

Guidance supporting the administration of mRNA-CV vaccine

Summary for storage of vaccine

Comirnaty (Pfizer [mRNA]) COVID-19

VACCINE LONG TERM STORAGE IN FREEZER

Undiluted vaccine stored for up to **31 days** at **2°C to 8°C** (includes distribution time)
Box containing vials has expiry printed on outer sticker. This is 31 days from when removed from freezer storage. Monitor temperature as per cold chain policy, if temperature varies from 2°C to 8°C, follow cold chain breach process.

Additional **2 hours** allowed to prepare vaccine for dilution. Purpose is to bring vial to **room temperature** (up to max 30°C) **before** adding diluent i.e., not cold to touch.

Once diluent added to vial, now have 6 hours for administration. This 6 hours is to be spent between **2°C to 30°C**.

DISCARD ANY UNUSED VACCINE 6 HOURS AFTER DILUTION

Stable for up to 31 days at 2°C to 8°C

Once removed from freezer, timer starts

Up to 2 hours

Once removed from fridge, timer starts

Up to 6 hours

Once diluent added, timer starts

The allowance of 2 hours between +8°C to +30°C is cumulative:

When vaccines are out of the refrigerator for an hour and not mixed, return to the refrigerator labelled with “1 hour out of fridge”. These have a **maximum of one hour** left for warming and reconstitution - **position to be used first**.

Allow vials 20 -30 min to warm to room temp. **If they are no longer cold to touch, they are ready to use.**

All vaccine movement times must be clearly logged:

- Time vaccines were **taken out** of the refrigerator.
- Time any **vaccines are returned** to the refrigerator PLUS calculate/record how long they were out.

Diluted vaccines can be stored at room temp or in fridge BUT need to warm before administered.

Actions when cold chain issues arise:

- **Clearly label the vaccines ‘not for use’.**
 - If the refrigerator is currently within the +2°C to +8°C, **leave the quarantined vaccines in the refrigerator.**
 - If the refrigerator is NOT within the +2°C to +8°C range, look for obvious reversible causes (door open, power interruption, ice build-up). If no cause found, pack labelled vaccines into a chilly bin, with a temperature monitoring device and prepare to transport to the back-up provider (details are in your cold chain policy).
- **In the Annual Cold Chain Management Record (Cold Chain History Section) record the cause of the error, temperature range, length of breach, advice received and actions taken..**

Contact your IMAC COVID Immunisation Advisor for advice and further actions. They are available 8.30-5pm weekdays.

NORTHERN:

Lisa.Box@auckland.ac.nz 027 241 6073

MIDLAND:

Olivia.Haslam@auckland.ac.nz 027 275 0090

CENTRAL:

Melanie.Miller@auckland.ac.nz 027 209 9849

SOUTHERN:

Sue.Rogers@auckland.ac.nz 027 213 8570

For guidance from 5pm -8pm and 8am -8pm at weekends call **0800 IMMUNE/466 863** for the on-call advisor.



Preparing mRNA-CV multi-dose vial

- For detailed instructions for mRNA-CV multi-dose vial preparation and administration see the most current IMAC COVID-19 education factsheet, 'Instructions for multi-dose vial Pfizer/BioNTech vaccine: preparation and administration' available from the IMAC COVID-19 Education website.
- To follow international guidance around the use of low dead space needles, the needle used to draw up mRNA-CV is also used to administer the injection. Unless you plan to administer the vaccine dose immediately, carefully replace the needle guard and place syringe onto a ridged tray for storage. Note that this differs from the recommendations for other multi-dose vial vaccines described in the Immunisation Handbook (IHB) Section A7.2.
- Staff administering pre-drawn-up vaccines and the public need to have confidence in the reconstitution and drawing up process, therefore a second person (checker) is required to confirm the correct process was followed.
- Those preparing and checking vaccines must be recorded at every site.**

Number of doses per vial

- With LDS needles you get 6 doses per vial, sometimes 7.
- With non-LDS needles you get 5 doses per vial, sometimes 6.
- If drawing up several doses with longer needles, you may not get the expected number of doses per vial.
- If you are getting more or less doses than expected, a dilution error may have occurred. Discard all doses from affected vial and report.

Requirements for extremes of body size

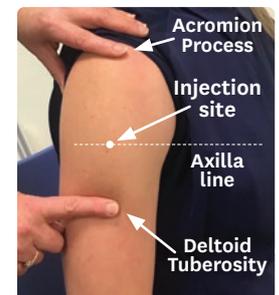
Adapting needle type, vaccine preparation and injection techniques.

- For **extremely thin individuals**, you can use the usual needle, you may need to bunch the skin a little to ensure you enter the muscle. If the skin is bunched avoid injecting too shallow i.e., subcutaneously.
- People with a **large upper arm**:
 - Estimate the depth from skin surface to the deltoid to decide whether 25mm would be deep enough to reach the deltoid muscle. Putting pressure onto each side of the injection site by pulling the skin taut may reduce the depth of adipose tissue enough for normal needle.
 - If a longer needle is required**, draw up vaccine dose from the vial using a **38mm long needle**. Ideally **gauge of 23 or 25G, but if not available, use 21 or 22G** [as listed in the IHB for very large or obese persons].
 - The vaccine must be drawn up using the 38mm needle**, so the needle contains vaccine. If needles are swapped the dose administered will be too small due to the volume of vaccine left in the needle.

- Each vaccinator requires **easy access to vaccine drawn up with longer length needle** to avoid having to go and draw one up, resulting in delays and stress for the consumer.
- Towards the end of the day** if the vaccine has not been needed, draw the plunger back to pull vaccine from the needle into the syringe, **swap to a standard 25G 25mm needle**, expel any spare vaccine back to 0.3mls and then give in the normal way. This will prevent wasted vaccine.
- Those preparing the vaccine for others to administer must follow this procedure **to ensure a ready supply of syringes with longer needles are available at all times.**

Guidance on vaccine administration

- Administer intramuscularly at 90-degree angle to the skin plane.
- As per instructions for anatomical landmarking of deltoid given in the IHB: "The vaccine recipient should be **seated with their arm removed** from the garment sleeve and hanging relaxed at their side.



The vaccinator places **their index finger on the vaccine recipient's acromion process** (the highest point on the shoulder) and their **thumb on the vaccine recipient's deltoid tuberosity** (the lower deltoid attachment point). The injection site is at the axilla line, between these anatomical landmarks. The vaccine should be **deposited at the bulkiest part of the muscle.**"

This method avoids the subacromial bursa, the axillary nerve and the humeral artery located in the midpoint. See Figure 2.7 in chapter 2 of IHB for details of surface landmark structures

- Needle enters at 90°, inject the vaccine smoothly, **pause before needle withdrawal to prevent tracking of vaccine**. Stabilize the muscle, **avoid bunching which increases risk of inadvertent subcutaneous injection**.
- The standard needle size is 25 G x 25mm.
- Plasters are not used regularly but should be available if needed.
- Complete the CIR to include the information provided on the vaccine dose label:
 - The batch number, consisting of two parts; the full batch and the sub batch, eg. 'EP216-012'. 'EP216' is the full batch and '012' is the sub-batch.
 - Vaccine expiry is the expiry date printed on the box, not the vial. This is 31 days from when HCL removed the vials from the freezer.
 - Details of injection site and date and time of vaccination event.

CALL 0800 IMMUNE (466 863) FOR ANY CLINICAL ADVICE