



**Western Cape
Government**

Health

Office of the Head: Health

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Enquiries: Dr K Cloete

E-mail: Keith.Cloete@westerncape.gov.za

TO: **DDG: CHIEF OPERATING OFFICER, CORPORATE SERVICES, TBH, GSH**
CHIEF DIRECTORS: PEOPLE MANAGEMENT, SUPPLY CHAIN MANAGEMENT, METRO DISTRICT HEALTH SERVICES, RURAL DISTRICT HEALTH SERVICES, STRATEGY AND SUPPORT, RED CROSS WAR MEMORIAL CHILDRENS HOSPITAL
EXECUTIVE DIRECTOR OF THE CITY OF CAPE TOWN
DIRECTORS: DISTRICTS, SUB STRUCTURES, EMS, PHARMACY SERVICES, SPC, SERVICE IMPROVEMENT OFFICE, FORENSIC PATHOLOGY SERVICES
DEPUTY DIRECTORS: PHC, PROGRAMMES, PEOPLE MANAGEMENT, FINANCE & SCM, PHARMACY SERVICES: METRO AND RURAL DISTRICT HEALTH SERVICES
RESPONSIBLE PHARMACISTS, FACILITY MANAGERS,

CIRCULAR H8 OF 2021: COVISHIELD - COVID-19 VACCINATION PROGRAMME: PROVINCIAL IMPLEMENTATION FRAMEWORK – JANUARY 2021

BACKGROUND

In early January 2021, South Africa announced its Covid-19 vaccine rollout plan. The objectives of the vaccine rollout plan are to protect healthcare workers and the impact on the health system, to reduce morbidity and mortality amongst vulnerable individuals and to reach herd immunity amongst the general population.

The Western Cape Covid-19 Vaccination Programme Implementation Framework is intended to guide implementation planning at district and sub-district levels. The Framework provides a detailed explanation of the Oversight and Governance Arrangements that have been established, the Programme Design and a strategy for Stakeholder Engagement and Communication.

The Vaccination Programme Design provides guidance on quantifying the demand within each phase of the vaccine rollout and provides a detailed description of the vaccination process. Also contained in the programme design section of the framework are the requirements for Vaccine Administration Locations (VALs), including storage and distribution. An overview of the vaccine information system is provided. A critical part of the Programme Design is the workforce requirements, inclusive of training needs, which are detailed in the framework.

IMPLEMENTATION

The Covid-19 vaccine will be rolled out in 3 phases:

- Phase 1: Frontline health care workers
- Phase 2: Essential Workers
 - Persons in congregate settings
 - Persons >60 years
 - Persons >18 years with co-morbidities
- Phase 3: Other persons >18 years

Presently South Africa has secured 1.5 million doses of the Covishield vaccine from the Serum Institute of India due for delivery at the end of January 2021. This first allotment of Covid-19 vaccines has been earmarked for Phase 1 on vaccination rollout and will therefore be utilised to vaccinate frontline health care workers.

Processes for the further procurement of Covid-19 vaccines have not yet been finalised. The Provincial Implementation Framework for the Western Cape Covid-19 Vaccination Programme therefore focusses primarily on the implementation of Phase 1 rollout and will be duly updated and revised as more information around vaccine availability and procurement becomes available.

IMPLEMENTATION DATE

As from January 2021, all districts and institutions are required to ensure that micro plans are finalised to guide implementation at the district, sub-district and facility level, in order to ensure implementation of the Covid-19 Vaccination Programme as soon as the vaccines are received from the National Department of Health.

Please feel free to further distribute the framework within the Department and to relevant stakeholders.

If you have any questions related to this Provincial Implementation Framework, contact Juanita Arendse (Juanita.Arendse@westerncape.gov.za) or Dr Krish Vallabhjee (Krish.Vallabhjee@westerncape.gov.za)

Yours sincerely



Dr Keith Cloete

Head: Western Cape Department of Health

Date: 25 January 2021



Western Cape
Government

Health

COVID-19 Vaccination Programme

Provincial Implementation Framework

January 2021

COVID-19 Vaccination Programme

Provincial Implementation Framework

January 2021

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ACRONYMS

AEFI	Adverse Events Following Immunisation
CDC	Community Day Centre
CIF	Case Investigation Form
CMD	Cape Medical Depot
COVID-19	Coronavirus Disease 2019
CRF	Case Reporting Form
CVCC	C-19 Vaccine Co-ordinating Committee
DoTP	Department of the Premier
EPI	Expanded Programme on Immunisation
EVDS	Electronic Vaccine Data System
FAQ	Frequently Asked Questions
HEI	Higher Education Institutions
HoD	Head of Department
HPV	Human Papilloma Virus
ICN	Internal Control Number
IEC	Independent Electoral Commission
IPC	Infection Prevention and Control
KTU	Knowledge Translation Unit
MAC	Ministerial Advisory Committee
NDoH	National Department of Health
NVCC	National Vaccine Co-ordinating Committee
OHS	Occupational Health and Safety
PHDC	Provincial Health Data Centre
SAHPRA	South African Health Products Regulatory Authority
SCM	Supply Chain Management
SOP	Standard Operating Procedure
VALs	Vaccine Administration Locations
WCDoH	Western Cape Department of Health
WHO	World Health Organisation

Executive Summary

The Western Cape reported its first case of COVID-19 on 11th March 2020 and to date there has been 1 159 519 tests conducted, of which 253 576 have been positive, constituting 15.2% of total tests and 19% of positive cases in the country. There have been 9 111 deaths, 3.6% of all cases provincially and 24.6% of all deaths nationally. The pandemic's devastating impact on lives and livelihoods has driven the development of several vaccines as an attempt to ensure herd immunity by targeting 70% of the population. Currently there are 10 leading vaccines which have been approved in various countries, with several others in development and testing phase. South Africa has secured 1 500 000 doses of the Covishield vaccine from the Serum Institute of India due for delivery at the end of January 2021.

This implementation framework lays out the current thinking and approach to the provincial COVID-19 Vaccine Programme, with a particular focus on phase I. The framework is viewed as a living document that will evolve as more information becomes available; and we learn as a province and a country. Phase 2 and 3 implementation planning will unfold as we learn more about the likely vaccines being procured and their delivery timeframes. The quantification of vaccine demand and resources will thus be refined accordingly. The implementation framework is intended to be used as a guide for planning at district and sub-district levels.

A provincial C-19 Vaccine Co-ordinating Committee (CVCC) has been established and will fulfil a stewardship role to enable a multi-sectoral provincial COVID-19 Vaccination Programme. The committee will keep relevant stakeholders informed on progress and connect with the National Vaccine Co-ordinating Committee (NVCC). A private health sector co-ordinating committee consisting of the relevant stakeholders and an expert advisory committee, also being established. These structures collectively represent the central governance arrangement for the vaccination programme.

A staggered approach to the vaccine roll-out has been adopted by the country with 3 phases, each phase targeting a different section of the population, based on risk. The first phase will target health workers; the second phase focuses on essential workers and people who are at high risk; and the third phase includes people older than 18 years falling outside of the target groups for the 2 previous phases. The Department has designed a vaccination pathway which includes pre-registration and accreditation processes; registration process for eligible vaccine recipients; appointment scheduling process; vaccine administration process; a supported discharge process in case of AEFI; and post-vaccination follow-up reminding recipients to return for their second dose.

At each vaccine administration location (VAL), the vaccine pathway will be co-ordinated by a suitably qualified health professional. Vaccinators are central to any vaccination programme and thus the Department endeavors to ensure that adequate numbers of suitably qualified health workers are recruited and trained to become COVID-19 vaccinators. A training programme is being

developed to equip vaccinators with the most up to date information, ensuring the safe and efficient administering of the vaccine. Each VAL will have a lead vaccinator who will provide support and supervision to all the vaccinators allocated to that site and will act as the link to sub-district / district co-ordinator for the programme. VALs must have the space and infrastructure to accommodate the, vaccine pathway together with the necessary IPC measures to limit the risk of COVID-19 transmission; vaccine storage requirements to maintain the cold chain; and information systems to keep track of progress.

Clear, honest communication is key to ensuring mass uptake of the vaccine in the face of vaccine hesitancy. A stakeholder engagement and communication strategy is being developed to build trust in the vaccine programme and focus areas include motivating people and sectors to “unite to vaccinate”, promoting acceptability and logistics around availability and accessibility of the vaccines. The COVID-19 Vaccination Programme is the largest in the history of the country and to ensure success, the government will need to mobilise a broad range of stakeholders to act collectively in advocating, promoting and enabling the programme. This is an opportunity to unite all sectors and sections of society around a common objective and build a movement for better health, while laying a strong foundation for Universal Health Coverage (UHC).

I. Background & Context

The first case of COVID-19 was identified in Hubei Province, China, in November 2019 and officially reported to World Health Organisation (WHO) in December 2019. By 1 February, WHO had declared COVID-19 a public health emergency of international concern. Since then, over 200 countries have reported cases of COVID-19. The first case in South Africa was detected in Kwazulu-Natal on 5th March 2020, and the first case in Western Cape was detected on 11th March 2020. To date, the Western Cape has conducted 1 159 519 tests, of which 253 576 have been positive, constituting 15.2% of total tests and 19% of positive cases in the country. There have been 9 111 deaths, 3.6% of all cases provincially and 24.6% of all deaths nationally. The pandemic has had a multi-sectoral impact on South Africa, including significant socio-economic consequences; a devastating effect on mortality and morbidity; and the knock-on effect of increased healthcare costs. The cumulative negative impact on South African families and communities has been massive.

Vaccination is considered one of the most cost-effective public health interventions and key to the primary prevention of infectious diseases like COVID-19. Currently there are several vaccines in various stages of development, with a few already having gone through the necessary clinical stages and have been approved for use in a number of countries. Individuals develop immunity to an infectious disease either through natural infection or through vaccination. A successful COVID-19 vaccination programme would protect people from severe illness and would stop the spread of the virus. Herd immunity refers to the indirect protection to an infectious disease that people derive from the direct immunity of individuals who are in the same network of connections. Therefore, the more individuals in a particular group that have immunity, the less likely it is that someone in that same group who does not have immunity will encounter the infectious disease. Lowering the possibility for a pathogen to circulate, necessitates the achievement of herd immunity and in the context of the COVID-19 pandemic an average of approximately 70% vaccine coverage (of total population) is necessary to achieve this to stop the spread of COVID-19.

The National Government will be the sole purchaser of the COVID-19 vaccines in South Africa and is involved in a number of bilateral engagements with vaccine suppliers, over and above the COVAX arrangements. On 7th January 2021 the National Minister of Health announced that South Africa will acquire 1 000 000 doses of the Covishield vaccine from the Serum Institute of India (SII) by the end of January and a further 500 000 doses in February 2021. AstraZeneca has partnered with the SII for the supply of the vaccine to a large number of countries, including South Africa. The South African Health Products Regulatory Authority (SAHPRA) is fast tracking the regulatory approval of the vaccine. It will also rely on the regulatory work of other countries to expedite the process. National Treasury has granted special permission to deviate from competitive bidding processes for a period of 6 months to enable the procurement COVID-19 vaccines. National government has undertaken to cover the cost of the vaccines, while provinces will be responsible for funding the staffing, consumables and any other associated costs required to implement the COVID-19 Vaccination Programme.

The majority of the vaccines currently available globally require 2 doses, 21-28 days apart. Given the limited availability of vaccines it will be necessary to procure available stock from different manufacturers hence there may be multiple vaccines in the programme that are NOT interchangeable in a 2-dose vaccine schedule. Vaccines will not be available for everyone immediately, and a prioritization system will be applied guided by the Ministerial Advisory Committee on Vaccines. At the time of writing, only the Covishield vaccine has been ordered and is due for delivery by the end of January. Table 1 shows the vaccines which have been licensed in a number of countries.

Table 1: Vaccines currently licensed globally¹

VACCINE	TECHNOLOGY	DOSES (weeks apart)	STORAGE	ALLOCATION FOR SOUTH AFRICA
AstraZeneca	NON-REPLICATING	2 (4)	Fridge: 2° – 8° C (6 months)	1 500 000
Johnson & Johnson	NON-REPLICATING	1	Fridge: 2° – 8° C (3 months) Freezer: -20° C (2 years)	TBC
Moderna	mRNA	2 (4)	Fridge: 2° – 8° C (30 days) Freezer: -20° C (6 months)	TBC
BioNTech/Phizer	mRNA	2 (3)	Freezer: -70° C	TBC
Sputnik V	VIRAL VECTOR	2 (3)	<i>Not yet available</i>	-
CanSino	VIRAL VECTOR	1	Fridge: 2° – 8° C	-
Novavax	PROTEIN-BASED	2 (3)	Fridge: 2° – 8° C	-
Sinopharm	INACTIVATED	2 (3)	<i>Not yet available</i>	-
Sinovac	INACTIVATED	2 (2)	Fridge: 2° – 8° C	-
Bharat Biotech	INACTIVATED	2 (4)	Room temperature (1 week)	-

The Ministerial Advisory Committee (MAC) on vaccines and our own Expert Advisory Committee are applying their minds and reviewing the evidence to advise on the safety and efficacy of vaccines in children and pregnant women.

Status of this Document

There are a number of variables known and unknown likely to impact the roll-out of the vaccine programme and greater clarity will emerge as vaccines are registered by SAHPRA and become available in the country. The implementation framework is thus a 'living document' that will evolve in line with developments as more specific details emerge with SAHPRA registration and procurement

¹ The table shows the leading vaccines globally, as per the vaccine tracker website available at: <https://www.nytimes.com/interactive/2020/science/coronavirus-vaccine-tracker.html> (accessed on 14 January 2021).

confirmation. This version of the implementation framework reflects the state of knowledge as at the 17th January 2021 and focuses predominantly on phase 1 of the staggered roll-out. Phase 2 and 3 implementation will unfold as more information becomes available on the vaccines to be procured and likely delivery timeframes.

This provincial implementation framework is intended to guide implementation planning at district and sub-district levels. The micro-plans will need to consider the following:

- Governance, co-ordination and planning
- Identification of target population
- Service delivery platforms and vaccination site readiness
- Human resources including training and supervision
- Vaccine, cold chain, logistics and infrastructure
- Safety surveillance
- Data management, information systems and monitoring and evaluation
- Communications and demand creation

II. Oversight & Governance of the Programme

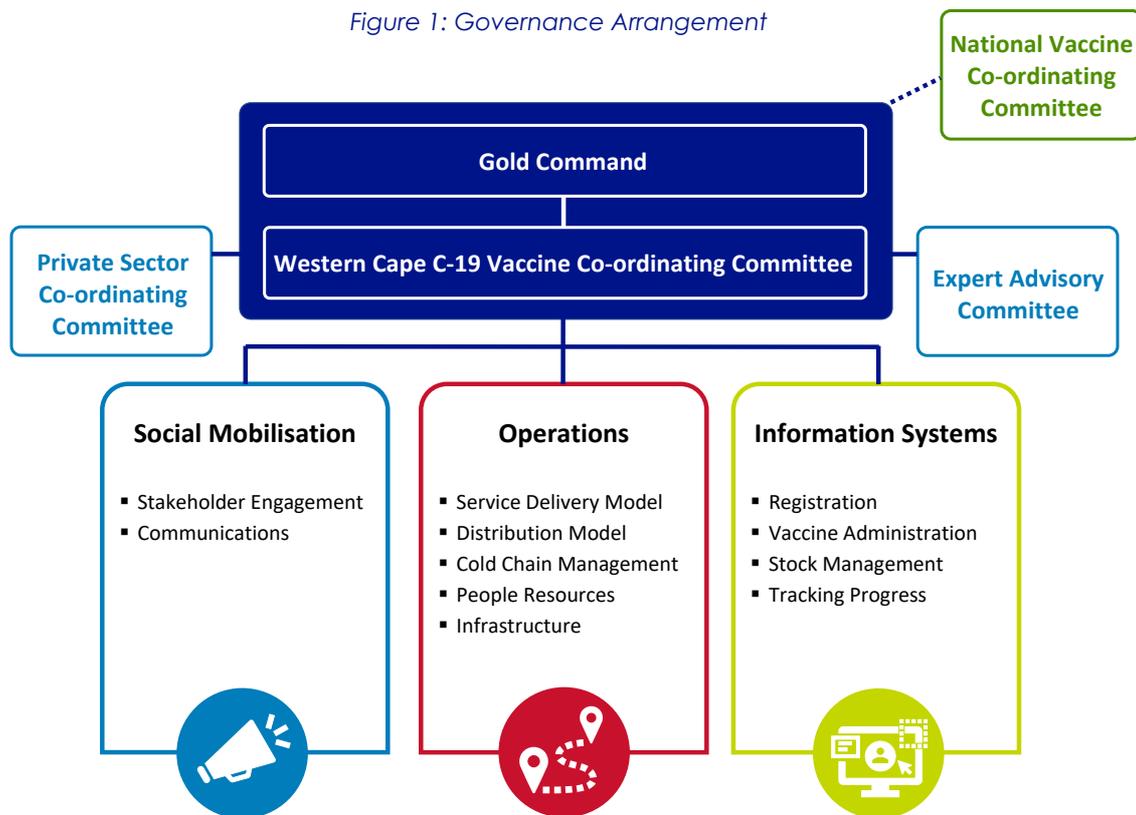
The WCGH sees the health system response to COVID-19 in general, and the vaccination programme specifically, as an important opportunity to build a collective commitment towards better health between the public sector, private sector and civil society. This is also in keeping with the national and provincial objectives of UHC and health system strengthening. WCGH will play a stewardship role in building this social compact towards a common objective through a decentralised and integrated service delivery model with local distributed leadership and governance for a united response of public, private and civil society.

Governance Arrangements

The provincial C-19 Vaccine Co-ordinating Committee (CVCC) has been established with the intended purpose of fulfilling a stewardship role to enable a multi-sectoral provincial COVID-19 Vaccination Programme. The committee will keep relevant stakeholders informed on progress and connect with the National Vaccine Co-ordinating Committee (NVCC). The CVCC will include the CD: Strategy (Chairperson), CD: ECSS and representatives from Service, Pharmacy Services, CMD, SCM, People Management, Information Systems, Health Impact Assessment. A private health sector co-ordinating committee which includes medical schemes, private hospital associations and groups, pharmacy groups, general practitioner and specialist associations, nursing association, allied health professions associations, logistics providers, pharmaceutical manufacturers, will also be established. Similar governance arrangements will be replicated at district & sub-structure levels, led by the District Managers. The local governance arrangements are important for constant monitoring and to ensure

the equitable distribution of vaccines. The office of the HoD and Gold Command will have oversight of the process, see figure 1.

Figure 1: Governance Arrangement



In addition, an expert advisory committee has been created to provide advice on science-based information, ethics and programme implementation to ensure equitable access to vaccines, prioritized on the basis of greatest need. This committee will include, amongst others, expertise on vaccines, infectious diseases, pharmacology & pharmacy services, programme implementation, ethics, human rights, behaviour change, community engagement and stakeholder mobilization. The Committee will make recommendations to the Department, who will take responsibility for decisions. It will advise on:

- the science of vaccines to support science-based communication
- ethical considerations
- operational logistics of the implementation
- vaccine pharmaceutical management
- community engagement and social mobilization
- any other related aspects of vaccine roll-out.

Risk Management

POTENTIAL CHALLENGES	IMPACT ON ACTIVITIES	MITIGATION INTERVENTIONS	RESPONSIBLE PERSON(S)
No consent	Target not reached	<ul style="list-style-type: none"> Put systems in place to enable consent Build trust through social mobilisation and a communication strategy to address vaccine hesitancy 	All involved, provincial to service delivery level
Cold Chain failure	Wasteful expenditure	<ul style="list-style-type: none"> Maintain optimal cold chain (2-8°C) or (-70°C) throughout distribution, at each delivery & service point Put a system in place to monitor cold chain management 	All involved
Poor management and reporting of AEFI	<ul style="list-style-type: none"> Potential to increase vaccine hesitancy in concerned clients/communities Reduce 2nd dose uptake Strengthen anti-vaccinators' crusade 	<ul style="list-style-type: none"> Train & create awareness on procedures to follow Ensure emergency provisions at each site Surveillance System to track AEFI Open communication about AEFI 	Vaccine administration Locations (Lead vaccine co-ordinator)
Social media misinformation	<ul style="list-style-type: none"> Potential to increase vaccine hesitancy in concerned clients/communities Reduce uptake /target not reached Strengthen anti-vaccinators' crusade 	<ul style="list-style-type: none"> Maintain a general, sustained, proactive approach to social mobilisation. Include positive messages on immunisation in general, through various social media platforms. Health message should be conveyed in laymen's terms as short, understandable, basic messages. Use credible voices and ambassadors 	National, Provincial and District Communication departments
Interruption of supply of consumables	<ul style="list-style-type: none"> Inability to administer vaccine Inability to respond to adverse reaction 	<ul style="list-style-type: none"> Monitor consumable stockholding & maintain buffer stock throughout campaign; Issue 'per vaccine point' stock list to all facilities liaison with SAPs strengthening contracted security at CMD and vaccination administration locations 	CMD & SCM
Unsafe disposal of sharps & vials	Contravention of the National Environmental Management Act, 1998 ('NEMA') and the National Environmental Management: Waste Act, 2008	Monitor waste management reports and maintain regular dialogue with Health Care Risk Waste contractor(s)	FIM & SCM
Inadequate facilities made available for patients awaiting vaccination	Media/reputational risk akin to SASSA grant queues at outset of initial lockdown, especially for Phase 2 elderly patients	Determine manageable schedule of vaccinations per vaccination point per day and provide appropriate waiting areas	Services & FIM
Crime Threat	Interpol issued an alert on 2 December 2020. Asked member states to prepare for criminal network targeting the vaccines, both physically and online.	The Provincial Department of Health engages with Law Enforcement and Crime Intelligence agencies on an ongoing basis.	SAPS and Crime Intelligence Provincial JOC WCDoh Representative

III. Vaccination Programme Design

A phased approach to roll-out

The Ministerial Advisory Committee on Vaccines and the National Department of Health (NDoH) have provided a framework which considers the science, ethics and implementation of a COVID-19 Vaccination Programme. This framework provides parameters for a staggered roll-out of the vaccine over 3 phases, which is dependent on vaccine availability. The first phase will target health workers within and outside of the public sector; the second phase focuses on essential workers, people 18 years and older with co-morbidities and people 60 years and older; and the third phase includes people older than 18 years who do not fall into any of the target groups identified in the previous phases, see table 2. Note the target groups are being refined and further prioritization will become necessary in the event that there are insufficient doses of the vaccines available.

Table 2: The groups targeted in each phase

PHASE 1	
TARGET GROUPS	RATIONALE
Health Care Workers (HCWs): <ul style="list-style-type: none"> <input type="checkbox"/> all categories of health care providers including traditional healers, and allied or complementary health professionals <input type="checkbox"/> Community Health Workers <input type="checkbox"/> Support staff 	To protect the health system to ensure it remains responsive and capable of meeting the demand for care
PHASE 2	
TARGET GROUPS	RATIONALE
Essential workers: <ul style="list-style-type: none"> <input type="checkbox"/> Police officers <input type="checkbox"/> Teachers <input type="checkbox"/> Municipal workers <input type="checkbox"/> Home Affairs, border control and port health services <input type="checkbox"/> Miners <input type="checkbox"/> Security workers <input type="checkbox"/> Workers in the retail food, funeral, banking industries 	High risk of transmission as they cannot work from home and therefore risk exposure. These workers provide services that are vital to everyday life and ensuring a functional state.
People living in congregated conditions: <ul style="list-style-type: none"> <input type="checkbox"/> Care homes <input type="checkbox"/> Detention centres <input type="checkbox"/> Shelters <input type="checkbox"/> Prisons <input type="checkbox"/> Including people who working in the hospitality and tourism industries, and education institutions 	High risk of transmission
Elderly people 60 years and older	High risk of severe disease and hospitalisations
People 18 - 59 years with co-morbidities like: <ul style="list-style-type: none"> <input type="checkbox"/> Diabetes <input type="checkbox"/> Chronic lung disease <input type="checkbox"/> Cardiovascular disease <input type="checkbox"/> Renal disease <input type="checkbox"/> HIV <input type="checkbox"/> Tuberculosis <input type="checkbox"/> Obesity 	High risk of severe disease and hospitalisations
PHASE 3	
TARGET GROUP	RATIONALE
People over 18 who were not eligible in previous phases	To achieve herd immunity, minimising the risk of transmission

Quantifying demand

The Department is currently in the process of determining the number of people needing to be vaccinated at each phase of the roll-out, preliminary figures are captured in table 3. As the criteria for target groups in each phase is refined and information becomes available, these numbers are subject to change. In the event that insufficient doses of the vaccine are available there will be further prioritization of the target groups identified within each phase. A breakdown to sub-district level is captured in Annexure 1, see Annexures.

Table 3: Current estimates of the number of people needing to be vaccinated per phase

PHASE	TARGET GROUP	No. of PEOPLE ²
Phase 1	Health Workers	103 535
Phase 2	Essential workers/congregate settings	1 27 000
	People 60 years and over	723 166
	People 18-59 years with co-morbidities	1 241 084
Total number of people to be vaccinated in Phase 2		2 091 250
Phase 3	People 18 years and older not included in the previous 2 phases	2 907 096
Total number of people to be vaccinated in the province		5 101 881

The principles for reprioritization within phase 1-3 centres around risk of exposure and risk of severe disease, see table 4 which captures the proposed re-prioritization of the Phase 1 target group.

Table 4: Re-prioritization of the target group for Phase 1 if there is a shortage of dosages

Category 1	Health workers conducting aerosol-generating procedures (i.e., intubation, ventilation, taking COVID-19 specimens)
Category 2	Health workers in direct contact with people known to be suspected COVID-19 cases
Category 3	Health workers in contact with people not suspected to have COVID-19
Category 4	Health workers that are not in direct contact with patients

PS: This framework is also being revised by the MAC on vaccines.

Making provision for wastage

A 10% buffer will be factored into the estimates for doses to make provision for wastage. Vaccine wastage is an important factor in calculating vaccine needs and is therefore crucial that all vaccine administration points monitor their wastage. Wastage monitoring and reporting for COVID-19 vaccines will be conducted in accordance with Circular H13/ 2015: Monitoring Vaccine Wastage at Service Level. Wastage monitoring and reporting will occur at all facilities offering COVID-19 vaccination. Minimizing the risk of an interruption in the vaccine supply depends on effective monitoring and reporting of wastage. To enable this vaccine wastage monitoring forms (see Annexure 2 and 3) must be submitted on the 5th of every month to the respective district/sub-structure pharmacy manager, who needs to then submit this information for the district/sub-structure to Nisaar Mia (nisaar.mia@westerncape.gov.za) by the 10th of each month. This is subject to change depending on the demands of each phase in the programme. In phase 1 it is envisioned that this reporting will occur weekly.

² Note these are preliminary figures and are subject to change as more information becomes available

Vaccination Process, how it will work in practice

The Provincial Government is committed to implementing a safe, high quality phased COVID-19 Vaccination Programme providing timely and efficient access to available vaccines. The 2 initial phases target specific priority groups. The delivery model will need to transition to support larger numbers of people as the programme moves from phases 1 to 3. The Department is intent on learning from its own experience and that of other countries and will adjust its approach as it learns and the global body of knowledge develops with regards to COVID-19 vaccination.

Vaccination Pathway

The vaccination pathway will vary slightly as it will be adjusted to accommodate the access consideration of each target group identified in accordance with the 3-phased approach. However, for the vast majority of people the process will involve the steps outlined in figure 2. Members of each identified group will need to be registered for and consent to vaccination. Where possible, support pathways will also be activated for particularly vulnerable people to enable equitable access to COVID-19 vaccines.



Figure 2: Western Cape Vaccination Pathway

Pre-registration & Accreditation

This part of the process involves the development of systems to generate a 'vaccine roll', similar to the IEC's voter roll; and includes accrediting of vaccine providers and administration locations, particularly relevant to non-state healthcare providers.

Registration

Targeted groups in each phase will be invited to register for vaccination and advised as to how to go about scheduling an appointment.

Appointment Scheduling

Registered individuals would need to schedule an appointment for the vaccination and systems are being put in place to do this in the most practical and efficient manner. Catch-up plans will also need to be in place for each phase in the event that individuals miss their scheduled appointments.

Vaccine Administration

This step of the process includes the issuing of a COVID-19 vaccine card with confirmation of the person's details, ascertaining informed consent and the preparation and administering of the vaccine. The manner in which consent is confirmed will be guided by the NDoH prescripts and

SAHPRA recommendations. Any individual concerns or specific questions related to the vaccination will also be addressed at this point in the process. Note as with other vaccines, administration of the COVID-19 vaccine should be postponed in individuals suffering from an acute severe febrile illness. However, the presence of a minor infection, such as cold, and/or low-grade fever should not delay vaccination.

Supported Discharge

As with all injectable vaccines, appropriate medical treatment and supervision should always be readily available in case of an anaphylactic event following the administration of the vaccine. Once the individual has received the vaccine, they will be asked to wait for between 15-30 minutes³, to monitor for any immediate adverse reactions to the vaccine and will be cared for accordingly. The section on managing adverse events deals with this in more detail.

Post-vaccination

A communication mechanism will be developed to remind people to return for their second dose of the vaccine and what to do in the event that they have an adverse reaction to the vaccine.

Vaccine Pathway Co-ordination

In Phase 1 the vaccine site co-ordinator should ideally be the resident Occupational Health and Safety (OHS) nurse. Where there is no such nurse present an alternative suitably qualified and positioned health worker must be identified to fulfil this role. The co-ordinator will be tasked to lead the respective roll-out teams for Phase 1. In phases 2 and 3 this is subject to change in accordance with the groups being targeted for these phases and their relevant delivery models. Each district / sub-structure will identify a vaccine co-ordinator for their respective vaccine programmes, who will provide technical support to all the site co-ordinators in their designated geographical areas.

Vaccine Administration Locations (VALs)

A number of possible locations have been identified for vaccine administration, for Phase 1 the following locations have been identified:

- Occupational health and safety centres/service sites at public and private health facilities
- Mobile sites attached to a facility where there is a hub and spoke arrangement with service points where amenities do not accommodate vaccine administration.

In phases 2 and 3 these sites will need to be expanded, in light of the sheer numbers and to enhance accessibility, see figure 3.

Due consideration must be given to the following in the selection of VALs:

- the number of vaccines to be administered daily

³ Once SAHPRA guidelines are published the adverse reaction monitoring timeframes will become clearer and the framework will be updated accordingly.

- Cold chain capacity including fridges and appropriate cooler boxes.
- the space availability and its suitability for the various activities involved in the vaccine pathway
- the extent to which the space can accommodate the necessary COVID-19 infection prevention control (IPC) protocols
- related amenities to administer vaccines and accommodate the people presenting for vaccination with dignity

Figure 3: Geographical Delivery Model



Vaccine Storage and Distribution

A centralized distribution from the CMD enhances the efficiencies of stock management in the province enabling the shifting of vaccines and consumables with the use of data. The CMD will make deliveries to all primary delivery/collection sites prior to the start of the vaccination programme in both metro and rural districts, stock dependent. Table 5 lists the necessary consumables to administer the Covishield⁴ and Pfizer vaccines. The CMD in conjunction with the SCM colleagues will secure the necessary consumables from suppliers and alternate consumables will be sourced where necessary. The quantities of each will be determined according to the number of doses required for each phase of the vaccination programme. The pre-determined quantum of the consumables required will be issued as a “package” to each facility. For Phase 1, all orders from facilities will be collated centrally and prepared by CMD. A delivery schedule will be provided to the districts prior to the vaccines being sent to facilities. Security and controls will be strengthened at the CMD and at VALs to protect the vaccine stock at all levels of the health system and while it is in transit.

Table 5: Consumable required for the Pfizer and Covishield Vaccines

Covishield

⁴ The Covishield vaccine is a multidose vial with 5 ml solution in a 10-dose vial, they are packaged in a box containing 50 vials and six boxes in a shipper

<ul style="list-style-type: none"> • 1ml syringes • Needles - 23g / 25g x 27mm for administration • Needles - 23g / 25g x 38 mm for administration to obese patients. • Needles - 18g for the drawing up of the vaccine dose from the multiuse vials. • Cotton wool • Alcohol swabs 	<ul style="list-style-type: none"> • Hand sanitiser • Plasters / micropore • Cooler boxes • Ice gel packs • Temperature loggers where necessary • Appropriate waste containers (sharps and medical) to be procured by facilities
Pfizer	
<ul style="list-style-type: none"> • Syringes – 2ml and 5 mls • Needles – gauge 23/25g x 27mm for administration • Needles - gauge 23/25 x 38mm for obese patients • 0.9% sodium Chloride as a diluent for the Pfizer vaccine 	

The vaccines will be allocated CMD ICN numbers and will be included in the CMD Cold Chain Depot. All receipts and issues of the vaccines will be controlled via Medsas at CMD. CMD will capture the vaccines issued according to the approved allocations for each VAL for both the public and private health sectors; similar to the procedure for the HPV and Flu vaccination programmes. National government has identified 3 potential vaccines to be considered for the country 2 of which requires sub-zero storage temperatures, Moderna (-40° C) and Pfizer (-70° C) and the Covishield vaccine, which needs to be stored at 2° - 8° C. The vaccines must always be protected from light and glass door fridges will require a UV screen. The Covishield vaccine can be stored, transported and distributed in accordance with the existing CMD Cold Chain Standard Operating Procedure (SOP) however the Moderna and Pfizer vaccines will require additional logistical arrangements to maintain the cold chain.

These vaccines need to be distributed directly from the freezing facility to VALs within set timeframes, thus necessitating a dedicated fleet of delivery vehicles customized for maintaining the cold chain. Negotiations with the current contracted courier have already commenced to ensure the availability of at least eight dedicated COVID-19 vaccine vehicles. Although these vaccines are not ideally suitable for our current infrastructure, careful planning and co-ordination with the health facilities, will enable the storage and distribution of these vaccines in a safe and effective manner that will not compromise the efficacy of the vaccines.

Information Systems

The province supports the NDoH proposed Electronic Vaccine Data System (EVS) being developed for the COVID-19 Vaccination Programme. However, in the event that the solution is not ready at the start of roll-out, the province is developing a number of contingency options to mitigate this risk. The intention is to align these efforts with the national systems and be able to switch over as soon as its appropriate. The Department is developing a web-based system similar to EVDS which, enables greater efficiency of the vaccine pathway (see figure 4); and the monitoring and reporting on the progress of the programme. Ideally a vaccine information system needs to be simple and easy to use across public, private and non-profit health sectors. This provincial system will be linked to the Provincial Health Data Centre to enhance analysis and reporting of vaccine data. The capability for

inter-operability across multiple systems is an important requirement. To further mitigate the risk to timely vaccine roll-out a paper-based system is also being developed in the event that both electronic systems are not yet available at the time of roll-out commencement. In Phase 1 existing databases of health workers in the public (provincial and local government), private, and non-profit sectors will be utilized for registration purposes to enable efficiencies in the process.

Figure 4: Vaccine Information System



Workforce Requirements

Vaccinators

Vaccinators are the backbone of any vaccination programme if as many people as possible are to be reached within a specific time. Based on experience, a vaccinator can vaccinate 40-50 people a day. It is estimated that approximately 414 vaccinators are required for phase one, 1st dose to be concluded in a week. In phase 2 to complete the 1st dose for 2 091 250 people, 1494 vaccinators required to complete the first dose in 4 weeks, 747 required to complete the first dose in 8 weeks and 498 required to complete the 1st dose in 12 weeks. **Please note these numbers are estimates for a single dose.** A register of vaccinators will be maintained by the Provincial Health Data Centre (PHDC) and table 6 provides a breakdown of the vaccinators

Table 6: Proposed Vaccinators required for Phase 1

VACCINATORS REQUIRED FOR PHASE 1	METRO DISTRICT				RURAL DISTRICTS					PROVINCE	
	KMSS	KESS	NTSS	SWSS	Cape Winelands	Central Karoo	Garden Route	Overberg	West Coast		
No. of HCW to vaccinate	8 438	6 595	27 168	33 680	8 169	1 615	9 598	3 147	5 125	102 535	
No. of vaccinator days (50 vaccines/day)	169	132	543	674	163	32	192	63	102	2 071	
NO. OF VACCINATORS REQUIRED IF 1 WEEK	34	26	109	135	33	6	38	13	20	414	
VACCINATORS REQUIRED FOR PHASE 2	METRO DISTRICT				RURAL DISTRICTS					PROVINCE	
	KMSS	KESS	NTSS	SWSS	Cape Winelands	Central Karoo	Garden Route	Overberg	West Coast		
Population over 60 years	93 576	85 919	141 557	157 047	84 818	9 614	80 213	31 820	38 602	723 166	
Population 18-59 years with comorbidities	194 401	243 215	215 953	208 958	164 855	9 314	91 416	47 150	6 5821	1 241 084	
Number of essential workers/congregate settings	18 432	21 263	21 743	23 106	17 169	1 160	10 398	5 328	8 401	127 000	
Total number to vaccinate	306 409	350 397	379 253	389 111	266 842	20 088	182 027	84 298	112 824	2 091 250	
No. of vaccinator days (50 vaccines/day)	6 128	7 008	7 585	7 782	5 337	402	3 641	1 686	2 256	41 825	
3 OPTIONS BASED ON 4/8/12 WEEK PHASE 2 DURATION											
1	NO. OF VACCINATORS REQUIRED IF 4 WKS	219	250	271	278	191	14	130	60	81	1 494
2	NO. OF VACCINATORS REQUIRED IF 8 WKS	109	125	135	139	95	7	65	30	40	747
3	NO. OF VACCINATORS REQUIRED IF 12 WKS	73	83	90	93	64	5	43	20	27	498

required per district / sub-structure in Phases 1 and 2 , assuming a 100% uptake if vaccination. As far as possible, the Department will 'recruit' and train staff members from within the Department to be vaccinators.

Professional Indemnity

Vaccinators should have indemnity to participate in the programme and while the Department provides indemnity for its own staff, clarity will need to be sought for the use of students and volunteers.

Clinical Supervision

Each VAL will have a lead vaccinator who ideally will be experienced in vaccination programmes. The lead VAL vaccinator will provide support to all the vaccinators in the specific area, serve as the link between the vaccinators and the districts / sub-structure vaccine co-ordinator, field queries, and ensure any concerns and AEFIs are addressed timeously. In addition, the VAL lead vaccinator will be expected to keep a register of all the COVID-19 trained vaccinators in their area.

Training

All health workers involved in implementation of COVID-19 vaccination need to have adequate knowledge and skills in order to ensure safe and efficient COVID-19 vaccine administration. The People Development Centre is working to develop and provide a training programme in line with the most up to date information, and the policy and regulatory framework see table 7. This programme is being developed in collaboration with infectious disease specialist, policy experts, Communications Directorate, Directorate Nursing Services, Directorate People Management, the Stellenbosch University's short course unit, Stellmed, and the University of Cape Town's Knowledge Translation Unit (KTU). Weekly short training check-ins will be provided to ensure that all updated information is communicated. Close collaboration with the NDoH will inform content inclusion to align the training with information shared on the National Knowledge Hub. Training support provided to the WCDoH vaccinators and support teams will also be extended to partners and private sector to ensure a uniformed approach.

The content areas covered in the programme currently include the following:

- General scientific information on the COVID-19 vaccine, product information, appearance packaging and presentations
- Cold chain requirements, storage and handling principles, and options/procedures for waste disposal, regulations on quality and safety, batches and shelf life
- The process of COVID-19 vaccine administration and infection prevention and control measures that should be practiced during the vaccine
- Identification of adverse events following the immunisation and how to report it
- Recording and registration forms and how to track defaulters, monitoring of wastage and reporting

- Effective and individualized communication about COVID-19 vaccination
- Scope of practice for nurse vaccinators
- How to approach vaccinating healthcare staff

Table 7: Training Programme

TRAINING PROGRAMME		
TRAINING INTERVENTION	MODE OF DELIVERY	TARGET GROUP
COVID-19 VACCINE TRAINING	3-hour podcast, available via online link or flash drive (Stellmed and PDC)	<ul style="list-style-type: none"> • vaccinators • team managers • support staff (e.g. pharmacy)
WEEKLY SHORT UPDATE TRAINING CHECK-INS	MS Teams (PDC and content experts)	<ul style="list-style-type: none"> • Vaccinators • team managers • support staff (e.g. pharmacy) <p>NOTE: Alternatively, one member of the COVID-19 vaccine team will update the rest of the team members.</p>
COVID-19 INFORMATION SESSIONS⁵	Online / Presentation by the Knowledge Translation Unit with the support of the Communications Directorate	All Health Care Workers

Districts / sub-districts are required to identify staff who can fulfill the role of a vaccinator as well as the supporting team members. The intention is to train as many eligible staff as possible as this will allow for a more flexible and greater reach for the vaccination programme. Potential additional vaccinators may be recruited from: clinical associates; professional nurses and doctors who have completed their community service; contract nurses (already part of the HPV campaign); staff nurses previously trained on EPI; final year medicine and 3rd and 4th year nursing students; and other staff cadres. Standard Operating Procedures for the nomination, attendance, reporting and recording of the training as well as outlines, programmes and dates will be shared in the comprehensive training implementation plan currently being developed. The institutional, district and sub-structure PDC unit will be expected to keep a register of all the COVID-19 trained vaccinators in their area.

Safeguarding the Service User

Social Distancing Considerations

Essential to mitigating the risk of the virus spreading, the Department needs to ensure that the necessary COVID-19 IPC protocols are accommodated and adhered to at all points of care along the vaccine pathway at each of the vaccine administration locations.

Management of Adverse Events following Immunisation (AEFI)

Any medical event occurring after immunisation can be classified as an adverse event whether or not the event has any causal relationship to getting the immunization. An adverse reaction to the

⁵ In Phases 2&3 Community Health Workers will also be included and the mode of delivery for this group is still to be determined

COVID-19 vaccine is likely to range from mild to severe and from common to rare. All adverse events must be reported on the standardised NDoH forms within 24 hours of presenting to a health care practitioner and be submitted to the relevant provincial CDC office. Adverse events, whether related to the vaccine or not, must be managed appropriately and with sensitivity, as the occurrence has potential to garner negative publicity and fuel vaccine hesitancy. Within the province each case needs to be allocated an EPID number which can be obtained from the provincial EPI Disease Surveillance Officer, Ms Lindi Mathebula and / or the Provincial EPI Manager, Ms Sonia Botha. They can be reached as follows:

- Telephone 021-483-9917 / 3156 /4266 / 9964;
- WhatsApp: 068 228 8726
- Email: Lindi.Mathebula@westerncape.gov.za or Sonia.Botha@westerncape.gov.za

EPID numbers need to be captured on both the AEFI reporting form and Case Investigation Form (CIF). The case investigation form needs to be completed for severe and serious reactions while the Case Reporting Form (CRF) for all minor reactions, severe local reactions and systemic reactions. The finalized National Guidelines on the reporting and investigation of AEFIs is awaited and will be distributed to all public and private health facilities, sub-district and districts, once received.

IV. Stakeholder Engagement & Communication

Stakeholder Engagement Strategy

The COVID-19 Vaccination Programme is the largest in the history of the country and central to its success is government's ability to mobilise a broad range of stakeholders to act collectively in advocating, promoting and enabling the programme. In its engagement with stakeholders at all levels of the provincial health system the Department will endeavor to be open, inclusive, collaborative, respectful and engage meaningfully, see figure 5.

Figure 5: Principles for Engagement



Thus, stakeholder relationships are a prerequisite for vaccine programme success, and the Department views the programme as an opportunity to:

- Build and enhance relationships with a diverse range of stakeholders from a range of sectors including but not limited to, all spheres and levels of government, private and not for profit health

sectors, statutory citizen representative structures, civil society, academia, the public at large, organized labour, business sector, the media, etc.

- Establish and strengthen effective partnerships
- Ensure stakeholders inform the Department's work and direction as we deliver on this vaccine programme and beyond
- Promotes a culture of collaboration and innovation with a broader set of health actors

There are 5 components to the stakeholder engagement strategy which includes inform, consult, involve, collaborate and empower, see table 8

Table 8: The Components of the Stakeholder Engagement Strategy

INFORM	CONSULT	INVOLVE	COLLABORATE	EMPOWERMENT
<ul style="list-style-type: none"> • Share knowledge about the vaccines and the science involved • Information on the vaccine programme and how it will be implemented 	<ul style="list-style-type: none"> • Initiate a dialogue to solicit advice and input on specific aspects if the programme (e.g. expert committee, private sector engagements) 	<ul style="list-style-type: none"> • Working with key stakeholders on a daily basis in the running of the programme, creating spaces for reciprocal sharing and learning 	<ul style="list-style-type: none"> • Working together with stakeholders to jointly deliver on programme initiatives 	Supporting stakeholders: <ul style="list-style-type: none"> • To make informed vaccination choices • in the actions they take to protect themselves from the virus • to champion safer choices

Communication Strategy

To ensure mass uptake of the vaccine a communication strategy it is necessary to address vaccine hesitancy. This hesitancy stems primarily from contextual influences, individual and social group influences and vaccine and vaccination specific issues. The strategy would have to establish trust in the provincial COVID-19 Vaccination Programme through honest and open communication. The focus areas of the strategy include, motivating people and sectors to “unite to vaccinate”, promoting acceptability and logistics around availability and accessibility of the vaccines, see table 9.

Communication in various phases cannot be “built” in a linear manner but takes place within a wider context. Messages will not be contained to one phase and will be overlapping with one another. Thus, communication of phase 2 (and 3) will need to happen in parallel with Phase 1. The following are key strategic considerations for the communication strategy:

- Provide credible science-based information (content and message senders) to support the rollout (TRUST);
- Inspire trust by remaining transparent, honest and consistent;
- Combining internal and external resources (internal team and agency contracts);
- Providing constant reassurance of the vaccine, the process, the ethics of the project
- Addressing various concerns pro-actively and responsively;
- Close cooperation with People Management components for change management, OHS and Wellness to ensure internal credibility and consistency;

- Alignment with both the provincial and national campaigns; and
- Establishing a multi-sectorial communications group with representation from local government, EPI, Knowledge Translation Unit, People Management and vaccine and public health experts.

Table 9: Communication Focus Areas

REASSURANCE		
Objective: We must provide reassurance that we continue to prioritise the wellbeing and safety of our employee and the broader public		
MESSAGING	AUDIENCE	COMMENTS
<input type="checkbox"/> Credible central and local re-assurance messages <input type="checkbox"/> Engaging stakeholders with respect and humility, including our employees <input type="checkbox"/> Clearly communicate the criteria for each targeted group as per each phase of the epidemic	Internal & External	<input type="checkbox"/> Support to be provided internally by the Department's communications team for internal communication around the vaccination of employees with the first information session scheduled for the 2nd week of January 2021.
INSPIRE TRUST		
Objective: Build trust in the vaccine, the vaccination programme and ethical consideration of decision-making		
MESSAGING	AUDIENCE	COMMENTS
<input type="checkbox"/> Science-based messages on the vaccines being procured for the country <input type="checkbox"/> Credible information on the logistical arrangements of roll-out for each phase of the programme <input type="checkbox"/> Transparent communication of the decision-making process <input type="checkbox"/> Credible information on the right of refusal and the likely consequences	Internal & External	<input type="checkbox"/> Messaging needs to expand as we move through the 3 phases and as information becomes available <input type="checkbox"/> Re-affirm the 3 pillars of trust <input type="checkbox"/> Constantly monitor the internal and external environment to address misinformation / fake news <input type="checkbox"/> Support messages from internal influencers (i.e., trusted clinical and management voice within the Department. <input type="checkbox"/> Promote role model stories of vaccination
BE PROACTIVE & RESPONSIVE		
Objective: To be collaborative and consistent, providing timely feedback		
MESSAGING	AUDIENCE	COMMENTS
<input type="checkbox"/> Message of collaborative <input type="checkbox"/> Evidence of being collaborative and the provision of timely feedback <input type="checkbox"/> Consistency in the messaging across time, phases and groups	Internal & External	<input type="checkbox"/> Rapid polling to be undertaken with employees <input type="checkbox"/> Evolving list of FAQs <input type="checkbox"/> Consistent information provided at all times and in all forums <input type="checkbox"/> Provide HoD Connect with options for follow-up

V. In Conclusion

The vaccine is a key weapon to turn the tide against the Covid-19 pandemic. This is an opportunity to unite all sectors and sections of the population around a common objective and build a movement of better health and lay a strong foundation for UHC amongst the public and private health sectors and civil society.

Given the number and range of moving parts in this situation, we need to be agile in the way we learn and respond. This implementation framework lays out the current thinking and approach of the Department, with a particular focus on phase I. It will be augmented in time as we develop our approach to phases II and III and as we have more definitive information about the availability of vaccines and its timelines.

The quantification numbers contained in this document must be treated as best estimates at this point and are being refined over time. This provincial implementation framework that will also guide the micro planning that must happen at local facilities and geographic areas.

VI. Annexures

Annexure 1: Sub-district breakdown of the vaccination demand per District⁶

SUB-DISTRICTS	PHASE 1	PHASE 2	PHASE 3
CITY OF CAPE TOWN DISTRICT TOTAL	75 881	1 425 170	
Southern / Western	33 680	389 111	
Khayelitsha / Eastern	6 595	350 397	
Klipfontein / Mitchell's Plain	8 438	306 409	
Tygerberg / Northern	27 168	379 253	
CAPE WINELANDS DISTRICT TOTAL	8 169	266 842	
Breede Valley	-	53 391	
Drakenstein	-	86 744	
Langeberg	-	32 182	
Stellenbosch	-	53 040	
Witzenberg	-	41 486	
CENTRAL KAROO DISTRICT TOTAL	1 615	20 088	
Beaufort West	-	13 380	
Laingsburg	-	2 443	
Prince Albert	-	4 265	
GARDEN ROUTE DISTRICT TOTAL	9 598	182 027	
Bitou	-	20 793	
George	-	58 496	
Hessequa	-	17 586	
Kannaland	-	5 945	
Knysna	-	22 343	
Mosselbay	-	32 572	
Oudtshoorn	-	24 293	
OVERBERG DISTRICT TOTAL	3 147	84 298	
Cape Agulhas	-	10 100	
Overstrand	-	32 057	
Swellendam	-	10 285	
Theewaterskloof	-	31 856	
WEST COAST DISTRICT TOTAL	5125	112 824	
Bergrivier	-	15 224	
Cederberg	-	12 460	
Matzikama	-	14 057	
Saldahna Bay	-	30 267	
Swartland	-	40 815	
PROVINCIAL TOTAL	103 535	2 091 250	2 907 096

PS: The numbers quoted in the table above are for a single dose.

⁶ Note for Phase 1 both public and private health workers are included and there is currently no sub-district breakdown available. For Phase 3 there is not district, sub-district, sub-structure breakdown available at this point.

Annexure 2: Guideline for the completion of the Waste Management Form

- ✓ **Facility** - enter name of the service delivery point
- ✓ **Reporting period** - enter name of reporting month and year
- ✓ **Target Population** - enter the monthly vaccination target for health facility (as determined by facility)
- ✓ **Column A: Start balance** – enter the stock balance at the beginning of the month, in doses.
- ✓ **Column B: Number of doses received** – enter number of doses of the vaccine received in the month of reporting
- ✓ **Column(s) C : Number of doses (unopened) discarded** – enter the number of doses that have been discarded due to expiry, VVM indication, heat exposure and breakage at the facility during operation.
- ✓ **Column D: Number of doses opened** – this is the number of doses opened for administration during immunisation sessions. The vaccinator must record the number opened each day for vaccination sessions, sum up the total doses opened during the month and report to the pharmacy.
- ✓ **Column E: Number of people immunised** – this is the number of people in the monthly target group vaccinated, this may include vaccination during an outreach session. Vaccinators must sum up the number of people immunised and report to the pharmacy
- ✓ **Column F: End Balance** – this is the balance at the end of month i.e. last day. This is the difference between {A+B} and {C+D}, where:
 - A= balance at start of the month
 - B= number of doses received
 - C= number of doses discarded (unopened), and
 - D= number of doses opened for use during all vaccination sessions throughout the month
$$F \longrightarrow \{A+B\} - \{C+D\}$$
 - F then becomes the start balance at the beginning of the next month

✓ Calculate required rates

1. **Vaccine Usage Rate (M)** $\longrightarrow \frac{E \times 100}{\{A+B-F\}}$; where

E= total number of children vaccinated during the month

A= start balance at beginning of the month

B= total number of doses received during the month

F= total balance at the end of the month

2. **Vaccine Wastage Rate (N) = 100 - M**, alternatively

$$\text{Vaccine Wastage Rate} = \frac{\{(\text{Total doses used}) - E (\text{No. of children immunised})\} \times 100}{\text{Total doses used}}$$

Total doses used is the sum total of doses discarded (unopened): {C} and doses opened for administration {D}

Total Doses Used $\longrightarrow \{C+D\}$

An excel version of the monitoring tool will also be supplied.



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