



# A practical approach to storing, handling, preparing and giving the Ad26.COVS COVID-19 vaccine

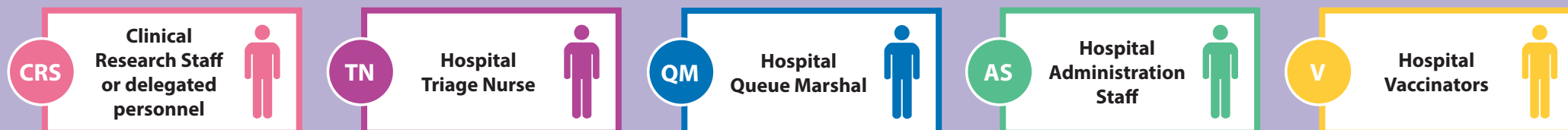


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## Indicators of who is responsible for what activity



# How to store and handle the COVID-19 vaccine

CRS

Store and prepare according to the Investigational Product Preparation and Administration Instructions (IPPI)/Instruction for use related to Clinical Study VAC31518COV3012.

## STEP 1: Storage upon receipt of vaccine

- **Ensure strict security measures are in place:** be aware additional security measures may be needed for the COVID-19 vaccine vials. Every vial will be accounted for.
  - Armed response vehicles to accompany transport carriers.
  - Store in freezer/refrigerator with lock, in an access controlled room. Only authorised individuals will be given access. Cameras, alarms, security guards will be arranged locally.

### Store in a freezer:

- Store the vaccine in a freezer at range of -15°C to -25°C for an uninterrupted period of up to 1 year.
- Record on Drug Accountability Logs.

### Store in a refrigerator:

- Store in a refrigerator at 2-8°C for up to **28 days**.
- Record the cold storage start date and time on label on carton box.
  - This is the date/time that carton box was removed from frozen conditions and put into the refrigerator.
  - Use **date/month/year** and **hours: minutes** format.
- Store in refrigerator with reliable continuous temperature monitoring device.
- Ensure cold chain is maintained at all times:
  - Check and record temperature storage  $\geq 2$  times a day.
  - Ensure a working back-up power supply is connected to the refrigerator/freezer in case of load shedding/power outages.
- Place entire carton box in refrigerator – avoid storing single vials on their own.

### DO NOT:

- Refreeze.
- Stack other supplies on top of thawing vaccine vials.
- Let vials touch each other.
- Let vials touch sides of refrigerator (metal).
- Remove vial caps.
- Wipe down vial with alcohol until vaccine is fully thawed.
- Store at room temperature.

## STEP 2: Thaw vial/s before injecting

- Allow a carton of 20 frozen vials to **thaw overnight** in refrigerator at 2-8°C.
- **Allow vaccine to acclimatise before preparing. To do this:**
  - Remove vaccine vial from carton box in refrigerator and check expiry.
  - Record on Drug Accountability Logs.
  - Leave vaccine vial at room temperature for 15-30 minutes to acclimatise: record acclimatisation start time.
  - After 15-30 minutes, check that no ice is in vial: record acclimatisation end time.
- Vaccine vial (unpunctured) is stable for a total of 12 hours at 9-25°C. Not recommended for shipping or storage.
- During vaccination process: after the first puncture, the vaccine (vial or filled syringe) can be held:
  - In the **refrigerator** at 2-8°C for up to **6 hours**.
  - At **room temperature** (8-25°C) for up to **2 hours**.

### DO NOT:

- Refreeze.
- Try to speed up thawing process by holding vial in hand or using heat source.

### AVOID:

- Exposure to direct sunlight.
- Shaking.

# How to prepare and draw up the COVID-19 vaccine

CRS

- If possible, use a designated preparation area that is not near water, sink, heating vents, fans, air conditioners or other equipment that causes air currents or where contaminated items are placed. Prepare and administer at room temperature. Avoid exposure to direct sunlight. Use aseptic technique.

## STEP 3: Inspect vaccine

- Check that it is the Ad26.COVS.2 COVID-19 vaccine and confirm the high dose vial has a red flip-off cap.
- Confirm concentration:  $2 \times 10^{11}$  VP/mL. It can reference VAC31518COV3001 or VAC31518COV3012.
- Check the appearance:
  - Check the colour: liquid should be colourless – slightly yellowish.
  - Check the clarity: liquid should be clear to slightly opalescent (this means slightly shiny) and free of visible/solid particles.
  - Check that vial has no cracks, abnormalities or evidence of tampering.

## STEP 4: Prepare vaccine

- Mix contents: gently swirl vial in an upright position for 10 seconds. **Do not shake!**
- Remove red, flip-off cap.
- Withdraw 0.25mL from the vaccine vial using a new sterile 1mL syringe and an appropriate needle (22-26G).
  - 1 1/2" and 1" needle lengths are provided. Prepare vaccine using needles in a ratio of 60:40 or at the proportion required at the vaccination sites.
- Check final volume is correct and no air is in syringe. Record date and time of first vial puncture and record volume withdrawn.
- Recap needle used for preparation. **Do not change needle between withdrawing from vial and injecting.**
- Stick label on syringe which at a minimum notes batch number, date of preparation and time of expiry.
- Complete accountability and preparation worksheet.
  - Record expiry date and time of prepared syringe:
    - This will be 2 hours after first puncture of vial if filled syringe is to be stored at room temperature.
    - This will be 6 hours after first puncture of vial if filled syringe is to be stored in a refrigerator at 2-8°C.
- Hand over the filled syringes to the vaccinator and complete chain of custody form. Ensure both temperature and security measures are maintained.



### Prepare materials needed to draw up 2 doses of Ad26.COVS.2 vaccine per vial:

- Ad26.COVS.2 vaccine vial ( $2 \times 10^{11}$  VP/mL – 0.5mL suspension): red flip-off cap
- 2x 1mL syringes
- 2x needles: allowed needles 22-26G x 1-2"
- 2x dispensing labels

**Note: a maximum of 2 doses can be withdrawn from the multidose vial. DO NOT attempt to withdraw any residual volume from the vial after withdrawing 2 doses.**

## STEP 5: Storage after first puncture

**Store in refrigerator for up to 6 hours**  
After the first puncture, the vaccine (vial or filled syringe) can be held in a refrigerator at 2-8°C for up to 6 hours.

**Keep at room temperature (maximally 25°C) for up to 2 hours**  
After the first puncture, the vaccine (vial or filled syringe) can be held at room temperature (8-25°C) for up to 2 hours.

## STEP 6: Disposal

- Do not discard used vials and material remaining in a vial after preparation. Follow sponsor directive. Mark vial as used with black marker pen.

# The vaccine client pathway

TN

- Ensure triage staff and queue marshals wear surgical mask and keep 1-2m distance from clients.
- Ensure queuing clients keep 1-2m apart from each other and wear masks.
- Have 70% alcohol-based hand sanitiser available for all clients entering vaccination area.
- Ensure triage station has a supply of surgical masks to give to symptomatic clients.

### Screen vaccine clients:

- Do temperature and weight and record: if temperature  $\geq 38^{\circ}\text{C}$ , give client a surgical mask to wear and refer to local health provider/clinic to further assess and manage.
- 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

QM

No to all

Does client have vaccination voucher code?

Yes

No

TN

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.

AS

Refer client to expedited registration station.

Refer client to registration station.

Assist client to self register on EVDS and complete consent process to obtain a voucher.

Client obtains voucher.

Unable to obtain voucher.

- Check eConsent voucher.
- Capture ID and details. If client < 18 years old, refer for assistance (not eligible).
- Confirm if client is registered:

Client registered

Client **not** registered

Refer client to vaccination waiting area.  
Ensure clients sit 1-2m apart.

Refer for assistance.

# Pre-vaccination health check

V

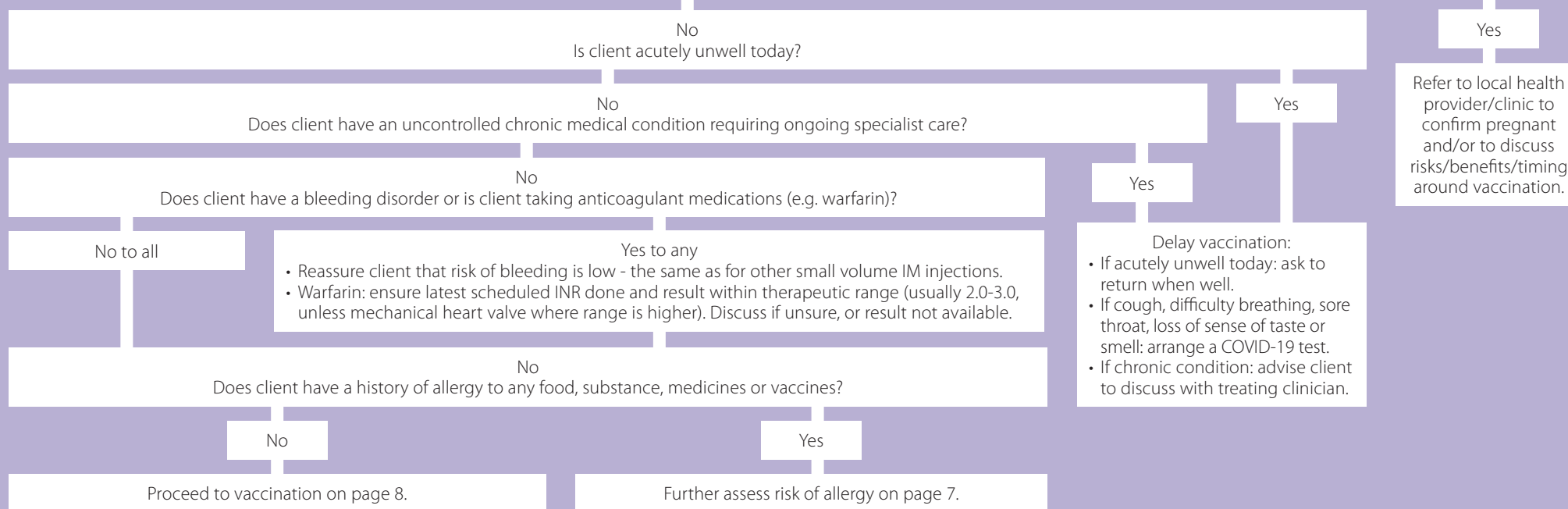
- Wear appropriate personal protective wear (PPE): surgical mask. Clean hands between each client. Gloves are not compulsory for vaccinating.
- Client will be screened for COVID-19 symptoms and will have weight and temperature done upon entering the facility. If temperature  $\geq 38^{\circ}\text{C}$ , client will be referred back to local health provider.

## Work through steps on the Electronic Vaccine Data System (EVDS) or the COVID-19 vaccination form

- Confirm identity.
- Complete informed consent process and questions with the client on EVDS/vaccination form:
  - If client does not give consent: document this on EVDS/vaccination form and end the visit.
  - If client gives consent: document on the EVDS/vaccination form and decide whether to proceed with vaccination today:

## Decide whether to proceed with vaccination today

- Ask client if s/he is currently taking part in any other research studies. If yes, discuss with clinical research team member before continuing.
- Is client known or suspected to be pregnant?



# Further assess risk of allergy before giving the COVID-19 vaccine

**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.

Proceed with vaccination on page 8.

Yes

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

No

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

Proceed with vaccination today but observe for symptoms for **30 minutes** see page 8.

Yes

Doctor to assess risk:

- Is client known with allergy to any ingredients in COVID-19 vaccines (Ad26.COVID.2.S vaccine ingredients<sup>1</sup>)?
- Ask specifically about agents most commonly responsible for allergic reactions: polyethylene glycol (PEG 2000) or polysorbate 80.

No

Yes or client not sure

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

V

<sup>1</sup>Sodium chloride, citric acid monohydrate buffer, polysorbate 80, 2 hydroxypropyl-β-cyclodextrin (HBCD), ethanol (absolute), sodium hydroxide, water for injection.

# How to give the COVID-19 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.

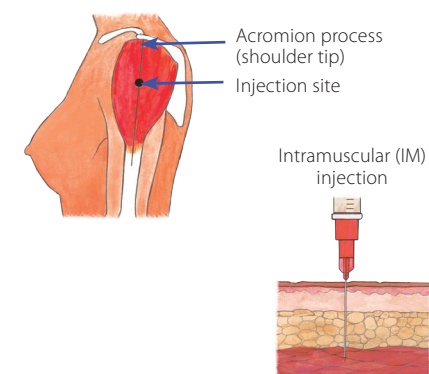
V

## Prepare

1. Receive prepared syringes and needles.
2. Do not replace this needle. Select syringe with appropriate needle size for each client according to the client's weight:
  - If < 90kg: use syringe with 22-26G x 1" needle.
  - If ≥ 90kg: use syringe with 22-26G x 1 ½" needle.
3. Check prepared syringe is within expiry date/time and its appearance is correct (colourless-yellowish with no solid particles). Avoid shaking.
4. Check that syringe has the correct volume (0.25mL).

## Give the vaccine

- Stand sideways-on to client for infection prevention and better control.
- Expose client's arm completely from shoulder to elbow.
- Locate injection site (non-dominant arm deltoid muscle): 3-5cm (about 2 fingers) below acromion process (bony tip of shoulder).
- If client has a rash, bruise, tattoo, redness, swelling, or other medical condition (e.g. amputation) involving intended site, use other arm. Record.
- Clean with cotton wool and water. Avoid alcohol swab.
- Give vaccine as intramuscular (IM) injection:
  - 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.
  - Insert needle at 90° angle to skin into thickest part of the muscle. Insert far enough to ensure delivery into muscle.
  - Do not aspirate. Depress plunger and inject vaccine slowly. Ensure full dose given.
  - Pull needle out quickly and smoothly.
  - Apply gentle pressure with sterile gauze. If bleeding tendency or on anticoagulants, apply prolonged pressure to site after injection.
  - Avoid rubbing injection site.



## Dispose of needle and check injection site

- Dispose of needle and syringe safely in medical sharps container.
- If any visible blood at injection site, have client apply pressure to site with piece of gauze/cotton wool.
- Dispose of all blood-stained gauze or cotton wool in medical waste.

**Continue to complete record and observe client post vaccination on page 9.**



V

**Record**

- Ask client to stay seated for a few minutes to avoid risk of injury from fainting while the following steps are completed:
  - Clean hands and record injection site/location, time of injection, full dose given and register vaccination, including vaccine batch number on EVDS/Vaccination form.
  - Advise the client post-vaccination and check understanding before discharging. See page 10.

**Observe post vaccination**



- Observe client for at least 15 minutes after vaccination. If client known with severe allergies: observe for longer (30 minutes) Record end of observation time.
- Be aware of symptoms needing attention: feeling faint, collapse or other signs of anaphylaxis: itchiness or rash, swelling of face, lips, tongue, difficulty breathing, wheezing, stridor, abdominal pain, nausea, vomiting, see page 11.

Generalised itch/rash or face/  
tongue swelling

Difficulty  
breathing

Dizziness/collapse  
or BP < 90/60

Abdominal pain  
or vomiting

Does client develop any adverse signs or symptoms?

No

Client may leave with vaccination and alert card.

Yes

Give urgent attention and manage on page 11.

V

### Advise the client who has just been vaccinated with the COVID-19 vaccine

- Protection against COVID-19 usually starts at least 2 weeks after receiving the vaccine, as it takes this time to train the immune system to fight COVID-19.
- Reassure the client that they cannot catch COVID-19 from the vaccine as there is no live coronavirus in it. But it is still possible to get COVID-19 as no vaccine is 100% effective.
- Even though the vaccine decreases the chance of getting COVID-19, it is not yet clear whether it prevents spread to others. This study is one of many to help understand this.
- Advise about possible side effects, the need for ongoing COVID prevention measures, what to do if s/he develops COVID-19 symptoms and when to seek help from the Safety Desk:

#### Educate about possible side effects:

- Common side effects include pain or redness at the injection site, headache, fever or chills, joint or muscle aches, fatigue, feeling unwell and nausea.
- These side effects show that your immune system is preparing to fight COVID-19. Many people get these side effects, but some do not.
- If they occur, side effects start 1-2 days after vaccination and should resolve within 3 days.
- If you need to, you can take paracetamol for pain and feeling feverish.
- The vaccine only very rarely causes more serious side effects, usually severe allergy, which occurs immediately after vaccination.



#### Discuss the possibility of getting COVID-19

- It might be that the client caught COVID-19 before being vaccinated (it can take up to 14 days before symptoms start).
- It might be that the client catches it within the first few weeks after being vaccinated while the immune system is still being trained up to fight COVID-19.
- If any of the following develop, consider COVID-19 and arrange a test: new continuous cough, sore throat, a change in smell or taste or a fever that lasts more than 2 days.
- Advise client to contact their healthcare worker, COVID-19 hotline or Safety Desk.



#### Advise ongoing measures to avoid catching coronavirus and prevent it from spreading, especially if you are over 55 years, or have a chronic condition or impaired immunity<sup>1</sup>:

- 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.
- As a healthcare provider, continue to wear standard PPE at work.



#### Ask the client to contact the Safety Desk if any of the following occur:

- They are concerned about side effects from the vaccine.
- They test positive for COVID-19.
- They are admitted to hospital for any reason.
- They become pregnant within 3 months of receiving the vaccine.
- They need a COVID-19 antibody test.
- They participate in another study.

Ask the client if s/he has any further questions and answer them. If unsure, contact the Safety Desk.

Safety Desk  
0800 014 956  
or visit  
[www.sisonke.samrc.ac.za](http://www.sisonke.samrc.ac.za)

COVID-19  
Public Hotline  
0800 029 999

<sup>1</sup>HIV, cancer or receiving chemotherapy, long-term corticosteroids or immunosuppressant therapy.

# Assess and manage immediate symptoms following vaccination



- With vaccination, fainting occurs commonly, severe allergy or anaphylaxis very rarely. If client feels faint: immediately lie client flat or sit client with his/her head between knees for several minutes.
- Be on the look out for the following and assess the client to distinguish a fainting episode from anaphylaxis:

## Collapse

- Lie client down and raise legs.
- Assess timing of collapse and duration of loss of consciousness.
- Check breathing, pulse and BP.

## Anaphylaxis symptoms other than collapse:

- Generalised itch or rash
- Swelling of face, lips, tongue
- Difficulty breathing, wheezing, stridor
- Abdominal pain, nausea, vomiting

- Collapse occurred suddenly, at the time of injection (before, during or immediately after).
- Loss of consciousness usually lasts 20 seconds to 1 minute and 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.

- 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.

## Fainting episode likely

- Management:**
- Observe until symptoms resolve.
  - Loosen any tight clothing.
  - Apply cool cloth to face/neck.

If 2 or more of: 1) Generalised itch/rash or face/tongue swelling 2) Difficulty breathing 3) BP < 90/60 or dizziness/collapse 4) Abdominal pain or vomiting, **anaphylaxis** likely

## Manage and refer urgently:

Use local anaphylaxis management protocols if available.

- 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.
  - Give sodium chloride 0.9% 1-2L IV rapidly regardless of BP. Then, if BP < 90/60, give further sodium chloride 0.9% 500mL IV rapidly, repeat until systolic BP > 90. Stop if breathing worsens.
  - Give 100% face mask oxygen, if available.
  - 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/slow IV and hydrocortisone 200mg IM/slow IV.
- Refer for test/s (tryptase sampling) to confirm vaccine-related anaphylaxis.

Report as Adverse Events Following Immunisation (AEFI) and replenish emergency kit

- Once client stable or referred, complete NDoH Case Reporting Form (CRF) for Adverse Events Following Immunisation (AEFI) or if anaphylaxis, Adverse Event of Special Interest (AESI) form, and report to sub-district or district office and provincial EPI manager within 24 hours. Also report to the safety desk call centre: 0800 014 956.
- Replace all medications/equipment used and seal emergency kit.

# If client contacts health worker within 1 week of 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).**

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

Yes

No

Check client's temperature.

< 38°C

≥ 38°C

**Vaccine-related fever is unlikely to cause severe illness.**

**Check for symptoms of other underlying causes needing urgent attention and referral.**

- Decreased consciousness
- Respiratory rate ≥ 30 or difficulty breathing
- BP < 90/60
- Neck stiffness, drowsy/confused or purple/red rash, **meningitis** likely
- Tender in right lower abdomen, **appendicitis** likely
- Severe abdominal/back pain
- Jaundice
- Easy bleeding or bruising

If none of above: how many days since client received the COVID-19 vaccine?

2 days or less

More than 2 days

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

No

Yes

If temperature > 40.5°C, cool the client down<sup>1</sup>.

**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.

**COVID-19 infection** is 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

COVID-19 negative

- Health worker or client to contact Safety Desk 0800 014 956.
- Manage using APC or PACK COVID-19.

Assess cause of symptoms further with APC or PACK Adult.

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.
  - Report as an Adverse Event Following Immunisation (AEFI).
  - Discuss/refer if any of:
    - Severe pain
    - Blisters
    - Enlarging redness (≥ 5cm)
    - Red swelling with fluctuant centre, **abscess** likely

If other symptoms: assess cause further with APC or PACK Adult.

<sup>1</sup>Cool the client down: give paracetamol 1g orally. Remove clothing. Use fan and water spray to cool client. Apply ice-packs to axillae, groin and neck. Stop once temperature < 39°C.