Western Cape Government
Health

PACK
Practical Approach to Care Kit

COVID-19 vaccination

Version 1
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 May 2021 · Western Cape Edition

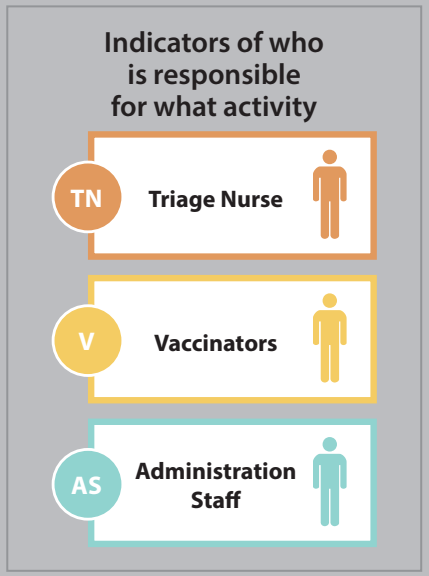
Contents

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.



Western Cape Government Health

Knowledge Translation Unit, University of Cape Town LUNG INSTITUTE

University of Cape Town Lung Institute

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The response to COVID-19 is rapidly changing as new evidence becomes available and health systems adapt. The KTU welcomes feedback on this guidance as it continues to be updated for future versions. Please send feedback to www.knowledgetranslation.co.za/contact/feedback

Summary table of Janssen® and Comirnaty® vaccines

	Janssen® (J&J) vaccine (Ad26.COV2.S)	Comirnaty® (PFIZER-BioNTech) vaccine (BNT162b2)
Vial	• 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	• 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
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
Refrigerator storage (2°C to 8°C)	For up to 3 months.	For up to 5 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.
Thawing	• Preferably, thaw overnight in refrigerator (2-8°C) for 12 hours. • Keep in original carton. • Protect from sunlight.	• 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	No 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: • In refrigerator (2-8°C) for up to 6 hours. • At room temperature (up to 25°C) for up to 3 hours.	After dilution: • Keep at room temperature (up to 25°C) for up to 6 hours. • Do not return to refrigerator.
Drawing up equipment	**For each dose:** • 1mL or 2mL syringe • 1x needle - use light blue needle 23G x 1" (25mm). If client is overweight, then use a longer needle: - 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:** • 2mL syringe and green 21G x1½" (40mm) needle • Preservative-free sodium chloride 0.9% **For each dose:** • 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: - 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.	

- **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.**

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

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- 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

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.

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

Yes

No

AS

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

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

Client ***not*** registered

Refer client to EVDS support staff member.

Pre-vaccination health check

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

V

- 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

- Reassure client that the risk of VITT[1] 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.

Yes

This client could be at risk of VITT[1]. 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.

[1]This 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

v

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).

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

Yes

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

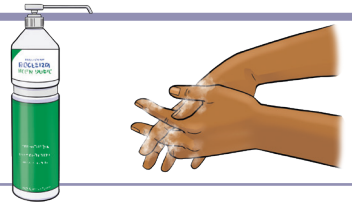
Janssen (J&J) vaccine (Ad26.COV2.S)	Comirnaty® (Pfizer-BioNTech) vaccine (BNT162b2)
• Polysorbate 80 • Sodium chloride • Citric acid monohydrate buffer • 2 hydroxypropyl-β-cyclodextrin (HBCD) • Ethanol (absolute) • Sodium hydroxide • Water for injection • Recombinant, replication-incompetent Ad26 vector, encoding a stabilized variant of the SARS-CoV-2 Spike (S) protein	• 2[(polyethylene glycol (PEG))-2000]-N,N-ditetradecylacetamide • 1,2-distearoyl-sn-glycero-3-phosphocholine • Cholesterol • (4-hydroxybutyl)azanediyl)bis(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

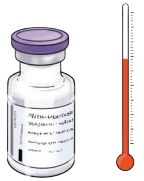
1

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



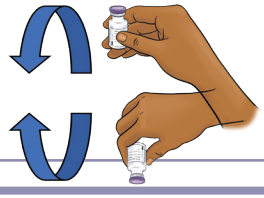
2

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.



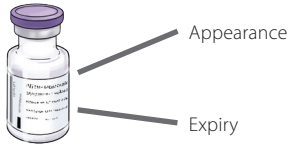
3

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.



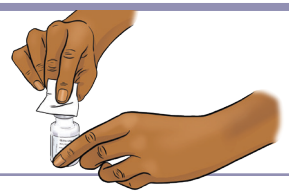
4

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).



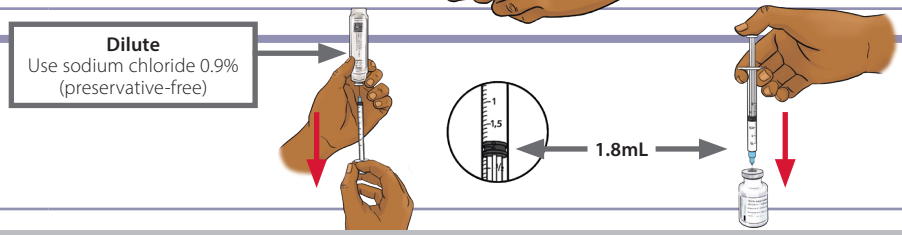
5

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

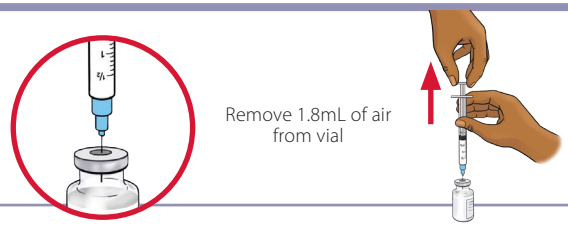
Dilute
- Dilute in original vaccine vial:
  - Using a 2mL syringe and 21G or narrower needle, withdraw 1.8mL of sodium chloride 0.9% for injection (preservative-free).
  - Inject this 1.8mL of diluent into vaccine vial.



How to draw up the Comirnaty® vaccine - continued

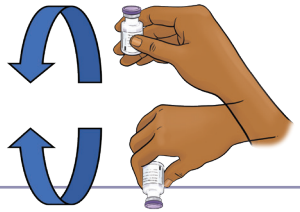
7

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.



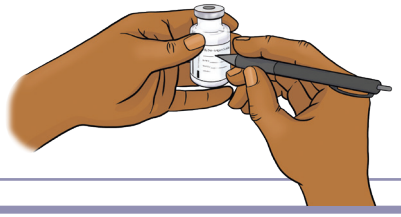
8

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.



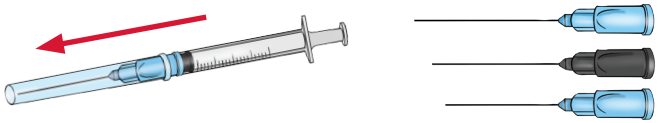
9

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

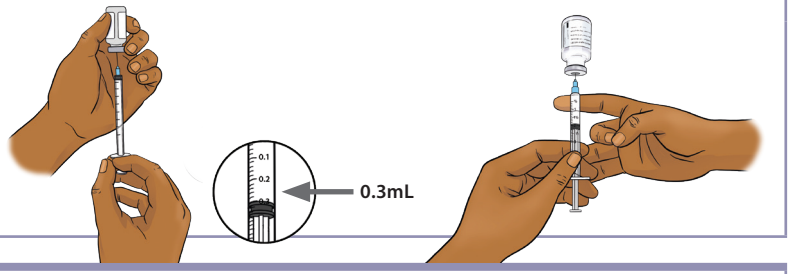
Draw up: choose appropriate needle length
- Use a light blue 23G x 1" (25mm) needle unless client is obese. If obese, use instead one of the following:
  - Black 22G x 1¼" (32mm) or blue 23G x 1½" (38mm).
- Attach to vaccine syringe (0.3mL, 0.5mL or 1mL syringe). Carefully uncap.



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

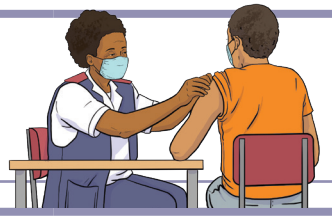
Do not change needles
Do not change needles. Use the same needle that you have drawn up the dose to administer vaccine.

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.

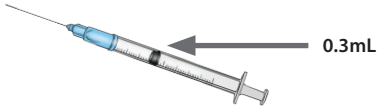
1

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.



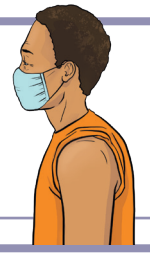
2

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



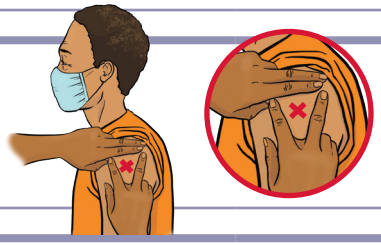
3

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.



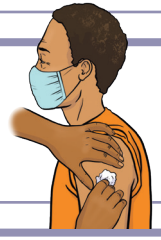
4

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.



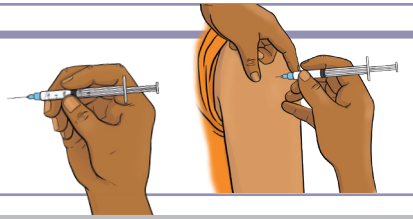
5

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



6

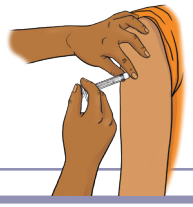
Insert needle
- Hold syringe firmly between the thumb and forefinger like holding a pencil.
- Gently stretch and support the skin with other hand. Avoid bunching the skin unless very low muscle mass ⮌ 15.
- Insert needle at 90° angle to skin into thickest part of muscle. Insert to hilt of needle (no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



How to administer the Comirnaty® vaccine - continued

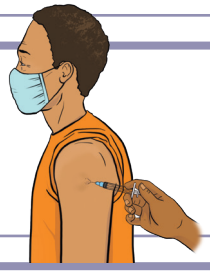
7

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



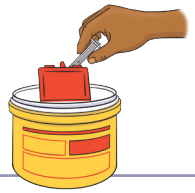
8

Remove syringe safely
- Pull needle out quickly and smoothly.



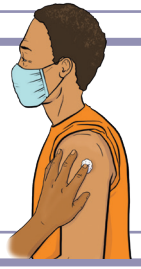
9

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.



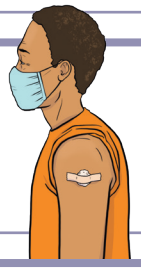
10

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.



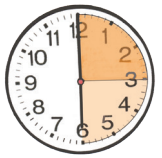
11

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

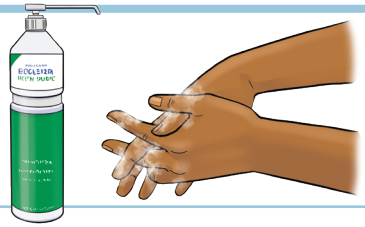
Record and observe
- Complete vaccination card and give to patient.
- If this is the 1st injection of the two Comirnaty® doses, inform client of return date for second vaccination.
- Give client a post vaccination information leaflet.
- Record in EVDS/Vaccination Site data sheet.
- Ask client to remain 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

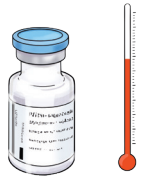
1

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



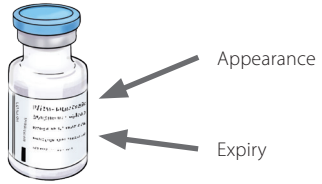
2

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



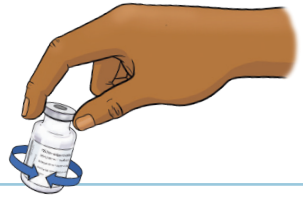
3

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.



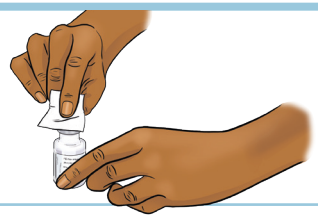
4

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.

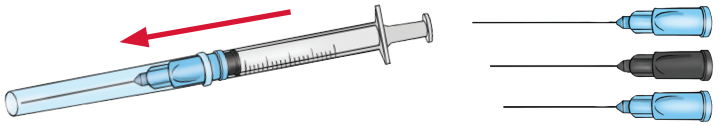


How to draw up the Janssen® vaccine - continued

6

Draw up
Choose approriate needle length

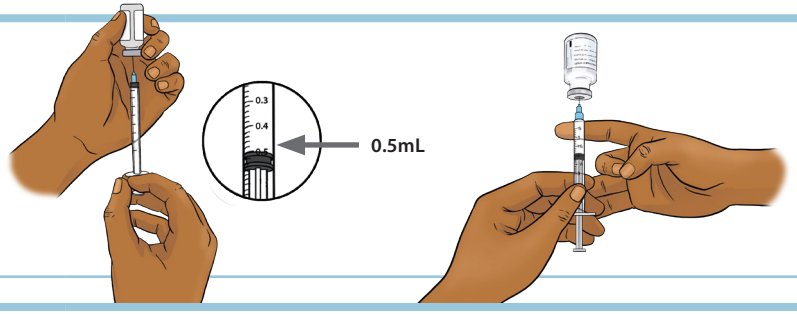
- Use a light blue 23G x 1" (25mm) needle unless client is obese. If obese, use instead one of the following:
  - Black 22G x 1¼" (32mm) or blue 23G x 1½" (38mm).
- Attach to vaccine syringe (0.5mL or 1mL syringe).
- Carefully uncap.



7

Withdraw vaccine and remove air bubbles

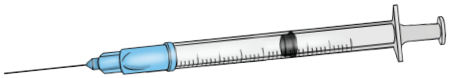
- Hold vial steady on flat surface and insert needle into rubber stopper. Then pick up vial and syringe and turn upside down to withdraw.
- Withdraw **0.5mL** of Janssen® COVID-19 vaccine.
- Tap out any air bubbles from syringe whilst needle is still in vial to avoid loss of vaccine.
- If amount of vaccine remaining in vial cannot provide a full dose of 0.5mL, mark and discard vial and any excess volume.



8

Do not change needles

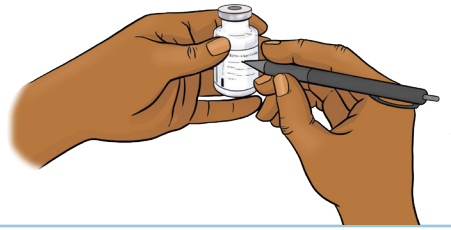
- Do not change needles. Use the same needle that you have drawn up the dose to administer vaccine.



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.



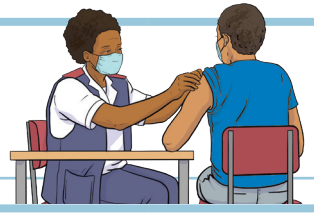
Time of first puncture and expiry time

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.

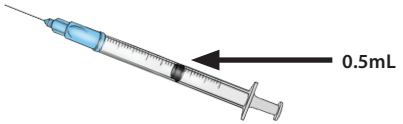
1

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

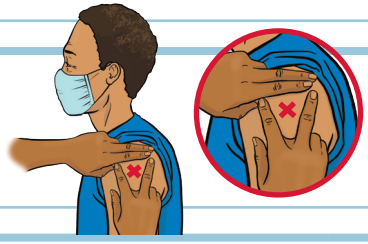


3

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.

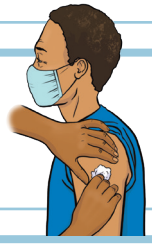
4

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.



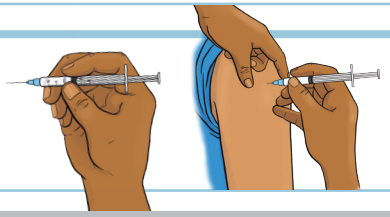
5

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



6

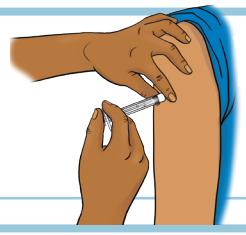
Insert needle
- Hold syringe firmly between the thumb and forefinger like holding a pencil.
- Gently stretch and support the skin with other hand. Avoid bunching the skin unless very low muscle mass ⮌ 15.
- Insert needle at 90° angle to skin into thickest part of muscle. Insert to hilt of needle (no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



How to administer the Janssen® vaccine - continued

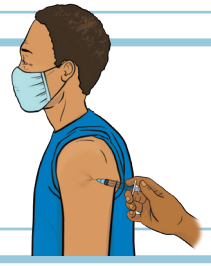
7

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.



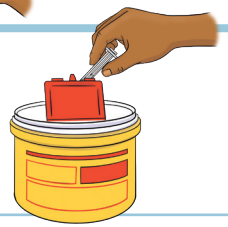
8

Remove syringe safely
- Pull needle out quickly and smoothly.



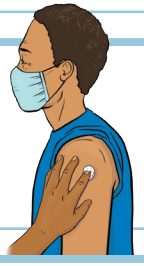
9

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.



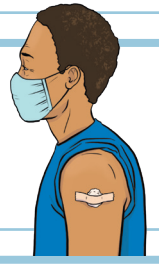
10

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.



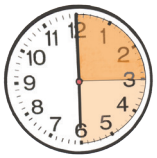
11

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.

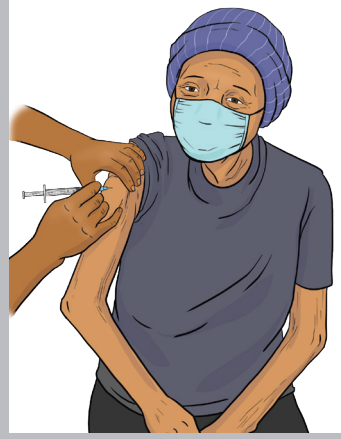


12

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

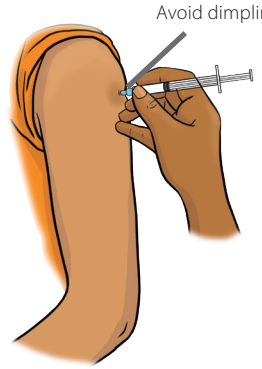


Elderly and low BMI
If low muscle mass in elderly client or client with low BMI, it is acceptable to bunch up the deltoid muscle before administering IM injection.

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.

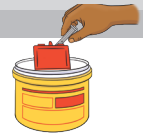
Vaccine leaks from injection site
- If vaccine leaks from injection site
  - If vaccinator thinks most of dose leaked out of injection site, then revaccinate at same visit using a different injection site. Use same dose, as initial dose considered an invalid dose.
  - If vaccinator thinks most of dose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



Avoid 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

Faintness likely
Observe until symptoms resolve.

No

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.

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.

- 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.

Treat as **anaphylaxis** →18.

Treat suspected anaphylaxis

Manage and refer urgently:

Priority management

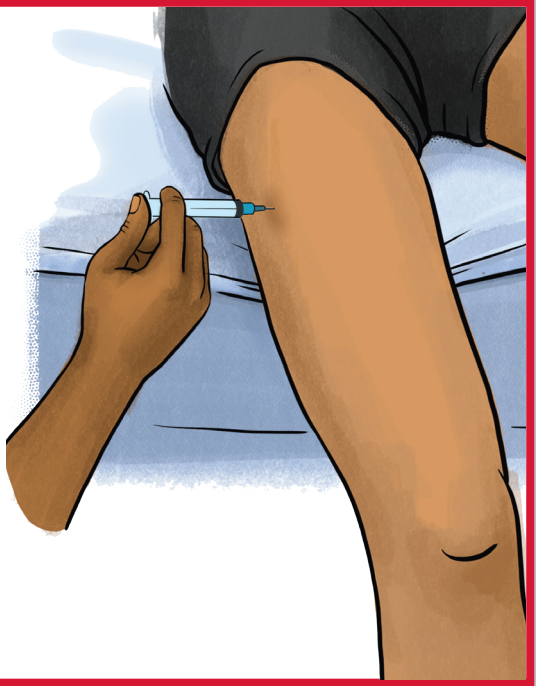
- Lie client down and raise legs.
- Call for help: ask colleague to inform supervisor and doctor, if available. Ask colleague to call emergency medical services and report suspected anaphylaxis.
- Give immediately adrenaline 0.5mL (1:1000 solution) IM into mid outer thigh. Repeat every 5 minutes if needed. 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).

Western Cape Government

VACCINATE LET'S DO THIS

CITY OF CAPE TOWN ISIXEKO SASEKAPA STAD KAAPSTAD

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.

Western Cape Government

VACCINATE LET'S DO THIS

CITY OF CAPE TOWN ISIXEKO SASEKAPA STAD KAAPSTAD

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 ≥ 38°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?

Yes

Check client's temperature:

< 38°C

COVID-19 vaccine reactogenicity (immune response) likely

- Reassure this is a common immune response.
- Give paracetamol 1g 6 hourly for up to 5 days, if needed.
- Advise to return:
  - If symptoms get worse.
  - If fever lasts more than 2 days since vaccination.
  - If headache, muscle aches or fatigue last more than 1 week after vaccination.

≥ 38°C

How many days since client received the COVID-19 vaccine?

2 days or less

Does client have difficulty breathing, a new cough, sore throat or a change in taste or smell?

No

If temperature > 40.5°C, cool the client down[1].

Yes

More than 2 days

COVID-19 infection likely

- Client needs a COVID-19 test.
- Advise to isolate from others while waiting for the test result.
- Reassure that the COVID-19 vaccine does not affect PCR or antigen test reliability.
- Explain that it is still possible (though less likely) to get COVID after being vaccinated and that the risk of severe COVID-19 is extremely low.

COVID-19 positive → Manage using PACK COVID-19.

COVID-19 negative → Assess cause of symptoms further using PACK Adult.

No

Does client have difficulty breathing a new cough, sore throat or a change in taste or smell?

Yes

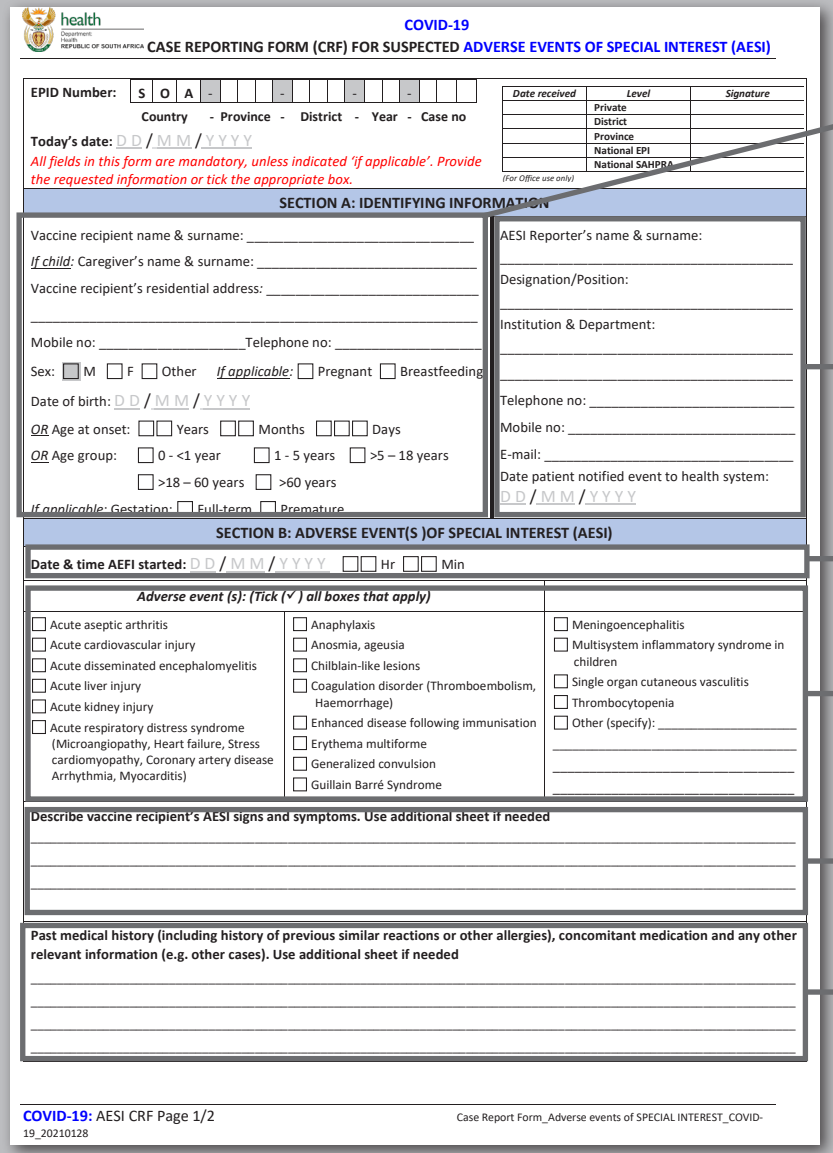
No

- If local reaction (redness, pain or swelling) at injection site:
  - Reassure that reactions usually resolve within 3 days.
  - Advise to apply ice packs/ cold cloth.
  - Discuss/refer if any of:
    - Severe pain
    - Blisters
    - Enlarging redness (≥ 5cm)
    - Red swelling with fluctuant centre, **abscess** likely
- If new joint pain in shoulder of vaccine arm, discuss/refer to exclude Shoulder Injury Related to Vaccine Administration (SIRVA).
- If other symptoms:

[1]Cool 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°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
Department: Health
REPUBLIC OF SOUTH AFRICA

COVID-19

CASE REPORTING FORM (CRF) FOR SUSPECTED ADVERSE EVENTS OF SPECIAL INTEREST (AESI)

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

Date received	Level	Signature
	Private	
	District	
	Province	
	National EPI	
	National SAHPRA	

(For Office use only)

Today's date: D D / M M / Y Y Y Y

All fields in this form are mandatory, unless indicated 'if applicable'. Provide the requested information or tick the appropriate box.

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: D D / M M / Y Y Y Y
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:
D D / M M / Y Y Y Y

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

Date & time AEFI started: D D / M M / Y Y Y Y ☐☐ Hr ☐☐ Min

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

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

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
19_20210128
Case Report Form_Adverse events of SPECIAL INTEREST_COVID-

Fill in vaccine recipient's details in this section.

Fill in your details in this section.

Record the date and time of event here.

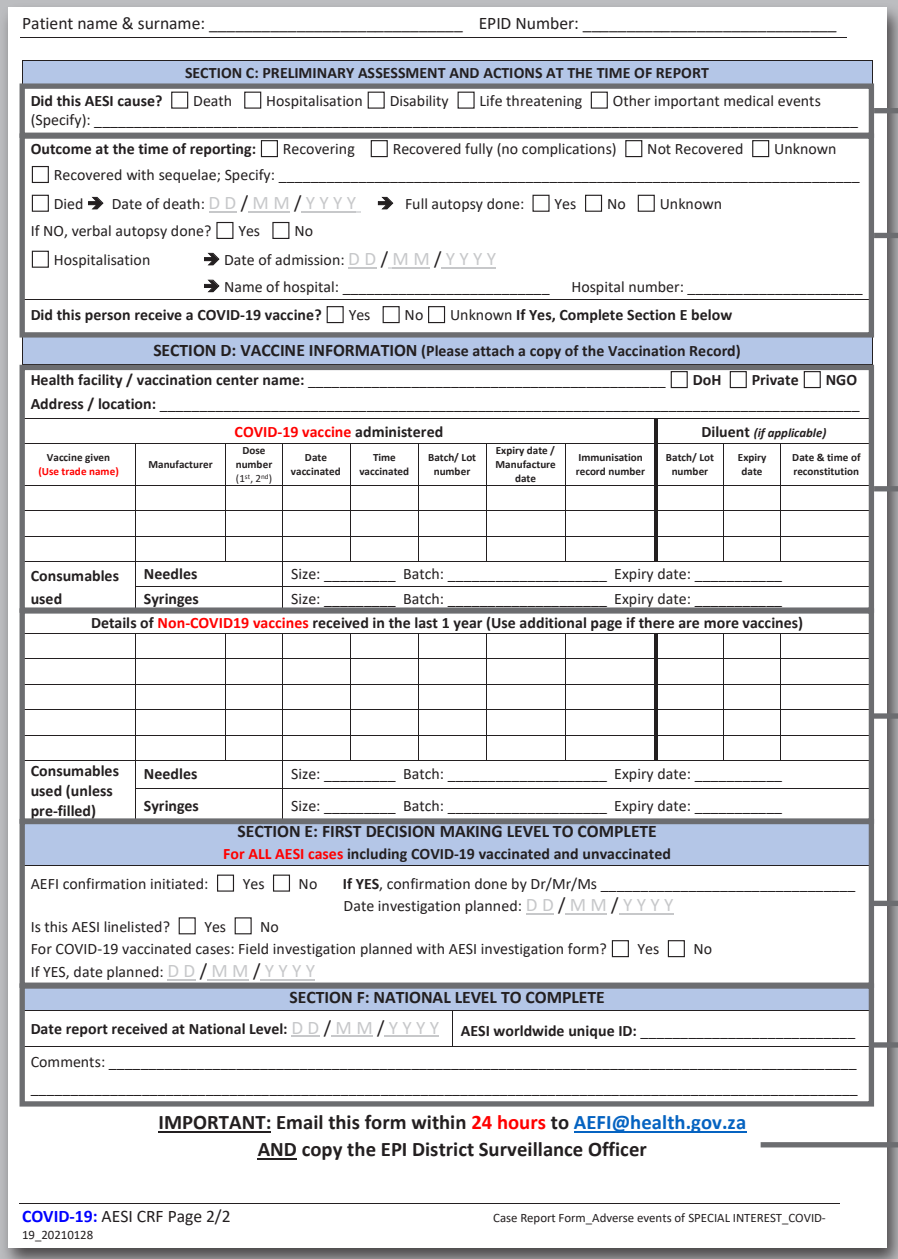
Tick type of adverse event (e.g. Anaphylaxis)

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: D D / M M / Y Y Y Y ➔ Full autopsy done: ☐ Yes ☐ No ☐ Unknown

If NO, verbal autopsy done? ☐ Yes ☐ No

☐ Hospitalisation ➔ Date of admission: D D / M M / Y Y Y Y

➔ 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 (1st, 2nd)	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)

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: D D / M M / Y Y Y Y

Is this AESI linelisted? ☐ Yes ☐ No

For COVID-19 vaccinated cases: Field investigation planned with AESI investigation form? ☐ Yes ☐ No

If YES, date planned: D D / M M / Y Y Y Y

SECTION F: NATIONAL LEVEL TO COMPLETE

Date report received at National Level: D D / M M / Y Y Y Y **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

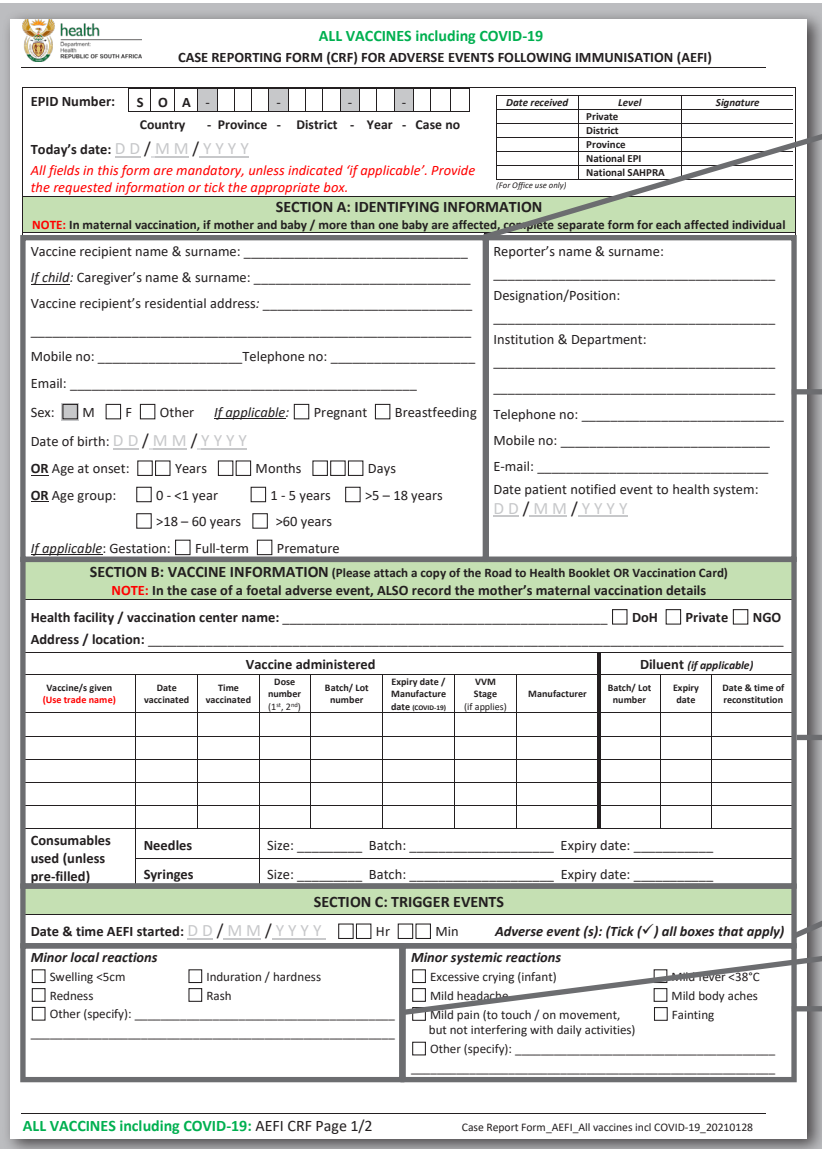
This section is for the first decision-making level to complete (Facility/sub-district/district level).

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).



health
Department: 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

Date received	Level	Signature
	Private	
	District	
	Province	
	National EPI	
	National SAHPRA	

(For Office use only)

Today's date: D D / M M / Y Y Y Y

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: D D / M M / Y Y Y Y

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: D D / M M / Y Y Y Y

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 (1st, 2nd)	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: D D / M M / Y Y Y Y ☐☐ Hr ☐☐ Min *Adverse event (s): (Tick (✓) all boxes that apply)*

Minor local reactions

☐ Swelling <5cm ☐ Induration / hardness
☐ Redness ☐ Rash
☐ Other (specify): _____

Minor systemic reactions

☐ Excessive crying (infant) ☐ Mild fever <38°C
☐ Mild headache ☐ Mild body aches
☐ Mild pain (to touch / on movement, but not interfering with daily activities) ☐ Fainting
☐ 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.

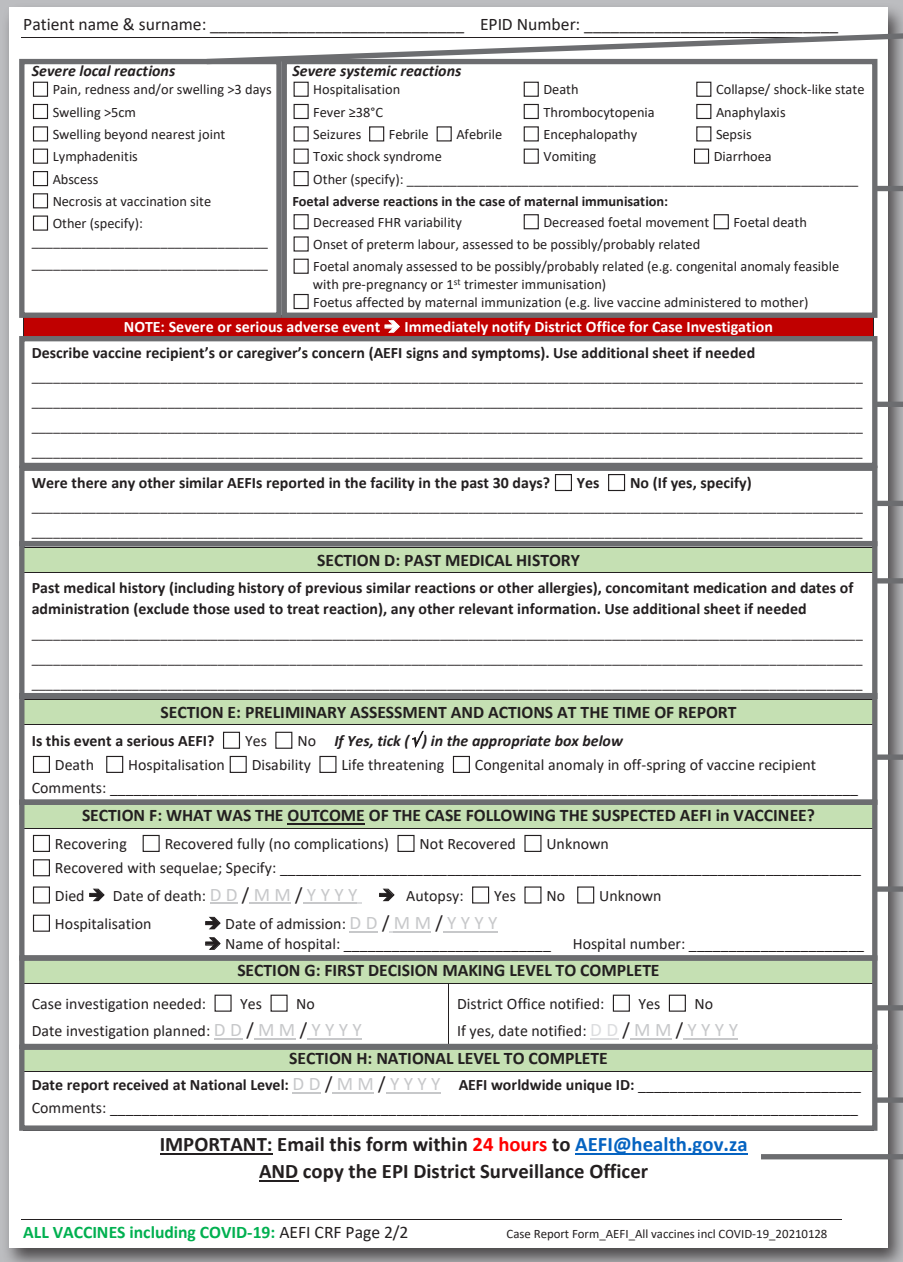
Tick appropriate box if minor local reaction (local means involving the injection site).

Tick appropriate box if minor systemic reactions.

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 AEFI form page 2



Patient name & surname: _____ EPID Number: _____

Severe local reactions

- ☐ Pain, redness and/or swelling >3 days
- ☐ Swelling >5cm
- ☐ Swelling beyond nearest joint
- ☐ Lymphadenitis
- ☐ Abscess
- ☐ Necrosis at vaccination site
- ☐ Other (specify): _____

Severe systemic reactions

- ☐ Hospitalisation ☐ Death ☐ Collapse/ shock-like state
- ☐ Fever ≥38°C ☐ Thrombocytopenia ☐ Anaphylaxis
- ☐ Seizures ☐ Febrile ☐ Afebrile ☐ Encephalopathy ☐ Sepsis
- ☐ Toxic shock syndrome ☐ Vomiting ☐ Diarrhoea
- ☐ Other (specify): _____

Foetal adverse reactions in the case of maternal immunisation:

- ☐ Decreased FHR variability ☐ Decreased foetal movement ☐ Foetal death
- ☐ Onset of preterm labour, assessed to be possibly/probably related
- ☐ Foetal anomaly assessed to be possibly/probably related (e.g. congenital anomaly feasible with pre-pregnancy or 1st trimester immunisation)
- ☐ Foetus affected by maternal immunization (e.g. live vaccine administered to mother)

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: D D / M M / Y Y Y Y → Autopsy: ☐ Yes ☐ No ☐ Unknown

☐ Hospitalisation → Date of admission: D D / M M / Y Y Y Y

→ Name of hospital: _____ Hospital number: _____

SECTION G: FIRST DECISION MAKING LEVEL TO COMPLETE

Case investigation needed: ☐ Yes ☐ No

Date investigation planned: D D / M M / Y Y Y Y

District Office notified: ☐ Yes ☐ No

If yes, date notified: D D / M M / Y Y Y Y

SECTION H: NATIONAL LEVEL TO COMPLETE

Date report received at National Level: D D / M M / Y Y Y Y **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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References

- 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.
- Aphapharmacists. Vaccine Administration Techniques. https://www.youtube.com/watch?v=-STH2nfCIk8. [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=Y3CQ0kMIbII. [Accessed 19 April 2021].

Western Cape Government
Health

PACK
Practical Approach to Care Kit

Practical Approach to Care Kit: Vaccine