COVID-19 VACCINATION PROGRAM

SAFE ✓ EFFECTIVE ✓ FREE ✓

Pfizer Vaccine in General Practice

An overview and lessons learned from state-led clinics

Dr Shannon Melody (Specialist Medical Advisor - Tasmanian Vaccination Emergency Operations Centre (TVEOC))

Nikki Lane (Clinical Nurse Consultant) TVEOC

Mel Monk (Clinical Nurse Consultant) TVEOC

KEEP ON TOP OF COVID

Tasmanian Government

Overview

- General overview of Pfizer
- Pfizer eligibility and medical indications
- Mixed brand schedules
- Adverse event profile for Pfizer
- 'Tips and tricks' - practical lessons from the TVEOC
- Questions

General overview of the Pfizer (Comirnaty) COVID-19 Vaccine

- Comirnaty (BNT162b2)
- Sponsor: Pfizer
- Provisionally approved by the TGA for people aged ≥16 years
- mRNA vaccine
- 0.3 mL (30 ug) per dose
- Two-dose schedule, at least 21 days apart
- Efficacy against symptomatic COVID-19 is about 95% after two doses (ATAGI)
- Administration route – intramuscular injection into deltoid muscle
- It is mandatory to report all COVID-19 vaccines to the Australian Immunisation Register (AIR)

Pfizer (Comirnaty) Vaccine Schedule

- 2 doses at least 21 days apart are recommended
- Minimum acceptable interval between the two doses is 19 days
- Recommended to complete the two dose course within 6 weeks
- Scenarios:
  - Vaccine given earlier than minimum recommended interval
  - May result in a sub optimal immune response. Third dose not currently recommended.
  - Vaccine given later than recommended interval (>42 days)
  - Give second dose as soon as possible. No further doses are required
- Special circumstances: Longer intervals between first and second doses may need to be recommended during program rollout if epidemiological considerations warrant a change

Co-administration with other vaccines

- Not routinely recommended
- Minimum 7 day interval between a COVID-19 vaccine and any other vaccine
- Interval can be shortened in special circumstances (increased risk of COVID-19 or another vaccine-preventable disease or logistical issues such as difficult scheduling visits to maintain the 7 day interval)
- If co-administration of flu and COVID-19 vaccine occurs – no need to revaccinate

Eligibility for Pfizer vaccine

- If otherwise eligible for a COVID-19 vaccine under the phased roll-out, and:
  - 16 to 59 years of age
  - Or any age over 16 with:
    - A history of cerebral venous sinus thrombosis (CVST)
    - A history of heparin-induced thrombocytopaenia (HIT)
    - A history of idiopathic splanchnic (mesenteric, portal and splenic) venous thrombosis (Have you ever had any blood clots in your abdomen, spleen or liver?)
    - A history of antiphospholipid syndrome with thrombosis
    - A severe adverse event attributed to the vaccine

Eligibility for Pfizer vaccine

- What about pregnancy?
  - RANZCOG-ATAGI recommend that pregnant women are routinely offered Pfizer mRNA vaccine (Cominarty) at any stage of pregnancy. This is because the risk of severe outcomes from COVID-19 is significantly higher for pregnant women and their unborn baby.
- What about past SARS-CoV-2 infection?
  - Individuals who have had **confirmed SARS-CoV-2 infection** may wish to defer vaccination for up to 6 months from the time of their infection. This is because they should still have antibodies from their natural infection.

Mixed brand schedules

- Comirnaty and COVID-19 vaccine AstraZeneca are **not considered interchangeable**
- The two-dose course should be completed with the same vaccine
- No ***clinical*** data yet on efficacy of mixed schedules
- Selected circumstances where a mixed schedule may be considered:
  - Anaphylaxis post-dose 1
  - Thrombosis with thrombocytopaenia syndrome (TTS) post dose 1
  - HIT or CVST (heparin-induced thrombocytopaenia, cerebral venous sinus thrombosis) post dose 1
  - Pregnancy or breastfeeding
  - Other serious events attribute to the first dose of COVID-19 vaccine?*
- What is the current pathway in Tasmania for consideration of mixed dose schedules?

Anaphylaxis after COVID-19 Vaccines

- Absolute contraindications to **Pfizer vaccine** include:
  - Anaphylaxis after a Pfizer vaccine
  - Anaphylaxis to any component of the vaccine (e.g. *polyethylene glycol (PEG))

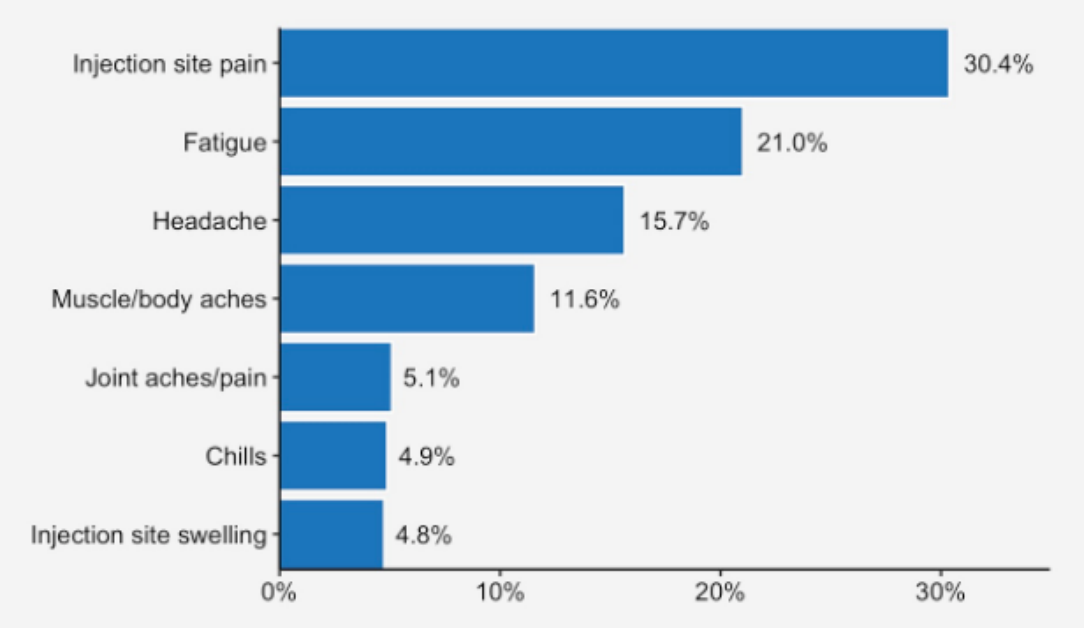
  *different forms of PEG are found in a number of products including various medications (including pegylated medications e.g. PEG-interferon alpha (Pegintron), PEG-filgrastim (Neulasta) PEG 3350 laxative (Miralax)) and some colonoscopy preparation products.
- Anaphylaxis remains rare but is more common following Pfizer than AstraZeneca
- Approx. 4.5 per 100, 000 (Pfizer) vs. 3.0 per 100, 000 (AstraZeneca)

Adverse event profile for Pfizer

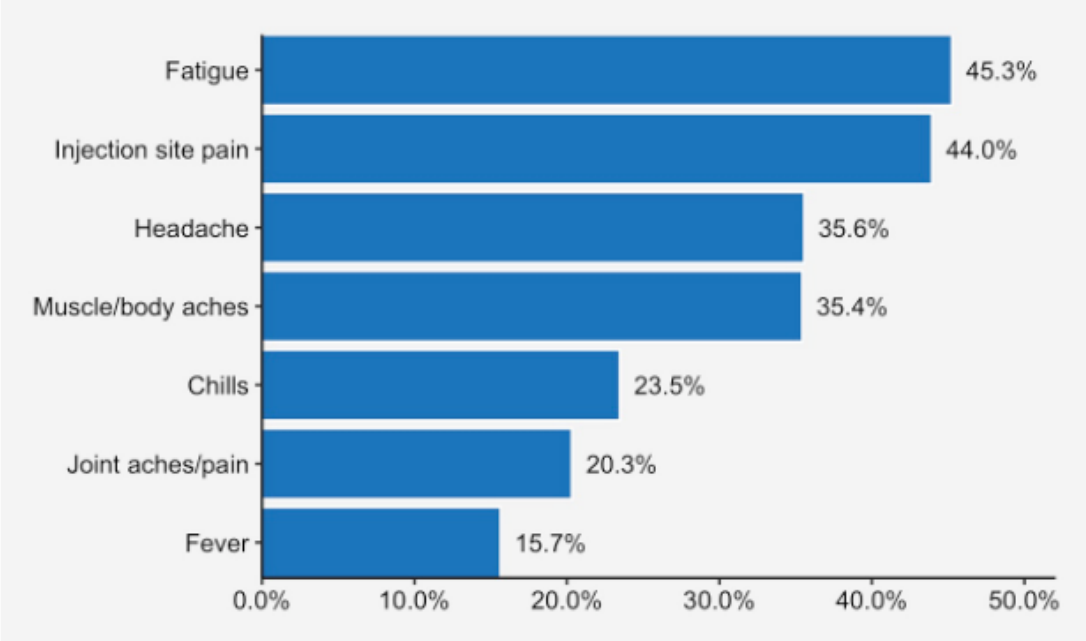
- Side effect profile: Dose 2 >> Dose 1
- Active surveillance efforts (AusVaxSafety):
  - Following dose 1:
    - 37.7% reported any adverse event
    - 6.5% reported missing word, study or routine duties for a short period (<1 day for most)
    - 0.6% reported seeing a doctor or ED in the days after vaccination
  - Following dose 2:
    - 58.1% reported any adverse event
    - 22.3%reported missing word, study or routine duties for a short period (<1 day for most)
    - 1.6% reported seeing a doctor or ED in the days after vaccination
  - For more information: COVID-19 vaccines | AusVaxSafety
  - What about myocarditis and pericarditis?
  - The TGA continues to monitor reports of myocarditis (inflammation of the heart) and pericarditis (inflammation of the membrane around the heart) following a safety concern in the US and Israel.

Adverse event profile for Pfizer

Dose 1 profile



Dose 2 profile



Transporting, Storing and Handling Pfizer Vaccine

- Information based on the Australian Technical Advisory Group on Immunisation (ATAGI) and Pfizer (Comirnaty Product Information) advice and Commonwealth COVID-19 Vaccination Course
- Shelf life is 6 months at -90°C to -60°C
- After thawing, shelf life is 31 days at 2°C to 8°C
- Undiluted vaccine vials can be stored at up to 30°C for 2 hours*
- *ATAGI recommends that pre-drawn doses kept at room temperature be used within an hour to minimise any remote risk of infection
- After dilution, vials must be kept at 2°C to 8°C and used within 6 hours from time of dilution
- Undiluted vaccine can remain in the fridge at 2°C to 8°C until expiry date
- During storage, minimise exposure to room light, and avoid exposure to direct sunlight and ultraviolet light (store in opaque containers)
- Refer to the National Vaccine Storage Guidelines Strive for 5

Pfizer (Comirnaty) vaccine

- Vials during their defrosting process
- Vials should arrive labelled with the expiry date (once thawed) on them. Must be used within 31 days of thawing

Pfizer (Comirnaty) Vial Presentation

- Multi-dose vial – contains 0.45 ml of undiluted vaccine
- Must be reconstituted with 1.8 ml of sterile 0.9% sodium chloride
- Once reconstituted – total volume is 2.25ml
- This will give 6 x 0.3ml doses
- It is possible to have more liquid in the vial and in some cases, you may get 7 doses from the vial
- **Do not** shake the vial – must always gently invert
- If the amount of vaccine remaining in the vial cannot provide a full dose of 0.3ml, discard the vial and any excess volume
- **Do not draw up from multiple vials to make a 0.3ml dose**

Table 1: Method for dose extraction

Step	Standard methods: 1. Method for single or multiple dose extraction in a setting where doses are infrequently administered (i.e. to a single patient at a time) (e.g. low volume general practice clinics)**	Standard methods: 2. Method for multiple dose extraction in dedicated immunisation clinics where doses are administered one after another (e.g. dedicated clinics being run in general practice) **	Acceptable alternative method: 3. Alternative method for dose extraction in a dedicated mass immunisation clinic where doses are administered one after another *Preferred method for Pfizer hubs only.*
	ATAGI prefers this method whenever one or more doses will be extracted from a vial, and the remaining contents of the vial will be stored. Use an aseptic technique throughout this procedure.	This method is only appropriate where multiple doses from a vial are to be drawn up in immediate succession for administration within a single vaccination session. Use an aseptic technique throughout this procedure. Vials should never be stored with a drawing up needle attached.	This is an acceptable alternative method where the same needle is used to draw up and administer a vaccine dose. Use an aseptic technique throughout this procedure. There are some potential disadvantages to this method. This includes increased risk of coring (compared with Method 2) and potential greater frequency of injection site reactions.
A	Attach a sterile drawing up needle to a sterile syringe, and insert the needle through the bung into the vial.	Attach a sterile drawing up needle to a sterile syringe, and insert the needle through the bung into the vial.	Attach a sterile injection needle of appropriate gauge and length for the vaccine recipient* to a sterile syringe, and insert the needle through the bung into the vial.
B	Draw up the required volume for a single dose. Do not touch the shaft of the needle and avoid moving the needle in and out of the vial.	Draw up the required volume for a single dose. Do not touch the shaft of the needle and avoid moving the needle in and out of the vial.	Draw up the required volume for a single dose. Do not touch the shaft of the needle and avoid moving the needle in and out of the vial.
C	Remove the filled syringe with the drawing up needle attached. Do not leave the drawing up needle in the vial. Avoid touching the top of the vial.	Remove the filled syringe from the drawing up needle, leaving the drawing up needle in the bung.	Remove the filled syringe with the needle attached. Avoid touching the top of the vial.
D	Detach the filled syringe and attach a new sterile injection needle*.	Attach a new sterile injection needle* to the filled syringe, ready for administration to the patient. Without delay or distraction, attach a new sterile syringe to the drawing up needle to draw up each dose. Attach a new sterile injection needle to each filled syringe.	If doses are not going to be administered immediately, the needle must be resheathed (using safe aseptic technique). Repeat the procedure for all required doses.
E	Administer the dose as soon as possible after drawing up.	The prepared dose can be administered immediately or must be used as soon as practical for the next recipient. Doses drawn up into a syringe must ideally be used within 1h if kept at room temperature, or 6h if stored at 2-8°C. Until ready to be administered, store any prepared syringes at the appropriate temperature as per product information. This includes storing in a suitably sized, clean container which is protected from light. Label the container clearly with the date and time doses were drawn, the name of the person who prepared the doses, vaccine name, vial batch number, vial identifier (if available) and expiry time of drawn doses. Discard any filled syringe where there is suspicion that contamination or a sterility breach has occurred. Any unused doses that have been withdrawn into a syringe must be discarded after 6 hours, even if stored at 2-8°C, due to potential infection control concerns.	The prepared dose can be administered immediately or must be used as soon as practical for the next recipient. Doses drawn up into a syringe must ideally be used within 1h if kept at room temperature, or 6h if stored at 2-8°C. Until ready to be administered, store any prepared syringes at the appropriate temperature as per product information. This includes storing in a suitably sized, clean container which is protected from light. Label the container clearly with the date and time doses were drawn, the name of the person who prepared the doses, vaccine name, vial batch number, vial identifier (if available) and expiry time of drawn doses. Discard any filled syringe where there is suspicion that contamination or a sterility breach has occurred. Any unused doses that have been withdrawn into a syringe must be discarded after 6 hours, even if stored at 2-8°C, due to potential infection control concerns.

*For guidance on the appropriate needle gauge and length, refer to the Australian Immunisation Handbook. ** **Methods 1 and 2** are preferred as they reduce the **risk of local reactions** by **avoiding vaccine on the exterior of the needle**. The potential for minor under dosing using these methods is not of **concern** as the patient will still receive most of the dose.

There are three methods for dose extraction

Standard methods		Acceptable alternative method
1. Method for single or multiple dose extraction in a setting where doses are infrequently administered (i.e. to a single patient at a time) (e.g. low volume general practice clinics)**	**2. Method for multiple dose extraction in dedicated immunisation clinics where doses are administered one after another** (e.g. dedicated clinics being run in general practice) **	**3. Alternative method for dose extraction in a dedicated mass immunisation clinic where doses are administered one after another** ***Preferred method for Pfizer hubs only.***
ATAGI prefers this method whenever one or more doses will be extracted from a vial, and the remaining contents of the vial will be stored. Use an aseptic technique throughout this procedure.	This method is only appropriate where multiple doses from a vial are to be drawn up in immediate succession for administration within a single vaccination session. Use an aseptic technique throughout this procedure. Vials should never be stored with a drawing up needle attached.	This is an acceptable alternative method where the same needle is used to draw up and administer a vaccine dose. Use an aseptic technique throughout this procedure. There are some potential disadvantages to this method. This includes increased risk of coring (compared with Method 2) and potential greater frequency of injection site reactions.

Method used in Tasmanian State-run clinics

Australian Technical Advisory Group on Immunisation (ATAGI)

Clinical guidance on use of COVID-19 vaccine in Australia in 2021 (v5.1)

Version 5.1
17 June 2021

This clinical guidance is for COVID-19 immunisation providers and program staff and is based on currently available data. It provides recommendations on the use of the Comirnaty (Pfizer) COVID-19 vaccine and COVID-19 Vaccine AstraZeneca. It will be updated as new information and vaccines become available.

Recent changes from previous versions of ATAGI Clinical guidance on COVID-19 vaccines in Australia include:

- *Updated vaccine recommendations: Comirnaty preferred over COVID-19 Vaccine AstraZeneca for people aged < 60 years*

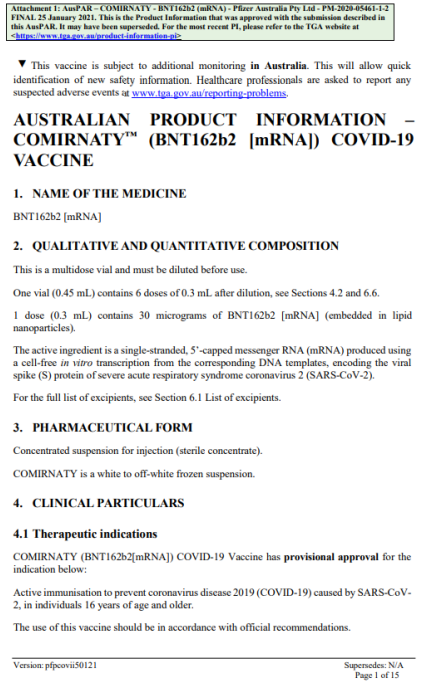
Australian Technical Advisory Group on Immunisation (ATAGI)

Guidance on the use of multi-dose vials for COVID-19 vaccination

Version 1.0
4 May 2021

Resources

- ATAGI Guidance on the use of multi-dose vials for COVID-19 vaccination
- ATAGI Clinical guidance on use of COVID-19 vaccine in Australia in 2021
- Australian Product Information Comirnaty COVID-19 vaccine
- COVID-19 Vaccination training program



Attachment 1: AusPAR – COMIRNATY - BNT162b2 (mRNA) - Pfizer Australia Pty Ltd - PM-2020-05461-1-2 FINAL 25 January 2021. This is the Product Information that was approved with the submission described in this AusPAR. It may have been superseded. For the most recent PI, please refer to the TGA website at <https://www.tga.gov.au/product-information-pi>

▼ This vaccine is subject to additional monitoring **in Australia**. This will allow quick identification of new safety information. Healthcare professionals are asked to report any suspected adverse events at www.tga.gov.au/reporting-problems.

AUSTRALIAN PRODUCT INFORMATION – COMIRNATY™ (BNT162b2 [mRNA]) COVID-19 VACCINE

1. NAME OF THE MEDICINE

BNT162b2 [mRNA]

2. QUALITATIVE AND QUANTITATIVE COMPOSITION

This is a multidose vial and must be diluted before use.

One vial (0.45 mL) contains 6 doses of 0.3 mL after dilution, see Sections 4.2 and 6.6.

1 dose (0.3 mL) contains 30 micrograms of BNT162b2 [mRNA] (embedded in lipid nanoparticles).

The active ingredient is a single-stranded, 5'-capped messenger RNA (mRNA) produced using a cell-free *in vitro* transcription from the corresponding DNA templates, encoding the viral spike (S) protein of severe acute respiratory syndrome coronavirus 2 (SARS-CoV-2).

For the full list of excipients, see Section 6.1 List of excipients.

3. PHARMACEUTICAL FORM

Concentrated suspension for injection (sterile concentrate).

COMIRNATY is a white to off-white frozen suspension.

4. CLINICAL PARTICULARS

4.1 Therapeutic indications

COMIRNATY (BNT162b2[mRNA]) COVID-19 Vaccine has **provisional approval** for the indication below:

Active immunisation to prevent coronavirus disease 2019 (COVID-19) caused by SARS-CoV-2, in individuals 16 years of age and older.

The use of this vaccine should be in accordance with official recommendations.

Preparation

- Prepare a clean area to draw up vaccine doses away from **direct patient contact and distraction**
- Obtain 1 multidose vial (MDV) from the vaccine fridge

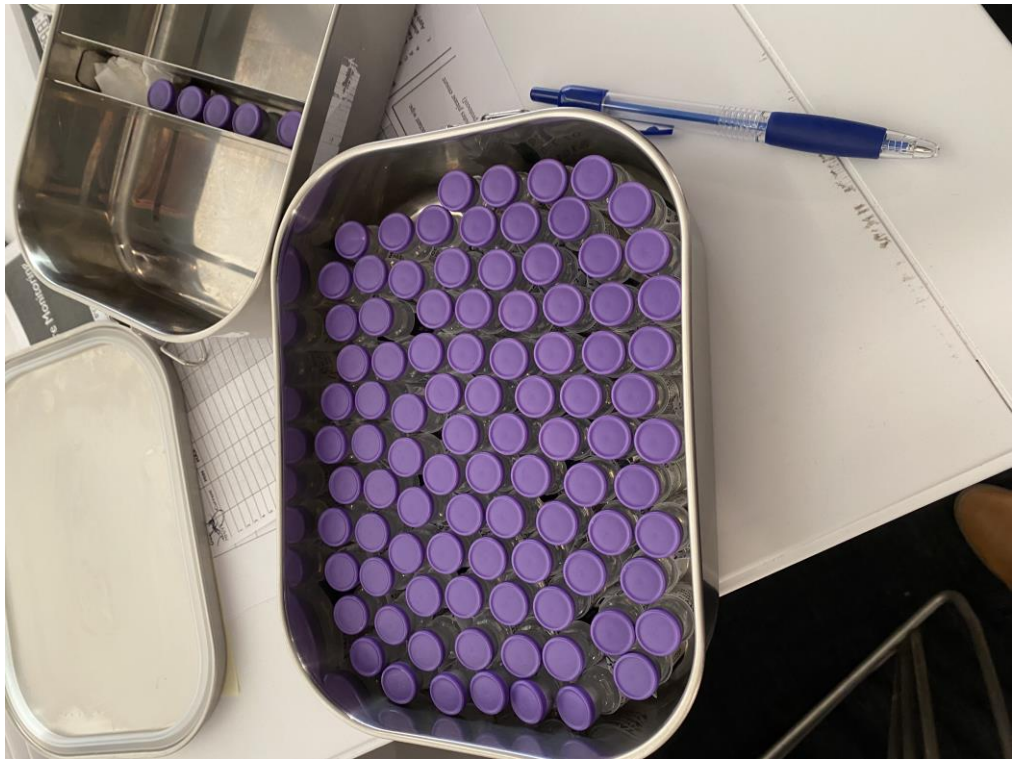
Dose preparation – What do you need?

- Separate sterile single use syringe for each dose - recommendation is to use a 1ml syringe for doses <0.5ml
- The recommended syringe is a low dead-volume syringe
- Sterile bevelled 21-22 gauge drawing up needle
- Separate sterile single use injecting needle 25 gauge for each dose to be given
- Procedure tray of suitable size to hold prepared doses
- 70% isopropyl alcohol wipes
- Suitable sized sharps container

Drawing Up Comirnaty (Pfizer)Vaccine

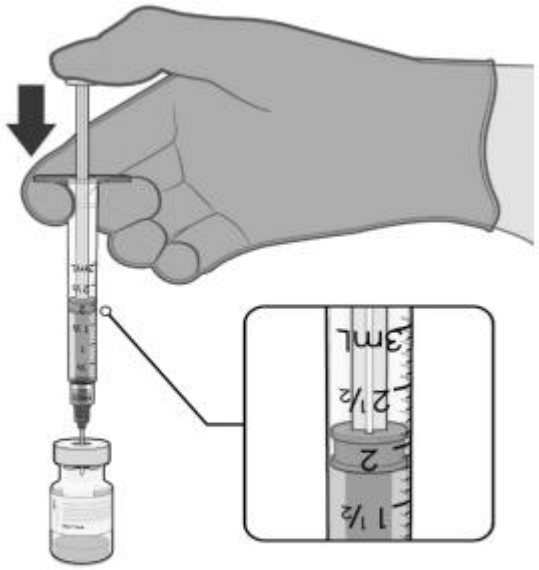
- If drawing up several doses for use – have an opaque container which is protected from light and labelled clearly with:
- Date and time doses drawn
- Name of person preparing doses
- Vaccine name
- Vial batch number
- Expiry time of drawn doses

- Remember: pre-drawn doses in syringes should be used within 1 hour if kept at room temperature and 6 hours if kept at 2-8°C (this is to minimise the risk of infection)



Dilution Step 1:

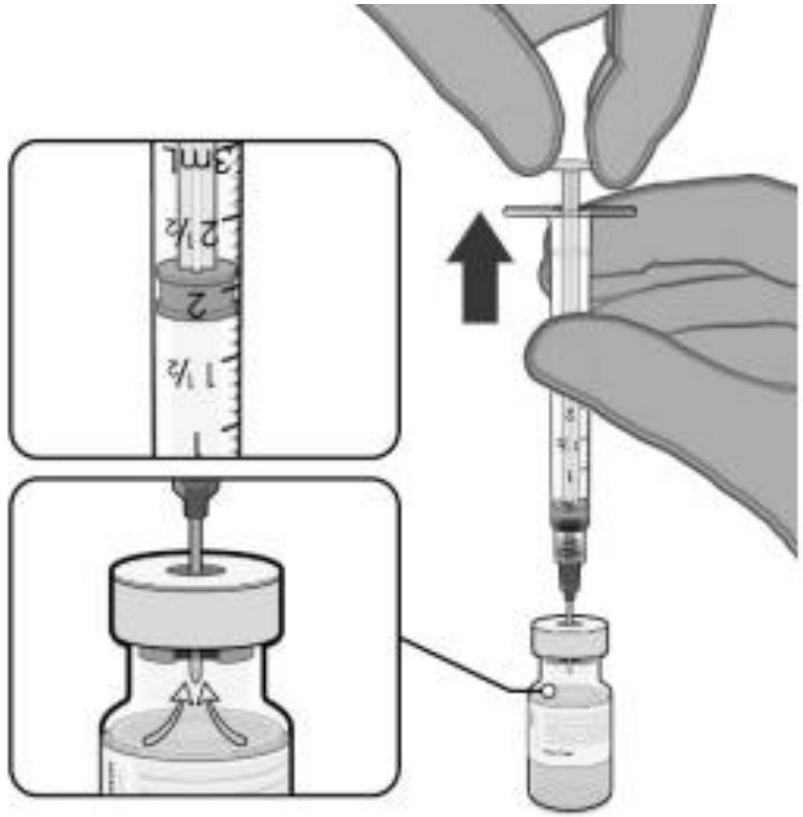
- Remove a vial from the vaccine fridge and disinfect the bung
- Prior to dilution, the thawed suspension may contain white to off white opaque amorphous particles
- Thawed vaccine must be diluted in its original vial with 1.8 ml sodium chloride (0.9%) using a 21 gauge or narrower needle and aseptic techniques



1.8 mL of 0.9% sodium chloride injection

Dilution Step 2:

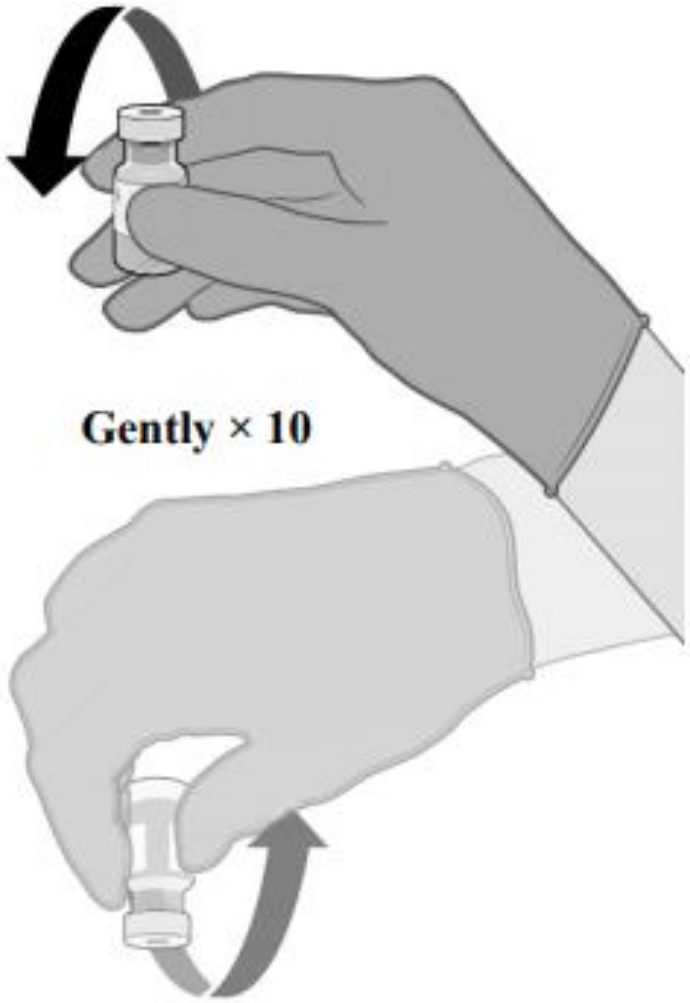
Equalise the vial pressure before removing the needle from the vial by withdrawing 1.8ml air into the empty diluent syringe



Pull back plunger to 1.8 mL to remove air from vial.

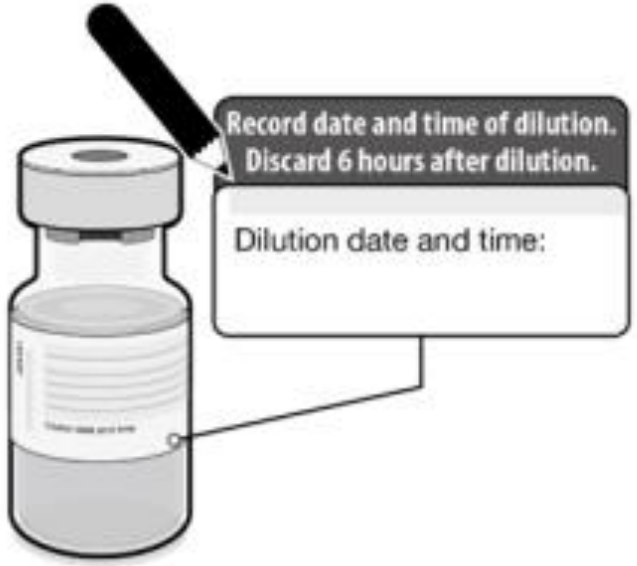
Dilution Step 3:

- Gently invert the diluted suspension 10 times (we have adopted the infinity invert). Do not shake.
- The diluted vaccine should present as an off-white suspension with no particulates visible. Discard the diluted vaccine if particulates or discoloration are present.



Note: In our state run clinics we teach to leave the needle and syringe in the vial. If you do remove the needle and syringe you will need to re swab the bung, wait 30 seconds and attach a 25G needle to a 1ml syringe to draw up the doses

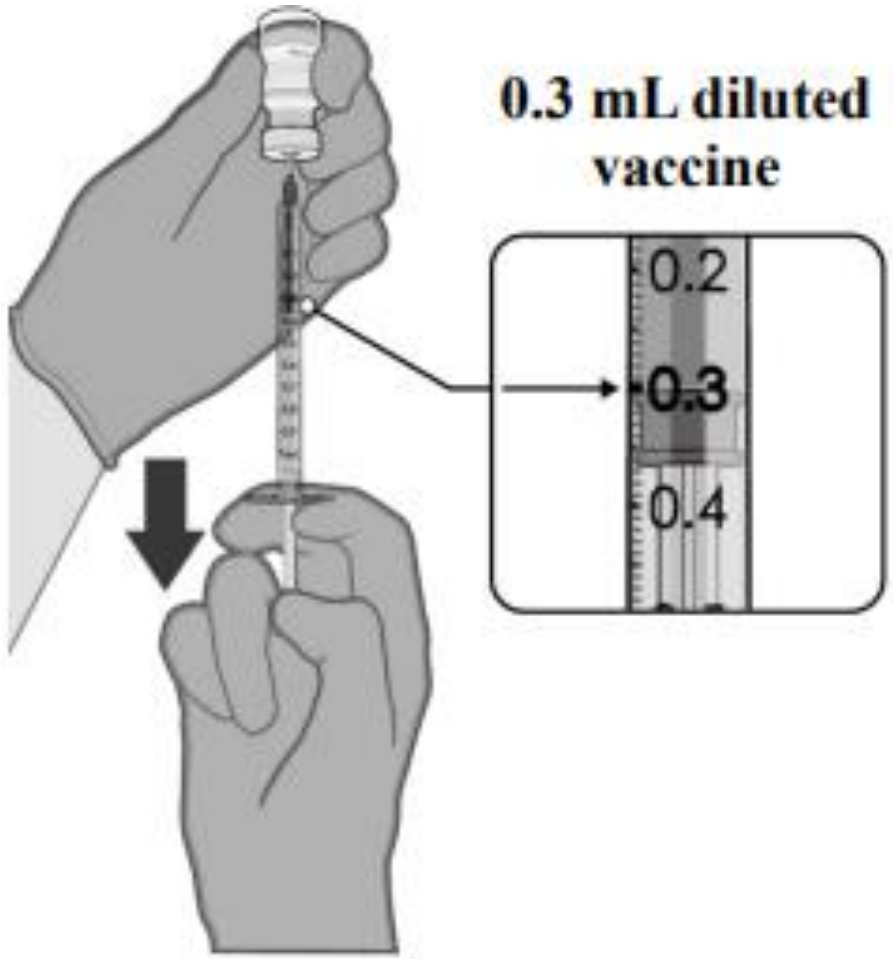
Dilution Step 4:



- Label the diluted vial with the date and time of dilution
- If refrigerated, allow the diluted suspension to come to room temperature prior to use

Preparation of Individual 0.3 ml doses

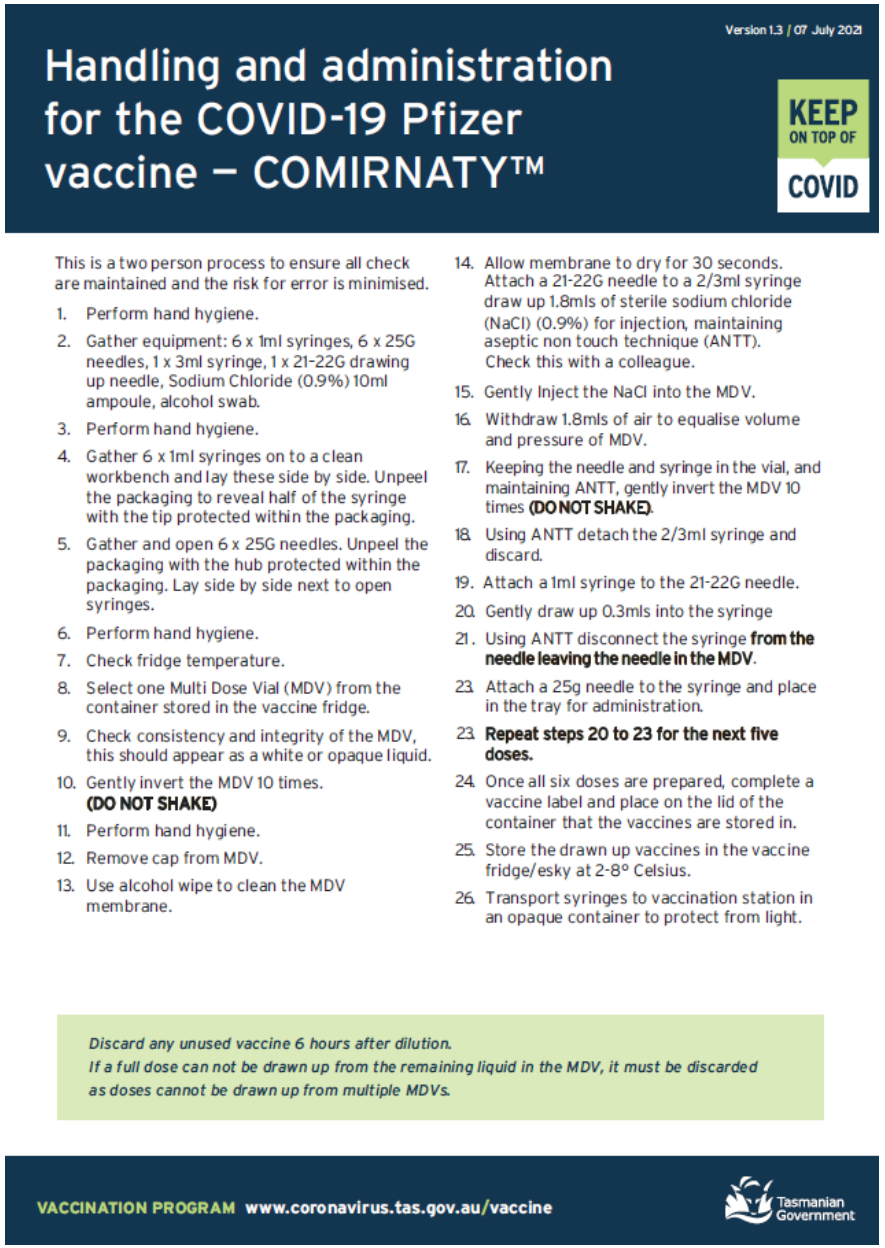
- Remove the 2-3 ml syringe and attach a 1ml syringe
- Withdraw 0.3mls, disconnect and reattach another 1ml syringe. Repeat for the 6 doses



Procedure

TVEOC have developed our own Handling and administration guidelines

Happy to share with you ☺



Version 1.3 / 07 July 2021

Handling and administration for the COVID-19 Pfizer vaccine – COMIRNATY™

KEEP ON TOP OF COVID

This is a two person process to ensure all check are maintained and the risk for error is minimised.

1. Perform hand hygiene.
2. Gather equipment: 6 x 1ml syringes, 6 x 25G needles, 1 x 3ml syringe, 1 x 21-22G drawing up needle, Sodium Chloride (0.9%) 10ml ampoule, alcohol swab.
3. Perform hand hygiene.
4. Gather 6 x 1ml syringes on to a clean workbench and lay these side by side. Unpeel the packaging to reveal half of the syringe with the tip protected within the packaging.
5. Gather and open 6 x 25G needles. Unpeel the packaging with the hub protected within the packaging. Lay side by side next to open syringes.
6. Perform hand hygiene.
7. Check fridge temperature.
8. Select one Multi Dose Vial (MDV) from the container stored in the vaccine fridge.
9. Check consistency and integrity of the MDV, this should appear as a white or opaque liquid.
10. Gently invert the MDV 10 times. **(DO NOT SHAKE)**
11. Perform hand hygiene.
12. Remove cap from MDV.
13. Use alcohol wipe to clean the MDV membrane.
14. Allow membrane to dry for 30 seconds. Attach a 21-22G needle to a 2/3ml syringe draw up 1.8mls of sterile sodium chloride (NaCl) (0.9%) for injection, maintaining aseptic non touch technique (ANTT). Check this with a colleague.
15. Gently Inject the NaCl into the MDV.
16. Withdraw 1.8mls of air to equalise volume and pressure of MDV.
17. Keeping the needle and syringe in the vial, and maintaining ANTT, gently invert the MDV 10 times **(DO NOT SHAKE)**.
18. Using ANTT detach the 2/3ml syringe and discard.
19. Attach a 1ml syringe to the 21-22G needle.
20. Gently draw up 0.3mls into the syringe
21. Using ANTT disconnect the syringe **from the needle leaving the needle in the MDV**.
23. Attach a 25g needle to the syringe and place in the tray for administration.
23. **Repeat steps 20 to 23 for the next five doses.**
24. Once all six doses are prepared, complete a vaccine label and place on the lid of the container that the vaccines are stored in.
25. Store the drawn up vaccines in the vaccine fridge/esky at 2-8° Celsius.
26. Transport syringes to vaccination station in an opaque container to protect from light.

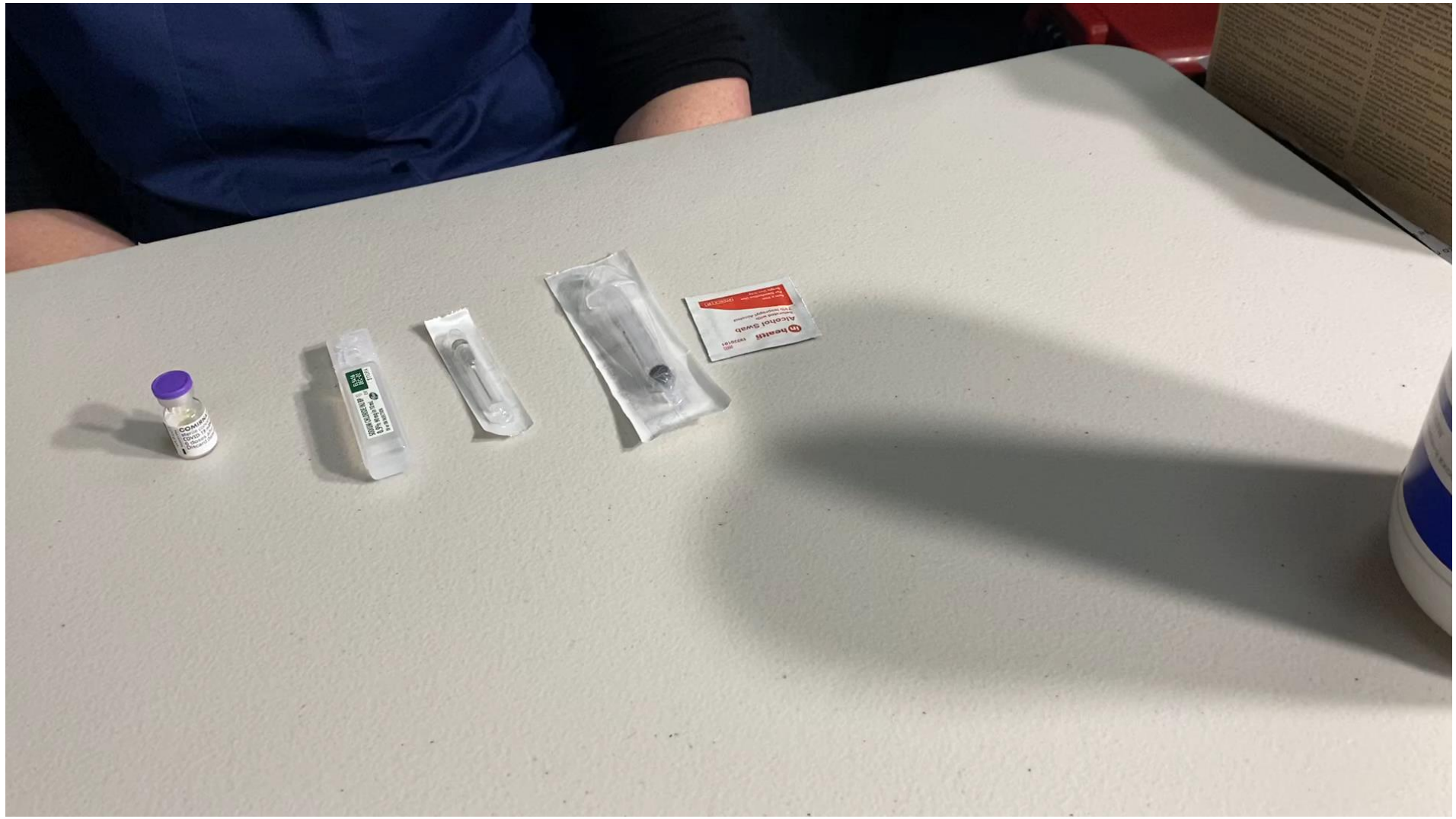
Discard any unused vaccine 6 hours after dilution.
If a full dose can not be drawn up from the remaining liquid in the MDV, it must be discarded as doses cannot be drawn up from multiple MDVs.

VACCINATION PROGRAM www.coronavirus.tas.gov.au/vaccine

Tasmanian Government

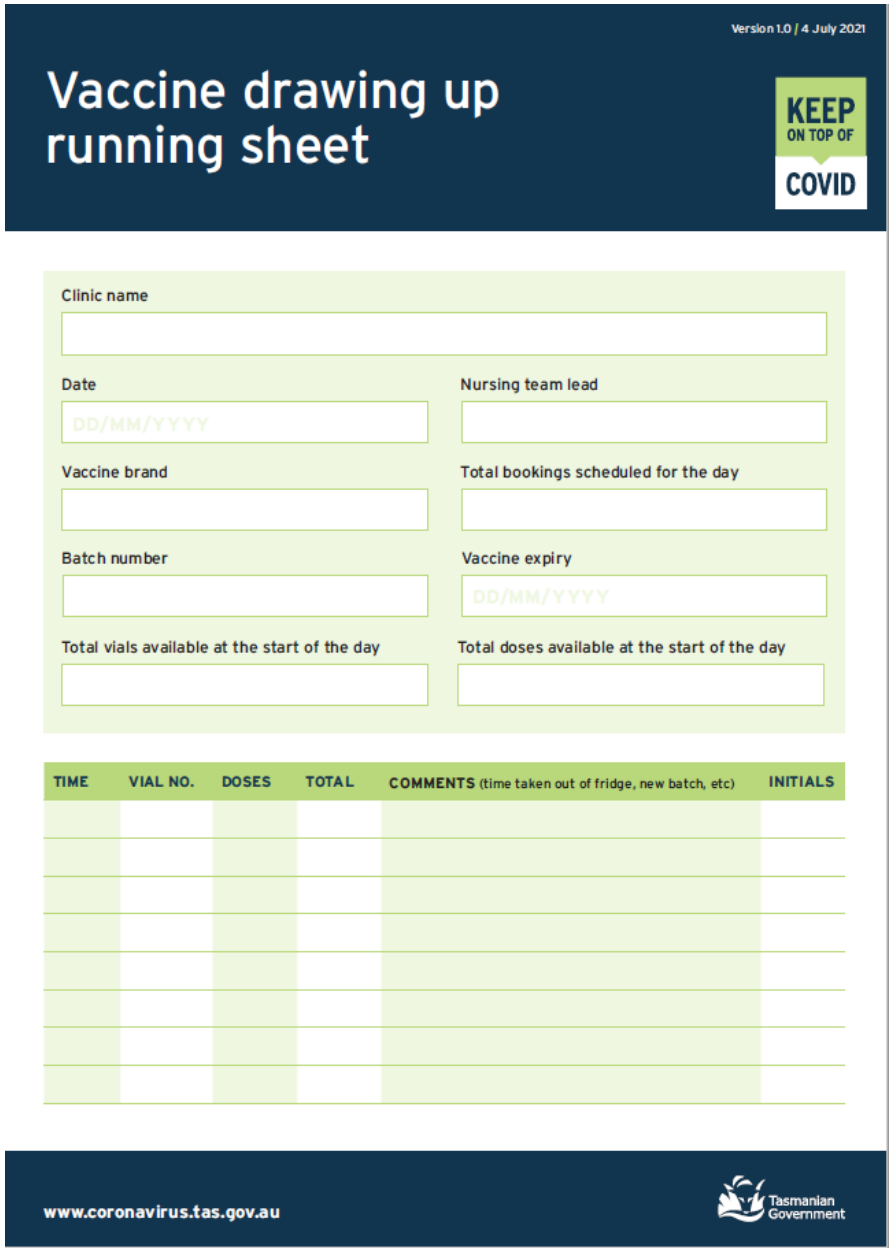
COVID-19 VACCINATION PROGRAM

SAFE ✓ EFFECTIVE ✓ FREE ✓



Drawing up **Pfizer** Demonstration

Stock management and reporting



Version 1.0 / 4 July 2021

Vaccine drawing up running sheet

KEEP ON TOP OF COVID

Clinic name

Date

DD/MM/YYYY

Nursing team lead

Vaccine brand

Total bookings scheduled for the day

Batch number

Vaccine expiry

DD/MM/YYYY

Total vials available at the start of the day

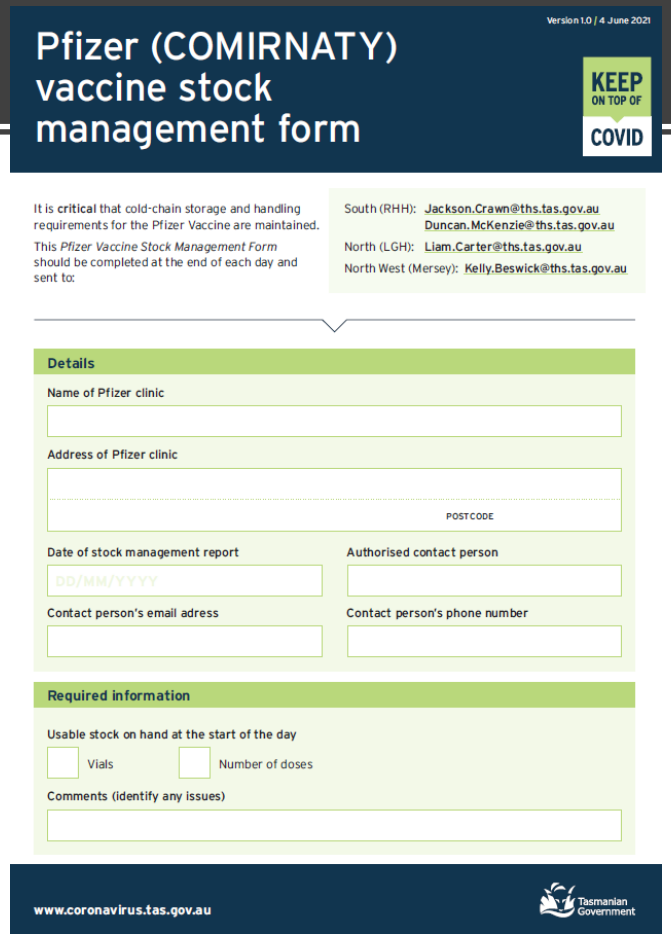
Total doses available at the start of the day

TIME	VIAL NO.	DOSES	TOTAL	COMMENTS (time taken out of fridge, new batch, etc)	INITIALS

www.coronavirus.tas.gov.au

Tasmanian Government

Stock Management Forms



Version 1.0 / 4 June 2021

Pfizer (COMIRNATY) vaccine stock management form

KEEP ON TOP OF COVID

It is **critical** that cold-chain storage and handling requirements for the Pfizer Vaccine are maintained.

This *Pfizer Vaccine Stock Management Form* should be completed at the end of each day and sent to:

South (RHH): Jackson.Crawn@ths.tas.gov.au
Duncan.McKenzie@ths.tas.gov.au
North (LGH): Liam.Carter@ths.tas.gov.au
North West (Mersey): Kelly.Beswick@ths.tas.gov.au

Details

Name of Pfizer clinic

Address of Pfizer clinic

POSTCODE

Date of stock management report

DD/MM/YYYY

Authorised contact person

Contact person's email adress

Contact person's phone number

Required information

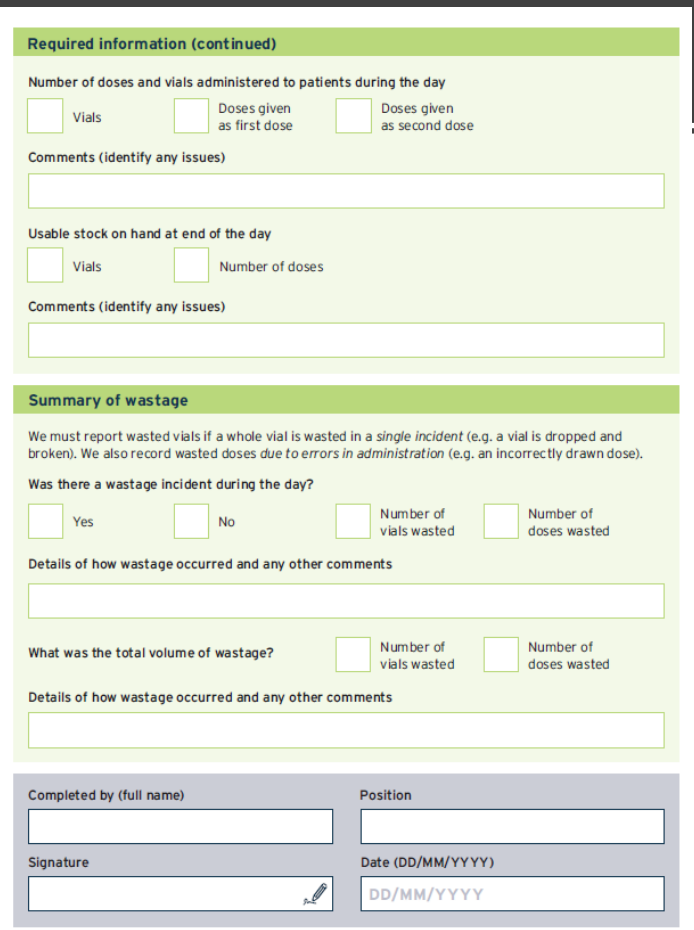
Usable stock on hand at the start of the day

☐ Vials ☐ Number of doses

Comments (identify any issues)

www.coronavirus.tas.gov.au

Tasmanian Government



Required information (continued)

Number of doses and vials administered to patients during the day

☐ Vials ☐ Doses given as first dose ☐ Doses given as second dose

Comments (identify any issues)

Usable stock on hand at end of the day

☐ Vials ☐ Number of doses

Comments (identify any issues)

Summary of wastage

We must report wasted vials if a whole vial is wasted in a *single incident* (e.g. a vial is dropped and broken). We also record wasted doses *due to errors in administration* (e.g. an incorrectly drawn dose).

Was there a wastage incident during the day?

☐ Yes ☐ No ☐ Number of vials wasted ☐ Number of doses wasted

Details of how wastage occurred and any other comments

What was the total volume of wastage?

☐ Number of vials wasted ☐ Number of doses wasted

Details of how wastage occurred and any other comments

Completed by (full name)

Position

Signature

Date (DD/MM/YYYY)

DD/MM/YYYY

COVID-19 VACCINATION PROGRAM

SAFE ✓ EFFECTIVE ✓ FREE ✓

Questions?


Tasmanian
Government