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CEOs: HOSPITALS
FOR ATTENTION: FACILITY MANAGERS, PHARMACY STAFF, MEDICAL OFFICERS, CLINICAL NURSE PRACTITIONERS, NIMART NURSES

CIRCULAR H61...../2021

COVID VACCINE PROJECT OFFICE: STATIONERY & PAPER-BASED TOOLS FOR C-19 VACCINATION ROLL-OUT

BACKGROUND

Phase 2 of the National Covid-19 vaccination programme will start on 17th May 2021 and will overlap with the mop-up of healthcare workers who have not been vaccinated as part of the Sisonke Programme. This circular provides a list of stationery & paper-based tools that will be required at primary, temporary outreach and mobile vaccination sites in the Western Cape. Electronic copies of all the items will also be distributed. Please ensure that these items are available at all the sites.

Item	Purpose	Availability
COVID-19 Screening Template (annexure 1)	Record of COVID-19 symptom screening for all attendees at vaccination site. To be retained at primary vaccination site.	Print at primary vaccination site as required
EVDS Paper-based Data Capture Form (annexure 2)	For contingency only, to be used in the event of power outages, wi-fi connectivity interruptions or unavailability of devices to electronically capture vaccination encounters.	Distributed from CMD. Place order for sufficient contingency to cover 1 week of vaccinations.
Client-held Vaccination Cards (annexure 3)	Provides details of vaccination (name, date, vaccine, batch number)-given to vaccinee after vaccination.	Automatically distributed from CMD with vaccine and non-pharm commodities- no need to order.
Post-vaccination Leaflets (annexure 4)	Given to vaccinees after vaccination. Provides details of possible side effects, how to manage them, and contact details for Call Centre if there are any concerns.	Automatically distributed from CMD with vaccine and non-pharm commodities- no need to order.

Bellville Health Park, c/o Mike Pienaar and Frans Conradie Boulevard, Private Bag X15, Parow, 7500

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Department of Health | Component

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<p>Management of Vaccine-related Anaphylaxis Leaflet (annexure 5)</p>	<p>Clinical guideline on identification and management of vaccine-related anaphylaxis. To be displayed in observation area at vaccination sites, and to accompany emergency trays for outreach teams.</p>	<p>Automatically distributed from CMD with vaccine and non-pharm commodities- no need to order.</p>
<p>Vaccine Fact Sheet (annexure 6)</p>	<p>Information leaflet that can be distributed in waiting areas at vaccination sites or to institutions/ congregate settings prior to vaccination</p>	<p>Print at primary vaccination site as required.</p>
<p>Paper-based Consent Forms (annexure 7.1: Generic consent for medical procedure; annexure 7.2: specific consent for Pfizer/ Cominarty vaccine; annexure 7.3: specific consent for J&J/Jansen vaccine)</p>	<p>To be administered to vaccinees that are unable to provide informed consent due to intellectual/ mental incapacity only. Consent must be obtained from a family member (if available) or CEO of the care institution prior to vaccination. The generic consent form for medical procedures as well as the specific vaccine consent form must be signed and retained by the institution. Consent must be recorded on EVDS (electronically or on the paper-based form) during the vaccination encounter. (Separate paper-based consent is not required for vaccinees who are able to provide informed consent- record on EVDS only (electronically or on the paper-based form))</p>	<p>Print at primary vaccination site as required.</p>
<p>Pre-vaccination health screening checklist (annexure 8)</p>	<p>List of pre-vaccination medical screening questions to be displayed in vaccination station. Vaccinator to use in conjunction with Vaccine Job Aid</p>	<p>To be distributed from District/ Sub-structure offices.</p>
<p>PAC Vaccine Job Aid (Cover page of Vaccine Job Aid: annexure 9)</p>	<p>Clinical tool for vaccinators- to be used in vaccination area. Contains guidelines on pre-vaccination medical screening, management & administration of vaccines, and management of post-vaccination adverse events</p>	<p>To be distributed from District/ Sub-structure offices.</p>
<p>Register for observation room (optional) (annexure 10)</p>	<p>To track entry times and exit times of each vaccinee at observation area, so that the full observation period of 15 minutes or 30 minutes is adhered to.</p> <p>Alternatively, observation times can be tracked by recording vaccination time on vaccination card and logging end of observation period electronically on EVDS.</p>	<p>Print at primary vaccination site as required</p>

Yours sincerely



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JO Arendse
Chief Director: ECSS

Date: 14 May 2021



Annexure 1: COVID-19 Symptom Screening Template

Vaccination Site
Date:

COVID-19 SYMPTOM SCREENING



Time in	Name	Surname	ID No/Vaccination code	Cough Y/N	Sore throat Y/N	Shortness of breath. Y/N	Loss of taste/ smell Y/N	Signature

Annexure 2: EVDS Paper-based Data Capture Form





COVID-19 VACCINATION FORM



VACCINATION SITE UID NUMBER																	
VACCINATION SITE NAME																	
VACCINEE INFORMATION		<i>(All personal particulars such as names, surname, date of birth, occupation, etc. should be official particulars that appear in your ID or passport, medical aid card, municipality bill, etc.)</i>															
Identity number/ Passport number																	
First name(s)																	
Surname																	
Date of birth		Y Y M M D D															
Sex		Male <input type="checkbox"/>						Female <input type="checkbox"/>									
Email address																	
Cellphone number																	
Alternative cellphone number																	
Preferred language																	
Are you a member of a medical aid scheme?		Yes <input type="checkbox"/>						No <input type="checkbox"/>						<i>(If yes, please provide medical aid details below)</i>			
Medical aid scheme																	
Medical aid number																	
Are you employed?		Yes <input type="checkbox"/>						No <input type="checkbox"/>						<i>(If yes, please provide employment details below)</i>			
Job Title																	
Name of primary employer																	
Full name of the institution where employed																	
Village/Town/City												Province					
Health professional		Yes <input type="checkbox"/>						No <input type="checkbox"/>									
Sector		Public <input type="checkbox"/>				Private <input type="checkbox"/>				NGD <input type="checkbox"/>							
Professional Registration Number																	
PRE- IMMUNISATION QUESTIONS		<i>(To be completed by the vaccinator)</i>															
Do you have any chronic conditions?		Yes <input type="checkbox"/>						No <input type="checkbox"/>									
<i>(If yes, please select relevant condition)</i>		TB <input type="checkbox"/>		Hypertension <input type="checkbox"/>		Diabetes <input type="checkbox"/>		Cardiac Disease <input type="checkbox"/>		HIV/AIDS <input type="checkbox"/>		Lung Disease <input type="checkbox"/>		Cancer <input type="checkbox"/>		Other, specify _____	
Have you been diagnosed with a COVID-19 infection in the last 90 days?		Yes <input type="checkbox"/>						No <input type="checkbox"/>						If yes, when did you test positive?			
Have you received any vaccinations in the past two weeks? <i>If yes, please indicate what vaccines were received</i>		Yes <input type="checkbox"/>						No <input type="checkbox"/>									
Vaccine name/s																	
Have you had any COVID-19 vaccine at any time? <i>If yes, what and when did you receive it?</i>		Yes <input type="checkbox"/>						No <input type="checkbox"/>									
Vaccine name																	
Date of vaccination		Y Y M M D D															
Name of clinic /Vaccination site where vaccine was received																	
ALLERGIES		<i>(History of allergies not a contraindication but should be reviewed with the vaccinator)</i>															
Do you have a history of severe symptoms after receiving another vaccination or an injectable medication (a shot given intravenously, intramuscularly, or subcutaneously)? <i>If yes, please describe the symptoms:</i>		Yes <input type="checkbox"/>						No <input type="checkbox"/>									
Do you have a history of an anaphylactic reaction to anything other than a vaccine or injectable medication? <i>If yes, please describe the reaction from the symptom list below:</i>		Yes <input type="checkbox"/>						No <input type="checkbox"/>									
Trouble breathing		Yes <input type="checkbox"/>						No <input type="checkbox"/>									
Broke out in hives		Yes <input type="checkbox"/>						No <input type="checkbox"/>									
Facial or tongue swelling		Yes <input type="checkbox"/>						No <input type="checkbox"/>									
Low blood pressure		Yes <input type="checkbox"/>						No <input type="checkbox"/>									

PREGNANCY <small>(Female vaccinee recipients only)</small>			
Do you suspect that you might be pregnant? Yes <input type="checkbox"/> No <input type="checkbox"/> <i>(Pregnancy might be a contra-indication and should be discussed with the vaccinator and recorded on EVIDS)</i>			
INFORMED CONSENT FORM <small>(To be read to the vaccinee by the vaccinator)</small>			
The COVID-19 vaccination will reduce the chance of you suffering from COVID-19 disease. Like all medicines, no vaccine is completely effective and it takes a few weeks for your body to build up protection from the vaccine. Some people may still get COVID-19 despite having a vaccination, but this should lessen the severity of any infection.			
The vaccine cannot give you COVID-19 infection, and you have to complete the vaccination schedule for this vaccine to reduce your chance of becoming seriously ill. You will still need to follow the guidance in your workplace and public areas, including wearing the correct personal protection equipment and taking part in any screening programmes. Like all medicines, vaccines can cause side effects. Most of these are mild and short-term, and not everyone gets them. This vaccine has been authorised for use by the South African Health Products Regulatory Authority, in terms of the Medicines and Related Substances Act (Act 101 of 1965) for the active immunisation of individuals ≥18 years old for the prevention of coronavirus disease 2019 (COVID-19).			
Name of vaccine			
Type of authorisation	<input type="checkbox"/> 1. Full registration <input type="checkbox"/> 2. Section 21 approval <input type="checkbox"/> 3. Study approval		
1. I understand that the majority of adverse reactions are mild to moderate in severity and usually resolve within a few days of vaccination; and these expected side effects have been described. 2. I confirm that I have been fully informed and all my questions answered. 3. I have also been informed that: 3.1 the quality, effectiveness, and safety of this vaccine have been verified by the South African Health Products Regulatory Authority (SAHPRA). 3.2 appropriate measures will be taken to prevent, monitor, and manage the unwanted effects on me of this vaccine			
CONSENT TO RECEIVE COVID-19 VACCINATION <small>(Please select one option)</small>			
I agree to receive the COVID-19 vaccination as explained to me Yes <input type="checkbox"/> No <input type="checkbox"/>			
Surname	Names		
Signature	Y X Y Y M M U U		
VACCINE INFORMATION			
Vaccine Name	Vaccine manufacturer	Vaccine batch number	Vaccine expiry date
			Y Y Y Y M M D D
VACCINE DOSE <small>(Circle the relevant dose and record the date)</small>			
1 st Dose / 2 nd Dose / 3 rd Dose		Y Y Y Y M M D D	
ADVERSE EVENTS FOLLOWING IMMUNISATION <small>(Vaccinee to be observed immediately after vaccination for any possible adverse events; if any adverse event is observed, it must be recorded in the AEFI System)</small>			
Did any adverse event occur? Yes <input type="checkbox"/> No <input type="checkbox"/>			
If yes, was it recorded in the AEFI system? Yes <input type="checkbox"/> No <input type="checkbox"/>			
VACCINATOR INFORMATION			
Surname		Names	
Identity number			
Job title		Facility of employment	
Professional body	HPCSA / SANC <small>(circle relevant body)</small>	Professional registration number	
Cellphone number			
Signature		Y X Y Y M M U U	

Annexure 3: Client-held Vaccination Card

 COVID-19 VACCINATION RECORD CARD 	
VACCINEE DETAILS	
Surname	
First name(s)	
Identity number/ Passport number	
Next appointment date	
EVDS vaccination number	
VACCINE DOSE	VACCINE NAME
MANUFACTURER	BATCH NUMBER
VACCINE DATE	
1 st Dose	
2 nd Dose	
3 rd Dose	
VACCINATOR DETAILS	
Surname	
First name(s)	
Signature	

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COVID-19 VACCINATION RECORD CARD

Bring this vaccination record to every vaccination and when visiting your health facility.

If you have experienced any adverse events after leaving the Vaccination Site, please report to the Adverse Events Following Immunisation system at **AEFI@health.gov.za** or call **071 302 8949**

For more information about COVID-19 and COVID-19 vaccine, please visit **www.sacoronavirus.co.za**

COVID-19 PUBLIC HOTLINE **0800 029 999**
 OFFICIAL WHATSAPP HELP SERVICE
 Send **Hi** to **0600 123 456** on WhatsApp

COVID 19 Vaccination Card Final for Print.indd 2

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Just had the COVID-19 vaccine? Well done and thank you!

Mild side effects are common in the first 3 days. Here's what to look out for.



Arm is sore or red
at the injection site



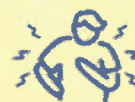
Fever/
chills



Headache



Fatigue



Muscle aches



Nausea

- Side effects can start around 6 hours after the vaccine, peak at 24 hours and resolve in 2-3 days.
- If you need to, treat pain and fever with paracetamol.
- Side effects may be more noticeable if you are young, healthy or had COVID-19 before.

These side effects show your body is building an immune response. The technical term for this is 'reactogenicity'. If you do not get side effects it does not mean that your body is not building an immune response.

Contact your healthcare provider or the COVID-19 hotline if:

- Your side effects are severe or last longer than 3 days.
- You develop any of the following symptoms within a month of vaccination:
 - a. New-onset severe headache especially if with blurred vision, vomiting, weakness on one side of the body or difficulty speaking.
 - b. Severe abdominal pain that does not go away.
 - c. A rash of tiny red spots around the site of injection.
 - d. A painful or cold leg.
 - e. Chest pain or shortness of breath.

Extremely rare side-effects affect 1-4 people per million vaccinated

They include a severe allergic reaction called anaphylaxis (within minutes to hours) and a rare form of blood clots (between 4 days and 3 weeks).



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Keep your vaccine card safe.

- This is your proof of vaccination.
- Keep your follow-up appointment if you have one.

Some vaccines are given in two doses (for example Pfizer-BioNTech COVID vaccine). The second dose is important to boost your body's immune response to the vaccine and help its protective effect last longer.

You might still get COVID-19. Here's why.

- You cannot catch COVID-19 from the vaccine as there is no live coronavirus in it.
- It is still possible to get COVID-19 as no vaccine is 100% effective.
- You might have caught COVID-19 before being vaccinated (it can take up to 14 days before COVID-19 symptoms start).
- You might catch it within the first 2 weeks after being vaccinated while your immune system is being trained up to fight COVID-19.



After vaccination, don't confuse vaccine side effects with COVID-19 symptoms!

- If your fever lasts more than 2 days or you develop a continuous cough, sore throat, or changes in your ability to taste or smell after your vaccination, you may have COVID-19.
- Isolate yourself and arrange to get a COVID test. Contact your healthcare provider or the COVID-19 hotline.

Even if you do get COVID-19, you are very unlikely to get severely ill or die from COVID-19.

Western Cape COVID-19 Hotline: 0860 142 142



We still don't know if the vaccine will stop the spread. Don't forget COVID-19 prevention!

- Wear a mask in public.
- Keep apart from others outside your home as much as possible.
- Avoid crowds and confined spaces - have small gatherings outside.
- Wash or sanitise your hands regularly.
- As a healthcare worker, continue to wear standard PPE at work.



We are not safe until we are all safe.



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Annexure 5: Management of Vaccine-related Anaphylaxis leaflet

COVID-19 vaccination: Anaphylaxis guide for clinics and outreach vaccination units



Any medicine carries a very small risk of anaphylaxis (a severe and often sudden allergic reaction). Anaphylaxis is very rare with vaccines. It is important to clinically tell the difference between minor reactions, like anxiety-associated fainting, which are more common, and anaphylaxis, as this can be life threatening.

Follow standard vaccine precautions

Check emergency kit:

Medications	Equipment
<ul style="list-style-type: none"> Adrenaline (epinephrine) injection (1:1000) solution – 5 ampoules IV fluids (normal saline 1L) – 2 sets Salbutamol inhaler - 1 inhaler Promethazine injection (25mg/mL) - 2 vials, + diluent¹ Hydrocortisone injection (100mg) - 2 vials, + diluent¹ 	<ul style="list-style-type: none"> Syringe with 0.01mL graduations and 26G IM needle – 2 sets Syringe 5mL and 24G/26G IM needle – 4 sets Gelcos + rapid-giving drip set - 2 sets Adhesive dressing Inhaler spacer with face mask Blood pressure cuff, baumanometer and pulse oximeter

Adverse Events Following Immunisation (AEFI) reporting form: available via NICD website.

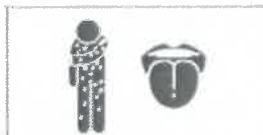
<https://www.nicd.ac.za/diseases-a-z-index/adverse-event-following-immunization-aeFI/>

¹Sterile water for injection.

Ask about allergy

If any previous history of severe allergy or anaphylaxis to any food, medicines or vaccines, discuss with a medical officer and observe for 30 minutes post-vaccination, if vaccine given.

Give urgent attention and inform supervisor and a doctor if patient has any of:



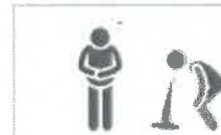
Generalised itch/rash or face/tongue swelling



Difficulty breathing



Dizziness/collapse or BP < 90/60



Abdominal pain or vomiting



Usually within minutes to an hour

First line priority

1. Ask colleague to call emergency medical services and report suspected anaphylaxis.
2. Lie patient down and raise legs. If vomiting, place in left lateral position.
3. Give immediately **adrenaline** 0.5mL (1:1000 solution) IM into mid-outer thigh. Repeat every 5 minutes if needed.
4. Give 1-2L **IV fluids** rapidly regardless of BP. Then, if BP < 90/60, give a further 500mL **IV fluids** rapidly, repeat until systolic BP > 90. Stop if breathing worsens.
5. If wheeze persists despite adrenaline, give 2-3 puffs **salbutamol** via spacer and face mask. Repeat, as needed.
6. If severe symptoms or if known asthma and wheeze persisting after other anaphylaxis symptoms/signs have resolved, give **promethazine** 25mg IM/slow IV and **hydrocortisone** 200mg IM/slow IV.

If client has been managed as anaphylaxis, ensure referral to hospital for test/s (tryptase sampling) to confirm vaccine-related anaphylaxis.

Report as Adverse Events Following Immunisation (AEFI)

Once patient stable/referred, complete Case Reporting Form (CRF) for Adverse Events Following Immunisation (AEFI) and report to sub-district or district office and provincial EPI manager within 24 hours.



UNIVERSITY OF CAPE TOWN
UNIVERSITEIT VAN KAPSTAD

Created January 2021 for use by clinics and outreach vaccination teams.

COVID VACCINATION FACT SHEET MAY 2021



There is a lot of scientific evidence that the vaccination gives us excellent protection against the coronavirus. Being vaccinated can save many of us from becoming very sick with the disease.



General information

What is a vaccine?

A vaccine is used to train your immune system to be able to deal with an infection and fight it off in the future.

Is there a vaccine for COVID?

Yes. In South Africa, the Johnson and Johnson vaccine is being provided to half a million health workers through the Sisonke trial. A further 31 million doses of this vaccine (covering 31 million people) have been ordered with the first delivery expected in the second quarter of 2021. The vaccine will be made available under the tradename Janssen COVID-19 Vaccine™, reflecting the partnership between Johnson and Johnson and the Belgium company Janssen. 20 million doses (covering 10 million people) of the Pfizer/BioNTech vaccine (under the tradename Comirnaty™) is being made available from May onwards. Both these vaccines protect against COVID caused by the 501YV2 variant that has been circulating in South Africa since November 2020. Both vaccines have been tested for safety and safety is continuously being monitored.

About the vaccine

What is contained in the vaccine?

All COVID vaccines contain instructions for the spike protein on the coronavirus. The Johnson and Johnson vaccine contains an adenovirus which has been modified so that it cannot cause disease or multiply in humans. The Pfizer/BioNTech vaccine contains a messenger RNA (mRNA) fragment. The vaccines naturally disintegrate within days after they have instructed your immune system to respond to the spike protein on the coronavirus. In addition, the vaccines contain the following non-active ingredients:



Johnson and Johnson vaccine:

- Sodium chloride
- Citric acid monohydrate buffer
- Polysorbate 80
- 2 hydroxypropyl-β-cyclodextrin (HBCD)
- Ethanol (absolute)
- Sodium hydroxide
- Water for injection

Pfizer/BioNTech vaccine:

- ALC-0315 = (4-hydroxybutyl) azanediyl) bis (hexane-6,1-diyl) bis(2-hexyldecanoate)
- ALC-0159 = 2-[(polyethylene glycol)-2000]-N,N-ditetradecylacetamide
- 1,2-Distearoyl-sn-glycero-3-phosphocholine
- cholesterol
- potassium chloride
- potassium dihydrogen phosphate
- sodium chloride
- disodium hydrogen phosphate dihydrate
- sucrose
- water for injections

Neither vaccine contains animal products or eggs. They are suitable for vegans and are halal. The rubber stoppers of the vaccine vials do not contain latex.

How will the vaccine be given?

You will get an injection in your upper arm. The Johnson and Johnson vaccine is a single-dose, and the Pfizer/BioNTech vaccine is given as two doses at least three weeks apart. Protection starts around two weeks after the first injection but is best one month after the single Johnson and Johnson vaccine and two weeks after the second Pfizer/BioNTech vaccine. It is important to know which of the vaccines you have received so that you know to return for a second dose if you have received the Pfizer/ BioNTech vaccine.



Are COVID vaccines safe?



All COVID vaccines being used have been tested many times to ensure safety and were created to check for any common side effects. Safety monitoring is being carefully rolled out alongside vaccines globally, and all serious side-effects are reviewed by independent scientists from multiple medicine safety agencies. In the United States, an extremely rare side effect of the Johnson and Johnson vaccine was reported in 8 people of 7 million who received the single dose. The side effect involved clots in unusual veins in the body (brain, abdomen) together with low levels of platelets, a component of the bloodstream that normally helps your blood clot and prevents bleeding. The National Department of Health and the South African Health Products Regulatory Authority (SAHPRA) are monitoring the safety of the vaccines as they are rolled out across the country, and asked that people who receive the Johnson and Johnson vaccine be aware of the symptoms of this extremely rare side effect.



What are the common side effects of the vaccines?

Common side effects are pain and redness in the upper arm where you are injected, headache, and feeling unwell, tired, and feverish. These side effects start around 6 hours after the vaccine, peak at 24 hours and usually resolve within 2-3 days. Side-effects occur more commonly in younger people and people who have had COVID before. You can use paracetamol or an anti-inflammatory if you need to.



What are the rare side effects of the vaccines?



These are extremely uncommon and usually affect around 1 to 4 people for every million vaccinations given. Some people experience a severe allergy to the vaccine, sometimes as anaphylaxis. This usually occurs within the first 15 minutes of vaccination and can be managed using medications available at the vaccination sites. Precautions can be taken in people with a severe history of allergy so please discuss this with your usual doctor or vaccination site staff. An extremely rare clotting condition may occur following the Johnson and Johnson vaccine. This usually presents with a severe headache that won't go away, abdominal pain, leg swelling, or small blood spots around the site of injection around 5 to 20 days post vaccination. The headache should not be confused with the usual headache that follows vaccination in the first 1-3 days. If you develop any of these symptoms, please seek healthcare urgently, and tell the doctor you have been recently vaccinated. Specialists in these rare side effects are on hand to help support your doctor to manage you in the best way possible. Serious side effects like these can be frightening even if extremely rare. It is important to remember that the risk of COVID-19 far outweighs the risk of these side-effects and safety agencies around the world have recommended the Johnson and Johnson and Pfizer vaccines for use.

If I feel sick after vaccination should I consider having a COVID test?

Several common vaccine side effects are similar to COVID symptoms. If you experience a mild fever, aching muscles, headache or fatigue, this is likely due to your body's reaction to the vaccine. If you develop a cough, sore throat, a change in your sense of taste or smell, or you have a fever over 38°C that lasts several days, you might have COVID and should isolate yourself and have a test. The vaccine does not interfere with the usual COVID tests used for diagnosis such as the polymerase chain reaction (PCR) and rapid antigen tests.





How was the vaccine made so quickly?

The COVID vaccine was made faster than any other vaccine in medical history. Experience with SARS and MERS outbreaks (both caused by coronaviruses), faster manufacturing, funding for multiple trials and regulators moving more quickly than before made the process much faster.

The genetic material of the virus that causes COVID was made available to all scientists around the world in January 2020 so that work on a new vaccine started very early.

What to expect

When is it my turn to get the COVID vaccine?

Vaccinations is happening in three phases, starting with people most at risk of COVID because of their job, age or health.

Phase 1	will focus on health workers and will reach all health workers not already covered by the Sisonke trial. This includes non-clinical health workers, community health workers and traditional health practitioners.
Phase 2	will focus on people 60 and older, and people in group settings, followed by those aged 50 and older and 40 and older.
Phase 3	will focus on people older than 18, people who were not vaccinated in phases 1 or 2.

Do I need the vaccine if I've already had COVID?

Yes, you should still be vaccinated if you've already had COVID or if you've had a positive antibody test. So far, we know that the natural immunity from having COVID may not last or provide protection as good as that following vaccination. The vaccination will boost any response your immune system put in place after a previous coronavirus infection.



You should wait until 4 weeks after testing positive for COVID or symptoms onset before getting the vaccine. If you were hospitalised with COVID, please consult your doctor about when it would be safe for you to get the vaccine.



Can I get the vaccine if I have symptoms of COVID or if I am in quarantine?

If you currently are in quarantine because of exposure to someone with COVID, you should wait until you have completed your quarantine period, before getting vaccinated. If you have had COVID you should wait until 4 weeks after your symptoms started. If you have COVID symptoms on the day of your vaccination, you will be referred for a test and the vaccination will be rescheduled.



Is it safe to get a vaccine if I have an underlying medical condition?

If you are an adult with an underlying medical condition or illness, you have a greater risk of severe illness from COVID. Because of this, you should consider getting vaccinated as vaccines become available to people in your age group. There are some special considerations for people living with certain conditions, but no underlying medical condition is a reason for not being considered for vaccination:

- **Allergy:** If you have suffered a severe allergy or anaphylaxis to a vaccination, medication or food in the past you need to talk to your usual doctor before receiving the vaccine. The risk of severe allergic reactions to any of the COVID vaccines is very low, can easily be managed and far outweighs the risk of getting COVID.
- **Long COVID-19:** Vaccination will add extra protection to the natural immunity that you may already have. Only if you are seriously debilitated, still under active investigation, or have become worse more recently, should you consider delaying vaccination. This is to avoid confusing a reaction to the vaccine with any change in your condition.
- **Bleeding disorders:** as with any injection, there is a small risk of bleeding at the injection site. Speak to your healthcare worker about your condition so that s/he can take precautions such as applying prolonged pressure after the injection.
- **Anticoagulant medications (like warfarin):** as with any injection, there is a small risk of bleeding at the injection site. As long as you are up to date with your scheduled international normalised ratio (INR) testing and your latest INR was below the upper threshold of your therapeutic range, you can receive the vaccination safely. The rare clotting condition described following the Johnson and Johnson vaccine is bought about through different pathways to usual clotting problems. People with usual clotting problems are at increased risk of developing clots during an infection with COVID-19 and are urged to take up vaccination. If you have any concerns speak to your usual healthcare provider or vaccination site staff.
- **Immunosuppressive disorders (like HIV, cancer or being on immunosuppressant therapy):** Immunosuppressive disorders including HIV, irrespective of CD4 count, are not a reason to refuse vaccination. Just like everyone who gets the vaccine, you have to continue to follow the general COVID protection measures after vaccination.

Can I have the vaccine if I am pregnant or breastfeeding?

Pregnant and breastfeeding women are receiving COVID-19 vaccinations throughout the world. Information regarding the safety of COVID-19 vaccines is incomplete but becoming increasingly available. Animal studies showed no safety concerns, and similar vaccines have been used in hundreds of thousands of pregnant and breastfeeding women without safety concerns. On 22 April SAHPRA gave permission for the Sisonke trial to restart after a global safety review on the rare clotting condition had been reviewed, but asked that breastfeeding women be excluded and that plans to



extend the trial to pregnant health workers be shelved. A review of available safety information and the risks of COVID-19 in pregnant women followed, leading to SAHPRA reversing this decision on 28 April, paving the way for pregnant and breastfeeding women to be included in rollout plans. Vaccinations through the Sisonke trial restarted on 28 April and plans for inclusion of pregnant and breastfeeding women to be included by mid-May are being finalized with local ethics committees.



I tested my antibodies after my vaccination and the test came back showing I had none. Does this mean my vaccine did not work?

There is no reason to be alarmed. Commercially available antibody tests are not designed to test vaccine-specific antibody responses and test for the n-protein (nucleocapsid), and not the spike protein. For this reason, we advise against antibody testing after vaccination. A negative antibody test does not mean you are not protected. You do not need to re-vaccinated.

What can I do now to help protect myself from getting COVID until I am able to get vaccinated?

Continue wearing your mask, practising social distancing, opening windows and doors and sanitising/washing your hands and frequently touched objects regularly, before and even after being vaccinated. We don't know whether the vaccine stops transmission yet, so it's important to stay safe and follow these good hygiene rules.

How to beat your fears

Will the vaccine change my DNA?

No, the vaccine will not work on your DNA. Evidence shows that some vaccines are made using RNA technology, but the technology used affects how the vaccine is made, not what it does to your body.



Is there a microchip in the vaccine?

There is no proof that microchips or trackers are in any of the vaccines. Getting vaccinated does not mean that you will be tracked or that any of your personal information will be stolen.

I'm not sure if I should get vaccinated. Do I really need to?

Uncertainty and doubts about the vaccine will impact all of us. If too few of us choose to get vaccinated, more people get sick. If more of us get vaccinated, fewer people get sick. You can do research by following trustworthy sources or the official Western Cape Government Facebook page for reasons for and information about the vaccine.



Remember: Whether you are a health care worker or a member of the general public, it is your decision to get vaccinated or not. Your choice will be respected.

Want to get vaccinated?

You can register via WhatsApp by sending the word 'Register' to 060 012 3456

OR Dial *134*832*ID Number# No ID Number? Just Dial *134*832#

OR use the internet go to: <https://vaccine.enroll.health.gov.za/#/>



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Annexure 7.1: Informed Consent for Medical procedure for Vaccinees Unable to Provide Informed Consent due to Incapacity



CONSENT TO MEDICAL PROCEDURE

I, Dr _____ have explained the nature, risks & possible consequences of the medical procedure to the undersigned patient or his/her legal guardian.
 Signature _____ Date _____

Circle whichever is applicable

Procedure Explained :	Personally	Via Interpreter
-----------------------	------------	-----------------

Nature of procedure :

Where applicable indicate side of procedure (Right or Left)

Circle whichever is applicable

TYPE OF ANAESTHETIC :	Local	Spinal	General	Procedural Sedation
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CONSENT TO USE OF BLOOD and/or BLOOD PRODUCTS IF NECESSARY DURING THE COURSE OF THE PROCEDURE

Consent granted by Patient/Guardian : _____
 Signature _____
 Consent withheld by Patient/Guardian: _____
 Signature _____

I consent to a sample of my blood being taken and tested for Hepatitis B and the Human Immuno Deficiency Virus (HIV) should contamination of a health care worker by my bodily fluids occur during the procedure.
 Patient's / Guardian's Signature _____

Full Name of Patient	_____	I, the undersigned, hereby consent to the performance of, and understand the nature, risks and possible outcomes of the above procedure. The doctors who perform the above may carry out additional or alternative measures (including general anaesthesia) if considered necessary.
Signature/Thumb	Date _____	
Print of patient		

COMPLETE THIS SECTION IF CONSENT IS GIVEN BY A PERSON ON BEHALF OF THE PATIENT

Print Name _____
 Signature _____ Date _____
 Relationship to patient _____
 Means by which consent was given: _____ Personally _____ Telephonically _____

NAME AND SIGNATURES OF WITNESSES TO THE PATIENT'S / GUARDIAN'S SIGNATURE ON THIS DOCUMENT.

Witness 1	Witness 2
Print Name _____	Print Name _____
Signature _____	Signature _____

June 2010

Annexure 7.2: Specific consent for Pfizer/Cominarty Vaccine



INFORMED CONSENT FORM – COMIRNATY™ (COVID-19 mRNA vaccine)

The COVID-19 vaccination will reduce your chance of suffering from COVID-19 disease. Like all medicines, no vaccine is completely effective. It takes a few weeks for your body to build protection after vaccination. Although some people may still get COVID-19 after receiving the vaccine, vaccination should lessen the severity of COVID-19 infection. The vaccine cannot give you COVID-19 infection. You will still need to follow the usual precautions in your workplace or public areas, including wearing a mask. The COMIRNATY™ vaccine schedule requires two doses.

Like all medicines, vaccines can cause side effects. Most of these are mild and should resolve within 2-3 days, and not everyone gets them.

This vaccine, COMIRNATY™, COVID-19 mRNA vaccine, has been authorised for use by the South African Health Products Regulatory Authority, in terms of Section 21 of the Medicines and Related Substances Act (Act 101 of 1965) for the active immunisation of individuals ≥16 years old for the prevention of coronavirus disease 2019 (COVID-19)

I understand that the majority of adverse reactions are mild to moderate in severity and usually resolve within a few days of vaccination, which could include but is not limited to injection site pain, fatigue, headache, myalgia and chills, arthralgia, pyrexia, and injection site swelling.

I confirm that I have been fully informed and my questions have been answered by

_____ Vaccinator

I have also been informed that:

- the quality, effectiveness, and safety of this vaccine have been verified by the South African Health Products Regulatory Authority (SAHPRA).
- appropriate measures will be taken to prevent, monitor, and manage the unwanted effects on me of the **Section 21**- approved vaccine.

This section to be read by the vaccinator. The vaccinator will then check a box on the EVDS to confirming that he/she has read and explained this section to the vaccinee.

PLEASE ANSWER THE FOLLOWING QUESTIONS:

1. Are you sick today? Y/N

If Yes, please provide details: _____

2. Have you received any vaccinations in the past two weeks? Y/N

If Yes, please indicate what vaccine: _____

3. Have you received any other COVID-19 vaccine at any time? Y/N

If Yes, please provide the date of vaccination: _____

4. Where did you receive the vaccine (e.g which clinic): _____

eConsent - COMIRNATY™

5. Have you been diagnosed with COVID-19 infection in the last 90 days? Y/N

If Yes, what date did you test positive: _____

6. Do you have a history of an anaphylactic reaction to anything other than a vaccine or injectable medication Y/N

If Yes, please describe: _____

7. Have you ever had an anaphylactic reaction:

Reaction	Yes	No
Trouble breathing		
Broke out in hives		
Facial or tongue swelling		
Low blood pressure		
Other severe symptoms after receiving another vaccination or injection (a shot was given intravenously, intramuscularly, or subcutaneously)?		

8. Female vaccine recipients only: Do you suspect that you might be pregnant today? Y/N

9. If Yes or unknown, please indicate when you had your last menstrual period.

I understand that I will only be protected after receiving 2 doses of the COMIRNATY™ vaccine, however, if I choose not to receive the 2nd dose I will inform my healthcare professional accordingly.

The vaccinator will ask the vaccinee each of these questions, and record the answers on the EVDS.

Full Names of vaccine recipient: _____

Vaccinator / Admin to conducting informed consent:

Signature of vaccine recipient/ recipient unique ID:

Vaccinator to ask vaccinee for consent to administer the vaccine.

Vaccinee's response will be captured by the vaccinator on the EVDS.

Full Name of the vaccinator: _____

Date: _____

eConsent - COMIRNATY™



Annexure 7.3 : Specific Consent for J&J/Jansen Vaccine



INFORMED CONSENT FORM – COVID-19 Vaccine Janssen

The COVID-19 vaccination will reduce your chance of suffering from COVID-19 disease. Like all medicines, no vaccine is completely effective. It takes a few weeks for your body to build protection after vaccination. Although some people may still get COVID-19 after receiving the vaccine, vaccination should lessen the severity of COVID-19 infection. The vaccine cannot give you COVID-19 infection. You will still need to follow the usual precautions in your workplace or public areas, including wearing a mask. The COVID-19 vaccine Janssen requires one dose.

Like all medicines, vaccines can cause side effects. Most of these are mild and should resolve within 2-3 days, and not everyone gets them.

This vaccine [COVID-19 vaccine Janssen, Ad26.COVID. S] has been registered for use by the South African Health Products Regulatory Authority (SAHPRA) in terms of the Medicines and Related Substances Act 101 of 1965, subject to certain conditions. It may be used for the active immunisation of people who are 18 years or older for the prevention of COVID-19.

I understand that the majority of adverse reactions are mild to moderate and usually resolve within a few days of vaccination. These could include vaccination site pain/tenderness, fatigue, headache, myalgia, nausea, and pyrexia/fever.

Very rare cases of thrombosis and thrombocytopenia have been observed. This includes severe cases of venous thrombosis at unusual sites such as cerebral venous sinus thrombosis, splanchnic vein thrombosis, as well as arterial thrombosis with thrombocytopenia.

To identify possible thromboembolism and/or thrombocytopenia those vaccinated should be seek immediate medical attention if they develop symptoms such as shortness of breath, chest pain, leg swelling, or persistent abdominal pain following vaccination. Additionally, anyone with neurological symptoms including severe or persistent headaches or blurred vision after vaccination, or who experiences skin bruising (petechia) beyond the site of vaccination after a few days, should seek prompt medical attention.

I confirm that I have been fully informed and my questions have been answered by

_____ Vaccinator

I have also been informed that the quality, effectiveness, and safety of this vaccine has been verified by the SAHPRA and that appropriate measures will be taken to prevent, monitor, and manage any unwanted effects of the vaccine on me.

This section to be read by the vaccinator. The vaccinator will then check a box on the EVDS to confirm that he/she has read and explained this section to the vaccinee.

PLEASE ANSWER THE FOLLOWING QUESTIONS:

1. Are you sick today? Y/N
2. If Yes, please provide details: _____

3. Have you received any vaccinations in the past two weeks? Y/N

eConsent - JANSEN

- a. If Yes, please indicate what vaccine: _____
4. Have you received any other COVID-19 vaccine at any time? Y/N
- a. If Yes, please provide the date of vaccination: _____
- b. Where did you receive the vaccine (e.g which clinic): _____

5. Have you been diagnosed with COVID-19 infection in the last 90 days? Y/N
- a. If Yes, what date did you test positive: _____
6. Do you have a history of an anaphylactic reaction to anything other than a vaccine or injectable medication Y/N
- a. If Yes, please describe: _____
7. Have you ever had an anaphylactic reaction:

Reaction	Yes	No
Trouble breathing		
Broke out in hives		
Facial or tongue swelling		
Low blood pressure		
Other severe symptoms after receiving another vaccination or injection (a shot given intravenously, intramuscularly, or subcutaneously)?		

8. Female vaccine recipients only: Do you suspect that you might be pregnant today? Y/N
9. If Yes or unknown, please indicate when you had your last menstrual period. _____

The vaccinator will ask the vaccinee each of these questions, and record the answers on the EVDS.

Full Names of vaccine recipient: _____

Vaccinator to conducting informed consent: _____

Signature of vaccine recipient/ recipient unique ID: _____

Vaccinator to ask vaccinee for consent to administer the vaccine.

Vaccinee's response will be captured by the vaccinator on the EVDS.

Full Name of the vaccinator: _____

Date: _____

eConsent - JANSEN



Annexure 8: Pre-vaccination Medical Screening Checklist

Prevaccination checklist for COVID-19 vaccines

Vaccinator to ask each client these questions before giving vaccination.

1. Have you been diagnosed with COVID-19 in the last 3 months?
2. Have you had any vaccinations in the past two weeks?
3. If female: do you suspect that you might be pregnant or are you breastfeeding?
4. Do you have any blood clotting disorders or are you taking a blood thinner?
5. Do you have any chronic medical conditions requiring ongoing specialist care?
6. Have you ever had an allergic reaction after receiving another vaccination or an injectable medication?
7. Have you ever had an anaphylactic reaction to anything other than a vaccine or injectable medication?

If client responds "Yes" to any of these, assess and manage further using algorithm in the WC PACK Vaccine job aid.

Created for the Western Cape Department of Health by the Knowledge Translation Unit.

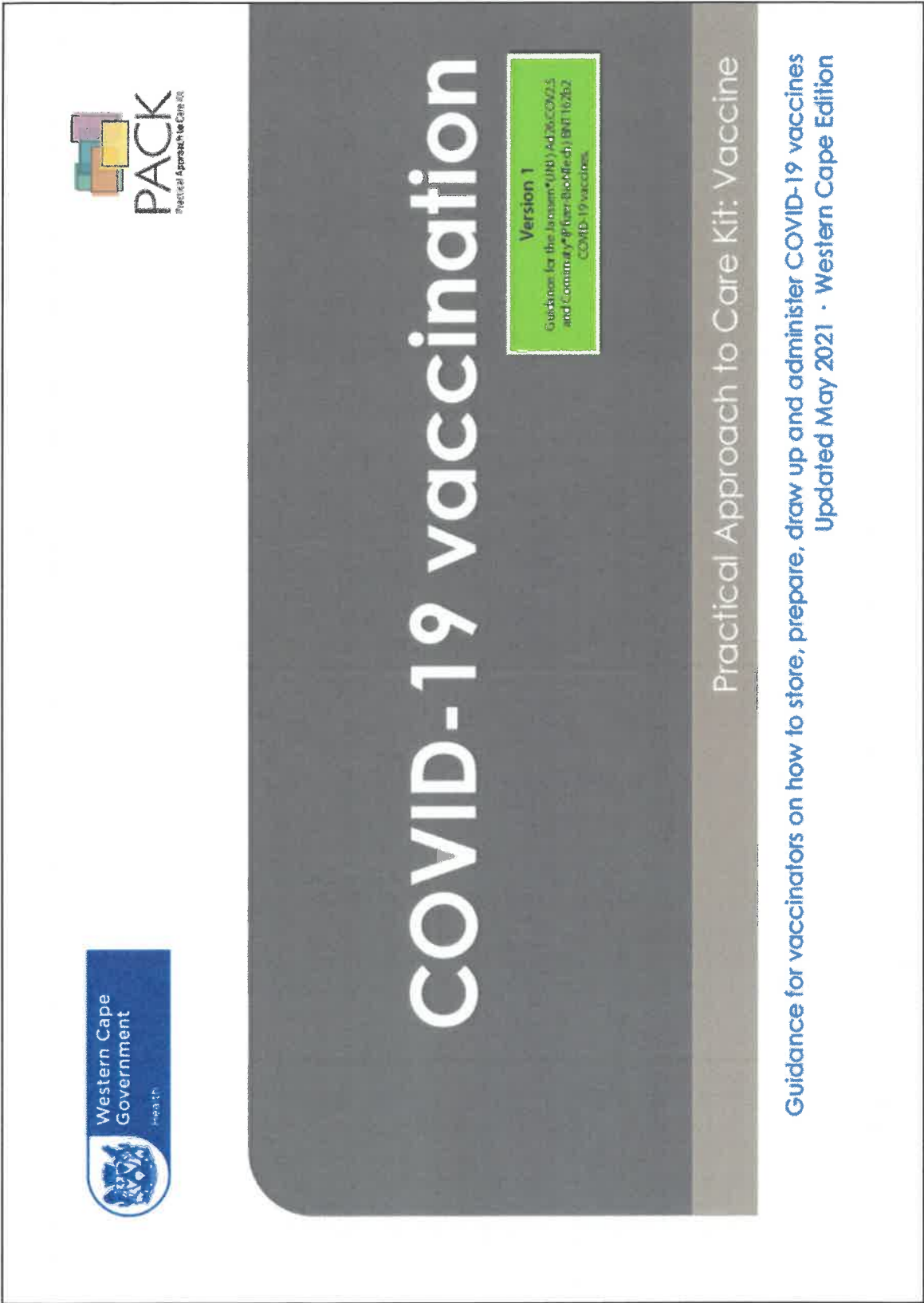


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Annexure 9: PACK Vaccination Job Aid (cover page)



Annexure 10: Register for Observation Area

Vaccination Site

Date:

REGISTER FOR OBSERVATION AREA



Name	Surname	ID No/Vaccination code	Time in	Time out	Signature of Nurse	Notes

