



Western Cape
Government

Health



PACK
Practical Approach to Care Kit

COVID-19 vaccination

Version 1

Guidance for the Janssen®(JNJ) Ad26.COVS.2
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 May 2021 · Western Cape Edition

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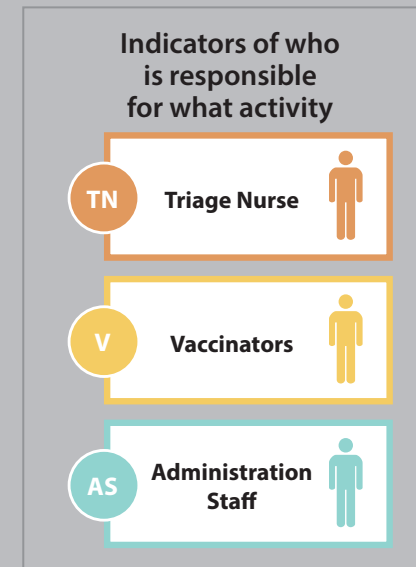
Orange-highlighted medications may be prescribed by a doctor or an authorised prescriber (clinical nurse practitioner or professional nurse) in accordance with his/her scope of practice within a specified field.

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.



Disclaimer: The content of this document has been developed specifically for health care professionals practising in the Western Cape, South Africa, and which content, at the date of first publication, is reasonably believed to represent best practice in the relevant fields of healthcare. This information is provided on an "as is" basis without any warranties regarding accuracy, relevance, usefulness or fitness for purpose. To the fullest extent permitted by law, University of Cape Town Lung Institute Proprietary Limited and all its affiliates (including The Lung Institute Trust) and the Western Cape Department of Health cannot be held liable or responsible for any aspect of healthcare administered with the aid of this information or any other use of this information, including any use which is not in accordance with any guidelines or (mis-)use outside the Western Cape, South Africa. Health Care Professionals are strongly advised to consult a variety of sources and use their own professional judgment when treating patients using this information. It is the responsibility of users to ensure that the information contained in this document is appropriate to the care required for each of their patients within their respective geographical regions. The information contained in this document should not be considered a substitute for such professional judgment.

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	One dose per client	Two doses per client – at least 21 days apart	
Approved for:	Clients ≥ 18 years old	Clients ≥ 16 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 6 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 5 days (120 hours) at 2°C to 8°C. 19 days in total.
Refrigerator storage (2°C to 8°C)	For up to 3 months.	For up to 5 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	15-30 minutes after removing from refrigerator.	15-30 minutes after removing from refrigerator.	
Preparation	<u>No</u> dilution needed.	Dilution needed. Use 1.8mL preservative-free sodium chloride 9mg/mL (0,9 %) solution for injection as diluent. Store diluent in vaccine fridge with thawed vaccines.	
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	For each dose: <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 	For dilution: <ul style="list-style-type: none"> 2mL syringe and green 21G x1½" (40mm) needle Preservative-free sodium chloride 0.9% For each dose: <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 	
Security	Keep vaccines in an access-controlled room. Lock refrigerator and rooms where the vaccines are stored. Monitor and take stock daily.		

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.

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

No to all

Yes to any

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

Yes

No

- 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.

Refer client to EVDS support staff member.

Assist client to self register on EVDS.

- Capture ID and details.
- Confirm if client is registered:

Client registered

Client **not** registered

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

Refer client to EVDS support staff member.

AS

Pre-vaccination health check

Many clients are anxious at this stage: be kind and reassuring.

- 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.
- Client will be screened for COVID-19 symptoms upon entering the facility.

STEP 1. Work through steps on the Electronic Vaccine Data System (EVDS)

Confirm identity. Then complete and record informed consent process and questions with the client on EVDS.

STEP 2. Ask about previous COVID-19 infection and other recent vaccines

- Ask client if s/he tested positive for COVID-19 infection in the past 3 months. If yes, delay vaccination: advise client to return at least 3 months after testing positive or onset of symptoms.
- Ask client if s/he received a vaccine in the past 2 weeks. If yes, delay vaccination: advise client to return at least 2 weeks after last vaccination (Comirnaty® vaccine doses need to be at least 21 days apart).

STEP 3. If woman of child bearing age, ask about pregnancy or breastfeeding. If none, move to next step.

- **If breastfeeding:** advise that vaccination is a personal choice. Explain that as non-live vaccines pose no risk for breastfeeding mother or their infants, COVID-19 vaccines are also not thought to be a risk. If client understands and consents, continue with vaccination process.
- **If pregnant:** advise client that data is still limited and vaccination is a personal choice. Explain that initial studies have found no increased risk of major pregnancy complications after the Comirnaty® vaccine. Experts advise that pregnant people should be vaccinated due to the high risk of complications from COVID-19. If client understands and consents, continue with vaccination process.

STEP 4. Ask about any blood clotting disorders or anticoagulant medications. If none, move to next step.

Client on anticoagulant medications
(e.g. aspirin, warfarin)

Current/previous blood clotting disorder

Does client have a history of a complicated blood clotting disorder (specifically thrombosis and thrombocytopaenia - blood clots with low platelets)?¹

No

Yes

- Reassure client that the risk of VITT¹ is extremely low. This is because the mechanism for VITT is immune-mediated and is not the same as the mechanism of common causes of blood clots, like deep vein thromboses (DVT) and/or pulmonary embolisms (PE).
- If on anticoagulants: advise not to stop medications before getting the Janssen® COVID-19 vaccine. If on warfarin: ensure latest routine INR result within therapeutic range (usually 2.0-3.0, unless mechanical heart valve where range is higher). Discuss if unsure, or result unavailable.
- If unsure, discuss with doctor.

This client could be at risk of VITT¹. Discuss with doctor and preferably arrange for Comirnaty® vaccine for client if possible.

STEP 5. Ask if client has a chronic medical condition requiring ongoing specialist care. If none, move to next step.

If yes, discuss with doctor: if client has discussed vaccination with treating specialist and specialist has indicated that client should proceed with it, then continue with pre-vaccination health check and vaccinate today. If client has not discussed with specialist or is unsure: advise to consult specialist before continuing to vaccination.

STEP 6. Ask if client has a history of allergy to any food, substance, medicines or vaccines

If no history of allergy, proceed to vaccination: if giving Comirnaty® vaccine → 7. If giving Janssen® vaccine → 11.

If history of allergy: further assess risk of allergy on page 6.

¹This includes Vaccine-induced Immune Thrombotic Thrombocytopaenia (VITT) and Heparin-Induced Thrombocytopenia and Thrombosis (HITT). This is where an immune response, triggered by this type of vaccine in VITT, or heparin in HITT, causes blood clots (in brain, abdomen or legs), along with low platelet levels (blood cells that help your body stop bleeding). Only very few people who have received COVID vaccines have had VITT, mainly females under the age of 50 years. Symptoms started 1-2 weeks after vaccination and included severe persistent headaches, neurological symptoms, abdominal pain, shortness of breath, chest pain and leg pain/swelling. The chance of VITT is extremely low. Educate the client about it, especially if female < 50 years but emphasise that because of the rarity of these events and the potential severity of COVID-19, the overall benefits of the vaccines far outweigh this risk.

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.

- If giving Comirnaty® vaccine → 7.
- If giving Janssen® vaccine → 11.

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.

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).

Yes

No

Proceed with vaccination today but observe for symptoms for **30 minutes**:

- If giving Comirnaty® vaccine → 7.
- If giving Janssen® vaccine → 11.

Yes or client not sure

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

Janssen (J&J) vaccine (Ad26.COV2.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

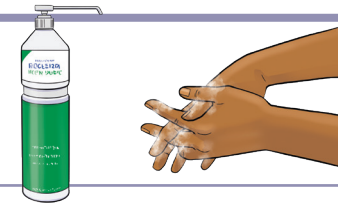
Note: Neither vaccine contains eggs, gelatin, latex, or preservatives.

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 vaccine and diluent to room temperature

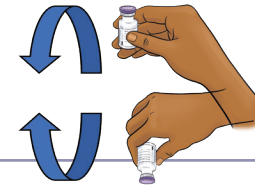
- If vaccine is in refrigerator:
 - Remove and allow to come to room temperature for 15-30 minutes.
 - Vials can be held at room temperature for up to 2 hours before mixing.
- If vaccine in cooler box:
 - No need to wait, remove and start preparing.



3

Gently invert to mix

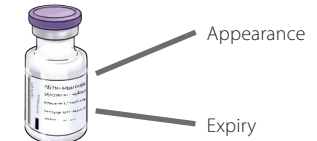
- Before inspection and dilution, gently invert (tip upside down) vaccine vial 10 times.
- Do not shake! If vial is shaken, discard it.



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.

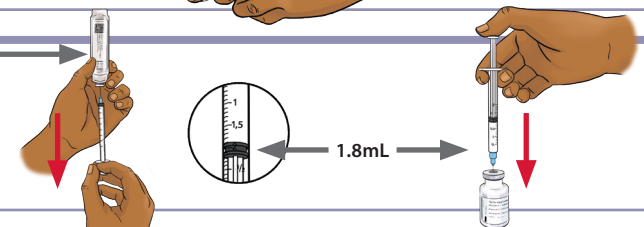


6

Dilute

- Dilute in original vaccine vial:
 - Using a 2mL syringe and 21G or narrower needle, withdraw 1.8mL of sodium chloride 0.9% for injection (preservative-free).
 - Inject this 1.8mL of diluent into vaccine vial.

Dilute
Use sodium chloride 0.9%
(preservative-free)



How to draw up the Comirnaty® vaccine - continued

7

Equalise pressure in vial

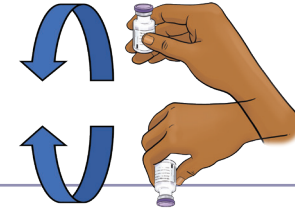
Before removing needle from vial, pull needle up slightly so the tip is no longer in liquid and withdraw 1.8mL of air into empty diluent syringe.



8

Gently invert to mix and inspect

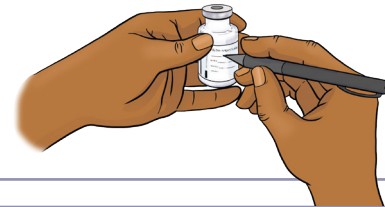
- Once diluted, gently invert (tip upside down) vaccine vial 10 times.
- Do not shake! If vial is shaken, discard.
- Contents of vial should be an off-white dispersion with no particles visible now. If discoloured or particles present, discard it.
- There is now 2.25mL after dilution, which provides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



9

Record dilution time and date and new expiry

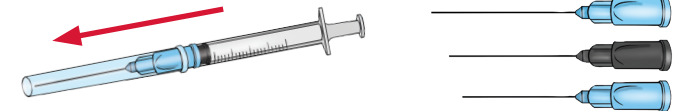
- Record time and date on vial that diluent added and new expiry time.
- Keep at room temperature (**up to 25°C**) for up to 6 hours.
- Discard any unused vaccine after 6 hours.
- Do not return to refrigerator or freezer storage.



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 to vaccine syringe (0.3mL, 0.5mL or 1mL syringe). Carefully uncap.

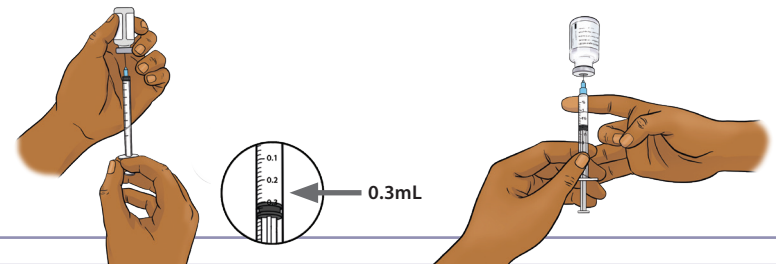


11

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®-BioNTech COVID-19 vaccine.
- Tap out any air bubbles from syringe whilst needle is still in the vial to avoid loss of vaccine.

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.



12

Do not change needles

Do not change needles. Use the same needle that you have drawn up the dose to administer vaccine.

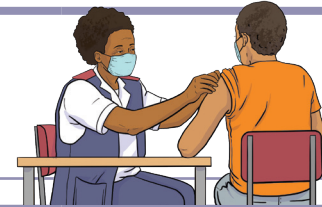


How to administer the Comirnaty[®] vaccine

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.

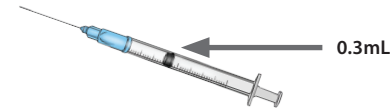
1 Position yourself well

- 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
 - No particles
 - Off-white suspension
 - No discoloration



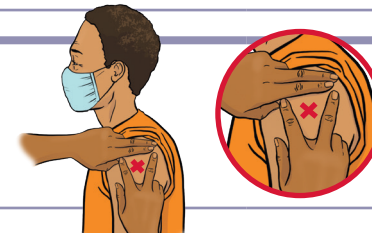
3 Expose injection site fully

- 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.



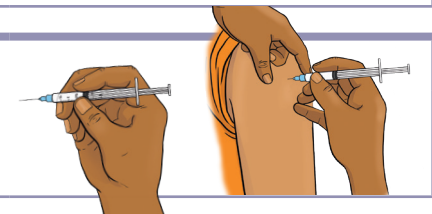
5 Clean

- 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



8

Remove syringe 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

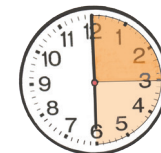
- Apply surgical tape to hold cotton wool in place.
- Ask client to stay seated for a few minutes to avoid risk of injury from fainting while you complete records.



12

Record and observe

- Complete vaccination card and give to patient.
- If this is the 1st injection of the two Comirnaty® doses, inform client of return date for second vaccination.
- 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).

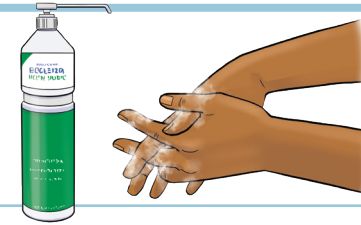


How to draw up Janssen® vaccine

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

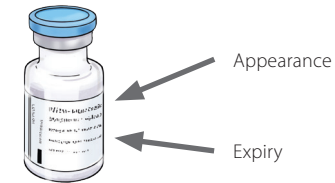
Check and inspect

• 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

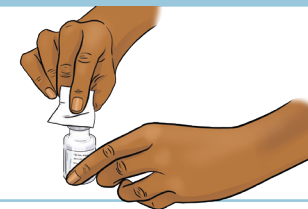
- Mix contents before each draw: gently swirl vial in an upright position for 10 seconds.
- Do not shake!



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.



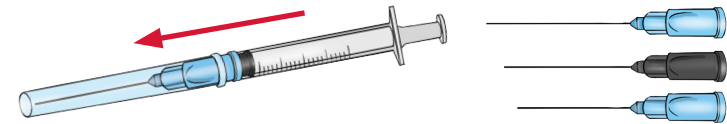
How to draw up the Janssen® vaccine - continued

6

Draw up

Choose appropriate needle length

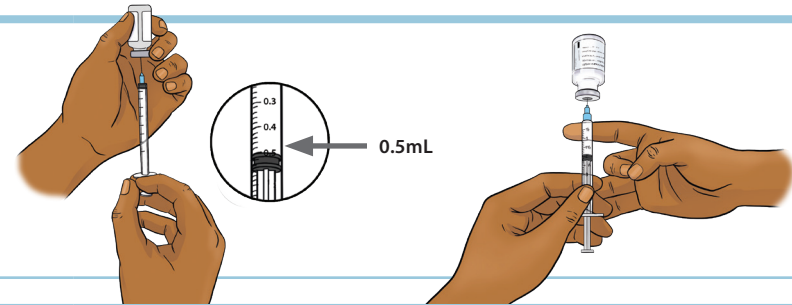
- Use a light blue 23G x 1" (25mm) needle unless client is obese. If obese, use instead one of the following:
 - Black 22G x 1¼" (32mm) or blue 23G x 1½" (38mm).
- Attach to vaccine syringe (0.5mL or 1mL syringe).
- Carefully uncap.



7

Withdraw vaccine and remove air bubbles

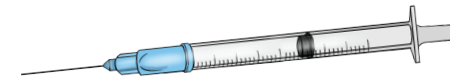
- Hold vial steady on flat surface and insert needle into rubber stopper. Then pick up vial and syringe and turn upside down to withdraw.
- Withdraw **0.5mL** of Janssen® COVID-19 vaccine.
- Tap out any air bubbles from syringe whilst needle is still in vial to avoid loss of vaccine.
- If amount of vaccine 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.



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.



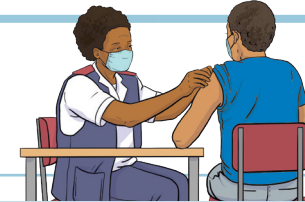
Time of first puncture
and expiry time

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.

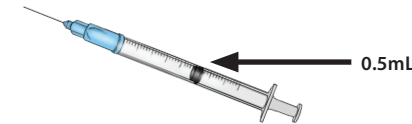
1 Position yourself well

- 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
 - Colourless – slightly yellowish fluid
- No particles
- No discoloration



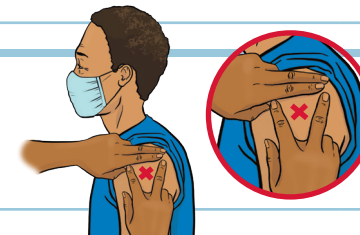
3 Expose injection site fully

- 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

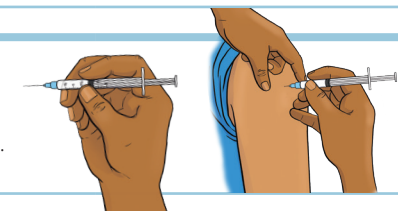
Clean

- 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.

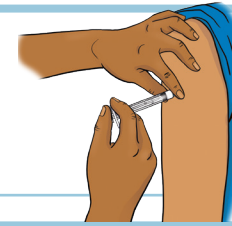


How to administer the Janssen® vaccine - continued

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 safely

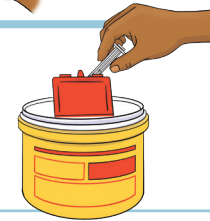
- Pull needle out quickly and smoothly.



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

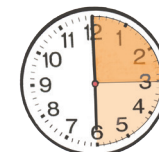
- Apply surgical tape to hold cotton wool in place.
- Ask client to stay seated for a few minutes to avoid risk of injury from fainting while you complete records.



12

Record and observe

- Complete vaccination card and give to patient.
- Give client a post vaccination information leaflet.
- Explain that this is a one dose per client regimen and s/he does not need to return for another vaccine 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).



Manage injection difficulties



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

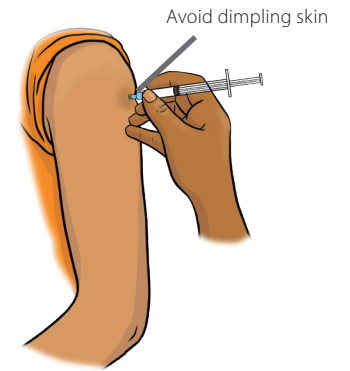
- If needle hits bone during injection, pull needle back slightly and then inject.

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



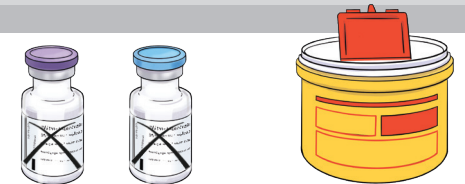
Avoid dimpling skin

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.

Do symptom/s improve quickly (minutes)?

Yes

No

Faintness likely
Observe until symptoms resolve.

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

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 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** 0.5mL (1:1000 solution) IM into mid outer thigh. Repeat every 5 minutes if needed. Adrenaline is the vital part of anaphylaxis management.

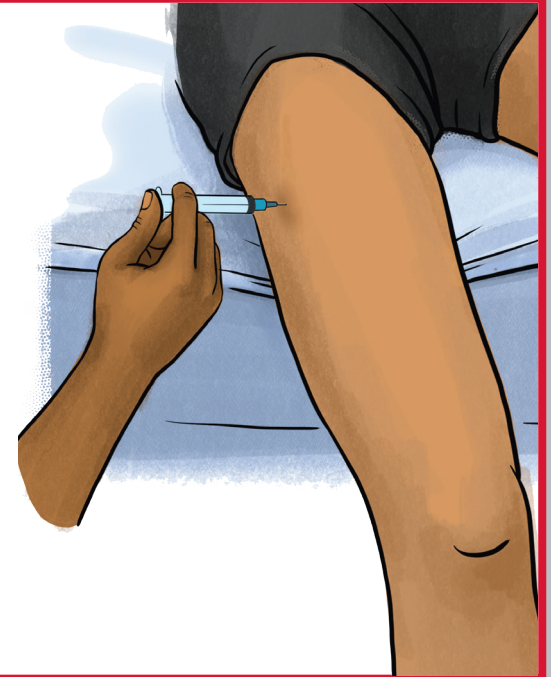
- Insert IV line and check BP:
 - If BP < 90/60 despite adrenaline: give **sodium chloride 0.9%** 1-2L IV rapidly.
 - Then, if BP still < 90/60, give further **sodium chloride 0.9%** 500mL IV rapidly, repeat until systolic BP > 90. Stop if breathing worsens.
- Give oxygen, if available, 8-10L/min via 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 or slow IV over 10-15 minutes and **hydrocortisone** 200mg 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.



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.

April 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, 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).



April 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 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.



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.

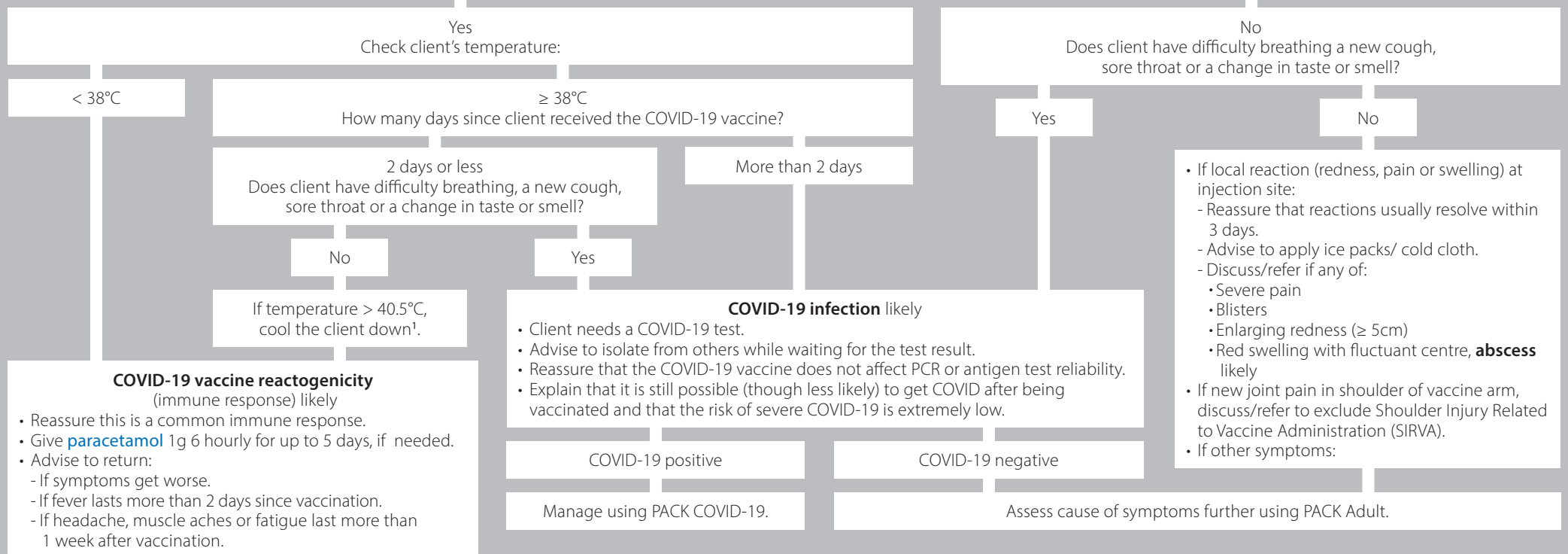
Give urgent attention to the client who has had a COVID-19 vaccination within the last month and any of:

- 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 clients who aren't 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 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 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: **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	Manufacturer	Dose number	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 2

Patient name & surname: _____ EPID Number: _____

Severe local reactions <input type="checkbox"/> Pain, redness and/or swelling >3 days <input type="checkbox"/> Swelling >5cm <input type="checkbox"/> Swelling beyond nearest joint <input type="checkbox"/> Lymphadenitis <input type="checkbox"/> Abscess <input type="checkbox"/> Necrosis at vaccination site <input type="checkbox"/> Other (specify): _____ _____ _____	Severe systemic reactions <input type="checkbox"/> Hospitalisation <input type="checkbox"/> Fever ≥38°C <input type="checkbox"/> Seizures <input type="checkbox"/> Febrile <input type="checkbox"/> Afebrile <input type="checkbox"/> Toxic shock syndrome <input type="checkbox"/> Other (specify): _____ Foetal adverse reactions in the case of maternal immunisation: <input type="checkbox"/> Decreased FHR variability <input type="checkbox"/> Decreased foetal movement <input type="checkbox"/> Foetal death <input type="checkbox"/> Onset of preterm labour, assessed to be possibly/probably related <input type="checkbox"/> Foetal anomaly assessed to be possibly/probably related (e.g. congenital anomaly feasible with pre-pregnancy or 1 st trimester immunisation) <input type="checkbox"/> Foetus affected by maternal immunization (e.g. live vaccine administered to mother)	<input type="checkbox"/> Death <input type="checkbox"/> Collapse/ shock-like state <input type="checkbox"/> Thrombocytopenia <input type="checkbox"/> Anaphylaxis <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 District Office notified: Yes No

Date investigation planned: DD/MM/YYYY 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).

Acknowledgements

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