COVID-19 Vaccination Program Procedures

Management of COVID-19 Vaccine AstraZeneca (ChAdOx1-S) from refrigerator to administration

Last updated: 15 April 2021

Purpose

This Procedure describes the process of receipting, storing, transporting and drawing up the COVID-19 Vaccine AstraZeneca (ChAdOx1-S) in NSW Health clinics.

This procedure MUST NOT be used for any other COVID-19 vaccine.

Responsibility

Staff preparing the refrigerated COVID-19 Vaccine AstraZeneca (ChAdOx1-S) 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 Vaccine AstraZeneca (ChAdOx1-S) can be stored at between +2° to +8°C for up to 6 months.

Each vial contains 4 mL or 5 mL of solution in an 8 or 10-dose vial (clear type I glass) with stopper (elastomeric with aluminium overseal). It comes in packs of 10 multidose vials.

Each vial contains at least the number of doses stated on the label. It is normal for liquid to remain in the vial after withdrawing the final dose. When low dead volume syringes and/or needles are used, the amount remaining in the vial may be sufficient for an additional dose. Care should be taken to ensure a full 0.5 mL dose is administered. Where a full 0.5 mL dose cannot be extracted, the remaining volume should be discarded. Do not pool excess vaccine from multiple vials.

Removing vaccines from the refrigerator for administration

This procedure covers the process from the removal of vials of vaccine from the refrigerator and drawing up individual doses into a syringe to the point of administration.

Procedure

Vaccine stock and cold chain management

1. All deliveries of the COVID-19 Vaccine AstraZeneca (ChAdOx1-S) must be accepted by appropriately trained staff at the site. The AstraZeneca acceptance form must be completed as soon as possible and by 9pm local time on the day of delivery. This form must be used by all sites and completed by a person authorised to accept deliveries of the vaccine.
2. All vaccine must be inspected and transferred to appropriately monitored vaccine fridge in accordance with PD2020_028 Vaccine Storage and Cold Chain Management
3. At the end of each day sites with vaccine should complete the Australian Government Vaccine Stock Management Form and email it to: SHEOV-VAC@health.nsw.gov.au.
4. Standard cold chain (+2°C to +8°C) procedures should be followed for all transport, storage and handling of the COVID-19 Vaccine AstraZeneca (ChAdOx1-S) (Please refer to the Strive for 5 guidelines and the My Health Learning Vaccine Storage and Cold Chain Management training).

5. The Multi Dose Vials should be stored in their original outer box packaging to protect them from light.
6. The vaccine can be stored in cold chain conditions of +2°C to +8°C for a maximum of 6 months as per the expiry date printed on the vial. Do not freeze the vaccine.
7. The vaccine does not contain any preservative.
8. Each dose should be used as soon as practical once withdrawn from the vial. You may pre-draw multiple doses from one vial and use within one hour if stored at room temperature, or within six hours if stored at 2-8°C. Although there are data supporting stability of vaccine doses after withdrawal into a syringe for up to 6 hours at room temperature (as reflected in the AstraZeneca vaccine product information [PI], ATAGI recommends that, as much as possible, pre-drawn doses be used within an hour in order to minimise any remote potential risk of infection.

   If any doses remain in the vial, refrigerate the multi-dose vial between +2°C and +8°C immediately after you finish the vaccine draw-up.

Removal of vaccine from the refrigerator

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 Centre (SHEOC) on 9859 5690. Refer to NSW Health policy directive PD2020_028 Vaccine Storage and Cold Chain Management.
2. Perform hand hygiene with either soap and water or an alcohol-based hand rub (ABHR) before gathering supplies or handling vials.
3. Remove only the required number of vials from the refrigerator, using the vials with the earliest expiry first. One 5mL vial contains sufficient vaccine for 10 doses when using standard needles and syringes (8 doses if it is a 4 mL vial).
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.
5. 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.

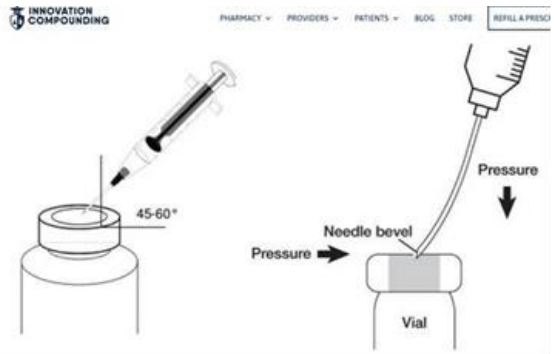
Workstation preparation

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.
2. Clean the workstation with a disinfectant wipe and discard into a clinical waste bin.
3. Perform hand hygiene with either soap and water or an alcohol-based hand rub (ABHR).
4. Ensure a yellow sharps container with enough free capacity is available.
5. Ensure an indelible black pen is available.
6. Put on an apron and any additional PPE including face mask and gloves
7. Perform hand hygiene to prepare the COVID-19 Vaccine AstraZeneca (ChAdOx1-S)

Dose preparation

1. Assemble the following materials required to perform drawing up:
   - Single use 70% alcohol swab x 2
   - Opaque container.
2. Inspect the vial to ensure its integrity maintained. The vaccine will appear clear to slightly opaque and colourless to slightly brown. There should be no visible particles within the MDV. **DO NOT SHAKE** while inspecting the vial.
3. Remove the protective stopper (elastomeric with aluminium overseal) from the top of the vial and inspect the bung to ensure integrity.
4. Cleanse the vaccine vial stopper with a single use 70% alcohol swab and discard the swab into a clinical waste bin.

5. If all doses are not being drawn up at the same time and it is the first time the vial has been accessed, complete and attach the “vial access label” (appendix 1 or electronically generated label). If the vial has been previously accessed ensure it has not reached its ‘maximum time since opening’.
6. The vial contents DO NOT require dilution.
7. 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 0.5 mL dose by re-puncturing the bung.
8. Draw up 0.5 mL of air into the syringe.
9. Ensure each re-puncture occurs at a different site on the bung. 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/

10. Inject the 0.5 mL air into the vial and draw up a 0.5 mL dose of vaccine ensuring that aseptic technique is maintained. Air should be injected prior to drawing up the first dose and then to equalise the pressure as required. If leakage is occurring the injection of air may only be required, every second dose.
11. Withdraw the syringe and needle and recap the needle using either a single-handed technique, forceps, or a suitable protective guard designed for re-sheathing. The needle must be properly recapped, and the sheath must not be held in the fingers.
12. Apply user applied ‘Syringe Label’ (appendix 1) or use electronically produced labels if drawing up is not completed at the point of care to be used immediately. Complete vial batch number, vial expiry, prepared syringe expiry (i.e. six hours after vial first access date and time) and sign. Obtain a check (of vial batch, vial expiry, calculated prepared syringe expiry) from a second person. The second person must document this check by signing the label.
13. 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.
14. The drawn-up vaccine should be administered as close to the time of preparation as possible and within the labelled expiry date/time i.e. within six hours from when the vial was first accessed.

If drawing up all doses at once the vial stopper does not need to be cleaned between drawing up each dose if aseptic technique is used and maintained. If all doses are not being drawn up at the same time the vial should be returned to the fridge as soon as possible and the vial stopper should be cleansed with a single use 70% alcohol swab prior to each access.

Do not remove another vial vaccine from the refrigerator until the prepared vaccine syringes have left the preparation workspace or have been discarded.

Handover of prepared vaccine syringes to immuniser/administrator

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

Administration of vaccine

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

- Prepared syringe (needle attached) of 0.5 mL COVID-19 Vaccine AstraZeneca (ChAdOx1-S) x 1
- Kidney dish for prepared syringes
- Cotton wool
- Band-Aid
- Sharps container.

3. Administration of prepared vaccines should be in accordance with local policy and the Australian Immunisation Handbook.
4. Sit patient in vaccination area, ensuring privacy if required.
5. Perform patient identification and pre-vaccination assessment.
6. Administer vaccine intramuscularly (preferred site of administration is the deltoid muscle of the upper arm).
7. Immediately discard used syringe and needle into sharps container (do not re-sheath the needle).
8. Provide patient with relevant post vaccination advice.
9. Ensure patient remains in 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).

Wastage

1. In the event of a potential or actual wastage incident (e.g. damaged vials or breach of cold chain requirements), that exceeds the threshold (5 or more vials at a time), the facility must notify the SHEOC by completing the provided wastage templates, scanning and emailing these to: SHEOC-VAC@health.nsw.gov.au. SHEOC will then collate these reports and provide them to the Department of Health.

Appendix 1

Vial label

(to be applied to the vial if all doses are not being drawn up at the same time and at time of first access)

COVID-19 VACCINE AstraZeneca
After first access the vial should be discarded either:
After 6 hours of continued or cumulative time at **room temperature** or;
After a maximum of 48 hours if returned to the **fridge immediately**
Access on:
DD/MM/YY at HH:MM Signed: _____ Checked:

Syringe label

(to be applied to each prepared syringe)

For IntraMUSCULAR Use Only

COVID-19 VACCINE AstraZeneca (ChAdOx1 S)
Syringe volume: 0.5 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 first access)