COVID-19 Vaccination Program Procedures

Management of COVID-19 Pfizer (Comirnaty) vaccine from refrigerator to administration

Last updated: 26 August 2021

Responsibility

Staff preparing the refrigerated COVID-19 Pfizer/BioNTech (Comirnaty) vaccine for administration must follow this procedure. When working in pairs, it is the responsibility of both people to continue to follow this procedure and observe all local COVID-19 precautions, including maintaining social distancing where possible.

Overview

The COVID-19 Pfizer/BioNTech (Comirnaty) vaccine must be thawed before use following removal from a frozen storage environment. Refer to 'Management of COVID-19 Pfizer (Comirnaty) vaccine from freezer to refrigerator' for information on this procedure.

Once thawed, the Comirnaty concentrate vaccine vial must not be re-frozen. A thawed concentrate vial can be stored at +2 to +8°C for up to 1 month (31 days).

Each vial tray contains 195 vials. If removing less than the full quantity of vials from the tray within the refrigerator, ensure that the tray remains enclosed with the lid, after removal of the required number of vials. Note each vial provides 5 doses when using standard stock needles and syringes for drawing up and 6 doses if using low dead space syringes and needles – see recommended procedures in appendix 1.

Moving from thawed concentrate vaccine to vaccine for administration

This procedure covers the process from the removal of vials of thawed concentrate vaccine from the vial tray in the refrigerator, dilution of the concentrate vaccine, and drawing up individual doses into a syringe to the point of administration.

This procedure may be adapted to suit one of the following models:

- The vaccine preparer performing dilution under observation by an authorised immuniser. The preparer will then draw up individual doses from the diluted vial into syringes for immediate administration at the point of care; or
- The dilution and drawing up of individual doses into syringes by the authorised immuniser that are independently checked and verified, labelled and subsequently administered to the patients.
- The dilution and drawing up of individual doses into syringes by the preparer that are independently checked and verified, labelled and subsequently supplied to the authorised immuniser. This model requires additional local risk assessment including cold chain management, workflow considerations that consider diluted vaccine stability and mitigation to reduce the risk of needle stick injuries on transfer of prepared syringes between individuals.

Procedure

1. Removal of thawed concentrate vaccines from the refrigerator

1.1. Check the temperature display and ensure that the refrigerator has not deviated from between +2°C and +8°C. If a deviation has been observed, DO NOT USE the multi-dose vial, quarantine the vials, advise your senior executive and contact the State Health Emergency Operations

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Centre (SHEOC) on 9859 5690. Refer to NSW Health policy directive *PD2020_028 Vaccine Storage and Cold Chain Management*.

1.2. Perform hand hygiene with either soap and water or an alcohol-based hand rub (ABHR) before gathering supplies or handling vials.

1.3. Remove only the required number of thawed concentrate vaccine vials from the vial tray in the refrigerator. If there is more than one vial tray, use the vials with the shortest post-thaw expiry. One vial contains sufficient vaccine for five doses when diluted using standard needles and syringes. When low dead space syringes and needles are used, six doses can be drawn up from one vial.

1.4. To reduce waste, the number of vials removed should generally be enough to cover no more than approximately 1 hour of anticipated usage when stored at room temperature **Note: the thawed concentrate COVID-19 Pfizer/BioNTech (Comirnaty) vaccine vials can be stored at room temperature for up to 2 hours prior to use, and for up to 6 hours when diluted.**

1.5. Seal the concentrate vaccine vials that have been removed from the fridge into a zip lock bag.

1.6. Document either by Completing a 'Concentrate Room Temperature Bag Expiry Label' (see Appendix 1B of this procedure) or via an electronic process e.g. iPharmacy. Include:

- Date and time concentrate vaccine vial was removed from the refrigerator (Use 24-hour clock format).
- Date and time of expiry. (i.e. date and time vial must be diluted before or discarded after). The expiry is 2 hours from the point the concentrate vaccine vials are removed from the refrigerator and kept at room temperature.
- Batch number of the concentrate vaccine vials.
- Signature of person completing the label (electronic system is permitted e.g. configured from Username and Password).

1.7. Attach the label to the zip lock bag containing the concentrate vaccine vial. (One per zip lock bag)

1.8. Obtain a check (of the time removed from fridge, calculated expiry and batch number) from a second person. The second person must document this check by signing the label or by electronic means.

1.9. Take the bag to the vaccine preparation station and place it in an empty lidded box labelled 'CONCENTRATE VACCINE VIALS'. Confirm this box is empty before adding the new bag of vials. Close the lid on the box. If using a monitored cold storage bag at +2^{o}C – +8^{o}C, vaccine cold chain management must comply with the *National Vaccine Storage Guidelines Strive for Five* and NSW Health policy directive *PD2020_028 Vaccine Storage and Cold Chain Management*.

2. Workstation preparation

2.1. The workstation must be clean and clear of any other materials or objects, other than what is necessary for the preparation and drawing up of the vaccine. Ensure that there are no previously drawn up vials remaining in the workspace.

2.2. Clean the workstation with a neutral detergent wipe and discard into a general waste bin.

2.3. Perform hand hygiene with either soap and water or an alcohol-based hand rub (ABHR).

2.4. Ensure a yellow sharps container with enough free capacity is available.

2.5. Ensure an indelible black pen is available.

2.6. Put on an apron and any additional PPE including face mask and gloves if required.

2.7. Perform hand hygiene to prepare the COVID-19 Pfizer (Comirnaty) vaccine.

3. Dilution

3.1. Assemble the following materials required to perform dilution:

- Sodium chloride 0.9% injection polyamp X 1 (must be preservative free)
- 3 mL syringe x 1
- 21G to 25G needle x 1
- Single use 70% alcohol swab x 2
- 'Vial Label after Dilution' label x 1 (appendix 1C)

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- Opaque container.

3.2. Remove a single vial of concentrated COVID-19 Pfizer (Comirnaty) vaccine from the zip lock bag within the lidded box labelled 'CONCENTRATE VACCINE VIALS'. Close the lid of the box. If using a monitored cold storage box, check the temperature prior to removing a vial, and ensure that the temperature is within range.

3.3. Inspect the vial to ensure it has thawed and is within expiry with its integrity maintained. Note that a frozen vial should be allowed to thaw in a refrigerator, and this can take up to 3 hours. If removed directly from the freezer, this can take up to 30 minutes at room temperature.

3.4. Allow the vaccine vial to come to room temperature if recently removed from the fridge.

3.5. Prior to dilution, the thawed concentrate suspension may contain white to off-white opaque amorphous particles.

3.6. Slowly and gently invert the vial 10 times to thoroughly mix the concentrate suspension, **DO NOT SHAKE**.

3.7. Remove the protective plastic cap from the top of the vial and inspect the bung to ensure integrity.

3.8. Cleanse the vaccine vial stopper ('scrub the hub' and allow to dry) with a single use 70% alcohol swab and discard the swab into a general waste bin. Set the concentrate vaccine vial to one side.

3.9. Cleanse the top and shoulders of the polyamp of sodium chloride 0.9% injection with a single use 70% alcohol swab and discard the swab into a general waste bin and allow the polyamp to dry.

3.10. Attach a 21G to 25G needle to a 3 mL syringe. A Luer lock syringe is preferred if available.

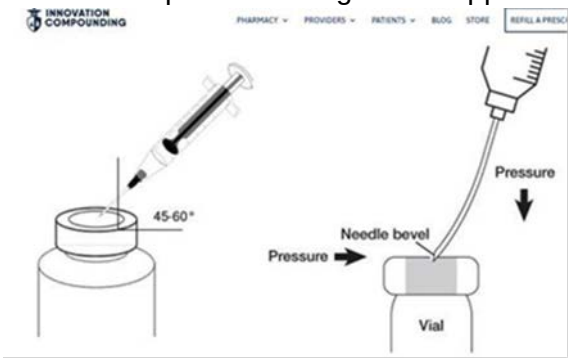
3.11. Using aseptic technique, snap the top off the sodium chloride 0.9% injection polyamp and use the 3 mL syringe and 21G to 25G needle to draw up 1.8 mL of sodium chloride 0.9% injection.

3.12. Check the volume of sodium chloride 0.9% injection drawn up is 1.8 mL.

3.13. The sodium chloride 0.9% injection polyamp is single use. Do not draw up further volumes of diluent from the polyamp. The remainder of the volume must not be used for another vial. The sodium chloride 0.9% injection polyamp should be placed into a tray to be checked with the vaccine vial and syringes after drawing up is completed.

3.14. Dilute the concentrate vaccine vial by adding the 1.8 mL of sodium chloride 0.9% injection to the vial

3.15. The needle should be inserted at a 45–60° angle with the opening of the needle tip facing up (i.e., away from the stopper). A small amount of pressure is applied, and the angle is gradually increased as the needle enters the vial. The needle should be at a 90° angle just as the needle bevel passes through the stopper.



https://innovationcompounding.com/tutorial-coring/

3.16. Slowly inject the 1.8 mL solution towards the inner wall of the vial in a single step. **Do not use any other type of diluent**.

3.17. Equalise vial pressure before removing the needle from the vial stopper by withdrawing 1.8 mL air into the empty diluent syringe, and then remove the needle/syringe from the vial.

3.18. Gently invert the diluted suspension 10 times. **DO NOT SHAKE**.

3.19. After dilution, each vial contains 2.25 mL from which 5 doses of 0.3 mL can be extracted using standard stock needles and syringes or 6 doses if using a low dead space needles and syringes.

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3.20. The diluted vaccine should present as an off-white solution with no particulates visible. If particulates or discolouration appears to be present, verify with a second person and quarantine/retain this vial and notify your pharmacist or team leader. **Do not use this vial for administration**. Remove gloves, if worn and perform hand hygiene.

3.21. Document the date & time of the dilution on the 'Vial expiry label after dilution' label (appendix 1C) write the date and time of dilution and sign. Obtain a check (of time diluted and volume of vial appears consistent with being diluted) from a second person. The second person must document this check by signing the label or by an electronic method as described previously.

3.22. Once the label is complete attach to the prepared diluted vaccine vial. The vial of diluted vaccine is viable for 6 hours from the point of dilution when kept at room temperature, however consideration for microbial contamination should be risk assessed locally if not used immediately.

3.23. The diluted vaccine vial should be protected from light and refrigerated unless it is to be used for drawing up immediately. Once vaccine has been diluted, **do not re-freeze the vial**.

3.24. Do not remove another vial of concentrate vaccine from the lidded box until the vial of diluted vaccine has left the preparation workspace or has been discarded.

4. Drawing up procedure

The procedure utilised to draw up the vaccine will be dependent on the equipment that has been supplied by the Australian Government for use in the COVID-19 vaccination program and the preferred drawing up method that has been agreed on for consistent use at the hub/clinic i.e. multiple puncture or single puncture technique. Hubs/clinics should trial new equipment when it is received to determine which drawing up technique will ensure that 6 doses of the vaccine are consistently achieved, and ensure staff are familiar with the equipment. This technique should subsequently be consistently used by all individuals involved in the drawing up process in that hub/clinic. When new equipment is introduced a phased approach may be required.
Staff involved in the drawing up process should check what equipment has been supplied and follow the appropriate procedure described in appendix 1.

5. Handover of prepared vaccine syringes to immuniser/administrator

5.1. Where vaccines are prepared and administered by different staff the handover process must be clearly documented as per local guidelines.

6. Administration of vaccine

6.1. Assemble the following materials required to administer prepared syringes:

- Prepared syringe (needle attached) of 0.3 mL COVID-19 Pfizer (Comirnaty) vaccine x 1
- Kidney dish for prepared syringe
- Cotton wool
- Band-Aid
- Sharps container.

6.2. Check the prepared vaccine syringe is within the expiry date and time (6 hours post dilution). If the prepared syringe is past the expiry time DO NOT USE and notify the pharmacist and/or team leader.

6.3. Administration of prepared vaccines should be in accordance with local policy and the Australian Immunisation Handbook.

6.4. Sit patient in vaccination area, ensuring privacy if required.

6.5. Perform patient identification and pre-vaccination assessment.

6.6. Administer vaccine intramuscularly (recommended site of administration is the deltoid muscle of the upper arm).

6.7. Immediately discard used syringe and needle into sharps container (do not re-sheath the needle).

6.8. Provide patient with relevant post vaccination advice.

6.9. Ensure patient remains in the centre for observation for **at least 15 minutes** post vaccination (or **30 minutes** for people with a history of anaphylaxis or who carry an adrenaline autoinjector (eg EpiPen).

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7. Administration of vaccine

7.1 For additional clinical advice including advice on interrupted doses and diluent leakage when reconstituting, see COVID-19 vaccine – Clinical considerations.

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Appendix 1: Drawing up procedure

A NSW Health Expert Workign Group has assessed the techniques for available equipment, and the detemined the following methods appropriate and reliable.

Equipment option 1: Vernacare 25G x 25mm low dead space (LDS) needle with standard 1mL tuberculin syringe (leur lock if available)

1. Cleanse the vaccine vial stopper with a single use 70% alcohol swab ('scrub the hub' of the vial)and discard the swab into a general waste bin. Allow the vial stopper to dry.
2. Use a new, sterile 23G or 25G 25mm length needle (or 23G/25G 38mm needle for people who are obese) and 1 mL tuberculin syringe (preferably Luer lock if available) to draw up each new 0.3 mL dose by re-puncturing the bung. Inspect the drawn up syringe for air bubbles.
3. Ensure each re-puncture occurs at a different site on the bung.
4. Recap the clean needle using either a single-handed technique, forceps, or a suitable protective guard designed for re-sheathing. The needle must be properly recapped using a one handed technique with gloves on, and the sheath must not be held in the fingers (to avoid the risk of needlestick injury).
5. The syringe is ready to administer the vaccine using the affixed needle that was used to draw up the dose. Do not affix a new needle for administration as this will result in partial loss of the drawn-up dose due to the dead space in the new needle.
6. Document the vial batch number, vial expiry, prepared syringe expiry (i.e. six hours after dilution date and time) and sign. This may be documented using a 'Syringe Label' (appendix 1D) or via an electronic system.
7. Repeat these steps to draw up all doses.
8. Place vaccine vial and sodium chloride ampoule in the tray with the 6 completed syringes
9. Cover the tray with batch sheet to protect from light while waiting to be checked
10. Obtain a check (of vial batch, vial expiry, calculated prepared syringe expiry and volume of vaccine) from an authorised health care practitioner. The authorised health care practitioner must document this check by signing the label or an electronic means.
11. If using forceps, single use forceps must be discarded into the sharps container after each 2 hour drawing up session. If re-useable forceps are used these must be cleaned using a 70% alcohol swab after each 2 hour drawing up session.

Note: If the Vernacare low dead space syringes and needles are available and supplies are constrained the following can be used to achieve the 6 doses:

- 4 25G x 25mm low dead space needles with standard syringes
- 2 standard 25G x 25mm needles and syringes.

Equipment option 2A: Terumo (Total Dose) 25G x 25mm low dead space (LDS) needle and Unifix 1mL leur lock syringe – Multiple puncture technique

1. Cleanse the vaccine vial stopper with a single use 70% alcohol swab ('scrub the hub' of the vial) and discard the swab into a general waste bin. Allow the vial stopper to dry.
2. Use a new, sterile 25G 25mm length Terumo LDS needle (or 23G/25G 38mm needle for people who are obese) and 1 mL Unifix syringe. To minimise the introduction of air bubbles the needle should be attached to the syringe using a light interlocking technique (the needle should be securely connected but not too firmly. Twist the needle into place until the first "click" is heard – see images below).

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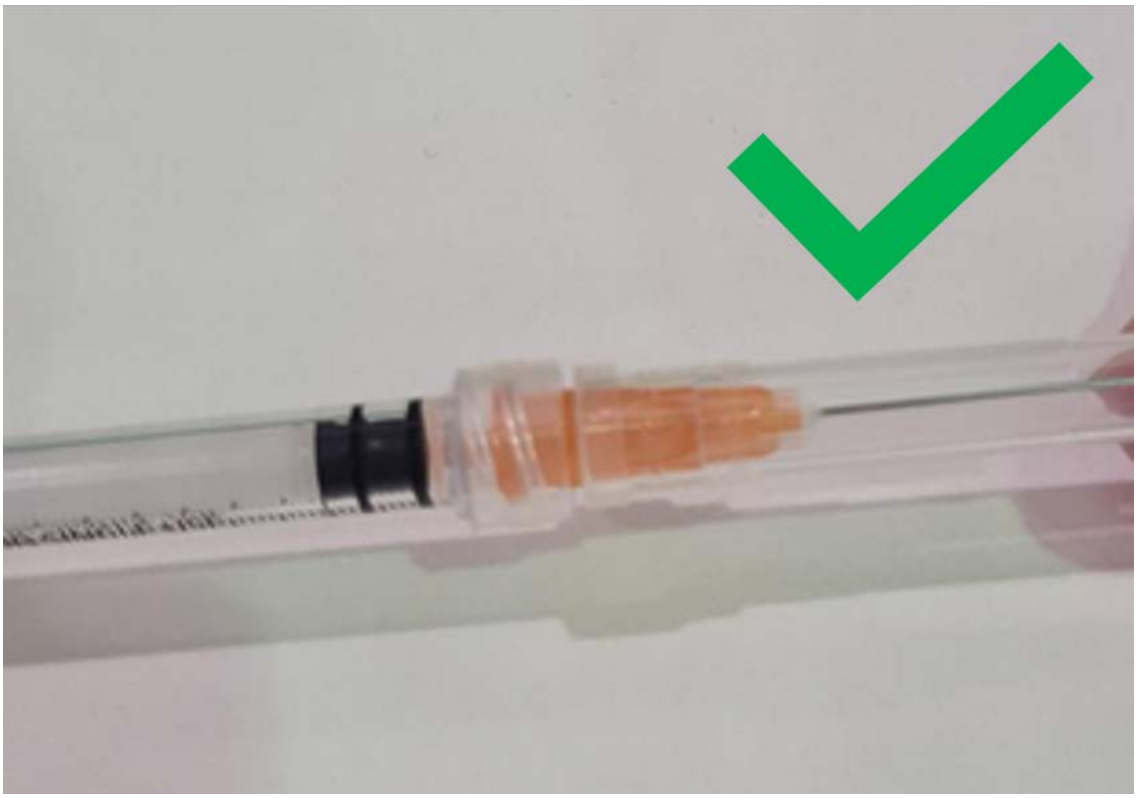

3. Draw up each new 0.3 mL dose by re-puncturing the bung.
4. Ensure each re-puncture occurs at a different site on the bung.
5. Recap the clean needle using either a single-handed technique, forceps, or a suitable protective guard designed for re-sheathing. The needle must be properly recapped using a one handed technique with gloves on, and the sheath must not be held in the fingers (to avoid the risk of needlestick injury).

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6. The syringe is ready to administer the vaccine using the affixed needle that was used to draw up the dose. Do not affix a new needle for administration as this will result in partial loss of the drawn-up dose due to the dead space in the new needle.
7. Document the vial batch number, vial expiry, prepared syringe expiry (i.e. six hours after dilution date and time) and sign. This may be documented using a 'Syringe Label' (appendix 1D) or via an electronic system.
8. Repeat these steps to draw up all doses.
9. Place vaccine vial and sodium chloride ampoule in the tray with the 6 completed syringes
10. Cover the tray with batch sheet to protect from light while waiting to be checked
11. Obtain a check (of vial batch, vial expiry, calculated prepared syringe expiry and volume of vaccine) from an authorised health care practitioner. The authorised health care practitioner must document this check by signing the label or an electronic means.
12. If using forceps, single use forceps must be discarded into the sharps container after each 2 hour drawing up session. If re-useable forceps are used these must be cleaned using a 70% alcohol swab after each 2 hour drawing up session.

Equipment option 2B: Terumo (Total Dose) 25G x 25mm low dead space (LDS) needle and Unifix 1mL leur lock syringe – <u>Single puncture technique</u>

1. Cleanse the vaccine vial stopper with a single use 70% alcohol swab ('scrub the hub' of the vial) and discard the swab into a general waste bin. Allow the vial stopper to dry.
2. Using a 1mL Unifix syringe and 21G or 22G needle withdraw 0.3mL
3. Using forceps, remove the syringe, leaving the needle in the vial
4. Attach a 25G length Terumo low dead space (LDS) needle to the syringe
5. Place syringe in a tray
6. Using forceps to steady the vial, attach a new 1mL syringe and withdraw another 0.3mL
7. Repeat these steps to draw up all doses
8. Document the vial batch number, vial expiry, prepared syringe expiry (i.e. six hours after dilution date and time) and sign. This may be documented using a 'Syringe Label' (appendix 1D) or via an electronic system.
9. Place vaccine vial (needle removed) and sodium chloride ampoule in the tray with the 6 completed syringes
10. Cover the tray with batch sheet to protect from light while waiting to be checked
11. Obtain a check (of vial batch, vial expiry, calculated prepared syringe expiry and volume of vaccine) from an authorised health care practitioner. The authorised health care practitioner must document this check by signing the label or an electronic means.
13. If using forceps, single use forceps must be discarded into the sharps container after each 2 hour drawing up session. If re-useable forceps are used these must be cleaned using a 70% alcohol swab after each 2 hour drawing up session.

Equipment option 3: SOL Millennium 1mL syringe and fixed 25G 25mm needle – Multiple puncture technique

1. Cleanse the vaccine vial stopper with a single use 70% alcohol swab ('scrub the hub' of the vial) and discard the swab into a general waste bin. Allow the vial stopper to dry.
2. Use a new, sterile SOL Millennium 1mL syringe and fixed 25G 25mm needle (or 23G/25G 38mm needle and 1mL syringe for people who are obese – this will be an alternate brand).
3. Draw up each new 0.3 mL dose by re-puncturing the bung.
4. Ensure each re-puncture occurs at a different site on the bung.
5. Recap the clean needle using either a single-handed technique, forceps, or a suitable protective guard designed for re-sheathing. The needle must be properly recapped using a

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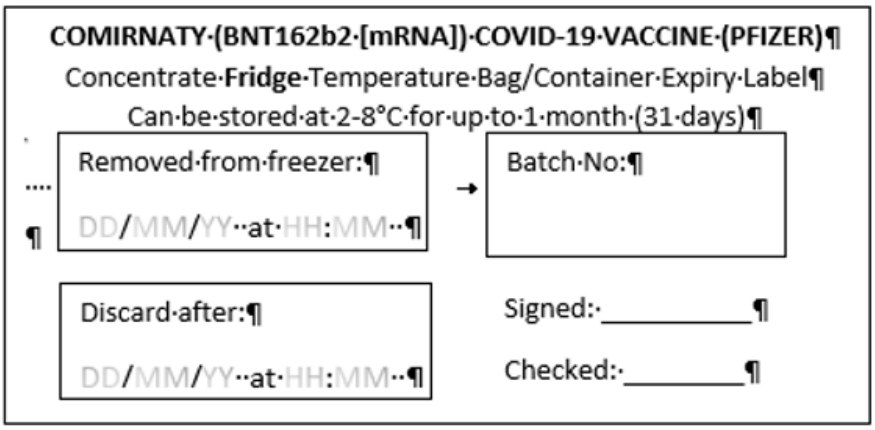
one handed technique with gloves on, and the sheath must not be held in the fingers (to avoid the risk of needlestick injury).

6. Document the vial batch number, vial expiry, prepared syringe expiry (i.e. six hours after dilution date and time) and sign. This may be documented using a 'Syringe Label' (appendix 1D) or via an electronic system.
7. Repeat these steps to draw up all doses.
8. Place vaccine vial and sodium chloride ampoule in the tray with the 6 completed syringes
9. Cover the tray with batch sheet to protect from light while waiting to be checked
10. Obtain a check (of vial batch, vial expiry, calculated prepared syringe expiry and volume of vaccine) from an authorised health care practitioner. The authorised health care practitioner must document this check by signing the label or an electronic means.
11. If using forceps, single use forceps must be discarded into the sharps container after each 2 hour drawing up session. If re-useable forceps are used these must be cleaned using a 70% alcohol swab after each 2 hour drawing up session.

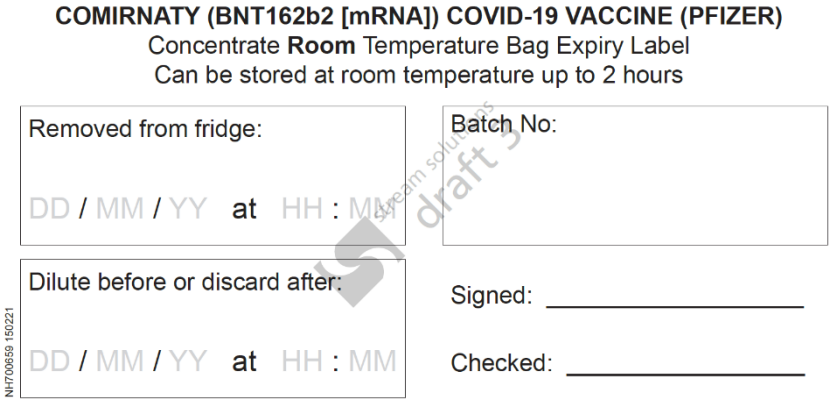
Appendix 2

A. Concentrate fridge temperature bag expiry label

(to be used when concentrated vaccine is removed from freezer)



B. Concentrate room temperature bag expiry vial preparation label



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C. Vial label after dilution

Discard 6 hours after dilution

Diluted on:

DD / MM / YY at HH : MM

Signed: _____

Checked: _____

NH700661 150221

D. Syringe label

For IntraMUSCULAR Use Only

COMIRNATY (BNT162b2 [mRNA]) COVID-19 VACCINE (PFIZER)
Diluent: Sodium Chloride Injection BP 0.9%
Syringe volume: 0.3 mL

Batch/Lot _____ Vial Expiry DD / MM / YY

Prepared by _____

Checked by _____

Do NOT use after DD / MM / YY at HH : MM (6 hours after dilution)

NH700660 150221

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