DEPARTMENT OF HEALTH

LDOH COVID-19 VACCINE

MINISTREIAL BRIEFING SESSION
PROVINCIAL VACCINE ROLLOUT PLAN
STATE OF READINESS
PRESENTATION TO NCOP
25 FEBRUARY 2021
ZOOM MEETING

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Plan Outline

1. Introduction
2. Purpose
3. Overview of planning framework
4. Governance Leadership and coordination
5. Target Population
6. Vaccine delivery platforms
7. Human resources requirements
8. Vaccine, cold chain, logistics and infrastructure
9. Social mobilisation and Demand Creation
10. Monitoring and evaluation

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Outline continue

11.Johnson and Johnson Vaccine Implementation study

11.1. Study aims and objectives

11.2 Methods

- Study design
- Study site
- Target population
- Study procedure
- Ethic al consideration

12. Critical implementation factors

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Introduction

- Since the declaration of COVID-19 –caused by a novel coronavirus as a public health emergency of international concern (PHEIC) by the WHO on 30 January 2020, every sector of society has been impacted.
- COVID-19 has since spread to all countries causing devastation in all sectors.
- In the absence of pharmacological treatment, except for supportive measures, public health interventions became the only hope of limiting the impact of COVID-19 on the health of communities.
- These public health interventions entail social, behavioural and environmental measures such as: universal making, hand hygiene, social distancing and avoiding poorly ventilated areas.
- Vaccination is the latest pharmacological public health intervention to be deployed to control the pandemic.

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Aim and Objectives of Vaccination

Overall Aim

- To protect the population against the SARS-Cov-2 virus by interrupting transmission through achievement of herd immunity

Objectives

- To reduce the morbidity and mortality caused by the COVID-19 disease through prioritization of high risk and vulnerable population
- To ensure readiness of the health service delivery platform for vaccination
- To ensure safe and efficiency delivery of Vaccine to target population in the public and private sector
- To empower the people of Limpopo with correct information with regard to Covid-19 vaccination
- To monitor and evaluate the implementation of the COVID-19 vaccination programs

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Functional Areas

A. Governance, Co-ordination and planning
B. Vaccine delivery platform
   - Human resources
C. Vaccine, cold chain, logistics and infrastructure
D. Communication and Demand creation
E. Vaccine Safety monitoring and management
F. Monitoring and evaluation , Information management System

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Overview

Worstream	Focus Area
Planning and co ordination	COVID-19 Vaccination planning and coordination
	COVID-19 Vaccine governance and co-ordination structures
	Budgeting and financing
	Monitoring and evaluation of vaccine plan
Vaccine delivery platform	Identification of target population
	Selection and accreditation of vaccination site
	Training and supervision of Vaccinators
	Development of vaccine protocols and guidelines
	Infection Prevention and control
	Healthcare Waste management
Vaccine logistics and cold chain	Cold chain management
	Procurement and supply of vaccines
	Procurement and supply of vaccine related supplies
	Vaccine Quality control
	Stock monitoring

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Overview

Functional Area	Focus Area
Vaccine safety monitoring	AEFI identification and reporting
	AEFI Surveillance Systems
	AEFI management
Vaccine demand creation and communication	Appropriate vaccine uptake communication
	Vaccine Safety communication
	Health Professional Vaccines communication
	Monitoring of vaccine knowledge, attitudes and practice (readiness)
Monitoring and evaluation	Monitoring and Evaluation framework
	Vaccine Plan indicators
	National Vaccine data management system

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Governance, Co-ordination and planning

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Governance, Co-ordination and Planning

PROVINCIAL EXECUTIVE MANAGEMENT

COVID - 19 SURGE COMMITTEE
CHAIRPERSON DR DOMBO
DEPUTY CHAIR DR NDWAMATO

VACCINE TECHNICAL WORKING WORKGROUP
CHAIRPERSON DR MALATJI
DEPUTY CAHIRPERSON MR KRUGER

COVID - 19 DITRICT VACCINATION TASK TEAM
DISTRICT EXECUTIVE MANAGEMENT
CHAIRPERSON OUTBREAK RESPONSE COMMITTEE

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Governance, Co-ordination and Planning

- The vaccine rollout strategy will be coordinated by NDOH with Provincial Health Department and the private sector
- In LDoH will coordinate the process through deployment two committees
  - **The COVID-19 Surge Committee** – responsible for oversight and coordination of the COVID-19 response
  - **Vaccine Technical Working Group (TWG**) which will report to the COVID-19 Surge Committee
- The Vaccine technical Working Group comprises of representative from the various units at the Provincial Department of health The Vaccine Technical working group will categorized according the functional areas

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Governance and Coordination Action plan

Workstream	Focus Area	Activities
Planning and co ordination	• COVID-19 Vaccination planning and coordination • COVID-19 Vaccine governance and co-ordination structures • Budgeting and financing • Monitoring and evaluation of vaccine plan	Submit COVID-19 plan to Surge and executive for approval
		Confirm appointment of technical working group
		Conduct Stakeholder engagements (district and province) and briefings
		Ensure development of districts to develop micro plans
		Finalise the budget for the vaccination plan

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Target Population Identification

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Target Population Identification

- Vaccines will not be **available** for everyone **immediately** and a **prioritization system** will have to be applied.
- Priority will be given to those:
  - in roles considered to be **essential for societal functioning**
  - most **at risk of infection and serious outcomes**, age above 60 those with **comorbid conditions**
  - hose living in overcrowded settings,
  - most at **risk of transmitting** SARS CoV 2 to others

Target Population

- The vaccine will be introduced through a phased approach
  - **Phase 1**:

    All front line health workers in both public and private sector will be targeted for vaccination
  - **Phase 2**:

    High risk groups including: Persons in congregate settings, >60 years old, >18 yrs with co-morbidities;

    Other essential workers including: Teachers, Police, Security, Retail Food, Funeral Parlour, Banking, Services Sectors (local govt, port health, DHA, etc), Miners
  - **Phase 3**:

    Open vaccination to all
- The following groups **have not been studied** for vaccine efficacy and will thus be excluded
  - Pregnant women and Children (less than 18 years)

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Phase 1 Target Population

- **LDOH staff members (Persal) = 44 526**
  - Facility based hospital staff
  - PHC staff (including mobile team)
  - Community based services CHWs
  - EMS
  - Depot
  - Provincial and district office staff
  - Malaria institute
- **NGO/ Non-Persal Staff = 6838**
  - Learnerships
  - Contractors: Social Workers
  - Outsourcing Contractors: SITA
  - Outsourcing Contractors: ANOVA
  - Periodic Appointments: Spraymen
  - Outsourcing Contractors: Red Cross staff
  - Lay Counsellors & Others

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Target Population Phase 1

Risk Category	Risk assessment	Classification
Category 1	Those conducting aerosol-generating procedures i.e. intubation, ventilation, taking Covid-19 specimens	Those in contact with patients
Category 2	Those in direct contact with known or suspected Covid-19 patients	
Category 3	Those in contact with patients (who are not known or suspected to have Covid-19)	
Category 4	Those with some (limited) in contact with patients	
Category 5	Those not in contact with patients	Those not in contact with patients

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Phase 1 Target Population

- As part of enrolment for the vaccines, all health workers will complete an online registration
- This will also be part of the consent procedures and risk assessment
- The vaccination can be conducted in waves (sequencing of vaccine clients)

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Vaccine Delivery Platform

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Vaccine Delivery Platform

- **Hub and spoke method**
  - Primary site in hospital 37 (specialised hospital excluded)
    - Hospital Staff
    - EMS
  - Outreach team to be attached to each hospital
    - PHC staff
    - Mobile teams will at the fixed PHC facility
- **Phase 2 and 3**
  - PHC Facilities
  - Possibly augmented venues will be in the community
    - schools, churches, community halls, traditional authority
    - Tents can be utilised

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Phase 1 Vaccination Platform

Hospital Based Vaccination sites

- Hospital staff
- EMS
- Forensic pathology staff

Mobile Vaccination Outreach teams

- PHC Staff
- Mobile clinic
- Nursing colleges
- Malaria institute
- District and provincial office
- DEPOT

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Vaccine Service Platform Phase 1

Vaccination Provision Platform	Target Group	Approach
Hospital setting vaccination	Hospital employee EMS Hospital Gateway Clinics	– The vaccination of hospital-based health care workers will be provided through the Occupational Health Care Services/Units. – Vaccine delivered to the hospital –stored in hospital pharmacy in accordance with manufacturer's cold chain instructions – Vaccinators may be occupational health workers, IPC or other staff members with experience in vaccination. – Virtual training will be conducted with vaccination team – Resources: Vaccinators (current and recruited), ancillary supplies, emergency equipment, waste disposal,

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Vaccine Service platform Phase 1

Vaccination Provision Platform	Target Group	Approach
Primary Health Care Vaccination outreach teams	Primary healthcare Employees Community Health care workers Administrative offices Nursing College Malaria Offices	– Each hospital will partner with PHC to establish vaccination outreach teams which will cover each **geographical service area. – These teams will develop a schedule and move from facility to facility vaccinating all eligible health care workers. – Vaccine will be distributed to hospital for collection daily stored in accordance with cold chain requirements

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Vaccine Service platform Phase 2 and 3

PHASE 2 AND 3		
Vaccination Provision Platform	**Target Group**	**Approach**
PHC OUTREACH	Population in public sector	– PHC TEAMS attached to hospital will vaccinate population in each geographical service areas in phase 1 and phase 2
Occupational Health	Occupational setting/ other essential workers Mining sectors	– LDOH will liaise with other sectors with essential/frontline workers eligible for vaccination – Using the current multi-sectoral forums, sectors will be engaged and plans made to rollout vaccination in the sectors. – The model to be used will be determined by the dynamics in each sector, resource availability in LDOH, vaccine allocation, etc. – The group will likely benefit from either mobile teams model or set up of vaccination centers in strategic places

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Vaccine Site Readiness

- For phase 1 , all hospital excluding specialised hospitals will used as vaccination sites for phase 1
- All hospital will also be vaccination training centres for all the clinics in the catchment areas
- Provincial EPI will develop a vaccination site readiness tool
- Districts will conduct vaccination readiness assessment using a standardised criteria
- Each district will establish mobile vaccination teams attached hospital in each geographical area
- District will ensure that all vaccination mobile teams are equipped to conduct phase 1 vaccination
- Is some areas depending on number of vaccine recipients hospitals maybe complexed as vaccination sites

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Vaccine Site Readiness Criteria

Focus	Criteria Items
Space	❑ Well ventilated dedicated room ❑ Vaccine Fridge ❑ Hand washing facilities ❑ Bed and tables chairs
Vaccine supply	❑ Vaccine vials ❑ Surgical supplies ❑ Relevant PPE ❑ Pre packaged Emergency box ❑ Waste management
Human resources	❑ Fully trained Vaccination team comprising of ❑ Professional nurse ❑ Enrolled Nurse ❑ Admin clerk
Data Management	❑ Computer with internet connectivity ❑ Phones ❑ Vaccine register and paper tools
AEFI reporting	❑ AEFI reporting form ❑ AEFI Case investigation forms
Other	❑ IEC material ❑ Vaccination Sign Posts

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Human Resources Planning

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Human Resources Assumptions

	Key assuptions Assumptions
Number of vaccinators available	• Number of mobile clinics = 96 mobiles (50% of the mobile clinics with two vaccinators and then the other 50% have one vaccinator) , Therefore, number of vaccinators from mobile clinic are 144 • Integrated School Health Programme (ISHP), approximately, there are 40 teams. However, programme functionality need to be maintained. Therefore, the assumption is that only 25 vaccinators maybe sacrificed towards the Covid19 vaccination • **Number of vaccinators available = 144 +25 169**
Vaccination capacity	Assuming one person can vaccinate 50 people 50 persons per vaccinator X total number of vaccinators (169) **= 8450 per day** **= 8450 * 5 = 42250 per week** **= 42 250 X 4 = 169 000 per month** **=169 000 X 12 = 2, 028 000**
Target Population	Additional vaccinators are required for phase 2 and phase 3 of the vaccination to cover estimated target population
Implementation risk	• We need to factor-in leaves of absence (including quarantine and Isolation leaves), therefore, a buffer arbitrary human resource factor of 30% In conclusion, • In summary, we need additional 300 vaccinators a day (Hired of six or 12 months' contracts).

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Phase 1 Scenario

	Scenario 1	Scenario 2	Scenario 3	Scenario 4
Total population	50 000	50 000	**50 000**	50 000
Target per day	2500	5000	**7500**	10 000
Number of vaccinators	50	100	**150**	200
Vaccination period	20 days	10 days	**7 days**	5 days

- **This shows that the province has capacity to vaccinate phase 1 population within a period of 2-3 week with current vaccinators**

Scenario Analysis Phase 2 and 3

	Target population	Estimated population	Scenario 1 3 month		Scenario 2 6 months		Scenario 3 12 months	
			Target per day	Vaccinators per day	Target per day	Vaccinators per day	Target per day	Vaccinator Per day
Phase 2:	Essential workers	250 000	4167	83	2083	42	1042	21
	Persons in congregate settings	110 000	1833	37	917	18	458	9
	Persons > 60 years	500 000	8333	167	4167	83	2083	42
	Persons > 18 years with co-morbidities	800 000	13333	267	6667	133	3333	67
	Subtotal	**1660000**	**27 666**	**554**	**13 834**	**276**	**6 916**	**139**
Phase 3	>18 years without co-morbidities	2 250 000	**37500**	**750**	**18750**	**375**	9375	188

For 6 months scenario the province would require an additional **276 – 169 =109 vaccinators for phase 2**

375 – 169 = 206 vaccinators for phase 3

***The procurement of vaccines and allocation to provinces will determine implementation

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Training, Support and Supervision

- The Vaccine TWG in collaboration with the provincial and district Resource Training centres will conduct training for the vaccinators and data capturers
- Training will use virtual platforms and non-virtual platforms at district level
- Train the trainer model will be used to train district trainers who will cascade training to vaccinator teams
- Hospital Vaccination sites will be become training centres for vaccinators in their catchment area
- Training plan including the items below is being developed
  - Training population
  - Training schedules
  - Trainers
  - Monitoring of training
- Preparation for training is scheduled for 2021/01/28

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Vaccine, Cold Chain Logistics and Infrastructure

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Vaccine, cold chain, logistics and infrastructure

- NDOH has committed to **procure vaccines** on behalf of provinces
- Provinces will have to be allocated with each batch that is procured
- The **delivery points** will be determined by the vaccine cold chain requirement vs the cold chain capacity in the province
- Depending on the type and packaging of the vaccine, LDOH will procure **consumables** (needles and syringes), incl. PPE
- The current Health Care Risk Waste Disposal Contract will cater for the vaccination project (there may be extra costs due to increased vaccination)

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COVID-19 Vaccine Profiles Phase 1

Vaccine name	Efficacy	Administration	Cold chain	Important attributes
Pfizer/BioNTech	95%	IM	-70^{0}C	
Moderna	95%	IM	2-8^{0}C	

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Vaccine, cold chain, logistics and infrastructure

Functional Area	Focus Area	Activities
Vaccine Logistics Cold chain management	Warehousing and facility storage	• Audit additional capacity requirements • Ancillary supplies
	Cold Chain Maintenance	• Conduct Cold Chain Audit • Purchase additional cold chain capacity where necessary (phase 2 and 3) • Refresher Cold chain master training
	Logistics and distribution	• Direct delivery from NDOH to hospital vaccination sites • Depot to be activated in phase 2 and 3 • Forecasting and Supply planning
	Stock monitoring	• Prevention of stock wastage • Reverse logistics
	Risk Management	• Prevention of theft during storage, distribution and vaccination

Vaccine Safety Monitoring

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Vaccine Safety Monitoring

- Safety monitoring is an important aspect on Vaccination program
- The COVID-19 vaccine although it has been through phase 3 Trial, it will requires close monitoring and reporting of Adverse event critical especially in phase 1
- The plan proposes to use both active and passive methods for surveillance of vaccine safety
- **Active surveillance** is recommended for Phase 1 of the COVID-19 vaccine, because population is accessible
- **Passive surveillance** for Phase 2 is recommended

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Vaccine Safety Monitoring

Functional Area	Objectives	Activities
Vaccine safety Monitoring	To ensure early detection and management of AEFI	• Develop COVID-19 Vaccination safety protocols and SOP • Compile a list of vaccine safety per district • Conduct training on COVID-19 vaccine safety monitoring to safety champions • Implement and monitor district safety training
	To ensure adequate reporting of AEFI using standardised tools and methods	• Develop protocol for AEFI reporting • Develop and disseminate tools for AEFI • Liaise with Communication to develop communications on vaccine safety communication material
	To ensure appropriate investigation of reported COVID-19 AEFI	• Develop guidelines and standardised tools for AEFI investigation

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Social Mobilisation and Demand Creation

Social Mobilisation and Demand Creation

Aim of social mobilization

To empower the people of Limpopo with correct information with regard to Covid-19 vaccination.

Objectives

- To support and encourage appropriate uptake of the vaccines by providing correct and timely information COVID-19 in terms of safety, availability and efficacy
- Addressing vaccine fears, myths and misconceptions to ensure uptake of the vaccine
- Managing and mitigating any potential disappointment resulting from unmet demand of the vaccine
- Ensure continued adherence to non-pharmaceutical measure as an important prevention strategy
- Generate awareness and understanding of the phased approach of prioritizing target groups

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Social Mobilisation and Demand Creation

- Vaccine education will encompass
  - General information on benefits of vaccination
  - Specific information on COVID-19 vaccine communication including vaccine safety
  - Communication on frequent asked questions, myths and concerns
    - Digital platform monitoring (to gather intelligence on community perceptions, ongoing myths and generally what drives local behaviour)
  - Importance of non-pharmaceutical measures
  - Communication of Roll out of each phase

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Target Audiences

- All citizens; vaccine eager and vaccine hesitant groups.
- A focus on priority for people to be vaccinated in the first phase: health care workers, frontline functionaries, people over 50 years of age and people under 50 years with co-morbidities.
- Civil society organisations, professional bodies, advocacy groups, organised labour including hesitant groups, medical fraternity, social influencers and youth platforms & networks.
- Elected and non-elected representatives: MPs, MPLs, Councillors, traditional and faith leaders
- Academia, alternative medicine practitioners, traditional healers, naturopaths, homeopaths etc.
- National and community media including traditional and digital media, which will disseminate correct/factual information by proactively addressing any mis/disinformation or incorrect messaging.
- Government employees (including Department of Health employees) to serve as conduits for messages to their communities.

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Platforms

- The department will then share educational resources and messages with myth busters through all platforms:
  - Electronic and digital media,
  - Community engagements to traditional leaders,
  - religious leaders and traditional healers using existing platforms

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Demand Creation Approach

Political Leadership

High level political support through the OTP and MEC Heath to provide information and improve acceptance and uptake

Vaccinators Support

Optimal support for the implementers with training and resources with clear messages, including ability to sell vaccination to clients

Vaccine Dashboard Communication

Use of up-to-date data to monitor implementation, to encourage the implementers and update the public

Social Mobilisation

Use of leaders, influencers and mobilisers in different communities and settings to create demand and improve acceptance and uptake

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Social Intelligence Driven Response

- The drivers of vaccination are complex, context-specific and change over time.
  - Regular and timely data collection, analysis and use of data on the behavioural and social drivers of vaccination uptake will inform evidence-based planning and guide interventions and responsive messaging
  - Management of crisis communication: Content guidance, detection and response to rumors, misinformation with real-time rapid response
  - Emphasizing the importance of continued universal masking, social distancing, hand hygiene and avoidance of large gatherings
  - Rapid and open sharing of information about the vaccination programme

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Monitoring and Evaluation
Health Information Systems and ICT

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Monitoring & Evaluation

Workstream	Focus area	Activities
Monitoring and Evaluation	Monitoring and evaluation framework	Develop monitoring and evaluation framework for the project
		Develop monitoring & evaluation tools for non-NIDS indicators
	Vaccine plan indicators	Provision of ICT infrastructure to vaccination sites
		Provide technical assistance to vaccination sites ICT
	National Vaccine data management system	Conduct training on EVDS

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Monitoring & Evaluation

The Draft National Indicator Data Set for COVID-19 Vaccination has been produced with definitions, means of calculations and data sources for each indicator and data element.

The selected priority indicators are:

Population

a) Vaccine uptake rate

b) Vaccine coverage (dose 1 & 2 & fully immunised) (>18 yrs &<60 yrs)

c) Vaccine coverage for vulnerable groups (60+ ages and those with co-morbidities)

d) Vaccine drop-out rate between dose 1 & 2

e) % of vaccine beneficiaries reporting adverse events

Health Systems

a) Vaccine availability levels

b) Vaccine stock out levels

c) Number of vaccines sites/facilities

d) % of vaccine sites ready for vaccine administration

e) Number of vaccinators in each district

f) % of vaccinators trained

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Proposed NDOH Health Information Systems and ICT

- Data needed for monitoring vaccine uptake and coverage, prioritization, planning, safety monitoring and vaccine effectiveness studies.
- **An electronic vaccination data system (EVDS**) is in the process of being developed by NDOH
- EVDS to support collection and provision of the following information
  - Patient information (including demographics, number of doses, etc.)
  - Health establishment where service is accessible (name and type, e.g. clinic)
  - Vaccine administered (manufacturer, batch number, etc.)
  - Safety information as part of a pharmacovigilance plan (Adverse Events Following Immunization – AEFI)
  - A record of vaccination to be issued to individuals where appropriate and required
- Provinces should have access to the system and be able to export relevant reports from the system

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NDOH EDVS Attributes

- Pre-registration of HCWs during Phase 1, other recipients during Phase 2 in order to receive vaccination appointment.
- The system will be prepopulated with existing databases (Persal, HPRS,SASSA database).
- Digitized Consent form (for vaccination, to use personal data and location data).
- Vaccinators to be able to see whether it is an individual's first or second dose and which vaccine has been administered. (Dose alerts - vaccine dependent)
- To be Linked to NHLS / NICD to determine effectiveness of vaccine i.e. if patient later tests positive
- Includes Adverse events following immunization (AEFI) monitoring
- The system will send reminders or notifications for subsequent doses including date and facility

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SUMMARY OF FUNDING REQUIREMENTS: VACCINATION COSTING

Vaccination campaign costing		
CATEGORY	**2020/21**	**2021/22**
		Rands
Compensation of Employees		**124 086 589**
Goods and Services	**21 619 000**	**108 393 000**
Cooler boxes (mobile teams)	630 000	
Cold Chain Monitors (eq<5000)	1 400 000	
2ml Syringes	4 164 000	
23G Needles	1 652 000	
Cotton Wool balls	1 023 000	
Security services (special)	9 664 000	106 304 000
consumables	440 000	
Loudhailers	425 000	
Data/airtime/wifi	100 000	2 089 000
Flexible tables and chairs	515 000	
Protective clothing	300 000	
Covid branded Ambrellas	170 000	
Community& SABC airtime	966 000	
Social media & advertising	170 000	
Machinery and Equipment	**14 485 000**	**2 900 000**
Vaccine Fridges	14 000 000	
Cold Rooms (5 Dist hospitals)		2 500 000
Gazebos		400 000
Industrial Printer (Colour)	280 000	
Heavy duty shredder	200 000	
Heavy duty paper trimmer	5 000	
Total Budget Required	**36 104 000**	**235 379 589**

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LIMPOPO DEPARTMENT OF HEALTH

COVID-19

THE SINGLE-DOSE AD26.COV2.S COVID-19 JOHNSON AND JOHNSON (JNJ) VACCINE IMPLEMENTATION (SISONKE) STUDY

15 FEBRUARY 2021

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Introduction and background to JnJ vaccine

- COVID Vaccination Programme Status has been paused since Sunday 6 February following concerns regarding efficacy of the Oxford-AstraZeneca (Covi-19 Shield) vaccine against mild & moderate COVID caused by the 501.V2 variant.
- The single-dose Ad26.COV2.S COVID-19 Johnson and Johnson (JnJ) vaccine has been tested in RSA through the ENSEMBLE study as part of a global study in multiple regions (North and South America, Africa)
- In RSA the ENSEMBLE clinical trial is currently implemented in 31 research sites.
- In South Africa and across world the vaccine was found to be:
  - 57% effective against moderate to severe disease, where nearly all of the cases were due to infection with the new variant.
  - 85% High vaccine efficacy (overall, after Day 28) was noted against severe/critical COVID-19 with efficacy observed as early as Day 7 (77% as of Day 14).
  - 100% protection against COVID-19-related deaths.

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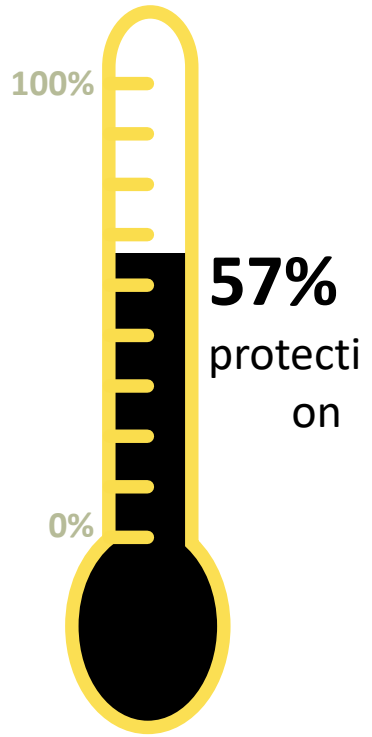
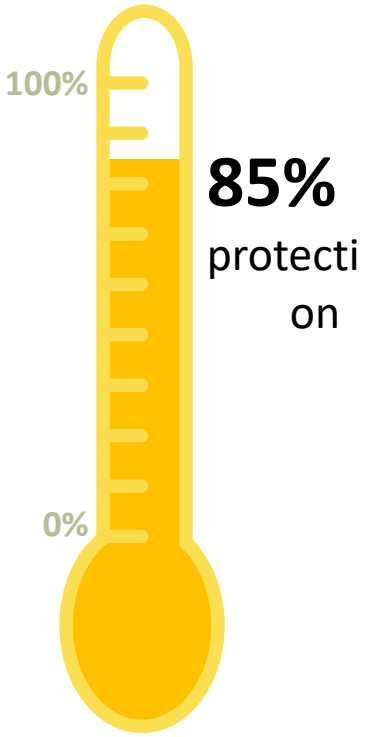
Ad26.Cov2.S Vaccine (J&J) Protects Against Severe COVID-19 In South Africa

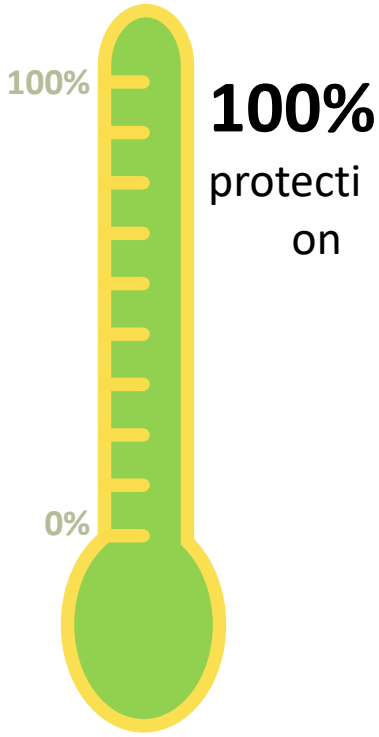
Tested in 43 783 people from 4 continents including 6,576 people in South Africa



Moderate-severe COVID



Severe COVID



Death

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Single-arm phase 3B JnJ research study

- NDOH is partnering with The ENSEMBLE, JnJ and SAMRC to implement the single dose Ad26:Cov-SAR2 implementation study
- The SAMRC, JnJ and ENSEMBLE research sites will make the vaccine available to health workers through an early access open-label, single-arm phase 3B implementation study called Sisonke.
- The purpose of the briefing is to share the details of the implementation study

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Single-arm phase 3B JnJ research study (2)

- That this is a single-arm phase 3B research study, called Sisonke
- The vaccine being researched in the study is called Ad26.COV2.S COVID-19 Johnson and Johnson (JnJ) vaccine
- That this vaccine is not registered in South Africa and is unlicensed
  - It is only approved for research purposes
  - It is only available through the study.
  - It may take up to 3 months to finalise the expedited registration the vaccine
- The research protocol has been approved by the South African Health Products Regulatory Authority (SAHPRA) and the study will be conducted under the auspices of SAHPRA.
- Ethics approval has been obtained from the SAMRC and the UKZN Human Research Ethics Committees.
- Approval from other Ethics Committees to which the ENSEMBLE sites are accountable is outstanding.

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Rationale for extension of the vaccine implementation study to health setting

- To date 40 000 South African health workers have developed COVID-19, 6 473 have been hospitalised and 663 of our colleagues have passed on. As at 17 February 2021, **3288 HCWs** in **Limpopo** have contracted COVID-19, with **35 deaths**.
- The proposed implementation study aims to
  - Fast track the development of more evidence for the effectiveness of the Johnson and Johnson vaccine through expanding the target population to HCWs
  - Make available the single dose J&J vaccine to HCWs on a voluntary basis under research conditions
  - Health care workers can volunteer to participate in a more detailed study to monitor vaccine effectiveness in a real-life setting
- Benefits of participating in the phase 3B study as a HCW:
  - Assist in getting more evidence on the vaccine i.e. benevolence/ altruism
  - Early access to the vaccine where would otherwise have to wait for all the studies to be completed to access approved and licensed product as part of vaccination campaign (which would take a minimum of three months from now)
  - **NB: THIS IS NOT A VACCINATION CAMPAIGN**

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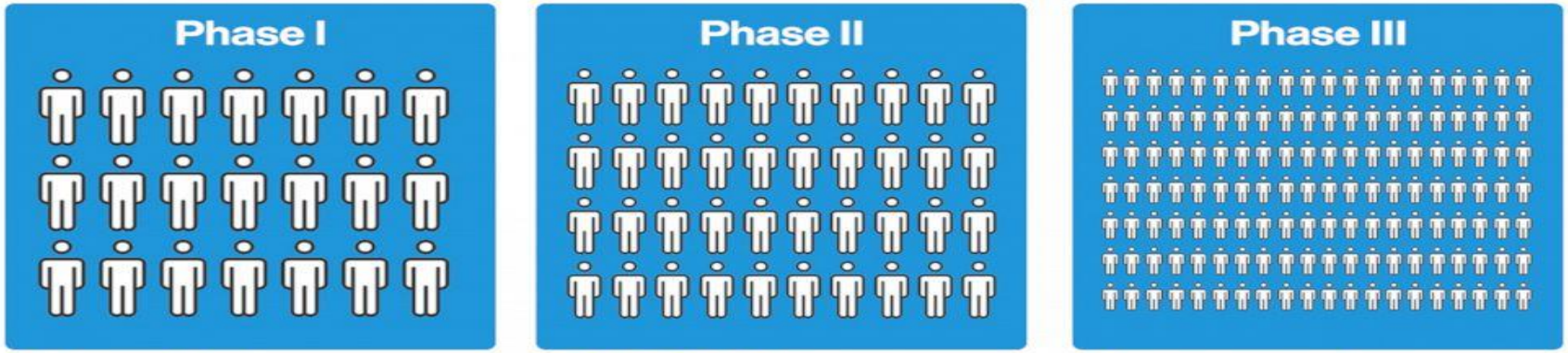
Study approach

- **Study Title**
  - Open-label, single-arm phase 3B implementation study to monitor the effectiveness of the single dose Ad26.COV2.S COVID-19 vaccine among health care workers in South Africa
- **Study design**
  - Phase 3b Vaccine implementation study
- **Phase 3b defined**
  - Phase 1 and 2 of the study has been conducted a safety of the vaccine has been established
  - Phase 3 aims to accumulate additional findings which may required as a condition for regulatory approval.
  - To test effectiveness of vaccine
  - Usually performed near/after the applicant has filed for regulatory approval

Covid-19 Vaccine Watch

VACCINE HUMAN TRIAL PHASES



Usually less than 100 people, and monitors for safety at multiple doses.

Slightly larger and looks for safety and early effectiveness.

Large scale, normally 30,000 patients, and is the test of effectiveness and long term safety in multiple populations.

SAFE AND EFFECTIVE VACCINE IN 12-18 MONTHS:
Reasons for rapid distribution of a safe and effective vaccine without cutting corners include: 1) Previous experience with coronaviruses like MERS and SARS. 2) Running trial phases simultaneously. 3) Government financing allowing development, trials, manufacturing and distribution without a financial risk to the companies. Any vaccine will require FDA authorization before being made available to the US population.

SOURCE: WHO

abc NEWS

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Study aims and objective

- **The aim**:
  - to determine the effectiveness of the single dose Ad26.COV2.S COVID-19 vaccine among health care workers (HCW) as compared to the general unvaccinated population in South Africa.
- **Primary Objective**:
  - To assess the effectiveness of Ad26.COV2.S vaccine on **severe COVID, hospitalizations and deaths in HCWs as compared** with the general unvaccinated population in South Africa.

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Who will can be included in the Vaccination?

- Any health worker working the public of private sector can participate in the study
- Inclusion of a health worker in the study is on voluntary basis
- No health worker will be coerced to participate in the study
- Informed consent procedure as per study protocol will be strictly adhered in on a voluntary basis
- Priority for enrolment will first be given to patient facing HCWS versus non patient facing healthcare workers
- Inclusion criteria
    - Age 18 and older
    - Health care worker in the private or public service
    - Willingness and ability to comply with vaccination plan and other procedures.
    - Capable of giving electronic or personal signed informed consent

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Exclusion criteria

- Any significant **acute or unstable chronic medical condition detected during eligibility assessment this includes acute COVID-19 infection**
- Participant reports being **pregnant at time of enrolment** or planning to be pregnant within 3 months.
- **Current participation in any other research studies** that would interfere with the objectives of this study.
- **History of severe adverse reaction associated with a vaccine** and/or severe allergic reaction (e.g., anaphylaxis) to any component of the vaccine.
- **Current signs and symptoms of COVID-19 (PUI) or confirmed COVID** (need to be sent for testing or isolation). The MAC is currently working on an advisory to guide on how long after a severe bout of COVID-19, is one eligible for vaccination

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Vaccine profile

- **Vaccine safety**
  - The vaccine has been reported as having an acceptable safety profile, with few reported side effects
- **Vaccine Efficacy**
  - A single dose of Ad26.COV2.S vaccine was efficacious in the prevention of moderate to severe/critical COVID-19 with VE of 67% and 66% post Day 14 and post Day 28 post vaccination.
- **Vaccine storage and administration**
  - It is administered on the deltoid arm as a single dose
  - Stable at 2-8 degrees Celsius and reported that it can be stored for 3 months at temperature of -20 degrees Celsius

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How will the study be implemented?

- Vaccination study planned to be implemented in phases as the vaccines becomes available
- A total 300 000 to 500 000 doses expected in next 2 months according to NDOH
- A total of 80 000 doses expected in South Africa week of 15 February2021
- Study sites: 20 public sector hospital across the country initially focussing on large hospitals
- LDOH study sites are two: namely **Pietersburg and Mankweng hospital**
- Sites were selected by the researchers in consultation with NDOH based on the number of healthcare workers and the COVID-19 caseload
- ENSEMBLE research site in Limpopo Province: Ndlovu Research Center, Elandsdoorn CRS
  - Responsible for vaccine receipt and distribution to LDOH study sites
  - Research study support including cold chain management
- The province is currently working on the expansion plan given the vastness of our province

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Where are the clinical trial research sites in South Africa?

- **Twenty (20) public sector hospitals** have been identified for the first two-week period.
- **Sixteen (16) of the ENSEMBLE Research sites** have been identified as Primary Distribution Sites receiving product from Biovac.
- The **ENSEMBLE Research sites** were chosen based on proximity to the identified public sectors hospitals.
- Six (6) of these ENSEMBLE Research sites are either within the grounds of the public sector hospital complex or within 1km

Research Sites	Province
Aurum Institute Klerksdorp CRS	North West
Aurum Institute Rustenburg CRS	North West
CAPRISA eThekwini CRS	KwaZulu-Natal
Chatsworth CRS	KwaZulu-Natal
Clinical HIV Research Unit (CHRU)	Gauteng
Elandsdoorn CRS	**Limpopo**
FAM-CRU (Family Clinical research Unit)	Western Cape
Groote Schuur HIV CRS	Western Cape
Josha Research CRS	Free State
Mzansi Ethical Research Centre	Mpumalanga
Nelson Mandela Academic Research Unit	Eastern Cape
Phoenix Pharma	Eastern Cape
Qhakaza Mbokodo Research Clinic CRS	KwaZulu-Natal
Soweto HVTN CRS	Gauteng
Synexus SA – Watermeyer	Gauteng
Wits RHI Shandukani Research Centre	Gauteng

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Doses allocated and target population

	Pietersburg	Mankweng
Doses allocated	4080	3080
Number of vials	2040	1540

Study sites	Number of HCWs
Pietersburg Hospital	2747
Mankweng Hospital	2055
Private sector & other Public sector facilities	2358
Total	**7160**

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HCW Study participant enrolment procedure

- **Recruitment**
  - Healthcare workers will be informed of the implementation study through information leaflet and stakeholder engagement
- **Study Enrolment**
  - Interested Healthcare workers can self enrol on the EVDS system using NDOH link
- **Informed Consent**
  - An sms will be sent to healthcare workers who have enrolled on EVDS
  - Healthcare workers go through the information provided and provide digital consent
  - Receive your vaccination voucher
- **Schedule appointment**
  - The EVDS system will schedule appointments for healthcare workers at the allocated vaccination sites

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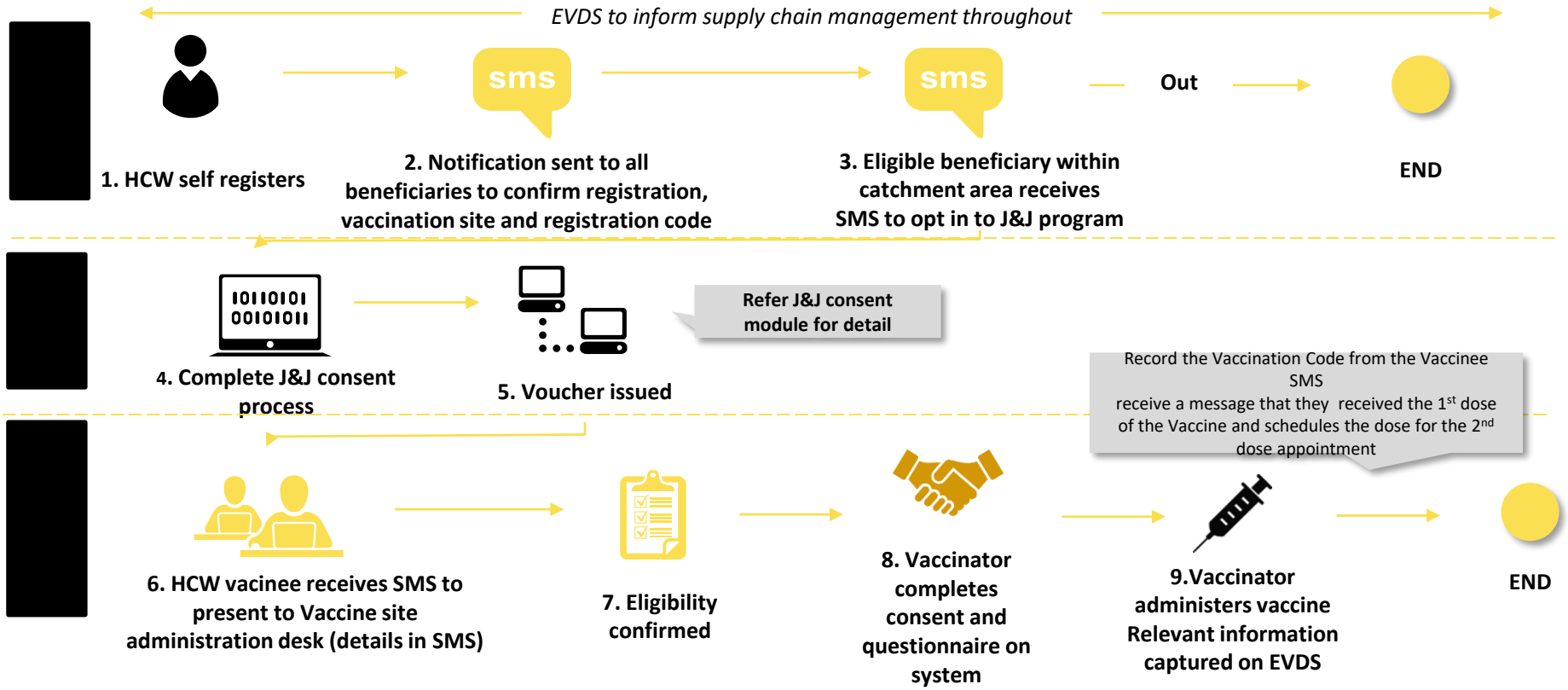
HCW Study participant vaccination procedure

- Vaccination Procedure
  - Registration desk to confirm eligibility of the participants
  - Research (or any government GCP trained) pharmacists to prepare all the doses and ensure cold chain requirement
  - A trained Vaccinator to administer the vaccine on the left deltoid arm as per protocol
  - Vaccinator to capture vaccine on EVDS
  - Vaccine recipient to be monitored for 15 minutes post vaccination
- Vaccine safety Monitoring
  - The vaccine recipient will be given a vaccine safety card
  - Side effects to be reported to research team as directed
  - Vaccine adverse event reporting will be followed
  - Each sites to have health professionals trained on vaccine safety monitoring
- Reporting and monitoring Implementation
  - All reporting will be done through EVDS
  - Paper tools are available as back up

4A


EVDS to inform supply chain management throughout
sms
sms
Out
1. HCW self registers
2. Notification sent to all beneficiaries to confirm registration, vaccination site and registration code
3. Eligible beneficiary within catchment area receives SMS to opt in to J&J program
END
4. Complete J&J consent process
5. Voucher issued
Refer J&J consent module for detail
Record the Vaccination Code from the Vaccinee SMS
receive a message that they received the 1st dose of the Vaccine and schedules the dose for the 2nd dose appointment
6. HCW vacinee receives SMS to present to Vaccine site administration desk (details in SMS)
7. Eligibility confirmed
8. Vaccinator completes consent and questionnaire on system
9.Vaccinator administers vaccine Relevant information captured on EVDS
END

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Uncertainties/unknown factors

- The following aspects are awaiting clarification/ more information from NDOH following their communique to LDOH
- Study governance
  - Principal Investigator not indicated in NDOH letter. Important as overall responsible for the study.
  - Names, roles and contacts of research team members assigned to Limpopo Province (Pharmacists, vaccinators, senior and assistant researchers, M&E and data managers etc.)
  - The study protocol outlining processes to be followed during the planning and implementation of the research study by the research team not yet available to the department
  - Responsibilities of the province vs the research team
    - ❖ financial, human, vaccination resources
    - ❖ Obtaining consent
    - ❖ Vaccine safety monitoring
- Study details
  - Length of the study not indicated
  - study information leaflet to target study participants that articulates pertinent study issues usually addressed in such leaflets including but not limited to:
    - ❖ Detailed definition and explanation of a phase 3B study
    - ❖ Pros and cons of participating in the study
    - ❖ Pre and post vaccination examinations, tests etc
    - ❖ Pre and post study obligations
    - ❖ Compensation to study participants including incidental / subsistence and travelling costs
    - ❖ Manner and length of follow up

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Uncertainties/unknown factors

- Study recruitment and participation
  - Can HCWs in other health facilities participate
  - The sequencing and prioritisation of the HCW participants
    - ❖ aerosolizing activities vs non-patient contact
  - Can non-PERSAL health care workers can participate in the study
  - whether other health facilities in the province will be enrolled in the study and if yes process of enrollment to be followed
  - Private sector HCW involvement including enrolment and study site
  - Informed consent form including translated versions
    - ❖ HCW not able to do electronic consent form
  - Enrolment through EVDS:
    - ❖ HCW with no access to smart phone
    - ❖ HCW that are computer/ web illiterate
- Indemnity
  - For adverse events following immunizations provided by and to the research team
  - If LDOH personnel used: are they provided indemnity cover by the research study
- Quarantine and QA JnJ study vaccine
  - Requirements for quarantine and QA
  - Period after arrival in country before release from national holding site

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Implementation Progress

- COVID-19 Vaccination started on the 19 February 2021 at both Polokwane and Mankweng hospitals
- The hospitals has manged to vaccinate a **total 1304 health care workers as @ 22/02/2021**
- The vaccinated healthcare workers included
  - Polokwane and Mankweng healthcare workers
  - Private hospitals frontline workers
  - Independent health professionals
- Challenge
  - EVDS enrolment and delay with obtaining vouchers which was the main challenges

Date	Number of clients vaccinated	
	Pietersburg	Mankweng
2021/02/19	20	60
2021/02/20	236	194
2021/02/21	524	270

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Conclusion

- The LDOH is committed to ensuring that the population is protected from COVID-19 infection through improving access to the COVID-19 vaccine
- The province is partnering with relevant stakeholders to ensure efficient implementation of vaccination for all phases
- Currently engaging stakeholders and district to facilitate rapid implementation and expansion of this study
- Rapid review of resource requirement indicates that the province has capacity to implement phase 1 of the vaccination with support support from stakeholders and partners
- The COVID-19 Vaccination plan, including the Implementation study, is flexible and will be updated as further information becomes available

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Thank You