



COVID-19 vaccination

Summary of recent changes (last updated 29 November 2021):

- Recommendations throughout expanded to include vaccinations of adolescent (12-17 years old) age group.
- Note added regarding expected additional vaccine dose for immunocompromised clients as part of primary vaccine course (p3).
- Recommendations for ultra-low freezer storage for Comirnaty® vaccine updated to 9 months (p3).

Note: this guidance does not cover booster vaccine doses offered exclusively for health care workers as part of the Sisonke trial.

Version 4

Guidance for the Janssen®(JNJ) Ad26.COV2.S and Comirnaty®(Pfizer-BioNTech) BNT162b2 COVID-19 vaccines.

Practical Approach to Care Kit: Vaccine

Guidance for vaccinators on how to store, prepare, draw up and administer COVID-19 vaccines
Updated November 2021 · Western Cape Edition

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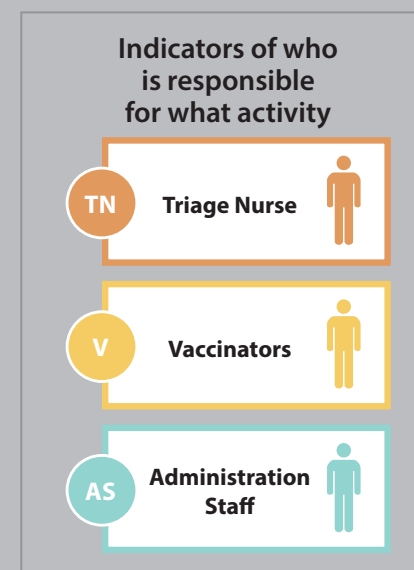
Orange-highlighted medications may be prescribed by a doctor or an authorised prescriber (clinical nurse practitioner or professional nurse) in accordance with his/her scope of practice within a specified field.

Blue-highlighted medications may be prescribed by a doctor or clinical nurse practitioner who is an authorised prescriber.

Green-highlighted medications may be prescribed by a doctor only

Arrows refer you to another page in the guide:

- The return arrow (↩) guides you to a new page but suggests that you return and continue on the original page.
- The direct arrow (→) guides you to continue on another page.



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Summary table of Janssen® and Comirnaty® vaccines

	Janssen® (J&J) vaccine (Ad26.COV2.S)	Comirnaty® (PFIZER-BioNTech) vaccine (BNT162b2)	
Vial	<ul style="list-style-type: none"> Blue topped multi-dose vial Each vial contains 2.5mL: 5 doses of 0.5mL. Liquid suspension for injection Colourless to slightly yellow, clear/shiny suspension 	<ul style="list-style-type: none"> Purple topped multi-dose vial Requires dilution (preservative-free sodium chloride 0.9% for injection) Before dilution: 0.45mL frozen liquid drug product After dilution: each vial contains 2.25mL: at least 6 doses of 0.3mL each 	<ul style="list-style-type: none"> Record 'new' expiry date and time every time vaccine moved from freezer to refrigerator to room temperature and after dilution/first puncture. Never re-freeze vaccine.
Each dose	0.5mL via intramuscular injection (deltoid)	0.3mL via intramuscular injection (deltoid)	
Number of doses	<ul style="list-style-type: none"> One dose per adult client (18 years old and over) - If immunocompromised¹, an additional 2nd dose - at least 28 days after 1st dose - as part of this primary course is needed. This can be implemented from 01 December 2021: it requires a referral form from a doctor or nurse prescriber and clients will need to re-register on EVDS. 	<ul style="list-style-type: none"> Two doses per adult client (18 years and older) – at least 21 days apart. In South Africa, two doses are given 42 days apart. - If immunocompromised¹, an additional 3rd dose - at least 28 days after 2nd dose - as part of this primary course is needed. This can be implemented from 01 December 2021: it requires a referral form from a doctor or nurse prescriber and clients will need to re-register on EVDS. One dose per adolescent (12-17 years old) 	<p>Note: If amount of vaccine left in vial cannot provide a full dose, discard vial and contents into pharmaceutical waste. Do not combine vaccine from multiple vials to obtain a dose.</p>
Approved for:	Clients ≥ 18 years old	Clients ≥ 12 years old	
Freezer storage	Freezer (-25°C to -15°C): up to 2 years	Ultra-low freezer (-75°C to -65 °C): for up to 9 months Freezer (-25°C to -15°C): for up to 14 days	NOTE: Once removed from the ultra-low freezer, vials may be kept for 14 days at -20°C, plus 31 days at 2°C to 8°C. 45 days in total.
Refrigerator storage (2°C to 8°C)	For up to 3 months.	For up to 31 days	
Thawing	<ul style="list-style-type: none"> Preferably, thaw overnight in refrigerator (2-8°C) for 12 hours. Keep in original carton. Protect from sunlight. 	<ul style="list-style-type: none"> If thawing in original tray of 195 packaged vials, thaw at 2-8°C for 3 hours (preferred) or If thawing an individual frozen vial, thaw for 30 minutes at room temperature (up to 30°C) for immediate use. Protect from sunlight. 	
Acclimatisation	Allow at least 15 minutes after removing from refrigerator.	Allow at least 15 minutes after removing from refrigerator.	
Preparation	<u>No</u> dilution needed.	<ul style="list-style-type: none"> Dilute once vaccine thawed: use 1.8mL preservative-free sodium chloride (0.9%) solution for injection. Store diluent in vaccine fridge with thawed vaccines. Use 1 diluent for 1 vial of vaccine. Do not freeze diluent. 	
Expiry times once prepared	After first puncture of vial, vaccine can be held: <ul style="list-style-type: none"> In refrigerator (2-8°C) for up to 6 hours. At room temperature (up to 25°C) for up to 3 hours. 	After dilution: <ul style="list-style-type: none"> Keep at room temperature (up to 25°C) for up to 6 hours. Do not return to refrigerator. 	
Drawing up equipment	<p>For each dose:</p> <ul style="list-style-type: none"> 1mL or 2mL syringe 1x needle - use light blue needle 23G x 1" (25mm). If client is overweight, then use a longer needle: <ul style="list-style-type: none"> - Black 22G x 1¼" (32mm) or blue 23G x 1½" (38mm) Alcohol swab (Webcol™) Cotton wool Water for cleaning Adhesive surgical tape (Micropore™) Alcohol hand sanitiser Vaccination card 	<p>For dilution:</p> <ul style="list-style-type: none"> 2mL syringe and green 21G x 1½" (40mm) needle Preservative-free sodium chloride 0.9% <p>For each dose:</p> <ul style="list-style-type: none"> 0.3mL, 0.5mL or 1mL syringe 1x needle - use light blue needle 23G x 1" (25mm). If client is overweight, then use a longer needle: <ul style="list-style-type: none"> - Black 22G x 1¼" (32mm) or blue 23G x 1½" (38mm). Alcohol swab (Webcol™) Cotton wool Water for cleaning Adhesive surgical tape (Micropore™) Alcohol hand sanitiser Vaccination card 	<ul style="list-style-type: none"> Adolescent vaccines Additional vaccine doses for immunocompromised¹ Updated Comirnaty® storage
Security	Keep vaccines in an access-controlled room. Lock refrigerator and rooms where the vaccines are stored. Monitor and take stock daily.		

¹Immunocompromised individuals applies to those 18 years and older and includes the following: HIV positive clients with a CD4 count less than 200 within the last 6 months, those on long-term high dose oral steroid therapy or systemic biologics for autoimmune conditions; those with cancers involving their bone marrow/blood; those who have had organ or bone marrow transplants; those without a spleen, those on long-term renal dialysis; and those that have a moderate to severe Primary Immunodeficiency Disorder (PID).

The vaccine client pathway

TN

- Ensure triage staff and queue marshals wear surgical masks and keep at least 1m distance from clients.
- Ensure queuing clients keep at least 1m apart from each other and wear masks.
- Have 70% alcohol-based hand sanitiser available for all clients entering vaccination area.

Screen vaccine clients:

- Ask each client if s/he has had close contact with anyone diagnosed with COVID-19 in the last 10 days. If yes, delay vaccination until 10-day quarantine period is complete.
- Ask each client if s/he has had new onset of any of the following in the last 14 days:
 - Shortness of breath or difficulty breathing
 - Cough
 - Sore throat
 - Loss of sense of smell or change in sense of taste
 - Persistent headache with blocked nose/runny nose/sneezing (newer symptoms being reported with the Delta variant)

No to all

Yes to any

Does client have a vaccination code confirming registration on the EVDS?

Yes

No

Does client have an appointment for today?

Yes

No

Does vaccination site have capacity to allow same-day vaccination for 'walk-ins' today?

Yes

No/unknown

If available at your vaccination site, direct client to administration staff to confirm ID and client details.

- Then direct client to vaccination waiting area.
- Ensure clients sit at least 1m apart.

- Advise client that s/he needs to enrol (self-register on EVDS).
- If administration staff available and client needs help with this, direct client to administration staff.

- Advise to return on scheduled appointment date and time.
- Alternatively, add client details to the reserve list, maintained by vaccination site, to be contacted if vaccine doses remain at the end of the day. Advise client that if s/he is not called, then to return on scheduled appointment day.

Manage as client with suspected COVID-19

- Give client a surgical mask to wear.
- Refer to local health provider/clinic to further assess, test and manage.
- Advise client that the EVDS will automatically reschedule his/her vaccination appointment and to return on that date. If client turns out to be COVID positive now, advise to wait at least 35 days before being vaccinated.

Re-scheduling information added

If problems, discuss with site manager or EVDS support staff member.

Pre-vaccination health check

Many clients are anxious at this stage: be kind and reassuring. If client has a fear of needles, provide extra support and distraction techniques during vaccination ↪ 15.

V

- The only absolute contraindication to vaccination is a history of immediate allergic reaction after a previous dose of COVID-19 vaccine or known allergy to an ingredient of vaccine.
- This page provides guidance on precautions and helps decide whether to proceed with vaccination when asking the medical questions in the 'Obtain Health Background' section on the EVDS.
- Wear appropriate PPE: surgical mask. Clean hands between each client. Gloves not compulsory for vaccinating. If client has disclosed a positive HIV status, wear gloves to vaccinate.

Work through steps on the Electronic Vaccine Data System (EVDS): use the guidance below to decide whether to proceed with vaccination during 'Obtain Health Background' section.

Question number in EVDS	If patient answers 'Yes'	If patient answers 'No'
1. Are you sick today?	Ask more about illness. Only delay vaccination if patient has a severe acute illness ¹ , so that symptoms of illness are not confused with possible adverse effects of vaccination.	Move to next question.
2. Have you received any vaccination in the past 2 weeks?	Delay vaccination: advise patient to return at least 2 weeks after last vaccination. EVDS will automatically re-schedule an appointment.	Move to next question.
3. Have you received any other COVID-19 vaccine at any time?	Ask what COVID-19 vaccine it was. If 1st dose of two-dose Comirnaty vaccine course, proceed with vaccination. If other COVID-19 vaccine, do not proceed/discuss with doctor.	Move to next question.
4. Have you been diagnosed with COVID-19 infection in the last 30 days?	Delay vaccination: advise client to return at least 1 month after recovering (at least 30 days after testing positive or onset of symptoms).	Move to next question.
5-10. Ask about previous anaphylactic reactions/severe allergy symptoms.	If 'Yes' to any of these questions: assess risk of allergy further on page 6.	
11. Do you have any chronic conditions?	<ul style="list-style-type: none"> • Tick relevant chronic condition box: reassure that chronic medical conditions are <i>not</i> contraindications. • If immunocompromise - reassure that s/he can still be vaccinated. Emphasise ongoing prevention measures. • If 'other', specify what chronic condition the patient has: <ul style="list-style-type: none"> - If blood clotting disorders or anticoagulant medications (blood thinners): only if patient had previous blood clots in <i>presence of low platelets</i>², discuss with doctor. Otherwise, proceed. • Advise not to stop anticoagulant medications. If on warfarin, ensure latest routine INR not above therapeutic range (usually 2.0-3.0), except for mechanical heart valve where a higher range is acceptable). Discuss if unsure. - If patient known with autoimmune disease: check if s/he has consulted his/her doctor about being vaccinated. If not, advise to do so, as medications may need adjusting. 	If 'no' to all, move to next question.
Have you ever been admitted to hospital with either of these rare conditions: Guillain Barré Syndrome (affects your nerves) or Capillary Leak Syndrome (affects your blood vessels)?	Arrange for Comirnaty [®] vaccine. If not available or unsure, discuss with doctor.	<ul style="list-style-type: none"> • If female, move to next question. • If male, proceed with vaccination.
12. Do you suspect that you might be pregnant today? Note: Do not do pregnancy test at this visit.	<ul style="list-style-type: none"> • Encourage vaccination: explain that COVID is more dangerous in pregnant women, especially towards end of pregnancy and in those with hypertension, diabetes, obesity, TB or untreated HIV. • Emphasize safety: explain that so far vaccine studies in pregnant women have not shown harmful effects on the developing baby or on pregnancy. Explain that the client has a greater chance of getting very sick from COVID than having a severe side effect of the vaccine. • If client understands and consents, continue with vaccination process. 	Proceed with consent process and vaccination.

If breastfeeding: reassure that there are no known risks for your baby when breastfeeding. There may be benefits for your baby if you are vaccinated. Advise not to stop breastfeeding. If client consents, continue.

If proceeding with vaccination, continue to follow EVDS steps and obtain informed consent by reading aloud the information provided for the relevant vaccine. If patient consents, draw up and give vaccine: if giving Comirnaty[®] vaccine ↪ 7. If giving Janssen[®] vaccine ↪ 11.

¹Severe acute illness usually presents with a high fever $\geq 38^{\circ}\text{C}$ (e.g. pneumonia or severe gastroenteritis). Mild illnesses are not a contraindication to vaccination. ²Cells that help your body stop bleeding.

Allergy risk assessment

Decide if safe to give vaccine today in client with a history of allergy and for how long to observe client post vaccination.

- Explain that a severe allergic reaction refers to any of the following that occur soon after being exposed (minutes to hours):
 - Swelling of the face, particularly of eyes, lips, tongue
 - A skin rash, often called hives, in the form of red, raised, itchy bumps
 - Anaphylaxis – severe allergic reaction which may have caused itchiness or rash, swelling of face, lips, tongue, difficulty breathing, abdominal pain, nausea, vomiting. Client may have a medic-alert bracelet.

Has client had a severe allergic reaction in the past?

No

Proceed with vaccination today and observe for symptoms for 15 minutes.

Continue to step 4 →5.

Yes

Has client had a severe allergic reaction to a COVID-19 vaccine before (i.e. first dose of a two-dose regimen like the Comirnaty® vaccine)?

No

Has client had a severe allergic reaction to a vaccine or an injectable medication?

No

Client had a severe allergy to another substance like food, pet/s, insect venom, latex, oral medication/s.

Proceed with vaccination today but observe for symptoms for **30 minutes**:
Continue to step 4 →5.

Yes

Doctor to assess risk and discuss with client:
• Is client known with allergy to any ingredients in COVID-19 vaccines? See table below. (ask specifically about agents most commonly responsible for allergic reactions: polyethylene glycol (PEG 2000) or polysorbate 80).

No

Yes or client not sure

Do not vaccinate: refer to allergy specialist for risk assessment. Explain risk to client.

Janssen® (J&J) vaccine (Ad26.COVS.2.S)

- Polysorbate 80
- Sodium chloride
- Citric acid monohydrate buffer
- 2 hydroxypropyl-β-cyclodextrin (HBCD)
- Ethanol (absolute)
- Sodium hydroxide
- Water for injection
- Recombinant, replication-incompetent Ad26 vector, encoding a stabilized variant of the SARS-CoV-2 Spike (S) protein

Comirnaty® (Pfizer-BioNTech) vaccine (BNT162b2)

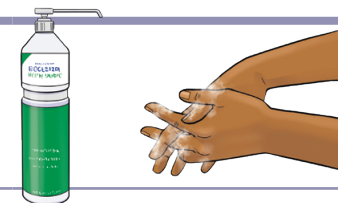
- 2[(polyethylene glycol (PEG))-2000]-N,N-ditetradecylacetamide
- 1,2-distearoyl-sn-glycero-3-phosphocholine
- Cholesterol
- (4-hydroxybutyl)azanediylbis(hexane-6,1-diyl)bis(2-hexyldecanoate)
- Potassium chloride
- Monobasic potassium phosphate
- Sodium chloride
- Dibasic sodium phosphate dehydrate
- Sucrose
- Nucleoside-modified mRNA encoding the viral spike (S) glycoprotein of SARS-CoV-2

Note: Neither vaccine contains eggs, gelatin, latex, or preservatives.

How to draw up the Comirnaty[®] vaccine

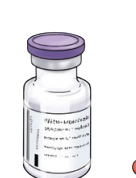
1 Clean hands

- Follow an aseptic technique.
- Clean hands well before vaccine preparation, between patients or at any time if hands become soiled.



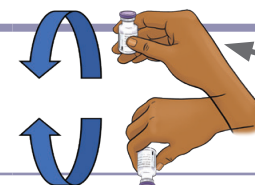
2 Bring thawed vaccine and diluent to room temperature

- If vaccine is in refrigerator:
 - Remove and allow to come to room temperature for 15-30 minutes.
 - Vials can be held at room temperature for up to 2 hours before mixing.
- If vaccine in cooler box:
 - No need to wait, remove and start preparing.



3 Gently invert to mix

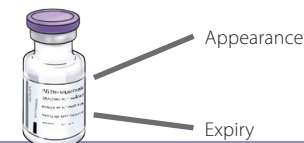
- Before inspection and dilution, gently invert (tip upside down) vaccine vial 10 times.
- Do not shake! If vial is shaken, discard it.



Hold vial on the sides and invert 10 times.

4 Check and inspect

- **Check:**
 - Correct vaccine and diluent.
 - Expiry date on vaccine and diluent.
- **Inspect:**
 - Vaccine liquid prior to dilution: should be a white/off-white suspension and may contain white/off-white tiny solid particles. Do not use if liquid is discoloured.
 - Vial: check for cracks or any abnormalities (evidence of tampering).



5 Clean stopper and allow to dry

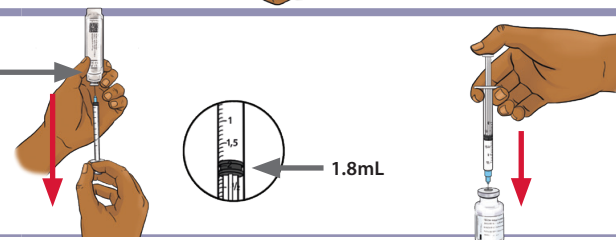
- Open: flip off purple plastic cap without touching rubber stopper.
- Wipe rubber stopper with an alcohol swab for each dose drawn up.
- Allow to dry before inserting needle.



6 Dilute

- Dilute in original vaccine vial:
 - Use a 2mL syringe and 21G or narrower needle. Ensure needle attached securely.
 - Withdraw 1.8mL of sodium chloride 0.9% for injection (preservative-free).
 - Remove needle from diluent and before adding diluent to vaccine vial, pull back plunger slightly to introduce a little bit of air into syringe – this will help to get all diluent into vial.
 - Then inject this 1.8mL of diluent slowly into vaccine vial to prevent foaming.

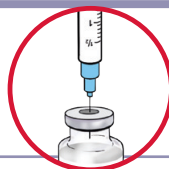
Dilute
Use sodium chloride 0.9%
(preservative-free)



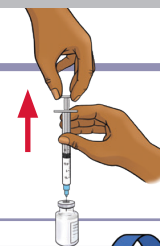
How to draw up the Comirnaty® vaccine - continued

7 Equalise pressure in vial

Before removing needle from vial, pull needle up slightly so the tip is no longer in liquid and withdraw 1.8mL of air into empty diluent syringe.

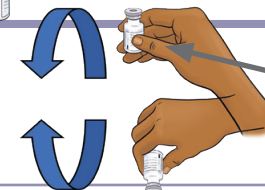


Remove 1.8mL of air from vial



8 Gently invert to mix and inspect

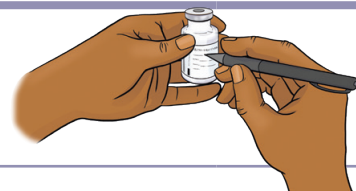
- Once diluted, gently invert (tip upside down) vaccine vial 10 times.
- Do not shake! If vial is shaken, discard.
- Contents of vial should be an off-white dispersion with no particles visible now. If discoloured or particles present, discard it.
- There is now 2.25mL after dilution, which provides at least 6 doses of 0.3mL.



Hold vial on the sides and invert 10 times.

9 Record dilution time and date and new expiry

- Record time and date on vial that diluent added and new expiry time.
- Keep at room temperature (up to 25°C) **for up to 6 hours.**
- Discard any unused vaccine after 6 hours.
- Do not return to refrigerator or freezer storage.



10 Draw up: choose appropriate needle length

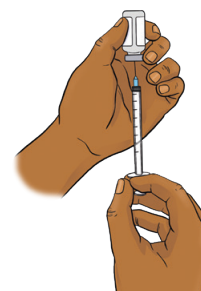
- Use a light blue 23G x 1" (25mm) needle unless client is obese. If obese, use instead one of the following:
 - Black 22G x 1¼" (32mm) or blue 23G x 1½" (38mm).
- Attach needle securely to vaccine syringe (0.3mL, 0.5mL or 1mL syringe). Carefully uncap.



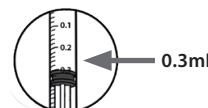
11 Withdraw vaccine and remove air bubbles

- Wipe vial stopper with an alcohol swab and allow to dry fully. Clean for *each* dose drawn up.
- Hold vial steady on flat surface and insert needle into rubber stopper. Then pick up vial and syringe and turn upside down to withdraw.
- Withdraw **0.3mL** of Comirnaty® COVID-19 vaccine.
- Adjust plunger to remove air bubbles whilst needle is still in the vial to avoid loss of vaccine. Try to avoid tapping syringe or vial.
- When drawing up 6th dose: insert needle into rubber stopper at an angle to allow access to vaccine in corner of vial.

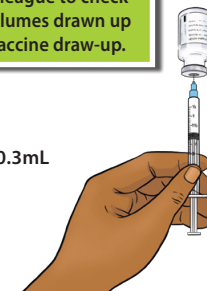
Note: If amount of vaccine left in vial cannot provide a full 0.3mL dose, discard vial and contents into pharmaceutical waste. Do not combine vaccine from multiple vials to obtain a dose. If vial empty, discard into sharps container.



If repeatedly unable to draw up 6 doses: ask a colleague to check technique and volumes drawn up at dilution and vaccine draw-up.



0.3mL



Adjust plunger to remove air bubbles whilst needle is in the vial. Try to avoid tapping.

12 Do not change needles

- Do not change needles. Use the same needle that you have drawn up the dose to administer vaccine.
- Never leave a needle in the vaccine vial between drawing up doses.
- If the vaccine is not administered immediately after drawing it up, carefully recap the needle.



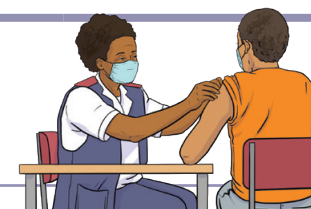
Use vaccine within 6 hours of dilution.

How to administer the Comirnaty® vaccine

At the beginning of each day, check the emergency tray/box is fully equipped and discuss team members roles/responsibilities and processes in the event of emergency.

1 Position yourself well

- If not done already, complete pre-vaccination health check ↪ 5.
- Protect yourself: sit or stand sideways-on to client. Check that client's mask is covering his/her nose and suggest client looks straight ahead.
- Lower your chair if possible so eye level with injection site.



2 Check contents of syringe

- Check contents of syringe:
 - Correct dose – 0.3mL
 - Off-white suspension
 - No particles
 - No discoloration



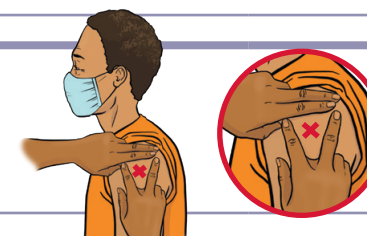
3 Expose injection site fully

- Ask client to expose his/her non-dominant arm (the one s/he does not write with). If possible, ensure whole shoulder and upper arm can be seen.
- Injection site is usually on left arm unless client is left-handed or has a rash, bruise, tattoo, redness, swelling, or other medical condition (e.g. amputation) involving intended site, then use right arm instead.
- Document injection site on the EVDS if *not* left deltoid.
- Ask client to rest his/her left hand in his/her lap and relax arm.



4 Locate injection site

- Find bony tip of shoulder (acromion process). Measure 2-3 fingers (3-5cm) below this.
- Use other hand to form a triangle below this.
- The injection site should be in centre of triangle in thickest part of deltoid muscle.
- Remember where this point is.



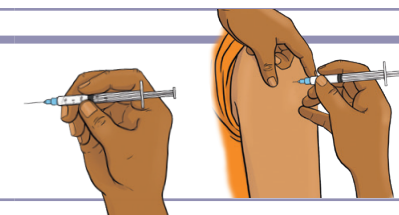
5 Clean

- Clean with cotton wool and water. Do not use an alcohol swab.



6 Insert needle

- Hold syringe firmly between the thumb and forefinger like holding a pencil.
- Gently stretch and support the skin with other hand. Avoid bunching the skin unless very low muscle mass ↪ 15.
- Insert needle at 90° angle to skin into thickest part of muscle. Insert to hilt of needle (no silver from needle showing) to ensure delivery into muscle.
- Avoid pushing too far and dimpling skin.



How to administer the Comirnaty® vaccine - continued

7 Stabilise syringe and inject vaccine

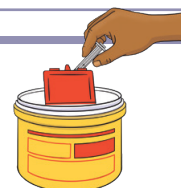
- Move other hand to stabilise tip of syringe.
- Do not aspirate – no need, as no large blood vessels here.
- Depress plunger and inject vaccine slowly.
- Ensure full dose given before withdrawing the needle.

**8 Remove syringe and needle safely**

- Pull needle out quickly and smoothly.

**9 Dispose of needle safely**

- Immediately, dispose of needle and syringe safely in medical sharps container. Do not try to recap needle.
- Avoid filling sharps container more than three-quarters of its capacity, or up to red line marked on container.

**10 Apply light pressure to injection site**

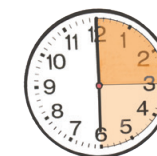
- Apply gentle pressure with cotton wool/gauze. If bleeding tendency or on anticoagulants, apply prolonged pressure to site after injection.
- Avoid rubbing injection site.

**11 Apply surgical tape**

- Apply surgical tape to hold cotton wool in place.
- Ask client to stay seated for a few minutes to avoid risk of injury from fainting while you complete records.

**12 Record and observe**

- Complete vaccination card and give to patient.
- Advise client about need for further doses:
 - If adult client (≥ 18 years old) and this is the 1st injection of the two Comirnaty® doses, inform client of return date for second vaccination.
 - If Immunocompromised¹ adult client, advise that a 3rd dose, at least 28 days after the 2nd dose is to be expected.
 - If adolescent (12-17 years old), advise that only 1 dose is currently needed.
- Give client a post vaccination information leaflet.
- Record in EVDS/Vaccination Site data sheet.
- Ask client to remain for observation for at least 15 minutes after vaccination. If client known with severe allergies, observe for longer (30 minutes).



¹Immunocompromised individuals applies to those 18 years and older and includes the following: HIV positive clients with a CD4 count less than 200 within the last 6 months, those on long-term high dose oral steroid therapy or systemic biologics for autoimmune conditions; those with cancers involving their bone marrow/blood; those who have had organ or bone marrow transplants; those without a spleen, those on long-term renal dialysis; and those that have a moderate to severe Primary Immunodeficiency Disorder (PID).

How to draw up Janssen® vaccine

1 Clean hands

- Follow an aseptic technique.
- Clean hands well before vaccine preparation, between patients or at any time if hands become soiled.



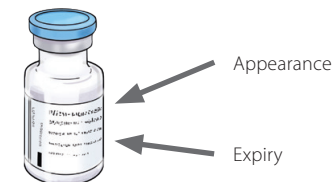
2 Bring vaccine to room temperature

- Remove vaccine from refrigerator/cooler box and allow to come to room temperature for 15-30 minutes.



3 Check and inspect

- **Check:**
 - Correct type of vaccine (concentration)
 - Expiry date on vaccine
- **Inspect:**
 - Check the colour: liquid should be colourless or slightly yellowish.
 - Check the clarity: liquid should be clear to slightly shiny and free of visible/solid particles.
 - Check that vial has no cracks, abnormalities or evidence of tampering.



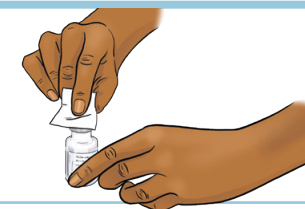
4 Swirl vial to mix

- Mix contents before each draw: gently swirl vial in an upright position for 10 seconds.
- Do not shake!



5 Clean stopper and allow to dry

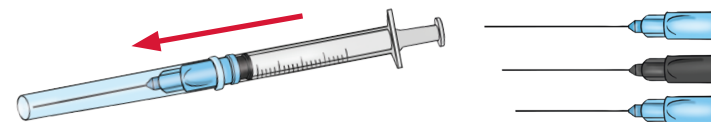
- Open: flip off blue plastic cap without touching rubber stopper.
- Wipe rubber stopper with an alcohol swab for *each* dose drawn up.
- Allow to dry before inserting needle.



How to draw up the Janssen® vaccine - continued

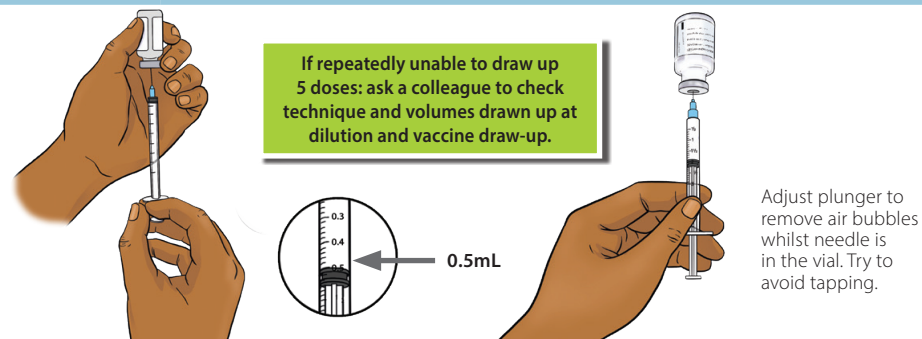
6 Draw up Choose appropriate needle length

- Use a light blue 23G x 1" (25mm) needle unless client is obese. If obese, use instead one of the following:
 - Black 22G x 1¼" (32mm) or blue 23G x 1½" (38mm).
- Attach to vaccine syringe (1mL or 2mL syringe). Ensure needle attached securely.
- Carefully uncap.



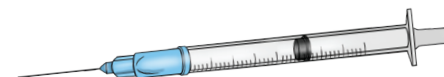
7 Withdraw vaccine and remove air bubbles

- Hold vial steady on flat surface and insert needle into rubber stopper. Then pick up vial and syringe and turn upside down to withdraw.
- Withdraw **0.5mL** of Janssen® COVID-19 vaccine.
- Adjust plunger to remove air bubbles whilst needle is still in the vial to avoid loss of vaccine. Try to avoid tapping syringe or vial.
- When drawing up 5th dose: insert needle into rubber stopper at an angle to allow access to vaccine in corner of vial.
- If amount of vaccine remaining in vial cannot provide a full dose of 0.5mL, mark and discard vial and any excess volume.



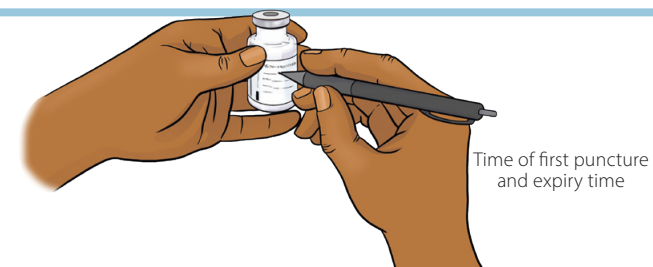
8 Do not change needles

- Do not change needles. Use the same needle that you have drawn up the dose to administer vaccine.
- Never leave a needle in the vaccine vial between drawing up doses.
- If the vaccine is not administered immediately after drawing it up, carefully recap the needle.



9 Record time of first puncture and new expiry time

- Record the date and time the vial should be discarded on the vial label. After first puncture, vaccine (vial or filled syringe) can be held:
 - In refrigerator (**2-8°C**) for up to **6 hours**.
 - At room temperature (**up to 25°C**) for up to **3 hours**.
- Discard if vaccine is not used within this time.
- Preferably, use immediately after first puncture.

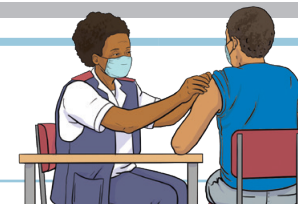


How to administer the Janssen[®] vaccine

At the beginning of each day, check the emergency tray/box is fully equipped and discuss team members roles/responsibilities and processes in the event of emergency.

1 Position yourself well

- If not done already, complete pre-vaccination health check ↪ 5.
- Protect yourself: sit or stand sideways-on to client. Check that client's mask is covering his/her nose and suggest client looks straight ahead.
- Lower your chair if possible so eye level with injection site.



2 Check contents of syringe

- Check contents of syringe:
 - Correct dose – 0.5mL
 - No particles
 - Colourless – slightly yellowish fluid
 - No discoloration



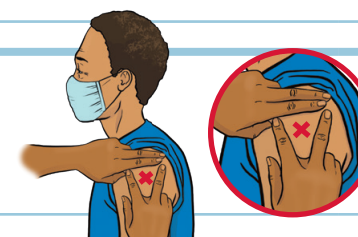
3 Expose injection site fully

- Ask client to expose his/her non-dominant arm (the one s/he does not write with). If possible, ensure whole shoulder and upper arm can be seen.
- Injection site is usually on left arm unless client is left-handed or has a rash, bruise, tattoo, redness, swelling, or other medical condition (e.g. amputation) involving intended site, then use right arm instead.
- Document injection site on the EVDS if *not* left deltoid.
- Ask client to rest his/her left hand in his/her lap and relax arm.



4 Locate injection site

- Find bony tip of shoulder (acromion process). Measure 2-3 fingers (3-5cm) below this.
- Use other hand to form a triangle below this.
- The injection site should be in centre of triangle in thickest part of deltoid muscle.
- Remember where this point is.



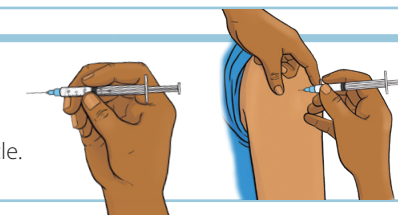
5 Clean

- Clean with cotton wool and water. Do not use an alcohol swab.



6 Insert needle

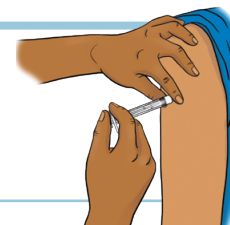
- Hold syringe firmly between the thumb and forefinger like holding a pencil.
- Gently stretch and support the skin with other hand. Avoid bunching the skin unless very low muscle mass ↪ 15.
- Insert needle at 90° angle to skin into thickest part of muscle. Insert to hilt of needle (no silver from needle showing) to ensure delivery into muscle.
- Avoid pushing too far and dimpling skin.



How to administer the Janssen® vaccine - continued

7 Stabilise syringe and inject vaccine

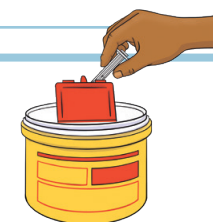
- Move other hand to stabilise tip of the syringe.
- Do not aspirate – no need, as no large blood vessels here.
- Depress plunger and inject vaccine slowly.
- Ensure full dose given before withdrawing the needle.

**8 Remove syringe and needle safely**

- Pull needle out quickly and smoothly.

**9 Dispose of needle safely**

- Immediately, dispose of needle and syringe safely in medical sharps container. Do not try to recap needle.
- Avoid filling sharps container more than three-quarters of its capacity, or up to red line marked on container.

**10 Apply light pressure to injection site**

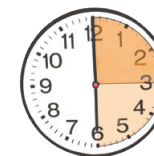
- Apply gentle pressure with cotton wool/gauze. If bleeding tendency or on anticoagulants, apply prolonged pressure to site after injection.
- Avoid rubbing injection site.

**11 Apply surgical tape**

- Apply surgical tape to hold cotton wool in place.
- Ask client to stay seated for a few minutes to avoid risk of injury from fainting while you complete records.

**12 Record and observe**

- Complete vaccination card and give to patient.
- Give client a post vaccination information leaflet.
- Advise client that this is a one dose per client regimen and s/he does not need to return for another dose unless immunocompromised¹, in which case a 2nd dose is to be expected, at least 28 days after the 1st dose.
- Record in EVDS/Vaccination Site data sheet.
- Ask client to remain for observation for at least 15 minutes after vaccination. If client known with severe allergies, observe for longer (30 minutes).



¹Immunocompromised individuals applies to those 18 years and older and includes the following: HIV positive clients with a CD4 count less than 200 within the last 6 months, those on long-term high dose oral steroid therapy or systemic biologics for autoimmune conditions; those with cancers involving their bone marrow/blood; those who have had organ or bone marrow transplants; those without a spleen, those on long-term renal dialysis; and those that have a moderate to severe Primary Immunodeficiency Disorder (PID).

Manage injection difficulties

Fear of needles

- A fear of needles can lead to needle avoidance and vaccine hesitancy. Negative experiences may lead to future vaccine refusals. It can also lead to fainting episodes.
- Fear of needles is not limited to childhood. It can distress adults and may have a genetic link and tends to run in families.
- If a client reports a fear of needles, provide extra support and distraction techniques during the vaccination.
 - Acknowledge this fear as phobic response. Avoid repeating words that may trigger further anxiety like 'injection', 'needle', 'jab', 'shot', 'prick'.
 - Encourage the client to:
 - **Look away:** encourage the client to look out the window or at the ceiling and focus on objects that won't induce anxiety.
 - **Breathe:** encourage the client to take slow and deep breathes from the bottom of his/her chest.
 - **Tense muscles:** if known to faint around needles, encourage client to tense leg, arm and tummy muscles during vaccination. If client starts to feel faint, manage symptoms 16.
 - **Imagine:** encourage client to visualise him/herself elsewhere that is pleasing to him/her like the beach, hiking, reading, spending time with friends.
 - **Find a role model:** if client has come with a trusted friend or family member who doesn't fear needles – ask them to go first so client watch their reaction.



Elderly and low BMI

If low muscle mass in elderly client or client with low BMI, it is acceptable to bunch up the deltoid muscle before administering IM injection.

Needle hits bone

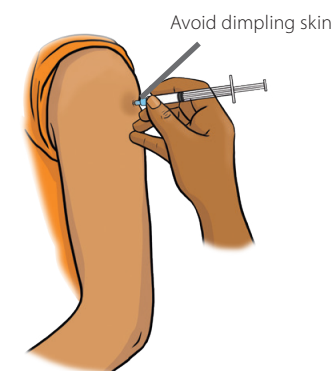
- If needle hits bone during injection, pull needle back slightly and then inject.

Needle touches nerve

- If client complains of sudden burning, shooting pain during injection, it is likely needle too close to a nerve: remove needle and try again being careful to locate correct injection site using landmarks.

Vaccine leaks from injection site

- If vaccine leaks from injection site
 - If vaccinator thinks most of dose leaked out of injection site, then revaccinate at same visit using a different injection site. Use same dose, as initial dose considered an invalid dose.
 - If vaccinator thinks most of dose remained in injection site, then that dose can be considered a valid dose.

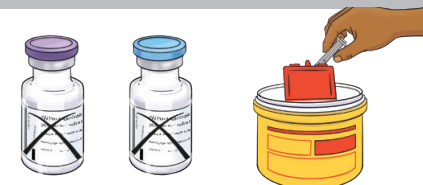


Avoid inserting needle too far, causing a dimple in the skin, as more likely to hit bone.

Disposal of empty used vaccine vials

Once all the full doses have been drawn up, dispose of the vaccine vial appropriately:

- Using a pen or permanent marker, deface vial by scratching over the label taking care not to cover the batch number and expiry date.
- At the end of the day, discard vials:
 - If vial empty, discard into yellow sharps container.
 - If residual vaccine in vial, discard into pharmaceutical waste.
- Avoid filling sharps container more than three-quarters of its capacity, or up to red line marked on container. Clearly mark box with "COVID-19".



Observation post vaccination

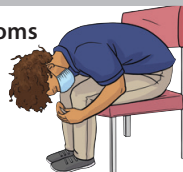
- Observe client for at least 15 minutes after vaccination. If client known with severe allergies: observe for longer (30 minutes).
- Check for signs or symptoms that may indicate an adverse reaction:



Collapse →17

Feeling faint/cardiovascular symptoms

- Light-headedness or dizziness
- Feeling warm or cold
- Sweating
- Palpitations
- Nausea
- Visual 'blurring' (darkening or white-out of vision)
- Reduced hearing ('whooshing' noise)
- Pallor reported by onlookers



- Ask client to lean forward and his/her head between knees, or lie down flat, for several minutes until feeling better.
- Loosen tight clothing – undo buttons around neck, loosen tie/belt.
- Apply a cool cloth to his/her face or neck.
- Calmly reassure client.

Skin/mucosal symptoms



- Itchiness
- Skin rash (hives)
- Swelling of eyes, lips, tongue, face, or hands/feet
- Nasal congestion

Respiratory symptoms



- Wheeze or cough
- Throat tightness
- Stridor
- Shortness of breath
- Hoarseness
- Oxygen sats < 92%
- Trouble swallowing
- Drooling

Gastrointestinal symptoms



- Nausea
- Vomiting
- Diarrhoea
- Cramps

Do symptom/s improve quickly (minutes)?

Yes

No

Faintness likely
Observe until symptoms resolve.

Decide when to treat for anaphylaxis

Are signs or symptoms generalised: are 2 or more body systems involved?

Yes

No. Does patient have generalised urticaria (raised, red rash/hives) involving the whole body?

Yes

No. Are signs or symptoms serious or life-threatening, even if only single body system (hypotension, respiratory distress, or significant swelling of the tongue or lips)?

Yes

Treat as anaphylaxis
→18.

No

- If isolated rash (raised, red rash in client who is otherwise well without other symptoms):
 - Monitor for 30 minutes to pick up any other symptoms:
 - If no other associated symptoms and client remains well, **pseudoallergic self-limiting rash** likely: reassure client and advise to take oral antihistamines.
 - Advise to seek urgent health care if any of the following develop: swelling of face, lips or tongue; difficulty breathing, abdominal pain, nausea or vomiting.
- If other symptoms: discuss with doctor/specialist urgently.
- If in doubt, treat as anaphylaxis →18.

Collapse following vaccination

Collapse

- Call for help.
- Lie client on his/her back and raise legs.
- Check response: if unresponsive, check circulation, airway and breathing.
 - If no pulse/not breathing, start CPR → PACK Adult.
 - If breathing and pulse present: assess timing of collapse and duration of loss of consciousness and check breathing, pulse and BP:

- Collapse occurred suddenly, at the time of injection (before, during or immediately after).
- Loss of consciousness usually lasts 20 seconds to 1 minute and is relieved by lying client down and raising legs.
- BP: briefly low but rapidly normal again.
- Pulse may be slow.
- Breathing usually normal but may be rapid, deep (hyperventilation).
- No other signs or symptoms present.

- Collapse occurred 5-10 minutes after the injection (could occur up to 1 hour after).
- Loss of consciousness is not brief and not relieved by lying client down and raising legs.
- BP < 90/60 and remains low
- Pulse > 120
- Breathing: may have wheeze, stridor, cough
- Other signs and symptoms (like swelling or rash) present.

Fainting episode likely

Management:

- If not already done, lie client flat and raise legs.
- Loosen any tight clothing: undo buttons around the neck, loosen tie/or tight belt.
- Apply cool cloth to face/neck.
- Calmly reassure client – explain what happened and assure them that they will be alright.
- Check for any other injuries they may have sustained falling.
- Stay with the client until they are fully recovered. Client should remain lying with legs up until feeling better.

Refer if:

- Head injury.
- Known with a heart condition or other serious illness.
- Client has unusual symptoms, such as chest pain, shortness of breath, confusion, blurred vision, or difficulty talking.

Report:

- Complete NDoH 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 → 23.
- Replace all medications/equipment used and seal emergency kit.

Treat as **anaphylaxis** → 18.

Treat suspected anaphylaxis

Manage and refer urgently:

Priority management

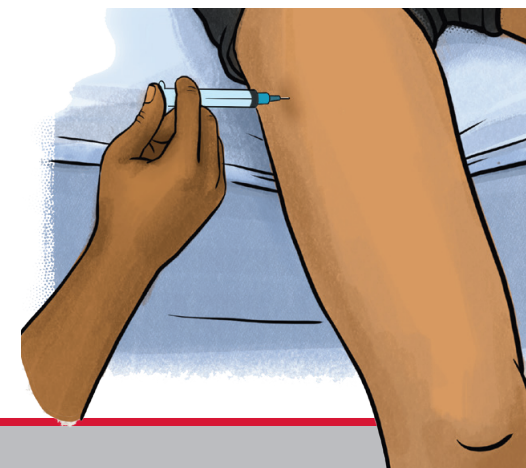
- Lie client down and raise legs.
- Call for help: ask colleague to inform supervisor and doctor, if available. Ask colleague to call emergency medical services and report suspected anaphylaxis.
- Give immediately **adrenaline** IM into mid outer thigh (see table). Repeat every 5 minutes if needed. Adrenaline is the vital part of anaphylaxis management.
- If signs of shock (cold peripheries, prolonged capillary refill time, tachycardia or low BP) present: give **sodium chloride 0.9%** 500mL IV rapidly. Repeat until signs of shock have resolved. Stop if breathing worsens.
- Give oxygen, if available, 8-10L/min via facemask or up to 100% oxygen, as needed.

Adjunctive treatment:

- If persistent wheeze or difficulty breathing despite adrenaline, also give **salbutamol** 2-3 puffs via spacer and face mask, if available. Repeat, as needed. Note: if nebuliser available and client not responding to inhaler: nebulise **salbutamol 0.5%** 0.5-1mL (2.5-5mg) and **ipratropium bromide** 2mL (0.5mg) in up to 4mL **sodium chloride 0.9%**.
- If severe symptoms or if known asthma and wheeze persisting after other anaphylaxis symptoms/signs have resolved, give **promethazine** 25-50mg IM (if < 16 years old, give 15mg IM) and **hydrocortisone** 200mg IM/slow IV (if < 16 years old, give 100mg IM/slow IV).
- **Refer all cases of suspected anaphylaxis.**
 - If delay in referral: take blood within 2 hours of symptom onset, if possible, to confirm vaccine-related anaphylaxis (tryptase sampling):
 - Collect blood in 2x yellow topped tubes (SST) and send with client on referral. If delay > 4 hours, store on ice.

Adrenaline (1:1000 solution) dosing

Age	Injection (1mg/mL)	Weight
12 year old	0.3mL	25-40kg
≥ 13 years old	0.5mL	> 40kg



Report:

- Complete NDoH Case Reporting Form (CRF) for Adverse Events of Special Interest (AESI) and report to sub-district or district office and provincial EPI manager within 24 hours ↻ 21.
- Replace all medications/equipment used and seal emergency kit.

May 2021

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 and usually resolve in 2-3 days. If needed, treat pain and fever with paracetamol.
- Side effects may be more noticeable if you are young, had COVID-19 before or after the second dose of a 2-dose vaccine course.

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.

- If your side effects are severe or last longer than 3 days, contact your healthcare provider or the Western Cape call centre.
- If any of the following symptoms develop within a month of vaccination, go to your nearest emergency centre:
 - New-onset severe headache especially if with blurred vision, vomiting, weakness on one side of the body or difficulty speaking.
 - Severe abdominal pain that does not go away.
 - A rash of tiny red spots around the site of injection.
 - A painful or cold leg.
 - Chest pain or shortness of breath.

Extremely rare side-effects affect 1-7 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).



May 2021

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 (Comirnaty™) 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 2 weeks 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 Western Cape call centre.

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

Western Cape call centre: 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.



Symptoms post vaccination

Note: no routine follow up visit is required. Use this page to manage clients who actively seek care. Report adverse events as an Adverse Event Following Immunisation (AEFI) ↗ 23.

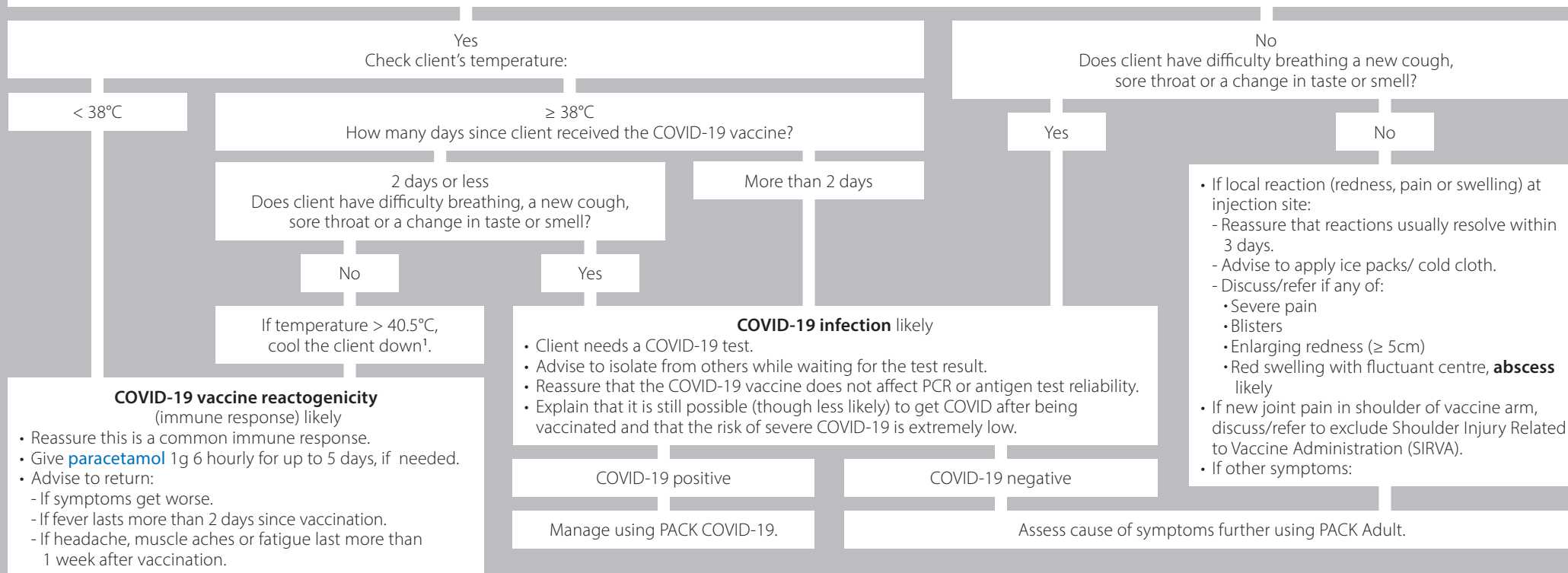
Give urgent attention to the client who has had a COVID-19 vaccination within the last month and any of:

- Decreased consciousness
- Seizures (fits)
- New neurological symptoms (weakness on 1 side, sensory loss)
- Respiratory rate ≥ 30 or difficulty breathing
- BP $< 90/60$
- Temperature $\geq 38^\circ\text{C}$ in elderly or frail client who is not able to take oral fluids well
- Blurred vision
- Severe and/or persistent headache (usually > 4 days after vaccine)
- Persistent severe abdominal or back pain
- Chest pain
- Severe leg pain or swelling of leg
- New or easy bleeding/bruising

Refer urgently.

Approach to the client not needing urgent attention

Does the client have fatigue, muscle aches, mild headache, feel feverish, or chills?



¹Cool the client down: give **paracetamol** 1g orally. Remove clothing. Use fan and water spray to cool client. Apply ice-packs to axillae, groin and neck. Stop once temperature $< 39^\circ\text{C}$.

How to complete an AESI form page 1

- AESI is an 'Adverse Event of Special Interest' and refers to certain pre-chosen medically important events that may have potentially been caused by the vaccine product.
- The list of these events is on page 1, Section B of the form, and includes anaphylaxis, thromboembolism, convulsions, Guillain barre syndrome.

health COVID-19
 Department of Health
 REPUBLIC OF SOUTH AFRICA **CASE REPORTING FORM (CRF) FOR SUSPECTED ADVERSE EVENTS OF SPECIAL INTEREST (AESI)**

EPID Number: S O A - - - - -
 Country - Province - District - Year - Case no

Today's date: DD / MM / YYYY
All fields in this form are mandatory, unless indicated 'if applicable'. Provide the requested information or tick the appropriate box.

Date received	Level	Signature
	Private	
	District	
	Province	
	National EPI	
	National SAHPRA	

(For Office use only)

SECTION A: IDENTIFYING INFORMATION

Vaccine recipient name & surname: _____
 If child: Caregiver's name & surname: _____
 Vaccine recipient's residential address: _____
 Mobile no: _____ Telephone no: _____
 Sex: M F Other *If applicable:* Pregnant Breastfeeding
 Date of birth: DD / MM / YYYY
 OR Age at onset: Years Months Days
 OR Age group: 0 - <1 year 1 - 5 years >5 - 18 years
 >18 - 60 years >60 years
If applicable: Gestation: Full-term Premature

AESI Reporter's name & surname: _____
 Designation/Position: _____
 Institution & Department: _____
 Telephone no: _____
 Mobile no: _____
 E-mail: _____
 Date patient notified event to health system: DD / MM / YYYY

SECTION B: ADVERSE EVENT(S) OF SPECIAL INTEREST (AESI)

Date & time AEFI started: DD / MM / YYYY Hr Min

Adverse event (s): (Tick (✓) all boxes that apply)

<input type="checkbox"/> Acute aseptic arthritis	<input type="checkbox"/> Anaphylaxis	<input type="checkbox"/> Meningoencephalitis
<input type="checkbox"/> Acute cardiovascular injury	<input type="checkbox"/> Anosmia, ageusia	<input type="checkbox"/> Multisystem inflammatory syndrome in children
<input type="checkbox"/> Acute disseminated encephalomyelitis	<input type="checkbox"/> Chilblain-like lesions	<input type="checkbox"/> Single organ cutaneous vasculitis
<input type="checkbox"/> Acute liver injury	<input type="checkbox"/> Coagulation disorder (Thromboembolism, Haemorrhage)	<input type="checkbox"/> Thrombocytopenia
<input type="checkbox"/> Acute kidney injury	<input type="checkbox"/> Enhanced disease following immunisation	<input type="checkbox"/> Other (specify): _____
<input type="checkbox"/> Acute respiratory distress syndrome (Microangiopathy, Heart failure, Stress cardiomyopathy, Coronary artery disease Arrhythmia, Myocarditis)	<input type="checkbox"/> Erythema multiforme	
	<input type="checkbox"/> Generalized convulsion	
	<input type="checkbox"/> Guillain Barré Syndrome	

Describe vaccine recipient's AESI signs and symptoms. Use additional sheet if needed

Past medical history (including history of previous similar reactions or other allergies), concomitant medication and any other relevant information (e.g. other cases). Use additional sheet if needed

COVID-19: AESI CRF Page 1/2
 Case Report Form_Adverse events of SPECIAL INTEREST_COVID-19_20210128

Fill in vaccine recipient's details in this section.

Fill in your details in this section.

Record the date and time of event here.

Tick type of adverse event (e.g. Anaphylaxis)

Describe what happened – record the signs and symptoms here.

Record the client's past medical history here. Include:

- Similar previous reactions
- Medications



Adverse events can also be reported electronically:

- The Med Safety App is a mobile app for use by both healthcare workers and the public
- Available for Android and IOS devices
- Uses the same case report form as paper-based system

How to complete an AESI form page 2

Patient name & surname: _____ EPID Number: _____

SECTION C: PRELIMINARY ASSESSMENT AND ACTIONS AT THE TIME OF REPORT

Did this AESI cause? Death Hospitalisation Disability Life threatening Other important medical events (Specify): _____

Outcome at the time of reporting: Recovering Recovered fully (no complications) Not Recovered Unknown
 Recovered with sequelae; Specify: _____

Died → Date of death: DD/MM/YYYY → Full autopsy done: Yes No Unknown
 If NO, verbal autopsy done? Yes No
 Hospitalisation → Date of admission: DD/MM/YYYY
 → Name of hospital: _____ Hospital number: _____

Did this person receive a COVID-19 vaccine? Yes No Unknown If Yes, Complete Section E below

SECTION D: VACCINE INFORMATION (Please attach a copy of the Vaccination Record)

Health facility / vaccination center name: _____ DoH Private NGO
 Address / location: _____

COVID-19 vaccine administered								Diluent (if applicable)			
Vaccine given (Use trade name)	Manufacturer	Dose number (1 st , 2 nd)	Date vaccinated	Time vaccinated	Batch/Lot number	Expiry date / Manufacture date	Immunisation record number	Batch/Lot number	Expiry date	Date & time of reconstitution	

Consumables used (unless pre-filled)

Needles Size: _____ Batch: _____ Expiry date: _____
 Syringes Size: _____ Batch: _____ Expiry date: _____

Details of Non-COVID19 vaccines received in the last 1 year (Use additional page if there are more vaccines)

Vaccine given (Use trade name)	Manufacturer	Dose number (1 st , 2 nd)	Date vaccinated	Time vaccinated	Batch/Lot number	Expiry date / Manufacture date	Immunisation record number	Batch/Lot number	Expiry date	Date & time of reconstitution	

Consumables used (unless pre-filled)

Needles Size: _____ Batch: _____ Expiry date: _____
 Syringes Size: _____ Batch: _____ Expiry date: _____

SECTION E: FIRST DECISION MAKING LEVEL TO COMPLETE
For ALL AESI cases including COVID-19 vaccinated and unvaccinated

AEFI confirmation initiated: Yes No If YES, confirmation done by Dr/Mr/Ms _____
 Date investigation planned: DD/MM/YYYY

Is this AESI linedlisted? Yes No
 For COVID-19 vaccinated cases: Field investigation planned with AESI investigation form? Yes No
 If YES, date planned: DD/MM/YYYY

SECTION F: NATIONAL LEVEL TO COMPLETE

Date report received at National Level: DD/MM/YYYY AESI worldwide unique ID: _____

Comments: _____

IMPORTANT: Email this form within 24 hours to AEFI@health.gov.za AND copy the EPI District Surveillance Officer

COVID-19: AESI CRF Page 2/2 Case Report Form_Adverse events of SPECIAL INTEREST_COVID-19_20210128

Tick the appropriate box regarding what consequences this AESI caused.

Then tick appropriate box regarding the outcome of the AESI at the time of time of reporting.

Record further detailed information about the vaccine.

N/A – for vaccine other than COVID-19

This section is for the first decision-making level to complete (Facility/sub-district/district level).

This section will be completed at National level.

Scan and email completed forms within 24 hours to AEFI@health.gov.za and cc in district level coordinators (find contact details in WC Circular H22/2021 - 01 March 2021).

How to complete an AEFI form page 1

- AEFI is 'Adverse Event following immunisation'.
- Fill out this form if a client develops any adverse reaction or event after receiving the vaccination. Events can be minor or severe and local (involving the injection site) or systemic (involving a whole body reaction like fever or a faint).



Adverse events can also be reported electronically:

- The Med Safety App is a mobile app for use by both healthcare workers and the public
- Available for Android and iOS devices
- Uses the same case report form as paper-based system

health Department of Health REPUBLIC OF SOUTH AFRICA

ALL VACCINES including COVID-19
CASE REPORTING FORM (CRF) FOR ADVERSE EVENTS FOLLOWING IMMUNISATION (AEFI)

EPID Number: S O A - - - - -
Country - Province - District - Year - Case no

Today's date: DD / MM / YYYY
All fields in this form are mandatory, unless indicated 'if applicable'. Provide the requested information or tick the appropriate box.

SECTION A: IDENTIFYING INFORMATION
NOTE: In maternal vaccination, if mother and baby / more than one baby are affected, complete separate form for each affected individual

Vaccine recipient name & surname: _____
If child: Caregiver's name & surname: _____
Vaccine recipient's residential address: _____
Mobile no: _____ Telephone no: _____
Email: _____

Sex: M F Other *If applicable:* Pregnant Breastfeeding

Date of birth: DD / MM / YYYY
OR Age at onset: Years Months Days
OR Age group: 0 - <1 year 1 - 5 years >5 - 18 years
 >18 - 60 years >60 years
If applicable: Gestation: Full-term Premature

Reporter's name & surname: _____
Designation/Position: _____
Institution & Department: _____
Telephone no: _____
Mobile no: _____
E-mail: _____
Date patient notified event to health system: DD / MM / YYYY

SECTION B: VACCINE INFORMATION (Please attach a copy of the Road to Health Booklet OR Vaccination Card)
NOTE: In the case of a foetal adverse event, ALSO record the mother's maternal vaccination details

Health facility / vaccination center name: _____ DoH Private NGO
Address / location: _____

Vaccine administered							Diluent (if applicable)			
Vaccine/s given (Use trade name)	Date vaccinated	Time vaccinated	Dose number (1 st , 2 nd)	Batch/ Lot number	Expiry date / Manufacture date (COVID-19)	VVM Stage (if applies)	Manufacturer	Batch/ Lot number	Expiry date	Date & time of reconstitution

Consumables used (unless pre-filled):
Needles: Size: _____ Batch: _____ Expiry date: _____
Syringes: Size: _____ Batch: _____ Expiry date: _____

SECTION C: TRIGGER EVENTS
Date & time AEFI started: DD / MM / YYYY Hr Min *Adverse event (s): (Tick (✓) all boxes that apply)*

Minor local reactions	Minor systemic reactions
<input type="checkbox"/> Swelling <5cm	<input type="checkbox"/> Excessive crying (infant)
<input type="checkbox"/> Redness	<input type="checkbox"/> Mild headache
<input type="checkbox"/> Other (specify): _____	<input type="checkbox"/> Mild fever <38°C
<input type="checkbox"/> Induration / hardness	<input type="checkbox"/> Mild body aches
<input type="checkbox"/> Rash	<input type="checkbox"/> Fainting
	<input type="checkbox"/> Mild pain (to touch / on movement, but not interfering with daily activities)
	<input type="checkbox"/> Other (specify): _____

ALL VACCINES including COVID-19: AEFI CRF Page 1/2
Case Report Form_AEFI_All vaccines incl COVID-19_20210128

Fill in vaccine recipient's details in this section.

Fill in your details in this section.

Complete the vaccine information here.

Record date and time of event here.

Tick appropriate box if minor local reaction (local means involving the injection site).

Tick appropriate box if minor systemic reactions.

How to complete an AEFI form page 2

Patient name & surname: _____ EPID Number: _____

Severe local reactions	Severe systemic reactions
<input type="checkbox"/> Pain, redness and/or swelling >3 days	<input type="checkbox"/> Hospitalisation
<input type="checkbox"/> Swelling >5cm	<input type="checkbox"/> Fever ≥38°C
<input type="checkbox"/> Swelling beyond nearest joint	<input type="checkbox"/> Seizures <input type="checkbox"/> Febrile <input type="checkbox"/> Afebrile
<input type="checkbox"/> Lymphadenitis	<input type="checkbox"/> Toxic shock syndrome
<input type="checkbox"/> Abscess	<input type="checkbox"/> Other (specify): _____
<input type="checkbox"/> Necrosis at vaccination site	<input type="checkbox"/> Death
<input type="checkbox"/> Other (specify): _____	<input type="checkbox"/> Collapse/ shock-like state
	<input type="checkbox"/> Thrombocytopenia
	<input type="checkbox"/> Encephalopathy
	<input type="checkbox"/> Sepsis
	<input type="checkbox"/> Vomiting
	<input type="checkbox"/> Diarrhoea

NOTE: Severe or serious adverse event → Immediately notify District Office for Case Investigation

Describe vaccine recipient's or caregiver's concern (AEFI signs and symptoms). Use additional sheet if needed

Were there any other similar AEFIs reported in the facility in the past 30 days? Yes No (If yes, specify)

SECTION D: PAST MEDICAL HISTORY

Past medical history (including history of previous similar reactions or other allergies), concomitant medication and dates of administration (exclude those used to treat reaction), any other relevant information. Use additional sheet if needed

SECTION E: PRELIMINARY ASSESSMENT AND ACTIONS AT THE TIME OF REPORT

Is this event a serious AEFI? Yes No *If Yes, tick (✓) in the appropriate box below*

Death Hospitalisation Disability Life threatening Congenital anomaly in off-spring of vaccine recipient

Comments: _____

SECTION F: WHAT WAS THE OUTCOME OF THE CASE FOLLOWING THE SUSPECTED AEFI IN VACCINEE?

Recovering Recovered fully (no complications) Not Recovered Unknown

Recovered with sequelae; Specify: _____

Died → Date of death: DD/MM/YYYY → Autopsy: Yes No Unknown

Hospitalisation → Date of admission: DD/MM/YYYY

→ Name of hospital: _____ Hospital number: _____

SECTION G: FIRST DECISION MAKING LEVEL TO COMPLETE

Case investigation needed: Yes No

Date investigation planned: DD/MM/YYYY

District Office notified: Yes No

If yes, date notified: DD/MM/YYYY

SECTION H: NATIONAL LEVEL TO COMPLETE

Date report received at National Level: DD/MM/YYYY AEFI worldwide unique ID: _____

Comments: _____

IMPORTANT: Email this form within 24 hours to AEFI@health.gov.za AND copy the EPI District Surveillance Officer

ALL VACCINES including COVID-19: AEFI CRF Page 2/2

Case Report Form_AEFI_All vaccines incl COVID-19_20210128

Tick appropriate box if severe local reaction involving the injection site.

Tick appropriate box if severe systemic reaction involving the whole body.

Describe in words what the concern in this case is .

Describe any other similar reports.

Record the client's past medical history here. Include:

- Similar previous reactions
- Medications

Indicate one or more of the consequences of the AEFI i.e why you consider it a serious reaction.

Record what the outcome of the AEFI was at time of reporting.

This section is for the first decision-making level to complete (Facility/sub-district/district level. If serious or severe AEFI, investigation required.)

This section will be completed at National level.

Scan and email completed forms within 24 hours to AEFI@health.gov.za and cc in district level coordinators (find contact details in WC Circular H22/2021 - 01 March 2021).

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References

- WCG Circular H198 of 2021 - Vaccination of Immunocompromised Clients. 29 November 2021.
- WCG Circular H177 of 2021 - Changes to the vaccine roll-out eligibility criteria update. 21 October 2021.
- WCG Circular H161 of 2021 - Expiry date of Comirnaty vaccine mRNA COVID-19 vaccine from Pfizer-BioNtech. 4 October 2021.
- WCG Circular H81 of 2021 - Vaccine implementation Framework. June 2021
- WCG Circular H90 of 2021 - Notices regarding COVID vaccinations. July 2021.
- WCG Circular H100 of 2021 - COVID Vaccine Project Office - Vaccinations for pregnant woman. July 2021.
- Janssen Pharmaceutica (PTY) LTD. Important Medicines Safety Information - COVID-19 Vaccine Janssen. 20 July 2021.
- WC Provincial Pharmacy and Therapeutics Committee (PPTC) Presentation: Focus on storage and administration of Comirnaty® and J&J (Janssen®) vaccine. H Hayes. 09 April 2021.
- Knowledge Hub. NDoH COVID-19 vaccine training.
- NDOH. Cold Chain and Immunisation Operations Manual. 2015.
- NDOH. Vaccinator's Manual. Expanded Programme on Immunisation in South Africa (EPI-SA). 4th edition. January 2015.
- NDOH. COVID-19 Vaccination Field Guide, Draft 11 May 2021.
- WCG Circular H22/2021: Adverse Events Following Immunisation (AEFI) monitoring for COVID-19 vaccination. 01 March 2021.
- FDA. EUA. Fact sheet for healthcare providers administering vaccine (vaccination providers). Emergency use authorization (EUA) of the Pfizer®-Biontech COVID-19 vaccine to prevent coronavirus disease 2019 (COVID-19). Revised: 10 May 2021.
- J&J. Summary of product characteristics. COVID-19 Vaccine J&J suspension for injection COVID-19 vaccine (Ad26.COV2-S [recombinant]).
- CDC. Interim Clinical Considerations for Use of COVID-19 Vaccines Currently Authorized in the United States. Updated 27 April 2021. <https://www.cdc.gov/vaccines/covid-19/info-by-product/clinical-considerations.html> [Accessed 10 May 2021].
- CDC. Wolicki J, Miller E. Vaccine Administration. <https://www.cdc.gov/vaccines/pubs/pinkbook/vac-admin.html> Updated November 2020. [Accessed 04 May 2021].
- UpToDate: COVID-19: Vaccines to prevent SARS-CoV-2 infection. Updated 07 May 2021. <https://www.uptodate.com/contents/covid-19-vaccines-to-prevent-sars-cov-2-infection> [Accessed 10 May 2021].
- BMJ Best Practice: Coronavirus disease 2019 (COVID-19): Primary prevention. <https://bestpractice.bmj.com/topics/en-gb/3000201/prevention> [Accessed 10 May 2021].
- GOV.UK. Information for Healthcare Professionals on Pfizer®/BioNTech COVID-19 vaccine.
- FDA. Fact sheet for recipients and caregivers. Emergency Use Authorization (EUA) of the Pfizer®-Biontech COVID-19 vaccine to prevent coronavirus disease 2019 (COVID-19) in individuals 16 years of age and older. Revised: 10 May 2021.
- CDC. Pfizer®-BioNTech COVID-19 Vaccine: Vaccine Preparation poster.02/18/2021 CS321570-N.
- CDC. Pfizer®-BioNTech COVID-19 Vaccine: Vaccine Preparation and Administration Summary. 03/15/2021 4 CS321570-F.
- CDC. COVID-19 Vaccine: Administration Errors and Deviations. 03/17/2021 CS321629-Y.
- Administering Vaccines to Adults: Dose, Route, Site, and Needle Size. www.immunize.org/catg.d/p3084.pdf#item=P3084 (8/20) [Accessed 3 May 2021].
- Shimabukuro T, Kim S, Myers TR et al for the CDC v-safe COVID-19 Pregnancy Registry Team. Preliminary Findings of mRNA Covid-19 Vaccine Safety in Pregnant Persons. NEJM. April 21, 2021. DOI: 10.1056/NEJMoa2104983 [Accessed on 26 April 2021].
- Jacobson BF, Schapkaitz, E, Mer M, et al on behalf of the Southern African Society of Thrombosis and Haemostasis. Recommendations for the diagnosis and management of vaccine-induced immune thrombotic thrombocytopenia. SAMJ. S Afr Med J. Published online 20 April 2021. <https://doi.org/10.7196/SAMJ.2021.v111i7.15772>
- Bjornstad M, Kosinski T, Burlage R. Evaluation of the Efficacy and Superiority of Different Vial Rubber Closure Disinfection Techniques. Int J Pharm Compd. 2020 Sep-Oct;24(5):434-438. PMID: 32886643.
- Apharmacists. Vaccine Administration Techniques. <https://www.youtube.com/watch?v=-STH2nfClk8>. [Accessed 20 April 2021].
- ImmunizeCanada. Intramuscular and subcutaneous injections: A guide for pharmacists. <https://www.youtube.com/watch?v=5axQQpTzxAE>. [Accessed 21 April 2021].
- University of Kansas. Davidow L. Vaccine Injection Technique Lecture and Demonstration. 17 November 2020. <https://www.youtube.com/watch?v=Y3CQ0kMlBll>. [Accessed 19 April 2021].

Practical Approach to Care Kit: Vaccine