and discuss recommendations

3

Monitoring visits

District teams, observer teams, or other competent authorities will also monitor vaccination sites. This will provide helpful oversight and insights to improve the process.

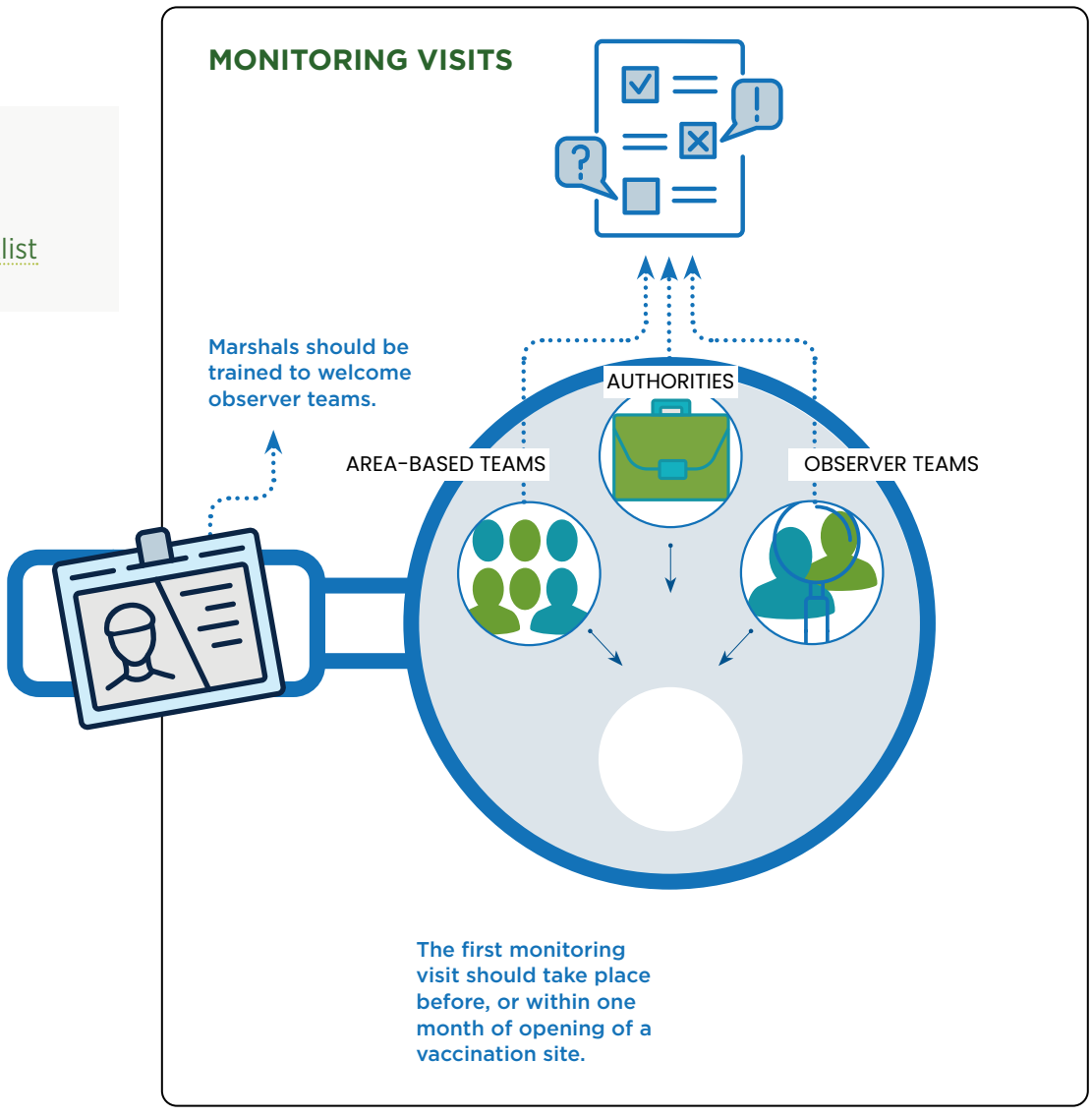
Members of observer teams should **identify themselves to the local site management to observe, without disrupting activities at the site**, and should be identifiable through bibs or identity cards

COLLABORATION MEANS BETTER OUTCOMES

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

ANNEXURE:

Supervisory checklist



SITE CLOSURE

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 receive a COVID-19 vaccination and have returned to the site for their follow-up injection if needed.

Let the public know if a site needs to close, to **ensure all eligible community members receive their vaccinations**

DECOMMISSIONING AND DEACTIVATING

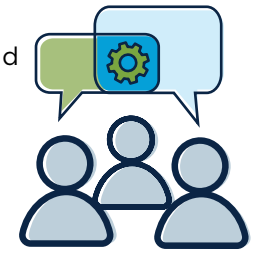
Whenever a vaccination site is closed, whether permanently or for a period of time, it should be decommissioned.

- ☐ **The vaccine service must be deactivated on the MFL, the EVDS and SVS (if vaccines were stored on-site)**
- ☐ **The EVDS scheduling should also be deactivated, and clients redirected to alternate vaccination sites**

The vaccination site manager should **escalate issues to the district or provincial teams** if they have questions about the process

Review and discuss

The vaccination team lead and site manager should discuss and clarify points that are unclear.



HOW TO ESCALATE SITE-RELATED ISSUES

ANNEXURES:

MFL User Manual

EVDS User Manual

SVS Training material

PHONE CALL

VACCINATION SITE MANAGER

EMAIL REPORT

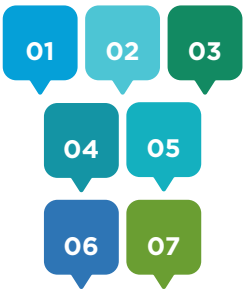
DISTRICT COVID-19 VACCINATION TEAM LEAD
(or applicable organisational structure)

PROVINCIAL VACCINE LEAD
(delegated by the Head of Department to manage the process)

3

Key messages

The Head of Department or Provincial Vaccine Lead should sign off on vaccination sites, as well as any changes to sites per province



The high-level vaccination site process has seven phases

1. site identification
2. activation
3. preparation and setup
4. 'go live'
5. maintenance
6. monitoring
7. deactivation/closure

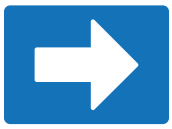
These processes require collaboration between the district COVID-19 vaccination implementation team, the area-based team, and the vaccination site manager

Sites must be registered on the MFL and designated as either a site providing vaccination services, distribution services, or both

Although a site has been activated as a vaccination service, **it will not necessarily be selected as a vaccination site**

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

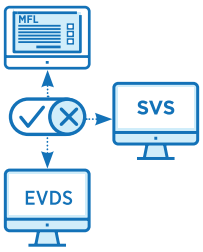
Paper-based forms may not be used unless absolutely necessary. The vaccination site manager must ensure that all information from paper forms is captured on the EVDS within 24 hours



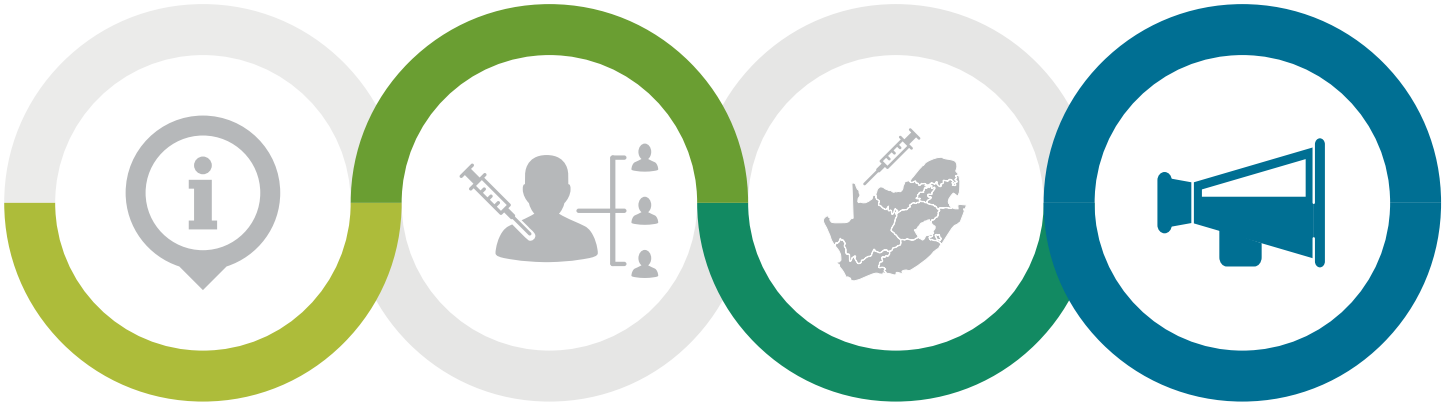
Vaccination sites must **use a one-directional flow process** and provide for social distancing

The site must be monitored twice daily by the vaccination site manager using the monitoring checklist

District teams, observer teams, or other competent authorities will also **monitor vaccination sites to provide oversight and improve the process**



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, the EVDS and SVS** (if vaccines were stored on-site)



CHAPTER 4

Advocacy, communication, and social mobilisation activities

Chapter 5

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

Chapter 6

Effective vaccine management, cold chain, logistics, and distribution of COVID-19 vaccines

Chapter 7

Planning the client journey, and administration of COVID-19 Vaccines

Chapter 8

Vaccine safety surveillance

Chapter 9
Monitoring & Evaluation

4

Chapter purpose

Chapter 4 describes advocacy, communication and social mobilisation activities.

Social mobilisation and demand creation is essential to ensure high levels of immunisation coverage.

The contents of this chapter will be useful for:

Provincial teams

District teams

Area-based teams

Vaccination site managers

Health promotion officials

Our COVID-19 vaccine ACSM strategy

The ACSM strategy supports the rollout of COVID-19 vaccines in South Africa through ...

- the dissemination of timely, accurate, and transparent information about the vaccine(s); and
- 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 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.

4

Social mobilisation and demand creation

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

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

- 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.
- 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 enrol on the EVDS;
  - ✓ that they should bring their 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.
- 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

- 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.
- 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.
- 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 providers (HCPs) with a professional qualification in health care, are a significant trusted source of health information to the public.

What HCPs say and how they interact with clients, can strongly influence vaccine acceptance

The vast majority of **South Africans trust HCPs for medical and health advice**

Tailored 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 jobs. 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.

For example, 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.

Although the reasons are myriad and/or not fully known, i.e. fear of side effects, there is a need to overcome vaccine hesitancy in the younger population through targeted and trusted messaging. The more people get vaccinated, the less chances the virus has to mutate into variants.

4

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.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).

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.

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.

NOTE

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.

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 a 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.

4

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 which 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.

Key messages

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

Encourage **community members to sign up** to be vaccinated using the EVDS

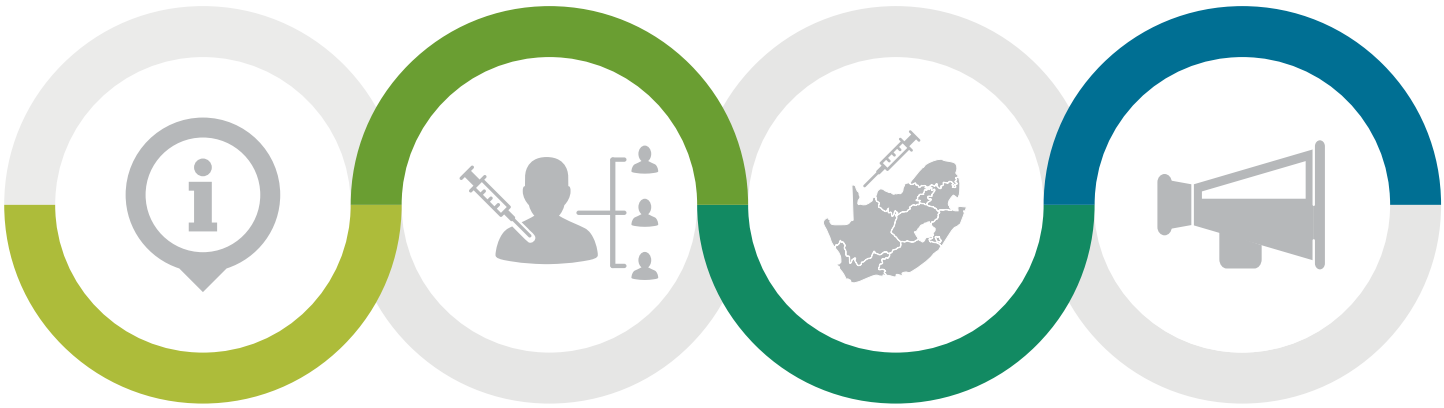
Use multiple channels of communication to **distribute positive promotional information** including **communication channels available in local community**

Very important to **tailor messages** by risk group

Help overcome vaccine hesitancy through targeted and trusted messaging

Use of **presumptive communication, counselling,** and **motivational interviewing techniques** is highly recommended

HCPs must never speak to the media about serious illness after vaccination; instead, **refer the media to the National AEFI coordinator**



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Chapter 5 outlines the training of health care workers.

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.

The contents of this chapter will be useful for provincial, district and area-based teams as well as vaccination site managers.

Provincial teams

District teams

Vaccination site managers

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.

District vaccination 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.

TRAINING WILL BE ONGOING

As new COVID-19 vaccines become available and recommendations relating to COVID-19 vaccines evolve, and as we learn more about the vaccines and how to optimise the vaccination programme, more training will be necessary and provided.

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 Act, new vaccinators could be included in the programme. These include all HCPs who are trained, competent, and 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**

A large number of **health workers**, including both **HCPs** and **support staff**, are needed to support COVID-19 vaccination efforts nationwide

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.

5

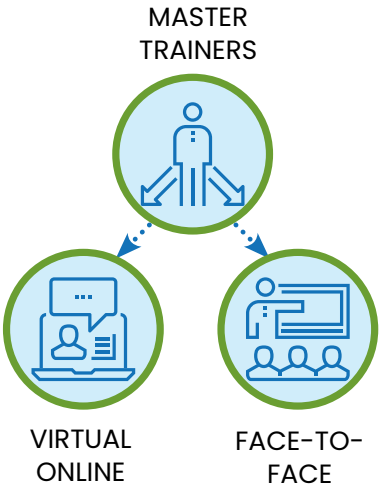
A device and internet connectivity are required to connect to the course. Accessing the course materials and recorded lectures online is free as the Knowledge Hub has been zero-rated

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.

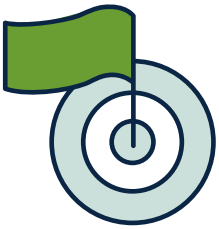
The Knowledge Hub (https://www.knowledgehub.org.za/form/covid-19-vaccination-training) will be used to provide vaccination programme training for **master trainers**, **vaccinators**, and other **health workers** in both the private and public health sector. Modules are updated or added (e.g. on SVS, EVDS, the MedSafety app) as new processes are finalised, or as new information about the vaccines and the programme becomes available.

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 has seven modules:

01 Introduction to COVID-19 vaccination training

02 Storage, handling, delivery, and waste management of COVID-19 vaccines

03 Organising COVID-19 vaccination sessions

04 AEFI monitoring for COVID-19 vaccination

05 COVID-19 vaccination data management

06 Communication with the community about COVID-19 vaccination

07 Ethical considerations for the COVID-19 vaccination programme

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.

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

Key messages

Training is important for those who prepare and administer the vaccine and for those responsible for other critical functions, including cold chain management, data capturing, communicating with vaccine recipients, AEFI management, and reporting

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

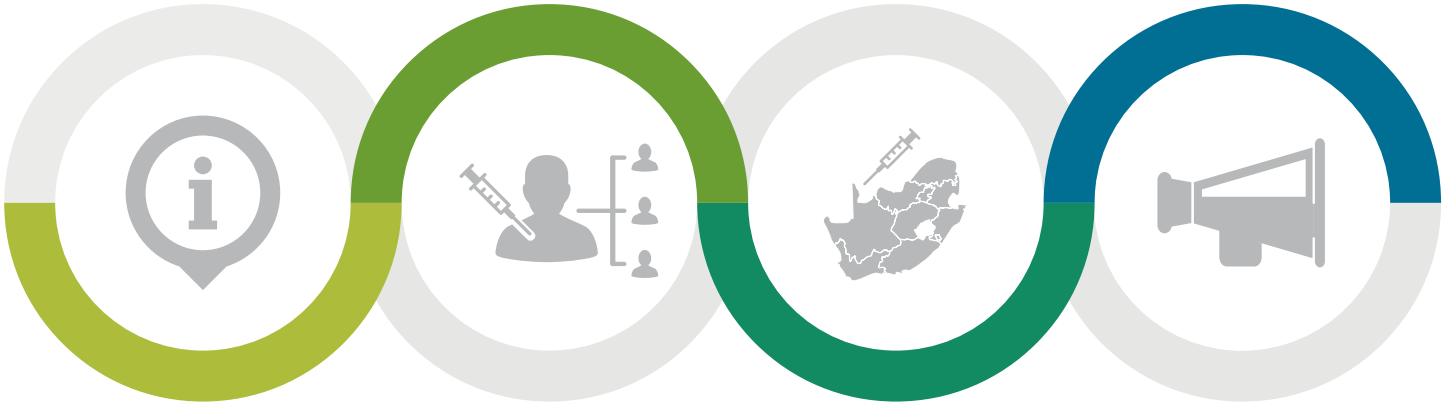
Training is available on the Knowledge Hub. The course is CPD-accredited with the Health Professions Council of South Africa (HPCSA) for 14 'Level 1' points (12 general points and 2 ethics points)

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"

Link for training: https://www.knowledgehub.org.za/lms/course/view.php?id=66

Private sector health workers and vaccinators should select 'Other' from the drop-down list of facility names

Participants must check that personal details and email addresses are captured correctly as this information will be used on the certificate and ongoing communication



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Chapter 6 describes effective vaccine management principles, logistics and distribution of COVID-19 vaccines.

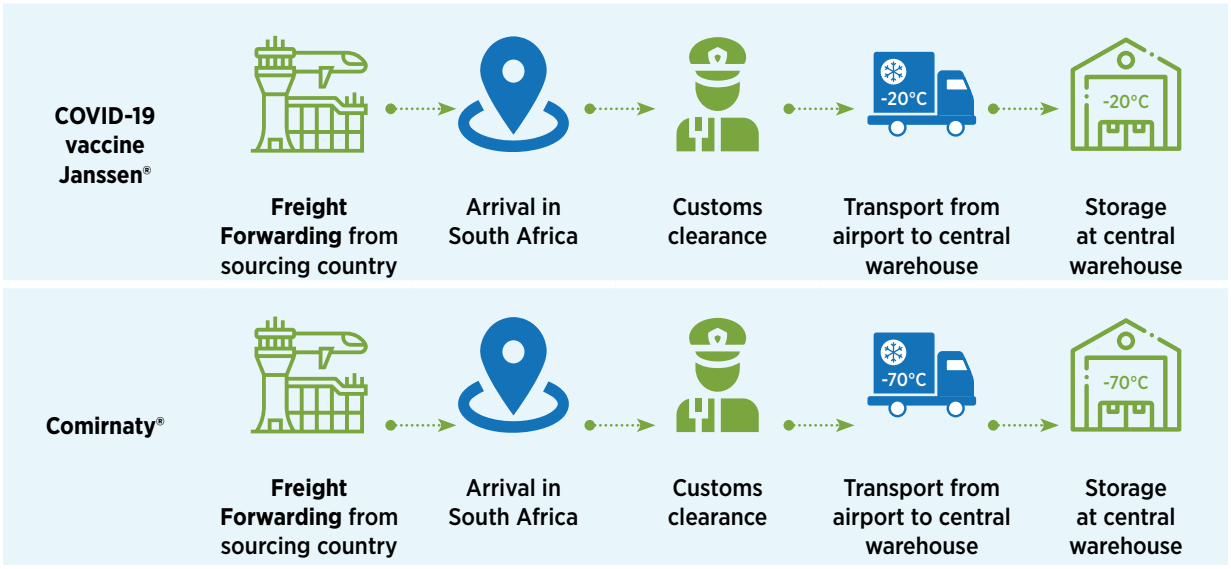
The contents of this chapter will be useful to:

- Vaccinators
- Vaccine champions
- Vaccine controllers
- Vaccination site managers
- Pharmaceutical services
- Persons involved in vaccine logistics and distribution

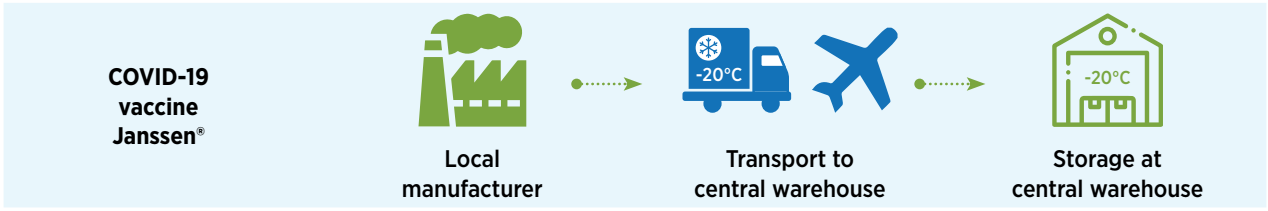
Overview of vaccine logistics, distribution, and storage

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

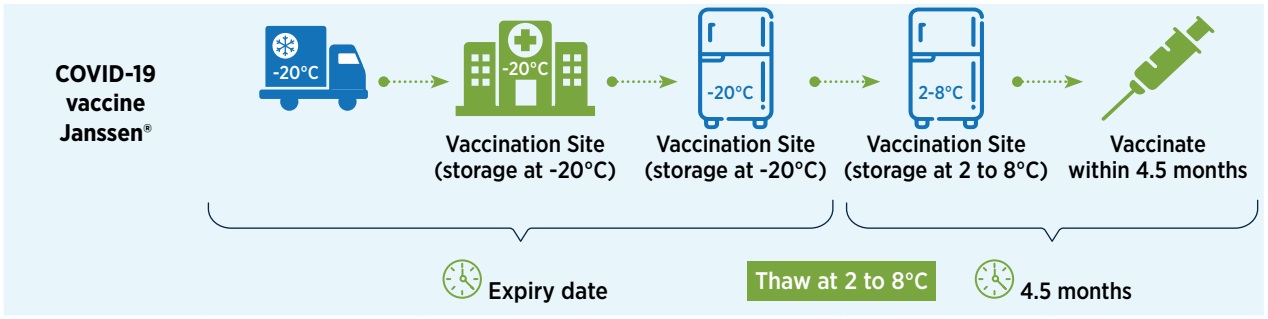
01 Import process & central storage – all vaccines

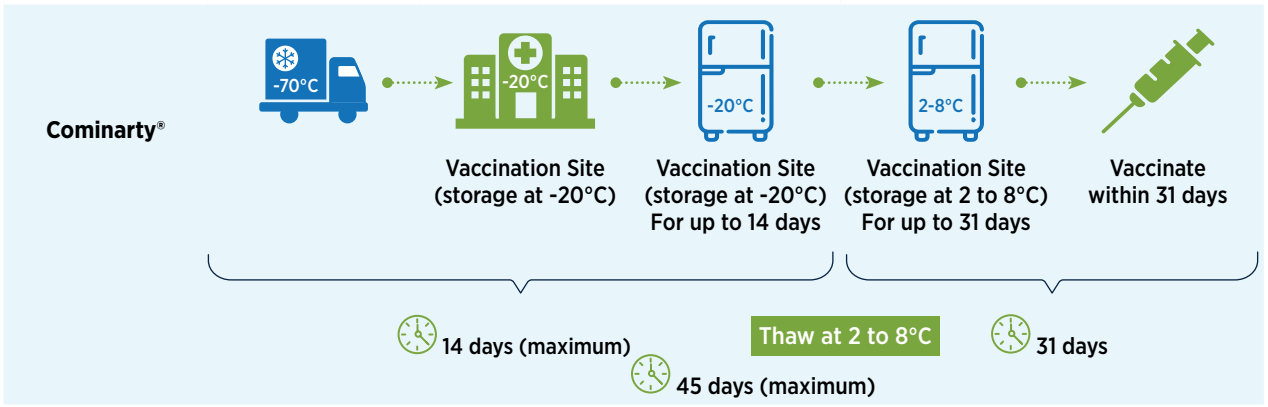


02 Local manufacture & central storage

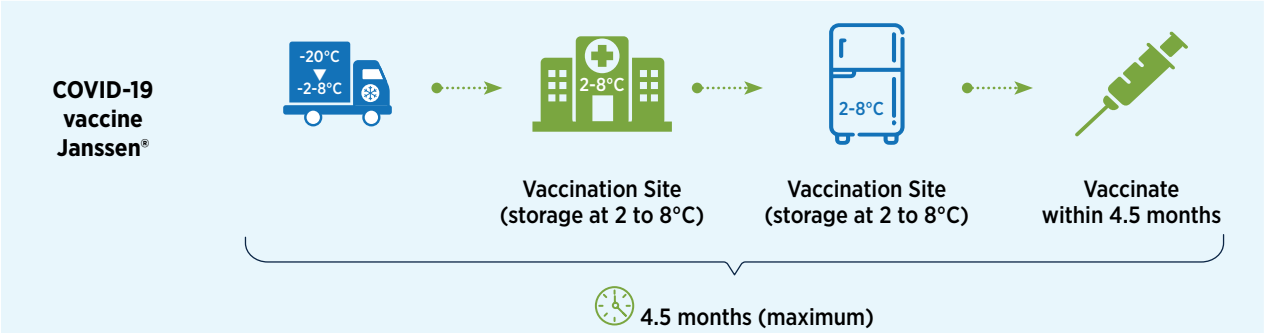


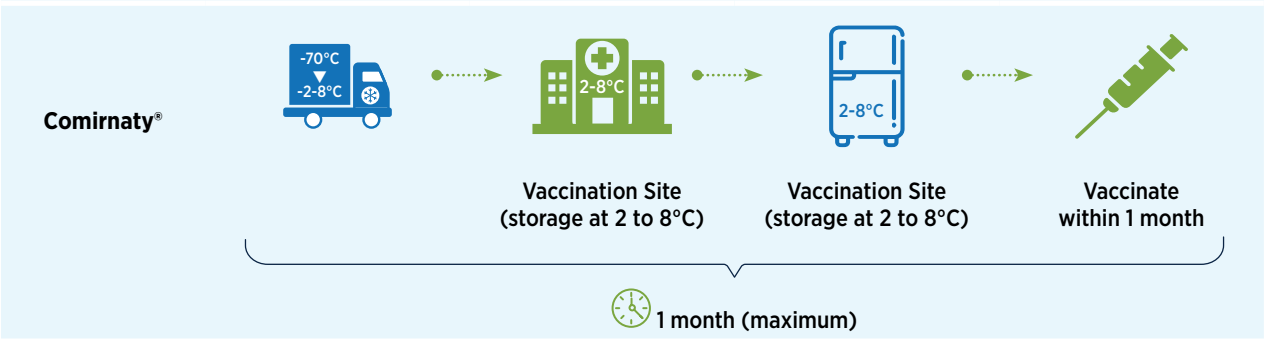
03 Primary distribution/vaccination site with -20°C storage





04 Primary distribution/vaccination site with 2-8°C storage





Distribution quantities are 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

The NDoH has developed a stock replenishment model that calculates 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

+

The wastage multiplication factor for vaccines and syringes

Orders received from the private and public sector facilities may be adjusted based on vaccine availability or programme priorities

Receiving COVID-19 vaccines from central distributors

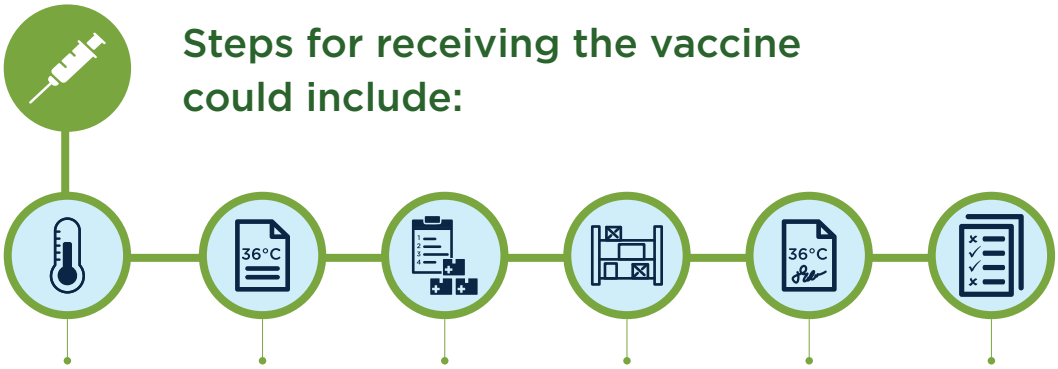
Vaccines will be distributed from central distributors contracted by the NDoH. The delivery lead time may vary depending on cold chain capacity at the primary distribution/vaccination site, the vaccine being distributed, and the size of the target population. Each primary distribution/vaccination site or organisation coordinating multiple distribution/vaccination sites must set up an account with the central distributor allocated by the NDoH.

Vaccination and distribution sites receiving the vaccine are required to follow the guidelines for stock receipts from the central distributor(s).

ANNEXURES:

- Communique from DSV
- Communique from Biovac
- SOP – Procedure to receive Comirnaty® Vaccine
- SOP – Procedure to receive COVID-19 vaccine Janssen®

Steps for receiving the vaccine could include:



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

Effective 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 risk of AEFI.

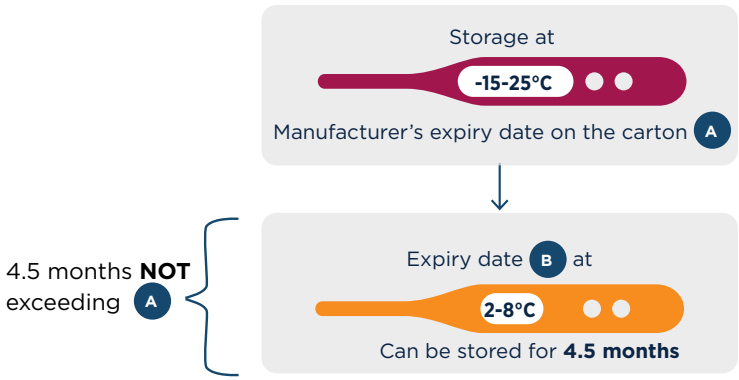
Table 8: Details about the COVID-19 vaccine Janssen® and the Comirnaty® vaccine

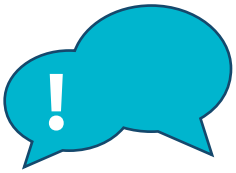
COVID-19 vaccine Janssen®	Comirnaty® Vaccine
Trade name	
Janssen Vaccines & Prevention B.V.	Pfizer-BioNTech
Manufacturer	
Covid-19 vaccine Janssen®	Comirnaty®
Approved for	
Individuals over 18 years of age	Individuals over 12 years of age
Dose	
0,5ml	0,3ml
Doses per vial	
Vial containing 5 doses	Vial containing 6 doses
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

COVID-19 vaccine Janssen®	Comirnaty® Vaccine
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 "expiry date (A)"	• 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 OR • The frozen vaccine could be moved back to -60°C to -80°C storage range – **This may only be done ONCE**
Distribution from primary vaccination site to another vaccination site	
• Distribution at 2°C to 8°C • Once removed from the freezer, the vials should be protected from light, for a single period of up to 4.5 months, not exceeding the printed expiry date (A)	• Distribution at 2°C to 8°C • Indicate date when the vaccine was transferred from (-25°C to -15°C) to (2°C to 8°C) • 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 • **Expiry dates (B) and (C) may not exceed the printed expiry date (A)**
ONCE VACCINE HAS THAWED AT 2 to 8°C IT MAY NEVER BE FROZEN AGAIN	
Thawing	
• Recommendation: When stored frozen at -25°C to -15°C, a vial should be thawed overnight at 2°C to 8°C • Doses for use the next day should be placed in the refrigerator the night before • Or refer to the professional information provided by the manufacturer with the medicine	• Recommendation: When stored frozen at -25°C to -15°C, a vial should be thawed overnight at 2°C to 8°C • Doses for use the next day should be placed in the refrigerator the night before • Or refer to the professional information provided by the manufacturer with the medicine
Storage at 2nd site – vaccination site	
• Store in a refrigerator at 2°C to 8°C for up to 4.5 months, not exceeding the original expiry date (A) • Upon moving the product to 2°C to 8°C storage, the "new" expiry date (B) must be written on the outer carton and the vaccine should be used or discarded by the updated expiry date • The original expiry date (A) should be made unreadable • 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	• Store in a refrigerator at 2°C to 8°C for up to 31 days, not exceeding the original expiry date (A) • 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 • The original expiry date (A) should be made unreadable • 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
Storage after first puncture of the vaccine vial (after opening)	
• The vaccine should preferably be used immediately after the first puncture of the vial. The product can, however, be stored between 2°C to 8°C for a maximum of 6 hours • The vaccine presents as a multi-dose vial with no preservative. Therefore, once a vial is opened for use, the date and time should be indicated • The vaccine must be discarded 6 hours after opening the vial or at the end of the immunisation session, whichever occurs first	

The transfer of Comirnaty® vaccine between temperature ranges

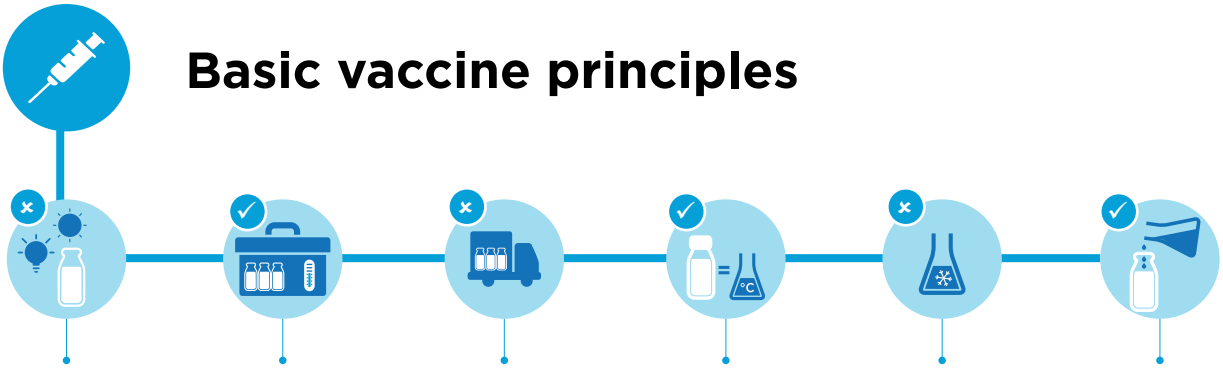
The transfer of Janssen® vaccine between temperature ranges





The expiry date on the outer tray or the vaccine vial must be updated when the vaccine tray or vial is moved to the next temperature range and the original expiry date must be **made unreadable**

Basic vaccine principles



Never expose opened vials to direct heat, light, or sunlight

For open vials, use a separate passive container with a temperature monitoring device to allow monitoring of temperature during use

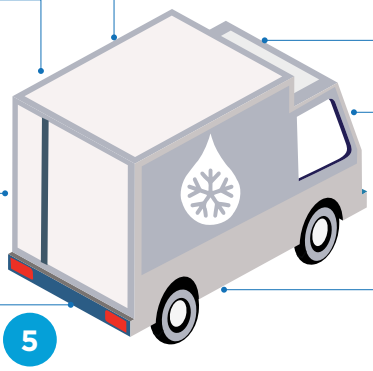
Never transport or return opened multi-dose vials to cold chain storage. Discard them after 6 hours or at the end of the immunisation session whichever occurs first

The vaccine and diluent should be at the same temperature at the time of reconstitution; therefore, the diluent should be stored in the refrigerator/ suitable passive container at the vaccination site

Diluents should NEVER be frozen

Always ensure that diluent quantity available matches the number of vaccine vials to be reconstituted

Vaccine distribution

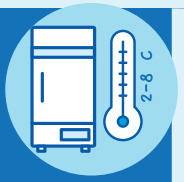


1. The **duration of the journey, transport conditions,** and **temperature profiles** of the routes should be known and considered when selecting passive containers and coolant packs
2. The correct type of **coolant pack** and **quantity** should be selected
3. **Validated passive containers that meet the WHO specifications** are recommended for vaccine distribution
4. An SOP is available for the packing and transport of vaccines in line with the manufacturer's specifications
5. **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
6. During distribution, each passive container should include a **continuous temperature monitoring device** that meets WHO specifications
7. Maintain **temperature records** to demonstrate compliance
8. The **vaccine properties** should be considered, including the heat and freeze sensitivity of each vaccine

6

Effective Vaccine Management

Storage between 2 to 8°C



- The use of a **purpose-built vaccine refrigerator** is recommended. Domestic refrigerators are not considered ideal 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**
- Sufficient cold storage 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 room 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

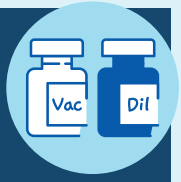
*All the above requirements are in line with the **Rules relating to Good Pharmacy Practice** published in terms of the Pharmacy Act 53 of 1974. All sites that store COVID-19 vaccines must have contingency plans to manage power failures, equipment breakdowns, or cold chain breaches.*

ANNEXURES:

SOP – Storage of Comirnaty® Vaccines

SOP – Storage of COVID-19 vaccine Janssen®

Effective management 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 **six hours after reconstitution**
- Reconstituted vaccine must be **stored within the cold chain** throughout the immunisation session

Multi-dose vial 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
- **Pre-draw of vaccine doses is not recommended for the following reasons:**
  - Increased risk of administration and dosing errors
  - Increased risk storing vaccines in inappropriate conditions (i.e. temperature and light)
  - Possibility of bacterial contamination
  - Possibility of reducing a vaccine's potency over time because of its interaction with plastic syringe components

Handling temperature excursions

Concerted efforts must be made to ensure that vaccines are stored and handled within the permissible temperature range. 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

ANNEXURES:

SOP – Management of temperature excursions with comirnaty® vaccines

SOP – Management of temperature excursions with COVID-19 vaccine Janssen®

Table 9: Handling temperature excursions

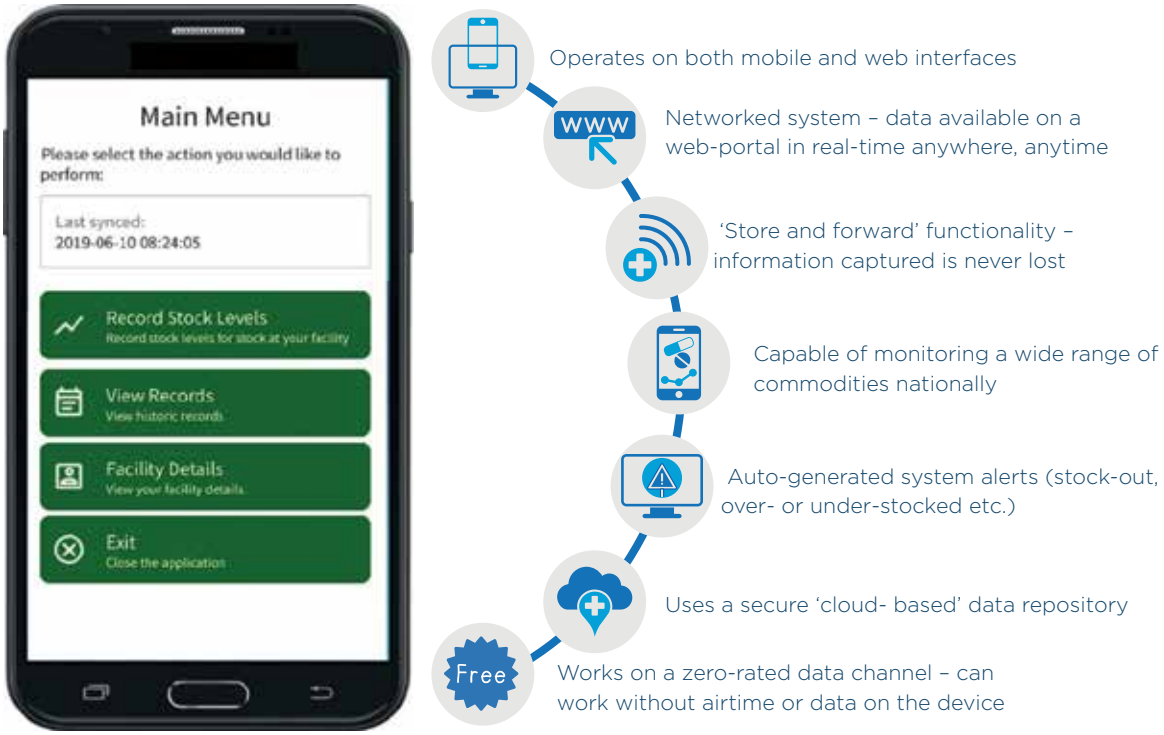
COVID-19 VACCINE JANSSEN®	COMIRNATY®
Temperature excursions while frozen	
• **If the vaccine has thawed, it may not be frozen again** • Place the vaccine in 2 to 8°C, and update the expiry date as discussed	• **If the vaccine has thawed, it may not be frozen again** Stability data indicates that the unopened vial is stable for up to: • **4 hours** when stored at temperatures from **-3 °C to 2 °C**
Temperature excursion while in 2 to 8°C storage in CLOSED 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 the 2 hours up to 30 °C if thawed at room temperature
Temperature excursion in OPEN 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**

Stock Visibility System

Only sites which store COVID-19 vaccines overnight need to use this instance of SVS

The NDoH Stock Visibility System (SVS) is used to monitor the availability of COVID-19 vaccines and related commodities (SVS COVID-19). SVS is not a transactional system and therefore an electronic stock management system or stock cards must be used with SVS to monitor vaccines and ancillary supplies. This will provide access to the relevant data to inform decision-making and help ensure that stock is replenished in the right quantities, at the right place and on time. Key features of the SVS COVID-19 instance include**:**

Figure 5: SVS COVID-19 features



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

According to the MFL site typology, primary distribution sites, primary vaccination sites, and fixed outreach services where vaccines are stored overnight must report vaccine stock levels **once** daily, preferably 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 USE SVS COVID-19 IN THE COVID-19 VACCINE SUPPLY CHAIN?

SVS COVID-19 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 COVID-19 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

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

SVS system activation process

1 MOBILE APP VERSION

Download the app on an **Android** device using the provided enrolment 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 WiFi to work.

2 DESKTOP WEB VERSION

Download the desktop version of the application onto a **Windows device** using the provided enrolment details. Capture stock levels on your computer which **must have network connectivity** (e.g. Wi-Fi dongle, fibre, etc.) to work.

3 INBOUND APPLICATION PROGRAMME INTERFACE (API) REPORTING

For those entities with **internal systems for managing stock** and the IT development capacity to support it, an **inbound API** may be made available as an alternative mechanism to enable the submission of stock updates.

For enrolment options 1 and 2, **only ONE person per site** that stores or distributes vaccines, meeting the registration criteria should enrol the reporting device, using either mobile **OR** desktop app versions. This is to ensure there is only one source of data emanating from each site. After the initial once-off enrolment process, any other person at that site who is trained and knowledgeable on using the app can submit data.

ANNEXURES

SVS COVID-19 Mobile App User Guide and Web Overview

SVS COVID-19 Training material and FAQs – also available on the COVID-19 web portal (covid19vaccinesza.app under the Information Repository)

Security measures to protect the vaccine

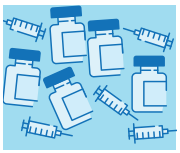
The access to vaccines should be limited to vaccinators, vaccine champions, vaccine controllers and vaccination site managers.

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.

Monitoring vaccine wastage

Vaccine wastage is defined as the number of vaccine doses discarded lost, damaged, or destroyed during the storage, distribution, and use of a vaccine. Immunisation programmes aim to improve vaccine coverage while reducing vaccine wastage, thus improving the cost-effectiveness of the immunisation programme

$$\text{Vaccine usage (rate)} = \frac{\text{Number of doses administered}}{\text{Number of doses issued}} \times 100$$

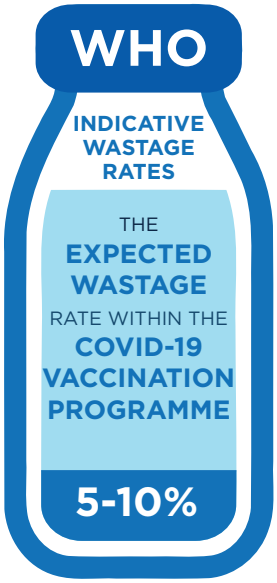


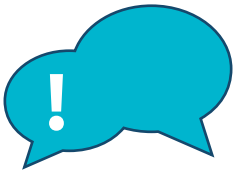
Vaccine wastage occurs in most vaccination programmes and is influenced by various factors that could be specific to the vaccine or the vaccinator. The wastage is divided into two categories i.e. **wastage in open vials and wastage in unopened vials.**

Wastage in unopened vaccine vials is unacceptable and is mainly due to poor stock control practices, poor cold chain or logistics processes. This type of wastage must be eliminated as it is considered avoidable.

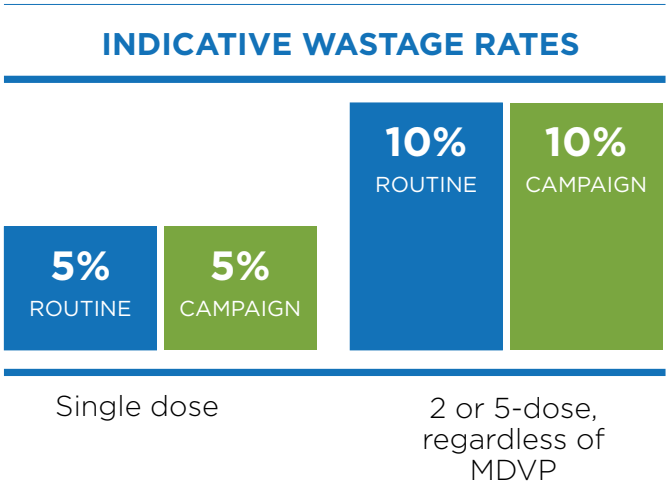
Wastage in opened vaccine vials usually occurs at the service delivery level and might be considered unavoidable and somewhat acceptable if the wastage occurred while preventing missed immunisation opportunities. This type of wastage can never be eliminated but can be reduced over time.

Expected vaccine wastage

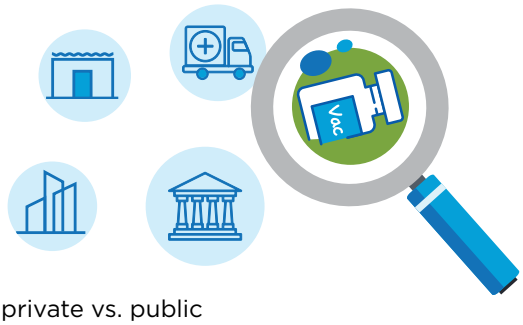




Any intervention to reduce vaccine wastage should not result in lower immunisation coverage or contribute to missed opportunities for vaccination



The indicative wastage rates
do have some limitations,
as they do not necessarily consider the
context in which vaccination services are provided



E.g. outreach services, urban vs. rural settings or private vs. public

These wastage rates assist the vaccination programme to identify vaccination sites where the vaccine wastage is higher than expected, and where further investigation will be required.

Vaccine wastage should always be weighed against the benefits of vaccination, which include a reduction in healthcare costs and maintaining high levels of vaccination coverage. Therefore, any measure or strategy to reduce vaccine wastage should not compromise immunisation coverage.

How to calculate vaccine wastage for the COVID-19 vaccination programme

In the vaccination programme two data sources are available that could be used when calculating vaccine wastage including the SVS and the EVDS.

Vaccine wastage is the opposite of vaccine usage, and therefore calculating overall vaccine wastage starts with calculating vaccine usage.

The formula for calculating vaccine usage at the service delivery point is as follows:

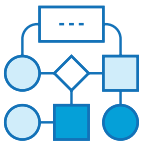
$$\text{Vaccine usage (rate)} = \frac{\text{Number of doses administered}}{\text{Number of doses issued}} \times 100$$

After vaccine usage has been calculated, overall vaccine wastage can be calculated with the following formula.

$$\text{Vaccine Wastage (Rate)} = 100 - \text{Vaccine usage rate}$$

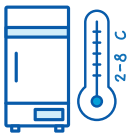
If the vaccine wastage exceeds 10%, further investigation is required to identify if vaccine wastage is due to avoidable or unavoidable vaccine wastage. The SVS and EVDS systems do not provide the required data elements for these calculations and therefore additional vaccine wastage monitoring tools are recommended.

Key messages

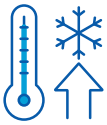


The vaccine supply chain should be designed to ensure the vaccines can be stored and distributed according to the manufacturer's recommendations

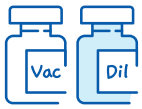
Effective vaccine management principles should be complied with, to ensure safe and potent vaccines are provided to the client



Storing vaccine vials at the correct temperature is important, and the expiry date of the product might change as the product is moved to different temperature ranges



Specific guidelines should be followed during temperature excursions

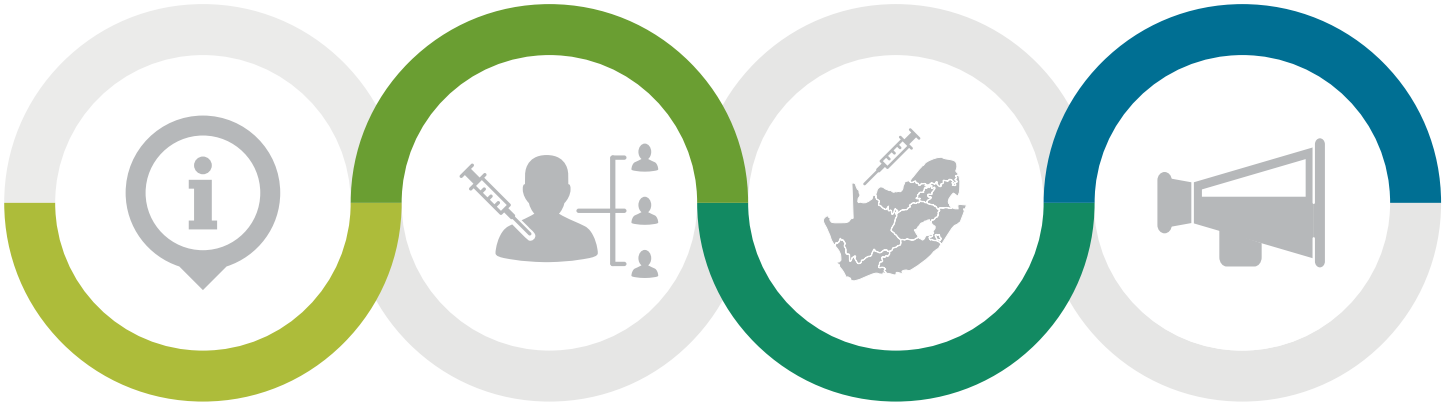


The Comirnaty® vaccine requires reconstitution with 1,8ml sodium chloride 0,9% solution, therefore the diluent should be available

Once opened Comirnaty® and the COVID-19 vaccine Janssen® vials should be discarded after 6 hours or at the end of the immunisation session

Vaccine wastage should be monitored to determine avoidable and unavoidable wastage, which will improve the efficiency of the vaccination programme

The SVS is used to monitor the distribution and availability of COVID-19 vaccines and ancillary supplies in the private and public sector



Chapter 1

Introduction

Chapter 2

Planning and mechanisms of vaccination service delivery

Chapter 3

Vaccination site set up and management

Chapter 4

Advocacy, communication, and social mobilisation activities

CHAPTER 7

Planning the client journey, and administration of COVID-19 Vaccines

Chapter 5

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

Chapter 6

Effective vaccine management, cold chain, logistics, and distribution of COVID-19 vaccines

Chapter 7

Planning the client journey, and administration of COVID-19 Vaccines

Chapter 8

Vaccine safety surveillance

Chapter 9
Monitoring & Evaluation

Chapter purpose

Chapter 7 describes the vaccine administration practice and use of EVDS.

The contents of this chapter will be useful to:

Vaccinators

Vaccination site managers

District teams

Provincial teams

The COVID-19 vaccination programme aims to curb death and severe disease, where age is the best proxy of risk in the adult population.

The programme uses age-based sequencing starting with the population older than 60 years and moving down. Vaccination services are offered in congregate settings such as old age homes, correctional services facilities, and in care homes. Similarly, employees are vaccinated through occupational health services in workplaces where this is possible.

Employees can be vaccinated through **occupational health services in workplaces** where this is possible

ACHIEVING EQUITY IN ACCESS AND USER EXPERIENCE

The user or client experience is critical in ensuring higher public uptake of the vaccination offering – for this reason it's important to standardise the process

Planning and coordinating the client's vaccination journey

All clients, irrespective of where they reside or work, will follow the same vaccination journey. This means that a quality service is delivered to all communities, no matter who or where they are. This section deals with the client journey and the EVDS workflow process, as well as showing how they intersect; **the client journey** is colour coded yellow and **the EVDS workflow process** blue.

People move through the same process to receive their vaccination, whether in a community hall, a marquee outside a hospital, an occupational health clinic on a mine, a private pharmacy, a pop-up site or a large stadium

THE CLIENT JOURNEY

- **THERE ARE EIGHT MAIN STEPS IN THIS JOURNEY**

EVDS WORKFLOW PROCESS

- **THIS FOLLOWS A SERIES OF DIFFERENT STAGES**

The **user or client experience is critical in ensuring higher public uptake of the vaccination offering**. Standardising the process is important to achieving equity in access and user experience.

Throughout the vaccination process, imagine people moving through each of the steps, from registering for their vaccine while at home, or in a taxi, to arriving to be vaccinated at a community hall, a marquee outside a hospital, an occupational health clinic on a mine, a private pharmacy or a pop-up site or a large stadium.

THE CLIENT JOURNEY

Social mobilisation and **demand creation**

Public

Employers

Congregate settings

Enrolment + scheduling

01

Enrolment on the EVDS

- By oneself
- With the support of a family member or community worker

02

- Assisted enrolment at vaccination site

System **scheduling** EVDS

- System scheduling on EVDS using SMS
- Site administered scheduling
- Self scheduling
- Unscheduled – walk-ins

Vaccination site

03 COVID-19 **screening**

04 **Confirmation** of client details

05 **Vaccine** administration

06 After vaccination & **observation**

07 **Disposal** of COVID-19 vaccine vial

No **AEFI**

AEFI

- *Manage*
- *Report*
- *Refer (if applicable)*

EVDS WORKFLOW PROCESS

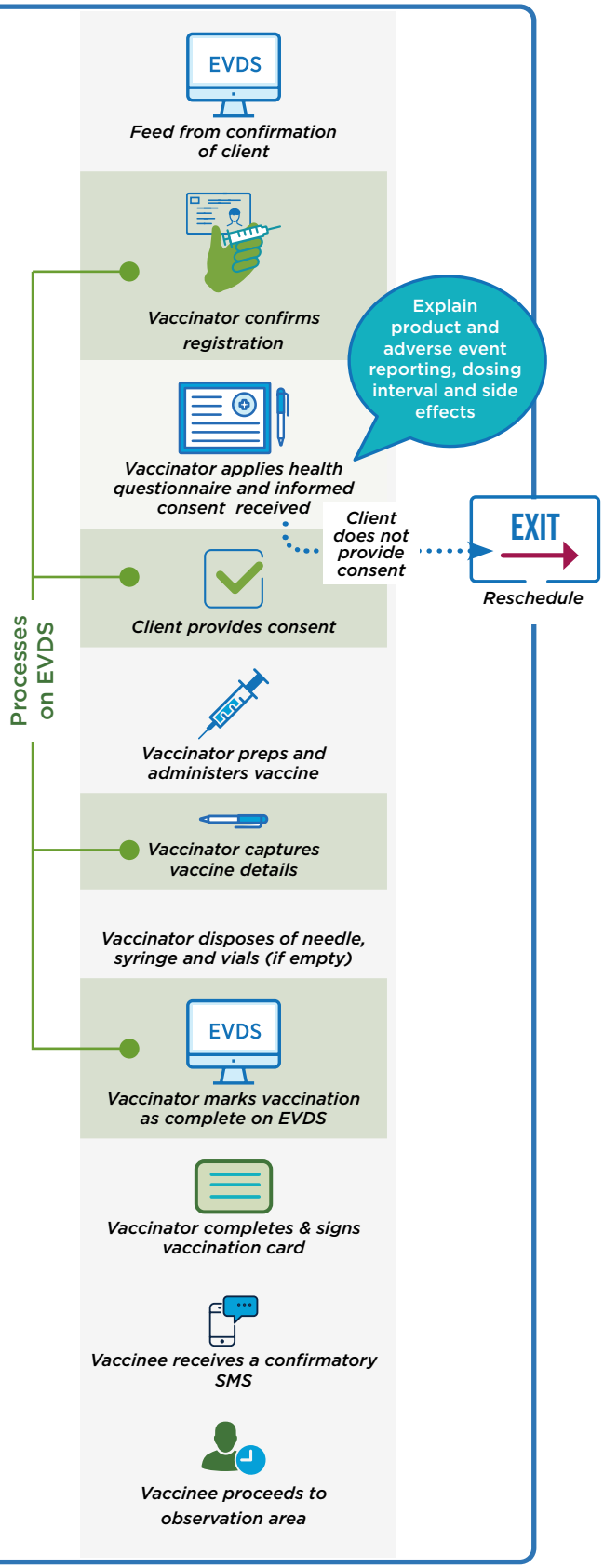
- Eligible people are invited to enrol through the self-registration portal
- EVDS sends SMS to the client to confirm enrolment
- The on-site registration assistant will help with enrolment on the EVDS

- The client is scheduled to receive the vaccine at an approved vaccination site. In some cases the clients will receive an SMS with details of the scheduled appointment

- The client will present with a vaccination code for their scheduled appointment
- Their details will be confirmed as matching those on the EVDS
- If the demographic information and medical aid details are incorrect, administrative personnel at the site will update details on EVDS immediately

- The client provides consent
- The vaccinator administers the vaccine and *only after this*, records the vaccination on EVDS
- On the EVDS, after administering the vaccine, the vaccinator selects the vaccine, batch number, expiry date and dose number.
- The system will record the date and time of dose automatically. An SMS will be sent from the EVDS, to the mobile number of the vaccinee to confirm that vaccine was administered.
- A reminder sms, with the date of the next appointment (if applicable) will be provided closer to the time.

- Record the administered dose on the EVDS and the vaccination card. Register vaccination as complete on EVDS.
- If applicable, an SMS will be sent to the vaccinee to provide details of the date and time of the next appointment.
- A similar process will be followed for any subsequent doses required.



7

Enrolment on the EVDS

01 Enrolment on the EVDS
02 SCHEDULING
03 COVID-19 SCREENING
04 CONFIRMATION OF CLIENT DETAILS
05 VACCINE ADMINISTRATION
06 AFTER VACCINATION & OBSERVATION
07 DISPOSAL OF COVID-19 VACCINE

THE CLIENT JOURNEY

- **Social mobilisation & public announcements create demand for vaccination**

In order to be vaccinated **clients need to be enrolled on the EVDS**

- **Clients have two options for EVDS enrolment**

Self-enrolment

- **On the internet**
- **Through Whatsapp**
- **On USSD** {through the official **Covid-19 vaccination registration portal**}

or

Assisted enrolment

Off-site
{for ease of access, this could be at home, at a friend, on their phone}

On-site
{Vaccination sites should provide for on-site enrolment on the EVDS}

- **On the EVDS clients fill in:**

Where they live

The preferred date and time for their vaccination

Enrolment on the EVDS 01

SCHEDULING 02

COVID-19 SCREENING 03

CONFIRMATION OF CLIENT DETAILS 04

VACCINE ADMINISTRATION 05

AFTER VACCINATION & OBSERVATION 06

DISPOSAL OF COVID-19 VACCINE 07

EVDS WORKFLOW PROCESS

- **Eligible people enrol through the self-registration portal**
- **The EVDS accommodates web-based, WhatsApp, and USSD registration**
- **EVDS sends SMS to the client** to confirm enrolment
- **The** on-site registration assistant **will help with enrolment on the EVDS**

TAKE NOTE

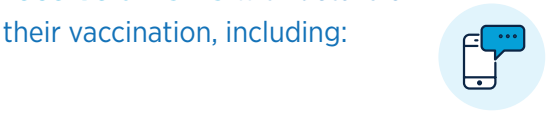
Being vaccinated with the COVID-19 vaccine is a choice. A client may exit the process at any point and may return at a later date to get vaccinated

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.

All clients follow the same vaccination journey irrespective of where they live or work

THE CLIENT JOURNEY

Clients enroled on EVDS will receive an SMS with details of their vaccination, including:



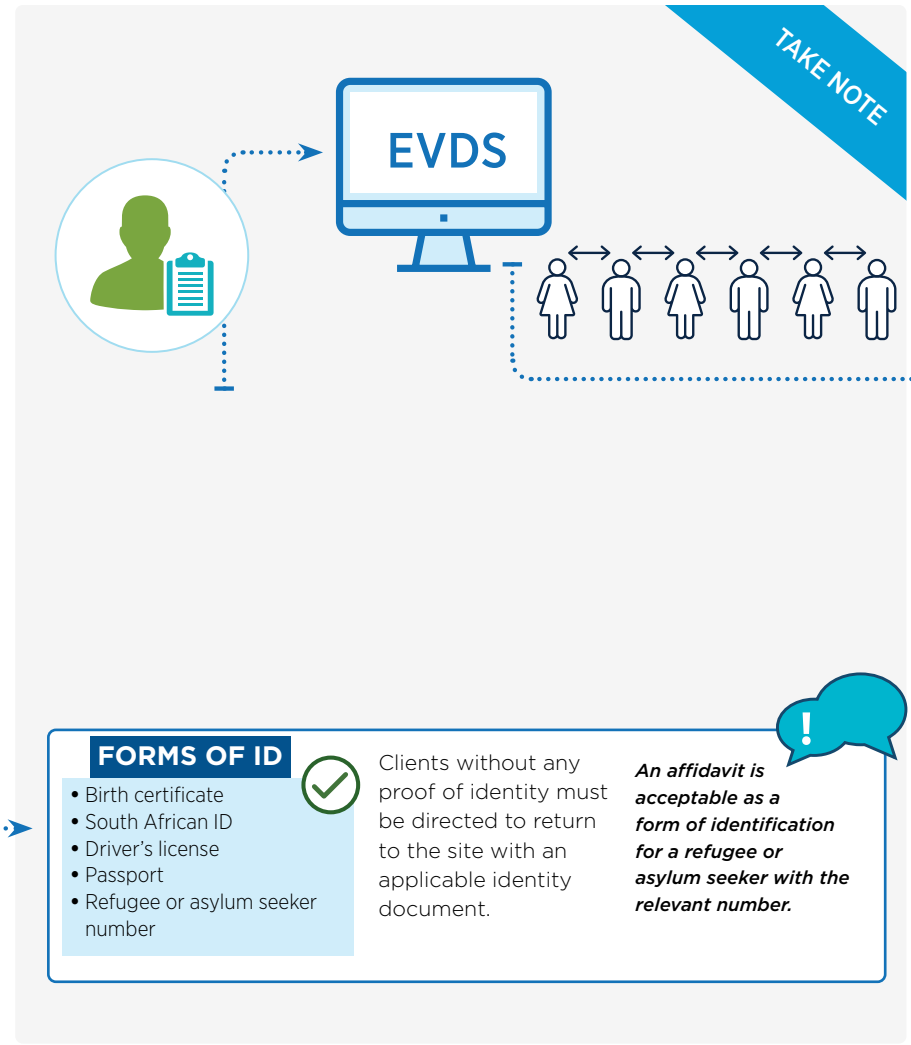
- **Clients will also receive a vaccination code**

Clients are required 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 scheduling at that site

A similar process will be followed for any subsequent doses as recommended by NDoH

EVDS WORKFLOW PROCESS



7

01 ENROLMENT ON EVDS

02 SCHEDULING

03 COVID-19 **screening**

04 CONFIRMATION OF CLIENT DETAILS

05 VACCINE ADMINISTRATION

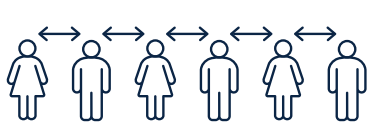
06 AFTER VACCINATION & OBSERVATION

07 DISPOSAL OF COVID-19 VACCINE

SITES AT WHICH PROCESS IS APPLICABLE

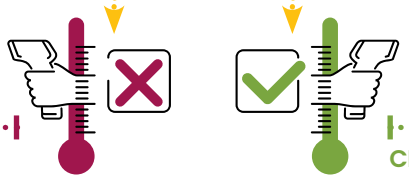
PRIMARY VACCINATION SITE	FIXED OUTREACH SERVICES	TEMPORARY OUTREACH SERVICES	MOBILE SERVICE	VACCINATION SITE MANAGER
✓	✓	✓	✓	

THE CLIENT JOURNEY



COVID-19 SCREENING

- **On arrival at a vaccination site, all clients and staff working there should be screened for COVID-19**



COVID-19 SYMPTOMS

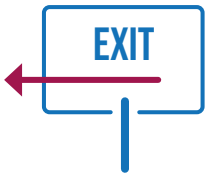
DIRECT TO NEAREST HEALTH ESTABLISHMENT

NO COVID-19 SYMPTOMS

CLIENTS MOVE ON TO CONFIRMATION OF CLIENT DETAILS

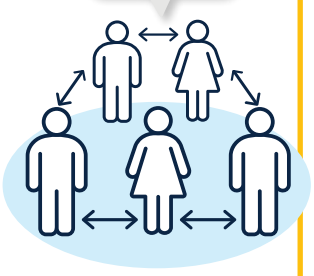
THE QUEUE MARSHAL

- **Directs those with COVID-19 symptoms to exit the site for examination and testing by their health care provider**
- **And directs those without COVID-19 symptoms to the waiting area**



EXIT

These **clients are welcome to return for vaccination** once they are well



Waiting area

STAFF MANAGING SITE WORKFLOW

VACCINE CONTROLLER | EVDS SCHEDULER | ADMINISTRATIVE STAFF | COVID-19 SCREENING OFFICER | QUEUE MARSHALL | VACCINATOR

EVDS WORKFLOW PROCESS

- **Nothing is required on the EVDS for the COVID-19 screening step**

TAKE NOTE

Queue marshals should be fully briefed by the vaccination site manager *on the processes at the site, and their specific roles at the various steps.*

QUEUE MARSHALS: ROLES & RESPONSIBILITIES

- **Welcome and direct** clients through entry and exit points
- **Facilitate a one-way flow** of clients
- **Assist in process of screening clients** as they enter the vaccination site (if needed)
- **Control and maintain order** in client waiting areas
- **Direct clients to ablution facilities** as needed
- Advise and **enforce social distancing** protocols
- Monitor and **enforce use of face masks**
- **Attend to clients' questions**
- **Register complaints, resolve or refer clients** to the right station
- **Issue health information** pamphlets and/or COVID-19 related educational material

FORMS OF ID

- Birth certificate
- South African ID
- Driver's licence
- Passport
- Refugee or asylum seeker number

Clients without any proof of identity must be directed to return to the site with an applicable identity document.

An affidavit is acceptable as a form of identification for a refugee or asylum seeker without the relevant number.

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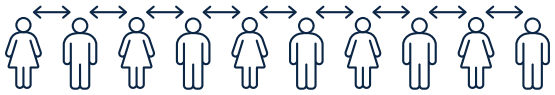
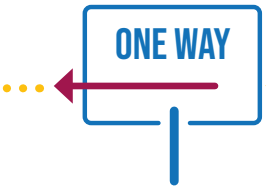
SITES AT WHICH PROCESS APPLICABLE

PRIMARY VACCINATION SITE	FIXED OUTREACH SERVICES	TEMPORARY OUTREACH SERVICES	MOBILE SERVICE	VACCINATION SITE MANAGER
✓	✓	✓	✓	

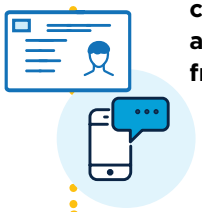
THE CLIENT JOURNEY



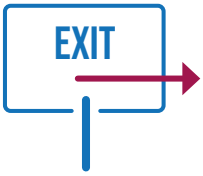
- The marshall directs clients to the administration desk



- Clients must bring proof of identification to confirm their personal and, if applicable, medical aid details, and present the vaccination code from the EVDS registration



- Clients whose details are successfully confirmed continue to the vaccination station
- If the client's name or proof of identification number is incorrect, they should re-enrol with the correct information



- Clients without any proof of identity must be directed to return to the site with an applicable identity documentor affidavit

A similar process will be followed for any subsequent doses, as recommended by the NDoH

STAFF MANAGING SITE WORKFLOW

VACCINE CONTROLLER | EVDS SCHEDULER | ADMINISTRATIVE STAFF | COVID-19 SCREENING OFFICER | QUEUE MARSHALL | VACCINATOR

EVDS WORKFLOW PROCESS

Paper records or registration **only to be used if EVDS is off-line or electricity shut-down**!

- **The client will present with a vaccination code for their scheduled appointment**
- **Their details will be confirmed as matching those on the EVDS**
- **If the demographic information and medical aid details are incorrect, administrative personnel at the site will update details on EVDS immediately.**

Confirmation of client details

TAKE NOTE

Marshals play an important role in reassuring clients and answering questions.

UNSCHEDULED, ENROLED ON EVDS WALK-IN CLIENTS

- Clients enroled on EVDS, but not scheduled could, queue to receive the vaccine if there is capacity.

If the vaccination site cannot accommodate same-day vaccination, advise the client to return on the scheduled appointment date and time, or another suitable date and time.

UNSCHEDULED, NOT ENROLED ON EVDS WALK-IN CLIENTS

These clients could:

- be registered on-site and receive the vaccine on the same day
- have an appointment scheduled for vaccination, if the vaccination site capacity does not allow same-day vaccination.
- self-enrol for a scheduled appointment on another day.

Alternatively, they 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.

The site should put measures in place to accommodate walk-in clients

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05 **Vaccine** administration

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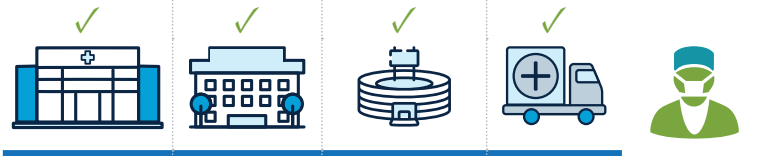
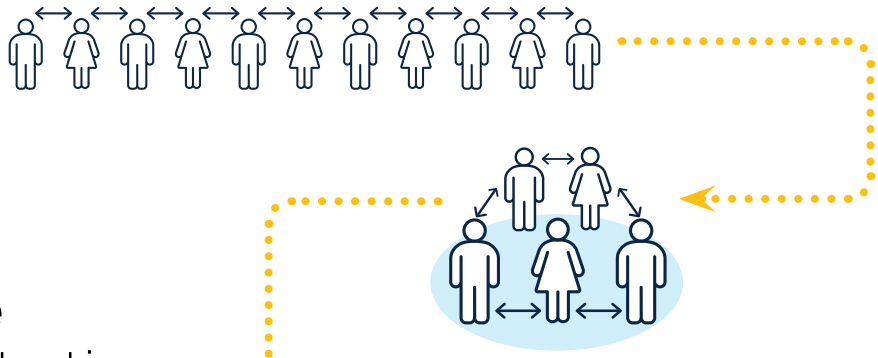
07 DISPOSAL OF COVID-19 VACCINE

SITES AT WHICH PROCESS IS APPLICABLE



THE CLIENT JOURNEY



- **The client provides consent prior to receiving the vaccine**

- **The vaccinator administers the vaccine**

HEALTH CARE PROVIDER ON-SITE

Every vaccination site has a designated health care provider responsible for client care if an adverse event occurs. The HCP may also fulfil another role at the vaccination site, for example as a vaccinator or vaccination site manager.

STAFF MANAGING SITE WORKFLOW

VACCINE CONTROLLER | EVDS SCHEDULER | ADMINISTRATIVE STAFF | COVID-19 SCREENING OFFICER | QUEUE MARSHALL | VACCINATOR

EVDS WORKFLOW PROCESS

- **The client provides consent, after this, the vaccinator administers the vaccine and only after this, records the vaccination on EVDS**
- **On the EVDS, after administering the vaccine, the vaccinator selects the vaccine, batch number, expiry date and dose number**
- **The system will record the date and time of dose automatically**
- **An SMS will be sent from the EVDS, to the mobile number of the vaccinee to confirm that the vaccine was administered**
- **A reminder sms, with the date of the next appointment (if applicable) will be provided closer to the time**

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TAKE NOTE

The following pages contain detailed information covering:

- Administering the health questionnaire
- Informed consent
- Administration of the vaccination
- Disposal of needles, syringes, and vials
- Vaccinee observation
- Adverse event following immunisation in observation area
- Disposal of medical waste

EVDS must be used to capture details of the vaccine administration process

TAKE NOTE

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 10: Precautions to consider before vaccination

COVID-19 VACCINE JANSSEN AND COMIRNATY®	
EXCERCISE CAUTION	• **People with a history of a severe allergic reaction to any component of the vaccine should NOT be vaccinated. This is the only CONTRAINDICATION for all COVID-19 vaccines.** Always refer to the professional information 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 • **Immunocompromised persons may have a reduced response** to any of the COVID-19 vaccines and may require additional doses in the future • 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**
DO VACCINATE	• COVID-19 vaccination should be offered to **women who are eligible to be vaccinated during any stage of pregnancy, and during lactation.** Health care workers are encouraged to discuss the benefits and possible risks of COVID-19 vaccination with their patients. These discussions should include the increased risk, of severe COVID-19 disease in pregnant women when compared to non-pregnant women, reassurance about the growing evidence supporting the safety of vaccines in pregnant and breastfeeding women, the strong immune response following vaccination and the benefits of immune transfer to the baby, and ongoing safety monitoring of vaccine use in pregnancy. Furthermore, that there are no known risks associated with other non-live vaccines given routinely to pregnant women • COVID-19 vaccination is strongly encouraged for **non-pregnant women** contemplating pregnancy • **COVID-19 vaccines may be administered without regard to timing of other vaccines**. This includes simultaneous administration of COVID-19 vaccine and other vaccines on the same day. If multiple vaccines are administered at a single visit, administer each injection in a different injection site (different arm), with the COVID-19 vaccine administered on the LEFT arm.
CHECK INTERVAL	• 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**
PRECAUTIONS	
WATCH SYMPTOMS	• 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 providers 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. **Myocarditis and pericarditis** have been observed following Comirnaty® vaccination. These very rare cases have primarily occurred within 14 days following vaccination, more often after the second vaccination, and more often in younger men • To identify possible **myocarditis or pericarditis** those vaccinated should be seek immediate medical attention if they develop symptoms such as (acute or persisting) chest pain, shortness of breath, or palpitations following vaccination. Healthcare professionals should follow the EML Standard Treatment Guidelines to diagnose and treat myocarditis and pericarditis if they occur

Informed consent

TAKE NOTE

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 more than one dose, ensure that clients are informed not to miss any subsequent doses and emphasise that it is important to complete the vaccination course.**

Everyone receiving health care services in our country has the right to information about the services they receive, 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 clients 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.

Annexures:

Annexure: Health questionnaire

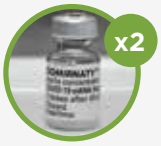
Informed consent – Comirnaty® vaccines

Informed consent - COVID-19 Vaccine Janssen®

The vaccinator must indicate:

which vaccine is being used

what happens if the client reacts to the vaccination (has an **adverse event following immunisation**)



whether a **subsequent vaccine dose** is needed at a follow-up visit to the vaccination site

how long between these doses

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 the client has provided their consent, the vaccine can be administered.

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.

RECORDING AND BILLING

- Anyone exiting the site, before being vaccinated, should not be recorded as having received the vaccine.
- Vaccinators MUST NOT record vaccination before the vaccine has actually been administered to the client.
- The medical aid of an insured client MUST NOT be billed until the vaccine administration process is completed.

Because vaccination is a choice clients may exit the process at any point. If the vaccination is recorded on EVDS, or the medical aid billed, before it is given, the transactions will have to be reversed, reducing the site's efficiency.

TAKE NOTE

Administration of the vaccine

Vaccines may be administered by a vaccinator who is a health care provider, is trained, competent, and acting within his/her 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.

NOTE

- Vaccine vials must be kept in a **passive container**, and protected from **light**, at the vaccinator's desk - the cold chain must be maintained at all times
- The vaccinator must **prepare** and **administer** the vaccine dose

- ✓ Right vaccine
- ✓ Right diluent
- ✓ Time
- ✓ Route
- ✓ Right dose

- **It is strongly advised that vaccine doses are not pre-drawn.** The vaccinator must prepare the doses prior to administration thereof. This is important to:
  - ☐ ensure the integrity of the cold-chain
  - ☐ prevent exposure of vaccines to undue light as vaccines are light sensitive
  - ☐ prevent any errors in the vaccination process to protect the vaccinator from medico-legal liability
  - ☐ prevent needle stick injuries as recapping poses a risk to the vaccinator and could contribute to contamination of the pre-drawn syringe
  - ☐ prevent vaccine wastage

Preparing to administer the COVID-19 vaccine Janssen®

1

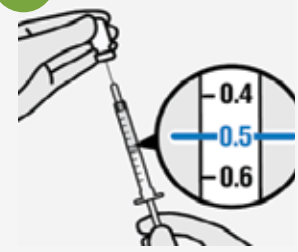
Remember to record date and time on the vial - and discard after six hours!

2

Swirl the vial gently

Do not shake.

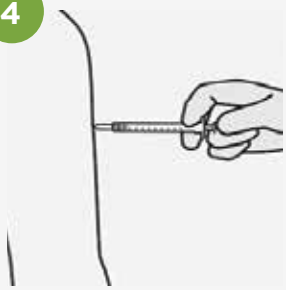
3



Withdraw 0.5 mL

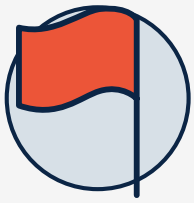
Use a sterile needle and sterile syringe to extract a single-dose of 0.5mL from the multi-dose vial

4



Inject 0.5 mL

Adminster by intramuscular injection only into the deltoid muscle of the upper arm



Open vaccine vials should be discarded after six hours

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

TAKE NOTE

Preparing to administer Comirnaty® vaccine

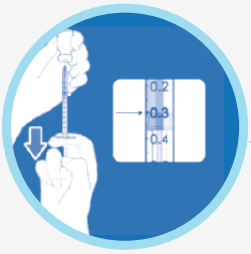
- Gently invert the undiluted vial 10 times before dilution
- Do not shake

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 technique

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

Indicate the date and time of reconstitution

- 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 Cominarty®

The Comirnaty® vaccine requires two doses administered at least 21 days apart

Booster doses are administered to a vaccinated population that has completed a primary vaccination series (currently one dose of COVID-19 vaccine Janssen® or two doses of Comirnaty® vaccine) when, due to waining immunity the clinical protection reduce below a acceptable rate in the target population. The **objective of a booster dose is to restore vaccine effectiveness** from that deemed no longer sufficient.

Additional doses of a vaccine may be needed as part of an extended primary series for target populations where the immune response rate following the standard primary series (currently one dose of COVID-19 vaccine Janssen® or two doses of Comirnaty® vaccine) is deemed insufficient. **The objective of an additional dose in the primary series is to optimize or enhance the immune response to establish a sufficient level of effectiveness** against disease.

TAKE NOTE

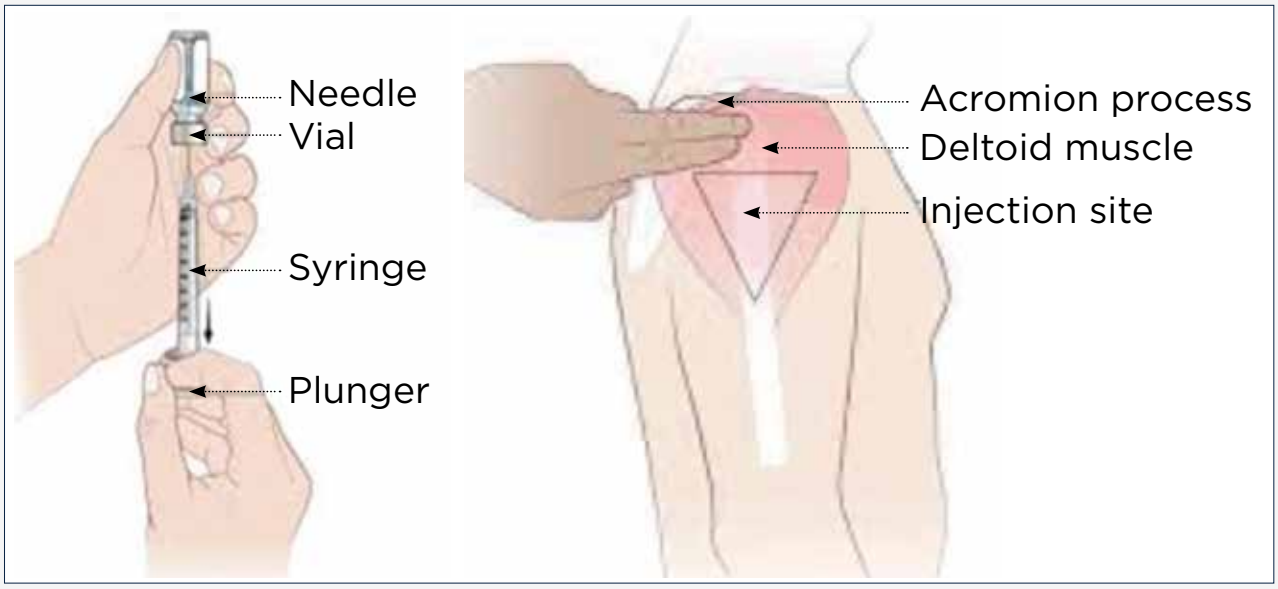
The vaccinator must:

Vaccine procedure

1. Always **disinfect hands** before starting with this procedure
2. Before opening a vial, **confirm** that the vaccine has not expired
3. **Clean the rubber stopper** of the vial with a cotton swab moistened with clean water, before each withdrawal from the vial
4. **Draw up the required dose** (see vaccine-specific instructions) using a sterile needle and syringe. Follow the **"one needle, one syringe, one time"** policy
5. **Expose the arm** completely from shoulder to elbow
6. Identify the injection site which is **3-5cm below the acromion process**
7. **Clean skin** with cotton wool moistened with water, not an alcohol swab
8. Administer the required dose of vaccine into the **deltoid muscle (upper arm) of the non-dominant arm.**
9. 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**
10. **Inject the vaccine slowly** and **remove needle quickly**
11. Apply gentle pressure with **sterile gauze** or **cotton ball**
12. **Do not rub** the site as this interferes with the absorption of the vaccine
13. **Discard needle and syringe as one** (without disconnecting or re-capping) into the sharps container
14. **Disinfect your hands** and make the client comfortable

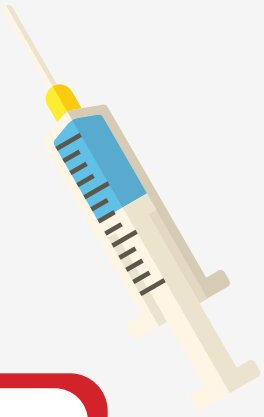
TAKE NOTE

ADMINISTERING THE COVID-19 VACCINE



Do's

- ✓ **DO clean vaccine spills with a viricidal**
- ✓ **DO administer COVID-19 vaccines intramuscularly**
- ✓ **ALWAYS disinfect your hands before and after the procedure**



Don'ts

- ✗ **DON'T predraw syringes with vaccines for use later**
- ✗ **DON'T leave the needle and syringe in a vial**
- ✗ **DON'T soak the cotton balls/swabs in water and leave for the day -this leads to infections**
- ✗ **DON'T administer COVID-19 vaccines intravenously or subcutaneously.**

TAKE NOTE

Example of sharps container

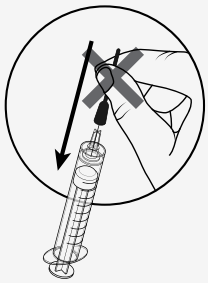
Disposal of needles, syringes, and vials

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.

Ensure the safe handling and disposal of sharps' containers:

Don'ts

- **DON'T recap needles before disposal into the container**
- **DON'T handle or shake the sharps' container more than necessary. Never squeeze, sit, or stand on sharps' containers**
- **DON'T fill sharps containers more than ¾ full, or above the 'full line' of the container as this increases the risk of needle-stick injuries**



DO NOT recap needles before disposal into the container

Do's

- **DO seal sharps containers when they are ¾ full**
- **DO 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**
- **DO 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**

TAKE NOTE

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.

ANNEXURES:

SOP - Vaccination process at vaccination site

Job aid - Preparing to administer Comirnaty® Vaccine

Job aid - Preparing to administer COVID-19 Vaccine Janssen®

Job aid – Administration of a COVID-19 Vaccine

Copy of the Vaccination Card

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02 SCHEDULING

03 COVID-19 SCREENING

04 CONFIRMATION OF CLIENT DETAILS

05 VACCINE ADMINISTRATION

06 After vaccination & **observation**

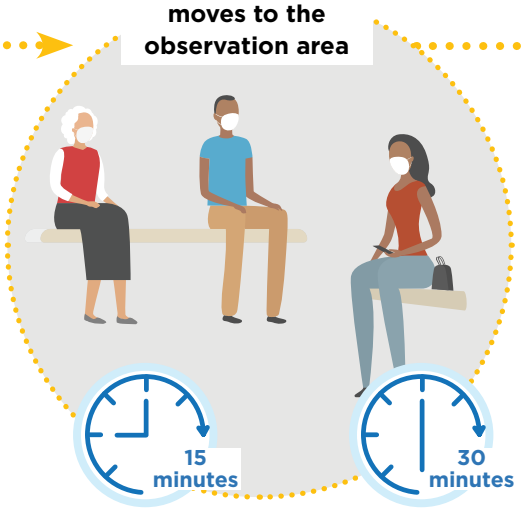
07 DISPOSAL OF COVID-19 VACCINE

SITES AT WHICH PROCESS IS APPLICABLE

PRIMARY VACCINATION SITE	FIXED OUTREACH SERVICES	TEMPORARY OUTREACH SERVICES	MOBILE SERVICE	VACCINATION SITE MANAGER
✓	✓	✓	✓	

THE CLIENT JOURNEY

- **The vaccinee receives SMS from EVDS confirming vaccination**
- **The vaccinee receives a completed vaccination card from the vaccinator**
- **The vaccinee moves to the observation area**



- **The vaccinee should remain in the observation area for at least 15 minutes**
- **If the vaccinee is considered at risk of anaphylaxis the waiting time should be extended to 30 minutes**

After receiving their vaccine, **vaccinees receive an SMS and vaccination card and are directed to a dedicated observation area**

Vaccinee must **keep a safe social distance and wear face masks**. After waiting the required time, they may leave the vaccination site if they are well

EXIT

At this time any competent health care provider must be duty to make sure vaccinees are well immediately after vaccination.

STAFF MANAGING SITE WORKFLOW

VACCINE CONTROLLER | EVDS SCHEDULER | ADMINISTRATIVE STAFF | COVID-19 SCREENING OFFICER | QUEUE MARSHALL | VACCINATOR

EVDS WORKFLOW PROCESS

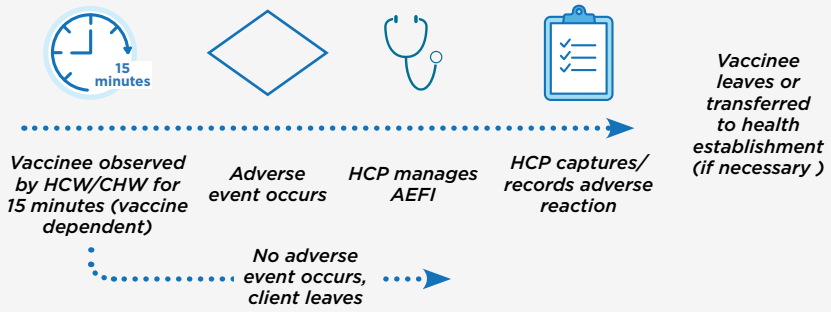
EVDS

- **Record the administered dose on the EVDS and the vaccination card**
- **Register vaccination as complete on EVDS.**
- **If applicable, an SMS will be sent to the vaccinee to provide details of the date and time of the next appointment**
- **A similar process will be followed for any subsequent doses required**

ENROLMENT ON EVDS 01
SCHEDULING 02
COVID-19 SCREENING 03
CONFIRMATION OF CLIENT DETAILS 04
VACCINE ADMINISTRATION 05
After vaccination & **observation** 06
DISPOSAL OF COVID-19 VACCINE 07

TAKE NOTE

ADVERSE EVENT FOLLOWING IMMUNISATION IN OBSERVATION AREA



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

TAKE NOTE

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:

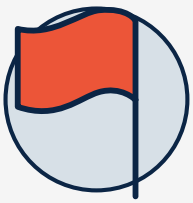
- Acute onset of signs and symptoms
- Urticaria (hives) or angioedema
- Bronchospasm, wheezing, dyspnoea, chest tightness
- Laryngeal oedema with upper airway obstruction or stridor
- Gastrointestinal symptoms such as nausea, vomiting, diarrhoea
- Hypotension and/or shock
- Dizziness, paraesthesia, syncope,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

All cases of anaphylaxis should be recorded immediately on an AEFI case reporting form before the vaccinee leaves the vaccination site.

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** can be contacted for support on **0800 029 999.**

For **detailed information on reporting of AEFI please refer to Chapter 8**.



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.

TAKE NOTE

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

Resuscitate (CAB) immediately – if required	
Place hypotensive or shocked patient in horizontal position. Do NOT sit the patient up.	
Severe anaphylaxis: administer oxygen by facemask at high flow rate of 15 L/min.	
Remove the trigger if possible.	
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. 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: 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 wheezing:	
Salbutamol 0.5%, solution, nebulised, with high flow oxygen. 0.5–1 mL (2.5–5 mg) salbutamol 0.5% solution, in 4 mL of sodium chloride 0.9%.	
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.	

Source: National Department of Health STG & EML PHC 2020

7

01 ENROLMENT ON EVDS

02 SCHEDULING

03 COVID-19 SCREENING

04 CONFIRMATION OF CLIENT DETAILS

04 VACCINE ADMINISTRATION

06 AFTER VACCINATION & OBSERVATION

07 **Conclusion** of vaccination session

END OF VACCINATION SESSION

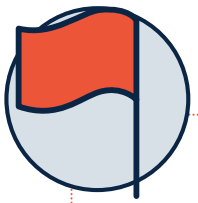
Concluding the vaccination session is **an integral part of the process and should be done properly**

Unused vaccine vials:

- **Any unused open COVID-19 vaccine vials must be dealt with according to the SOP for the disposal of that specific vaccine**
- **Count the unopened COVID-19 vaccine vials and write down the number on the tally sheet**
- **Unopened vaccine vials from temporary outreach and mobile units should be returned to primary vaccination site in a vaccine carrier with the required coolant packs**
- **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**

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

- **Used and unopened vaccine vials that have expired or passed six hours after reconstitution or suffered heat exposure should be discarded into pharmaceutical waste containers or a biohazard container**
- **Before vials are disposed of, the label should be defaced with a permanent marker or the label removed. Do not break vials during disposal**
- **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**



Discard opened multi-dose vials, do not return or transport them!

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.

Managing problems that arise

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

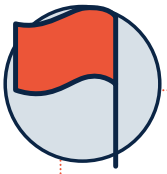
Crowd control and unexpected walk-ins

The strategy for vaccination encourages self-enrolment on EVDS but also recognises and accommodates that in many communities, clients will likely arrive at vaccination sites without electronic enrolment on the EVDS.

Thus, a process 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 to return at a later date as this would be a missed opportunity.

Every site must designate an administrative clerk to **back-capture all paper-based vaccination forms within 24 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.



Paper records or registration **only to be used if EVDS is off-line or electricity shut-down**!

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

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, 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.

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 far as possible.

Limitations of paper-based vaccination forms:

- 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 forms being illegible, decreasing the accuracy of health records
- Paper-based forms could contribute to adverse events following immunisation, if previous vaccination history on EVDS can 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.

Load shedding

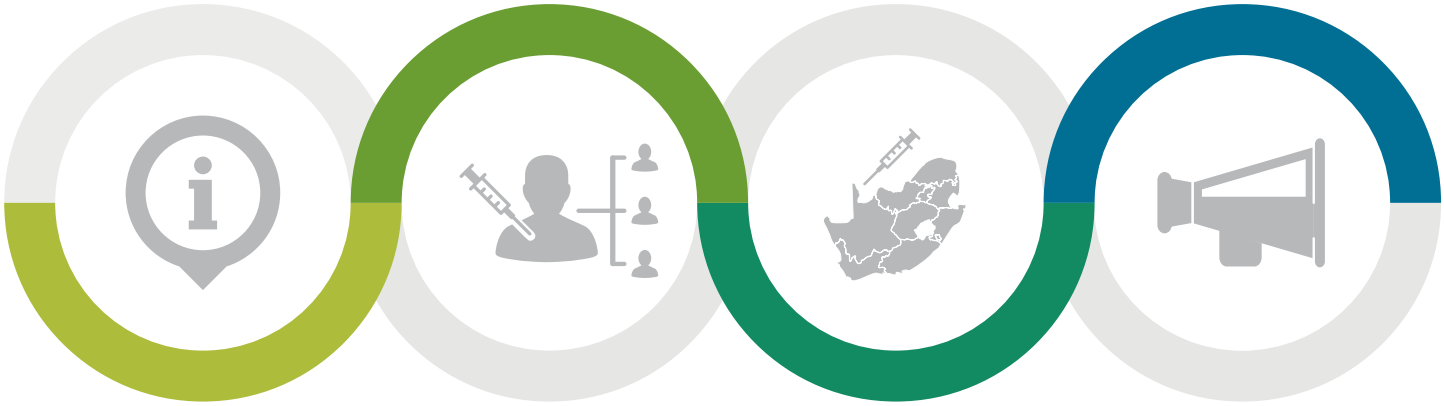
The vaccination site manager should consider the possibility of load shedding or power failure. Therefore, backup power sources to sustain cold storage and the use of tablets or computers required for SVS and EVDS, should be ensured.

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.

Key messages

	The client experience is critical - it is thus important to standardise the vaccination process to achieve equity in access and user experience
	Every vaccination site should accommodate walk-ins and provide for on-site enrolment on the EVDS
	Being vaccinated with the COVID-19 vaccine is a choice and a client may exit the process at any point and return at a later date to get vaccinated
	On arrival at a vaccination site, all clients and staff must undergo COVID-19 screening
	A one-way flow system and queue management at the vaccination site is important to make the process efficient and effective
	Paper records /registration may only be used if EVDS is off-line or electricity shut-down
	Vaccinators MUST NOT record vaccination before the vaccine has actually been administered to the client
	The medical aid of an insured client MUST NOT be billed until the vaccine administration process is completed
	A separate observation area is needed at all vaccination sites and measures in place to manage any vaccinee who experiences any AEFI



CHAPTER 8

Vaccine safety surveillance

Chapter 9
Monitoring & Evaluation

Chapter purpose

Chapter 8 describes the vaccine safety surveillance process, adverse events following immunisation (AEFI) reporting, investigation and causality assessment.

The contents of this chapter will be useful for:

Provincial and district surveillance officers

Pharmacovigilance committees

Vaccinators

Vaccines are extremely safe and effective. However, COVID-19 vaccines, similar to other vaccines and medicines, do have side effects. Adverse reactions may therefore occur, which is why it is very important to monitor the safety of the COVID-19 vaccines.

AEFIs in the context of COVID-19 vaccine roll-out

DEFINTION: AEFI

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 AEFIs with a COVID-19 vaccine. Current vaccine safety surveillance systems have been adapted to ensure that post-vaccination safety information is collected and processed, that the safety of the public is assured and to counter any real or perceived safety concerns

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

With the COVID-19 vaccine introduction, in addition to AEFIs monitoring, any AESI will also be monitored.

DEFINTION: AESI

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 AESIs include serious events that have followed other immunisations, for example, the following:

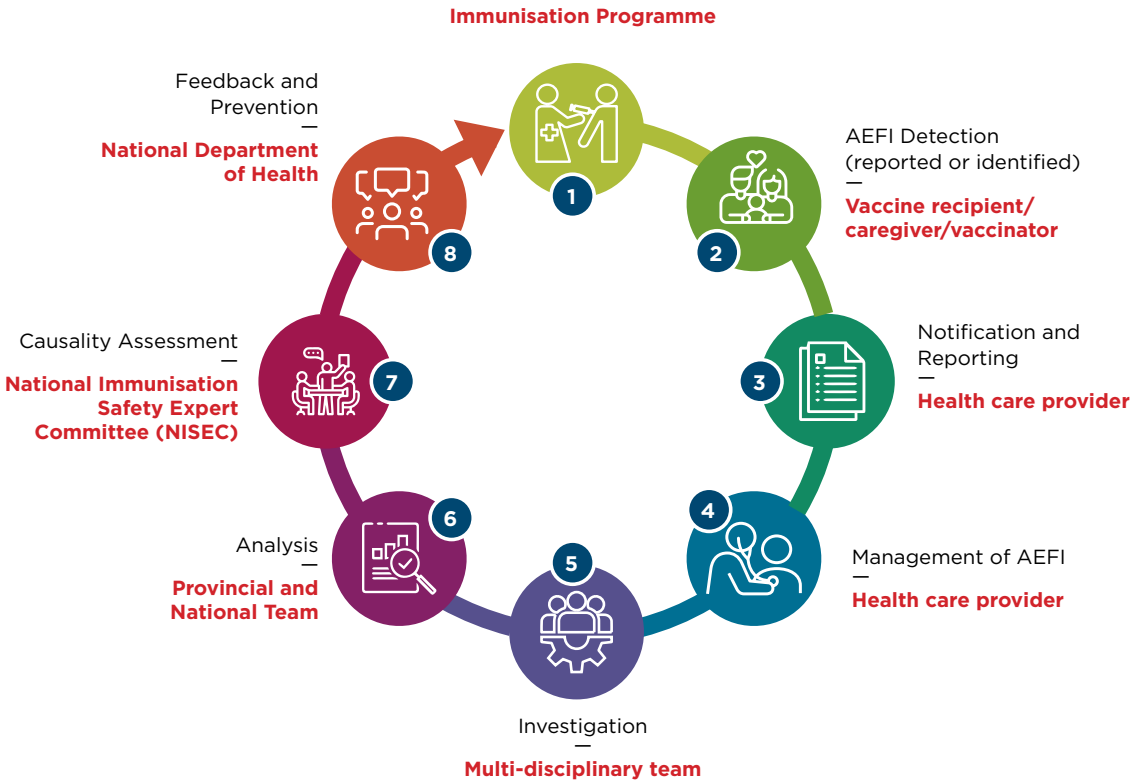
- Guillain-Barré syndrome (GBS)
- Acute disseminated encephalomyelitis (ADEM)
- Anaphylaxis
- Serious events potentially related to novel platforms and adjuvants
- Serious events related to vaccine failure/immunogenicity (vaccine-associated enhanced disease)
- Events that are potentially important for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

The vaccine safety surveillance cycle

The process for COVID-19 vaccine safety surveillance is the same as for EPI vaccines

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).** 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 following immunisation 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.

AEFI surveillance cycle, key players and stakeholders



Vaccine Manufacturing Industry	South African Health Products Regulatory Authority (SAHPRA)	National Department of Health (NDoH)	World Health Organization (WHO)	Ministerial Advisory Committees on Vaccines and Immunisation

Objectives of AEFI surveillance for the COVID-19 vaccines

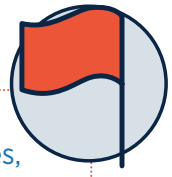
- Estimate rates of AEFI occurrence in the local population compared with trial and international data
- Identify problems, if any, with vaccine lots/brands leading to vaccine quality defect-related reactions
- Detect, correct and prevent immunisation error-related events
- Reduce the incidence of immunisation stress-related responses (ISRR) from apprehension or pain, through education and messaging
- Prevent false blame from the public, arising from coincidental events
- Timeous monitoring to prevent morbidity and mortality in recipients of COVID-19 vaccines
- Maintain confidence by addressing concerns, and raising awareness about vaccine risks

Categories of AEFI reporting for COVID-19 vaccines

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. The trigger events which follow immunisation can be classified into local or systemic reactions which may be minor or severe, while the outcomes of these adverse events could either be classified as non-serious or serious.

Vaccinators have the responsibility of providing education to clients on possible side effects, identification of adverse events and immediate reporting thereof to their health establishment and/or health care provider/s.



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

AEFI reporting implications for COVID-19 vaccination

Health care providers must report ALL AEFIs, 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 AEFIs must be done within **48 hours** since the AEFI has been identified or the health establishment or vaccination site has been notified thereof.

Causality assessment is conducted for cases where the trigger reactions are severe or the outcome of the event is serious.

The table below provides a summary of the different categories of AEFIs, with a brief description of each category. Implications for reporting and investigation of AEFIs within the context of COVID-19 vaccination are highlighted.

Categories of AEFIs and implications for COVID-19 vaccines

MINOR REACTIONS Report within 24 hours		• Do not pose a potential risk • Usually occur within a few hours of vaccination • Resolve after short period of time • Important to inform and reassure vaccinees about such events • The outcome of these events might be serious or non-serious	**Local and systemic reactions can occur as part of the immune response. Other vaccine components can trigger reactions. Reporting of all COVID-19 AEFIs is compulsory.**
SEVERE REACTIONS Report within 24 hours Investigate within 48 hours		• 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 • The outcome of these events might be serious or non-serious	**Vaccines are only approved for use when frequency of severe reactions is very rare. Information on rare and very rare AEFIs with COVID-19 vaccines is lacking.**
SERIOUS EVENTS Report within 24 hours Investigate within 48 hours		• Death • Hospitalisation or prolongation of existing hospitalisation • Persistent or significant disability or incapacity • Congenital anomaly/birth defect • Life-threatening • Event of medical significance	**Information on serious, rare and very rare adverse events following COVID-19 vaccination is lacking.**
CLUSTERS Report within 24 hours Investigate within 48 hours		Two or more AEFI cases of the same or similar events related in: • Time/place/geographical setting; and/or • Vaccine (batch/lot, manufacturer, facility)	**Clusters are anticipated when vaccines are administered on a massive scale, as with COVID-19. Chances for immunisation errors, immunisation stress-related response and coincidental events are much higher than with routine immunisation.**
SIGNALS		Information arising from: • 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	**Signal detection, verification and response is a key activity in COVID-19 context. Best done by pooling data.**

Causes of AEFIs 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 temporarily associated with immunisation.* The table below provides a summary of the causes of AEFIs and the 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 and administration may be in use. All these factors can introduce human error.

Causes of AEFIs and implications for COVID-19 vaccination

INCONSISTENT WITH CAUSAL ASSOCIATION TO IMMUNISATION		CONSISTENT WITH CAUSAL ASSOCIATION TO IMMUNISATION
Vaccine product-related reaction	**Vaccine quality defect-related reaction**	**Coincidental event**
Caused or precipitated by a vaccine due to one or more of the inherent properties of the vaccine product	**Caused or precipitated by a vaccine, due to one or more quality defects of the product**	**An event that happens after vaccination but is not caused by the vaccine or vaccination process**
Implications for COVID-19	**Implications for COVID-19**	**Implications for COVID-19**
• Rare and very rare adverse events are not known until the vaccine is used in large populations • Important to monitor all AEFIs	• Potential vaccine quality defects might not be known for new vaccine platforms • Rapid scaling up of vaccine production could pose potential risks	• Coincidental events can occur due to comorbidities in vaccine recipients • Coincidental events can also occur in healthy individuals without comorbidities • Could be a newly acquired or diagnosed illness • Other exposures to drugs or toxins prior to event • Compare with the expected incidence (background rate) of event in the unvaccinated population
Immunisation error-related reaction	**Immunisation stress-related response**	
Caused by inappropriate vaccine handling, prescribing or administration	**Arising from anxiety about the immunisation and fear of injection**	
Implications for COVID-19	**Implications for COVID-19**	
• Vaccination on massive scale within short time interval • Staff who are not familiar with immunisation might assist • Use of multiple vaccines with different specifications for administration	Immunisation stress-related responses are anticipated due to: • Vaccinating older age groups • Different vaccinating environments • Novelty of the vaccines to public Example: Fainting following vaccination	

Preventing immunisation programme errors contributing to AEFIs

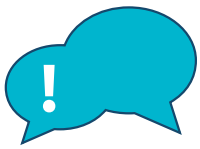
- Screen the client for any contraindications to vaccination. Contraindications are rare characteristics in vaccinees that increase the risk of a serious adverse reaction if the vaccine is given. In the case of a contraindication, **do NOT vaccinate.**
- Screen for precautions, which are events or conditions that should be considered in determining if the benefits of the vaccine outweigh the risks. If so, vaccinate with **CAUTION**. Refer to Chapter 7 for more information on contraindications and precautions.
- Vaccination should take place in a controlled setting, with the vaccinee staying at the vaccination site at least 15 minutes after vaccination.

Common principles which should be adhered to in practice, to prevent any immunisation error related to AEFI
Screen for contraindications to vaccination e.g. previous anaphylaxis If any contraindication → **do NOT vaccinate**
Screen for precautions and determine if the benefits of the vaccine outweigh the risks. If any precautions → **vaccinate with CAUTION**
Do not store and/or pack other diluents or medicines together with any COVID-19 vaccines to avoid reconstitution errors
Always check the labels of vaccines and diluents before reconstitution – use the diluent recommended by the manufacturer
Follow manufacturer's recommendations on vaccine preparation, route and technique of administration
Check expiry- or manufacturing date of vaccine and diluent. Check for signs of freezing. **Do NOT use beyond specifications**
Draw the vaccine into the syringe just before vaccination and **do not touch the needle** to avoid contamination of the vaccine and/or the syringe
Do not touch the vial stopper of the vaccine vial to avoid contamination of the vial. If reconstituted, discard open vaccine vial at end of immunisation session
Do not cover the vaccine carrier with the lid while the reconstituted vaccine vial is in the foam pad
Discard vaccine if reconstituted or opened after 6 hours or at the end of the session, whichever occurs first
When in doubt, contact your supervisor for clarification. **Do not hesitate to report issues or concerns when identified**

Reporting and investigation process for AEFIs and AESIs

The ultimate goal of timely reporting and investigation of all AEFIs and AESIs is:

- Timely **causality assessment** of reported cases should take place **within a maximum of 30 days of reporting**.
- If any programme errors are identified, immediate remedial action can be taken.
- Preventing any safety risks
- Ensure 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.

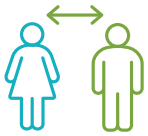


All health care providers have a **professional responsibility** to report any adverse events

Who is responsible for AEFI and AESI reporting?

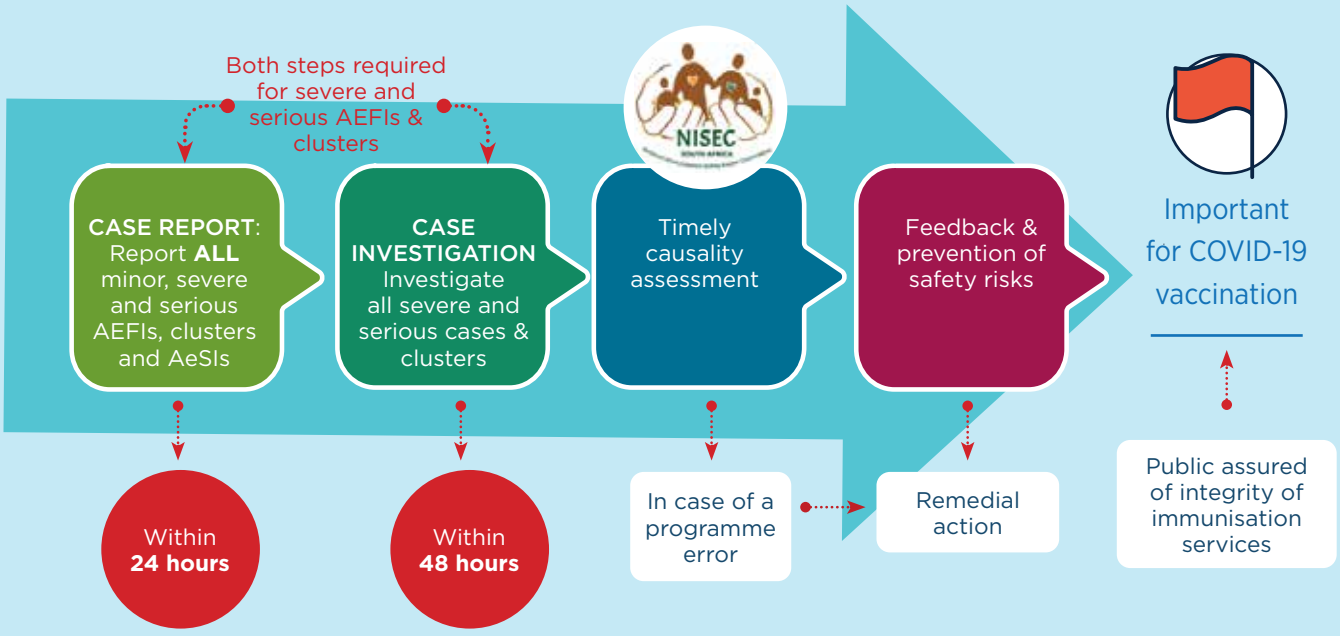
All health care providers providing vaccination services

Health care providers providing clinical treatment of AEFIs and AESIs in health establishments



Vaccinees

Researchers conducting clinical trials or field trials



Goal of reporting and investigation of AEFIs

For COVID-19 vaccines, reports of severe and serious AEFIs must reach SAHPRA within 24 hours of occurrence through an expedited process. Reports of minor AEFIs must reach SAHPRA within seven days. All case reporting forms submitted to the EPI 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 AEFIs and AESIs surveillance

The table below 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.

Data collection tools for AEFI and AESI

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

All paper-based data collection tools are available as annexures 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-aefi/ and https://www.sahpra.org.za/health-products-vigilance/.

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

The case reporting form (CRF) which is available on the Med Safety App, should be completed for ALL AEFIs and AESIs, 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.

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

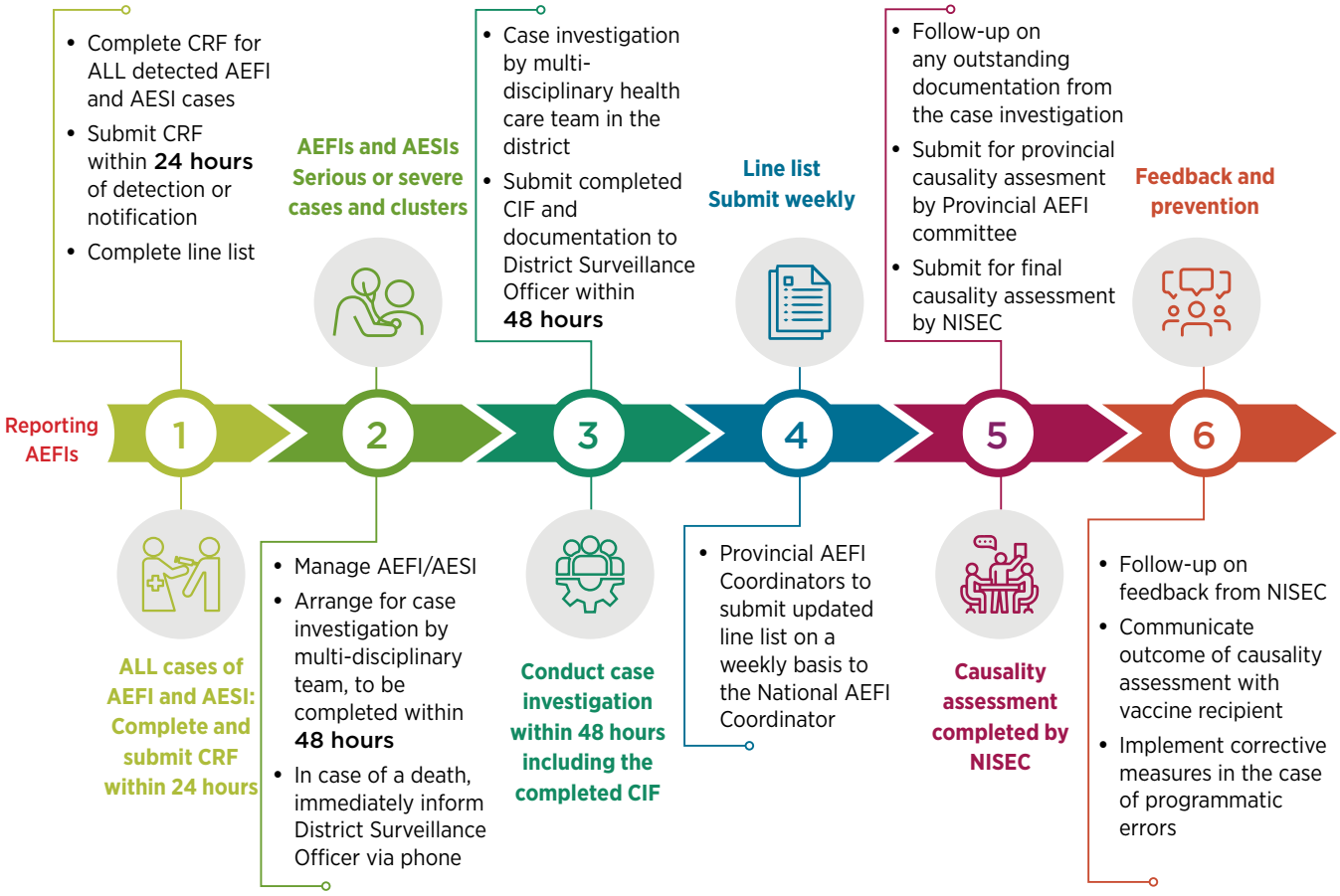
Health care workers must adhere to the stipulated timelines for reporting of ALL AEFIs and AESIs, followed by case investigation of severe and serious cases and clusters. Furthermore, ensure that all forms are accurately completed, and all supporting documents are attached for preliminary causality assessment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

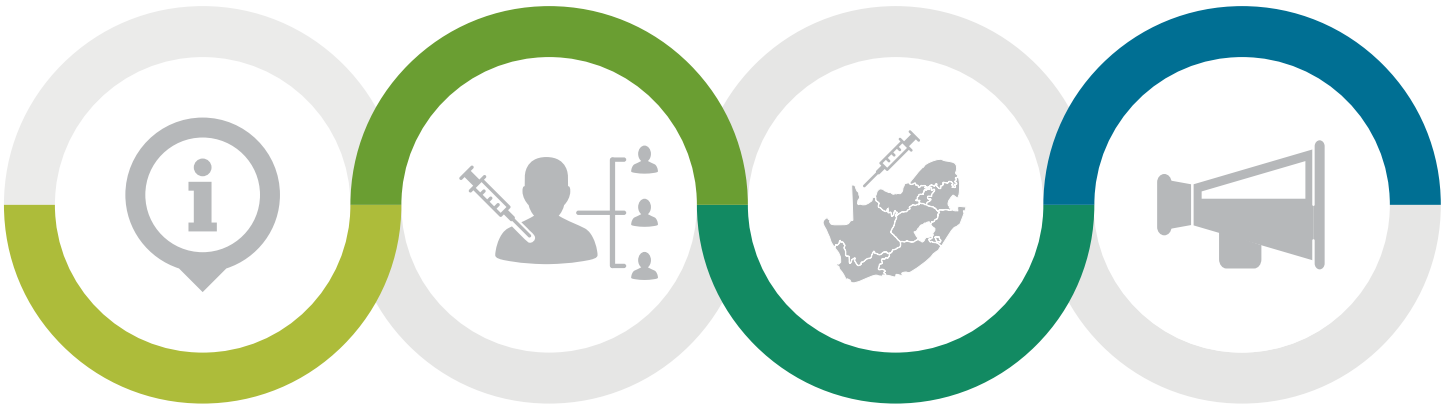
DOWNLOAD INSTRUCTIONS AND INFORMATION VIDEOS ABOUT THE MED SAFETY APP

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)

Key steps in the reporting process for all AEFIs and AESIs





Chapter 1

Introduction

Chapter 2

Planning and mechanisms of vaccination service delivery

Chapter 3

Vaccination site set up and management

Chapter 4

Advocacy, communication, and social mobilisation activities

CHAPTER 9

Monitoring & Evaluation

Chapter 5

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

Chapter 6

Effective vaccine management, cold chain, logistics, and distribution of COVID-19 vaccines

Chapter 7

Planning the client journey, and administration of COVID-19 Vaccines

Chapter 8

Vaccine safety surveillance

Monitoring and Evaluation

In Chapter 9 the monitoring and evaluation framework is described. The contents of this chapter will be useful for provincial, district and area-based teams as well as vaccination site managers. Monitoring the outcomes of the COVID-19 vaccination programme is essential.

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 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 resources 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 and 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. 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 mid-year population estimates. 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 and disaggregation is contained in the National Indicator COVID-19 Vaccination Set as a reference document.

Core Indicators

Indicator Group	Indicators
Vaccination Sites	Number of vaccination sites compliant to vaccination standards
Vaccination Sites	Number of sites assigned to provide for COVID-19 vaccination
Vaccinators	Number of vaccinators allocated per site
Vaccinators	Average number of vaccinees vaccinated by each vaccinator/day
Vaccinators	Number of vaccinators clinically trained on COVID-19 vaccination
COVID-19 Vaccine Supply Chain	Number of vaccines procured
COVID-19 Vaccine Supply Chain	Number of vaccine doses distributed to vaccination sites
COVID-19 Vaccine Supply Chain	% site reporting vaccine stock out
Vaccination Coverage	% of people fully vaccinated against COVID-19
Vaccination Coverage	Proportion of target population fully vaccinated against COVID-19
Dose uptake	Vaccine dose 1 vaccine uptake rate
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)
Adverse Events Following Immunisation	Number of vaccinated individuals reporting minor to severe adverse events following immunisation
Post-vaccination COVID-19 infection	Post-vaccination COVID-19 infection rate

Disaggregation	Data Source
Geographic, private & public sector	Master Facility List / Permit system
Geographic, private & public sector	Electronic Vaccination Data System
Geographic, private & public vaccination sites	Electronic Vaccination Data System
Private & public vaccination sites	Electronic Vaccination Data System
Private & public health facilities	Knowledge Hub
None	Invoices of procured vaccines
Private & public vaccination sites	Distributor reports
Private & public health vaccination sites	Stock Visibility System
Geographic coverage, age categories, gender, vaccine type, insured/uninsured, private & public vaccination sites	Electronic Vaccination Data System
Geographic coverage, age categories, gender, vaccine type, Private & public vaccination sites, beneficiary group [Health Care Workers, Essential workers, Persons in congregate settings,]	Electronic Vaccination Data System
Geographic coverage, age categories, gender, vaccine type, Private & public vaccination sites, beneficiary group [Health Care Workers, Essential workers, Persons in congregate settings,]	Electronic Vaccination Data System
Geographic coverage, age categories, gender, vaccine type, private & public vaccination sites, beneficiary group	Electronic Vaccination Data System
Geographic coverage, age categories, , gender, vaccine type, private & public vaccination, trigger event and outcome sites,	Vigilance Hub and VigiFlow (SAHPRA)
Geographic, cases, admissions, mortality	DATCOV, EVDS and NICD

Annexures

No	Document Description	URL Link
1	SOP_Confirmation of Registration_20122021	https://www.knowledgehub.org.za/system/files/elibdownloads/2022-01/SOP_Confirmation%20of%20Registration_20122021.pdf
2	SOP_COVID-19 Control Tower Supply Planning and Allocation Process_20122021	https://www.knowledgehub.org.za/system/files/elibdownloads/2022-01/SOP_COVID-19%20Control%20Tower%20Supply%20Planning%20and%20Allocation%20Process_20122021.pdf
3	SOP_COVID-19 Screening Process_20122021	https://www.knowledgehub.org.za/system/files/elibdownloads/2022-01/SOP_COVID-19%20Screening%20Process_20122021.pdf
4	SOP Distribution of Comirnaty® Vaccine to Sites_20122021.pdf	https://www.knowledgehub.org.za/sites/default/files/filefield_paths/SOP_Distribution%20of%20Comirnaty%C2%AE%20Vaccine%20to%20Sites_20122021.pdf
5	SOP_Distribution of COVID-19 vaccine Janssen®to Sites_20122021	https://www.knowledgehub.org.za/system/files/elibdownloads/2022-01/SOP_Distribution%20of%20COVID-19%20vaccine%20Janssen%C2%AEto%20Sites_20122021.pdf
6	SOP_Health Establishments Replenishment Process_20122021	https://www.knowledgehub.org.za/system/files/elibdownloads/2022-01/SOP_Health%20Establishments%20Replenishment%20Process_20122021.pdf
7	SOP_Management of Temperature Excursions with Comirnaty® Vaccine_20122021	https://www.knowledgehub.org.za/system/files/elibdownloads/2022-01/SOP_Management%20of%20Temperature%20Excursions%20with%20Comirnaty%C2%AE%20Vaccine_20122021.pdf
8	SOP_Managing of Non-Functional Refrigerators Freezers_20122021	https://www.knowledgehub.org.za/system/files/elibdownloads/2022-01/SOP_Managing%20of%20Non-Functional%20Refrigerators%20Freezers_20122021.pdf
9	SOP_Observation of vaccinee following COVID-19 vaccination_20122021	https://www.knowledgehub.org.za/system/files/elibdownloads/2022-01/SOP_Observation%20of%20vaccinee%20following%20COVID-19%20vaccination_20122021.pdf

10	**SOP_Preparation of Cold Chain Equipment_20122021**	https://www.knowledgehub.org.za/system/files/elibdownloads/2022-01/SOP_Preparation%20of%20Cold%20Chain%20Equipment_20122021.pdf
11	**SOP_Procedure to Receive Comirnaty® Vaccine _20122021**	https://www.knowledgehub.org.za/system/files/elibdownloads/2022-01/SOP_Procedure%20to%20Receive%20Comirnaty%C2%AE%20Vaccine%20_20122021.pdf
12	**SOP_Procedures to Receive COVID-19 vaccine Janssen®_201221**	https://www.knowledgehub.org.za/system/files/elibdownloads/2022-01/SOP_Procedures%20to%20Receive%20COVID-19%20vaccine%20Janssen%C2%AE_201221.pdf
13	**SOP_Routine Monitoring of Vaccine Handling_ 20122021**	https://www.knowledgehub.org.za/system/files/elibdownloads/2022-01/SOP_Routine%20Monitoring%20of%20Vaccine%20Handling_%2020122021.pdf
14	**SOP_Site Maintenance_Daily Activities_20122021**	https://www.knowledgehub.org.za/system/files/elibdownloads/2022-01/SOP_Site%20Maintenance_Daily%20Activities_20122021.pdf
15	**SOP_Site Readiness_20122021**	https://www.knowledgehub.org.za/system/files/elibdownloads/2022-01/SOP_Site%20Readiness_20122021.pdf
16	**SOP_Storage of Comirnaty Vaccines_20122021**	https://www.knowledgehub.org.za/system/files/elibdownloads/2022-01/SOP_Storage%20of%20Comirnaty%20Vaccines_20122021.pdf
17	**SOP_Storage of COVID-19 Janssen vaccine _20122021**	https://www.knowledgehub.org.za/system/files/elibdownloads/2022-01/SOP_Storage%20of%20COVID-19%20vaccine%20_20122021.pdf
18	**SOP_The Management of Temperature Excursions with COVID-19 vaccine Janssen®**	https://www.knowledgehub.org.za/system/files/elibdownloads/2022-01/SOP_The%20Management%20of%20Temperature%20Excursions%20with%20COVID-19%20vaccine%20Janssen%C2%AE.pdf
19	**SOP_Vaccination process at vaccination site_20122021**	https://www.knowledgehub.org.za/system/files/elibdownloads/2022-01/SOP_Vaccination%20process%20at%20vaccination%20site_20122021.pdf
20	**SOP_Vaccination site approval_ Guideline**	https://www.knowledgehub.org.za/system/files/elibdownloads/2022-02/Vaccination%20site%20approval_Guideline_V14.1.pdf

21	SOP_Vaccination site closure_20122021	https://www.knowledgehub.org.za/system/files/elibdownloads/2022-01/SOP_Vaccination%20site%20closure_20122021.pdf
22	SOP_Waste Disposal of COVID-19 Ancillary Items_20122021	https://www.knowledgehub.org.za/system/files/elibdownloads/2022-01/SOP_Waste%20Disposal%20of%20COVID-19%20Ancillary%20Items_20122021.pdf
23	SOP_Waste Disposal of COVID-19 Vaccines_20122021	https://www.knowledgehub.org.za/system/files/elibdownloads/2022-01/SOP_Waste%20Disposal%20of%20COVID-19%20Vaccines_20122021.pdf
24	AEFI Line List_20122021	https://www.knowledgehub.org.za/system/files/elibdownloads/2022-01/AEFI%20Line%20List_20122021.pdf
25	AESI Line List_20122021	https://www.knowledgehub.org.za/system/files/elibdownloads/2022-01/AESI%20Line%20List_20122021.pdf
26	Case Investigation Form_AEFI serious, severe, cluster_AESI_All vaccines	https://www.knowledgehub.org.za/system/files/elibdownloads/2022-01/Case%20Investigation%20Form%20%28CIF%29%20AESI.PDF
27	Case Report Form_Adverse events of SPECIAL INTEREST_ COVID-19_20122021	https://www.knowledgehub.org.za/system/files/elibdownloads/2022-01/Case%20Report%20Form_Adverse%20events%20of%20SPECIAL%20INTEREST_COVID-19_20122021.pdf
28	Case Report Form_AEFI_All vaccines incl COVID-19_20211221	https://www.knowledgehub.org.za/system/files/elibdownloads/2022-01/Case%20Report%20Form_AEFI_All%20vaccines%20incl%20COVID-19_20211221.pdf
29	Comminique from Biovac_20122021	https://www.knowledgehub.org.za/system/files/elibdownloads/2022-01/Comminique%20from%20Biovac_20122021.pdf
30	Communique from DSV_20122021	https://www.knowledgehub.org.za/system/files/elibdownloads/2022-01/Communique%20from%20DSV_20122021.pdf
31	COVID-19 Vaccination Card Final	https://www.knowledgehub.org.za/system/files/elibdownloads/2022-01/COVID-19%20Vaccination%20Card%20Final.pdf

32	**Emergency Trolley Checklist_20122021**	https://www.knowledgehub.org.za/system/files/elibdownloads/2022-01/Emergency%20Trolley%20Checklist_20122021.pdf
33	**EVDS User Manual v1.3_20122021**	https://www.knowledgehub.org.za/system/files/elibdownloads/2022-01/EVDS%20User%20Manual%20v1.3_20122021.pdf
34	**Health Questionnare_20122021**	https://www.knowledgehub.org.za/system/files/elibdownloads/2022-01/Health%20Questionnare_20122021.pdf
35	**Informed Consent - COVID-19 vaccine Janssen®_20122021**	https://www.knowledgehub.org.za/system/files/elibdownloads/2022-01/Informed%20Consent%20-%20COVID-19%20vaccine%20Janssen%C2%AE_20122021.pdf
36	**Informed Consent Form - Paper based_20122021**	https://www.knowledgehub.org.za/system/files/elibdownloads/2022-01/Informed%20Consent%20Form%20-%20Paper%20based_20122021.pdf
37	**Job Aid for Queue Marshals**	https://www.knowledgehub.org.za/system/files/elibdownloads/2022-01/Job%20Aid%20for%20Queue%20Marshals.pdf
38	**Job Aid relating to Injection Preparation_Comirnaty Vaccine**	https://www.knowledgehub.org.za/system/files/elibdownloads/2022-01/Job%20Aid%20relating%20to%20Injection%20Preparation_Comirnaty%20Vaccine.pdf
39	**Job Aid Relating to Injection Preparation_Janssen Vaccine_20122021**	https://www.knowledgehub.org.za/system/files/elibdownloads/2022-01/Job%20Aid%20Relating%20to%20Injection%20Preparation_Janssen%20Vaccine_20122021.pdf
40	**Job Aid_ Dealing with Adverse events_20122021**	https://www.knowledgehub.org.za/system/files/elibdownloads/2022-01/Job%20Aid_%20Dealing%20with%20Adverse%20events_20122021.pdf
41	**Job Aid_Administration of a COVID-19 Vaccine_20122021**	https://www.knowledgehub.org.za/system/files/elibdownloads/2022-01/Job%20Aid_Administration%20of%20a%20COVID-19%20Vaccine_20122021.pdf
42	**Job Aid_SVS Vaccines_Site and Ancilliary Upload Process_ v0.2_20122021**	https://www.knowledgehub.org.za/system/files/elibdownloads/2022-01/Job%20Aid_SVS%20Vaccines_Site%20and%20Ancilliary%20Upload%20Process_v0.2_20122021.pdf

43	**MFL User guide v 1.2.4_20122021**	https://www.knowledgehub.org.za/system/files/elibdownloads/2022-01/MFL%20User%20guide%20v%201.2.4_20122021.pdf
44	**Site Go-Live_User Guide_20122021**	https://www.knowledgehub.org.za/system/files/elibdownloads/2022-01/Site%20Go-Live_User%20Guide_20122021.pdf
45	**Supervisory Checklist_Intra Campaign_20122021**	https://www.knowledgehub.org.za/system/files/elibdownloads/2022-01/Supervisory%20Checklist_Intra%20Campaign_20122021.pdf
46	**SVS Covid-19 Mobile App User Guide and Web Overview_20122021**	https://www.knowledgehub.org.za/system/files/elibdownloads/2022-01/SVS%20Covid-19%20Mobile%20App%20User%20Guide%20and%20Web%20Overview_20122021.pdf
47	**SVS Presentation_20122021**	https://www.knowledgehub.org.za/system/files/elibdownloads/2022-01/SVS%20Presentation_20122021.pdf
48	**Twice Daily Maintanance Checklist_20122021**	https://www.knowledgehub.org.za/system/files/elibdownloads/2022-01/Twice%20Daily%20Maintanance%20Checklist_20122021.pdf
49	**Minimum Standards for COVID-19 Vaccination Sites and the Provision of Vaccination Services**	https://www.knowledgehub.org.za/system/files/elibdownloads/2022-01/Minimum%20standards%20for%20vaccination%20sites%20and%20the%20provision%20of%20vaccination%20services_FINAL.pdf
50	**COVID-19 Vaccine Transfers v10 11 January 2022**	https://www.knowledgehub.org.za/sites/default/files/filefield_paths/COVID-19%20Vaccine%20Transfers%20v10%2011%20January%202022.pdf
51	**Informed Consent Form - COMIRNATY update 14122021.pdf**	https://www.knowledgehub.org.za/system/files/elibdownloads/2022-02/Informed%20Consent%20Form%20-%20COMIRNATY%20update%2014142021.pdf
52	**Vaccine paper based form**	https://www.knowledgehub.org.za/sites/default/files/filefield_paths/COVID%2019%20Vaccine%20paper%20based%20form.pdf
53	**Covid-19 vaccination training for Health Care workers**	https://www.knowledgehub.org.za/course/covid-19-vaccination-training-health-workers

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