

COVID-19 VACCINATION HUB



Western Health

Western Health (WH) COVID-19 Vaccination Hub

Western Health Staff Outreach Operating Guideline

Version - 1

15th April 2021

Contact: Lisa Smith (Project Lead)

Phone: 0409 799 045

Email: lisa.smith@wh.org.au



Contents

1. Purpose	3
2. Site Accreditation	3
3. Location	3
4. Site Model.....	3
5. Service Provision	4
5.1 Workflow	4
5.2 Pharmacy Preparation Workflow	4
5.3 Coolers for offsite /outreach	5
5.4 Emergency management	5
6. Workforce	6
7. Information and Communication Technology (ICT)	7
8. Equipment.....	7
9. Communication	7
10. Appendices	8
10.1 ATAGI Site Requirements Form.....	8
10.2 Operational Readiness Checklist	15
10.3 Daily Reporting Template.....	17
10.4 ATAGI requirements	19
10.5 Pre-Vaccination Screening – Outreach Reference Guide.....	21

1. Purpose

The purpose of this document is to outline functional requirements to establish an outreach vaccination service at a Western Health site.

The [Information-on-COVID-19-Pfizer-COMIRNATY-Vaccine](#) to be read in conjunction with this document details the requirements for operationalising a Pfizer outreach.

The Operating Guideline describes the various components and associated processes of the governance structures, vaccine recipient journey, workforce requirements, clinical and non-clinical support of port requirements, equipment and capital requirements and communications procedures.

This Operating Guideline is to be used with reference to the [Victorian COVID-19 Vaccination Hub Guidelines](#).

2. Site Accreditation

Site readiness requirements for the Pfizer COMIRNATY vaccine have been developed by the Australian Government in consultation with expert advice from the Australian Technical Advisory Group on Immunisation (ATAGI), standards outlined in the Australian Immunisation Handbook.

WHCVH must confirm compliance with the minimum requirements as per [Victorian COVID-19 Vaccination Hub Guidelines](#) prior to delivery of vaccine doses.

Outreach services must ensure the [site readiness form](#) is completed prior to commencing operations in an outreach service.

3. Location

Western Health operates a primary COVID-19 Vaccination Hub at Sunshine Hospital. The location of the Western Health Staff Outreach model will be located at the various WH campuses depending on space availability and demand for the service.

4. Site Model

The outreach site model involves the temporary set up of a vaccination space on a WH campus.

This is a flexible model which will operate based on demand and availability. Operating from 0815 hours (first vaccination) until 1615 (last vaccination).

Appointments will be booked through Timify to allow pre vaccination checks to be completed and contact made, if required, based on information provided. This model also provides the flexibility of walk-in capability for 50% of the vaccinations.

Pre vaccination screening will be undertaken as per QRG Pre Vaccination Screening – Western Health staff Outreach (see appendix [10.5 Pre Vaccination Screening](#)). The Sunshine Hub Medical officer will be readily available via phone and can be contacted on 0478 908 747 for any queries that may arise.

The staff shift time 0800 - 1630.

The operating model allows 4 vaccination sessions to run concurrently with 4 immunisers delivering up to 32 vaccinations each, a total of 128 doses.

At all campuses other than Footscray Hospital, a fleet rental car will transport the required equipment and consumables to site and return to Sunshine Hub. The fleet rental vehicle will contain the receptacle for vaccine storage.

All staff including Security and PSA will make own arrangements for transport to site and return.

5. Service Provision

Service provision is supported by Western Health policies, procedures and guidelines which must be in place to support local operations at the outreach service.

5.1 Workflow

The administrative and clinical workflow detailed in the *WH COVID-19 Vaccination Hub Operating Guideline – AstraZeneca* found in the hub site's [Quick Reference Guide section](#) outlines the vaccine recipient journey commencing with online scheduling via Timify including required pre immunisation checks. The vaccine administration, post vaccination observation and check out will be recorded in CVMS.

5.2 Pharmacy Preparation Workflow

The cold chain requirements for the Pfizer vaccine are subject to strict quality control. The delivery of Pfizer vaccine to the WHCVH and Sub-Hubs is detailed in the [Victorian COVID-19 Vaccination Hub Guidelines](#).

Upon arrival of Pfizer vaccine shippers to the Sunshine Hospital, arrangements are in place to ensure that the vaccine cold chain requirements are met.

The confirmation of doses required based on CVMS bookings for the following day's operations enables decanting from the JKWC pharmacy to the outreach service for Pfizer vaccine.

The pharmacy, including transportation and cold chain management of the Pfizer vaccine is detailed in the *WH Vaccination Hub – Management of COVID-19 Vaccine Procedure* found in the hub site's [Quick Reference Guide section](#).

The Pharmacy Satellite clinic at Footscray will be utilised for vaccine preparation and cold chain requirements when the outreach model is operational on the Footscray campus. For all other sites the portable refrigerator will be utilised for vaccine storage and transportation.

5.3 Coolers for offsite /outreach

Coolers should be used only as a last option, as the risk of freezing is high. Coolers are not recommended for more than 8 hours or extreme conditions.

Conditions for using icepacks can be found in [National Vaccine Storage Guidelines 'Strive for 5' | Australian Government Department of Health](#). Temperature should be monitored and recorded every 15 minutes, or a temperature logger should be used.

The temperature must be recorded at least hourly during mobile and outreach immunisation clinics. This includes the current minimum and maximum temperature measured with a digital thermometer.

A specialised vaccine cooler is recommended in an extreme climate (environmental temperature is <0°C or >40C) or for long-term portable storage more than 8 hours. Specialised coolers have thicker walls for insulation resulting in a minimum 'cold life' of 120 hours in temperatures of 43°C if the lid is not opened.

5.4 Emergency management

In the event of a medical emergency, the local response should be enacted. At Footscray & Williamstown Hospital, call 8345 0444 (444) MET call, clearly advise the location and no treating team. For all other campuses 000 should be called.

A portable AED and First Aid kit (including an anaphylaxis kit) is located within the clinical stores area.

All staff working at the WH staff outreach should familiarise themselves with the local campuses [Emergency Response](#)

The requirements for PPE during adult Code Blues are found here: <https://coronavirus.wh.org.au/wp-content/uploads/2020/07/PPE-v-8.3.pdf>

All patients attending the WH staff Outreach vaccination hub should be treated Tier 2 patients, suspected or confirmed as COVID-19 cases.

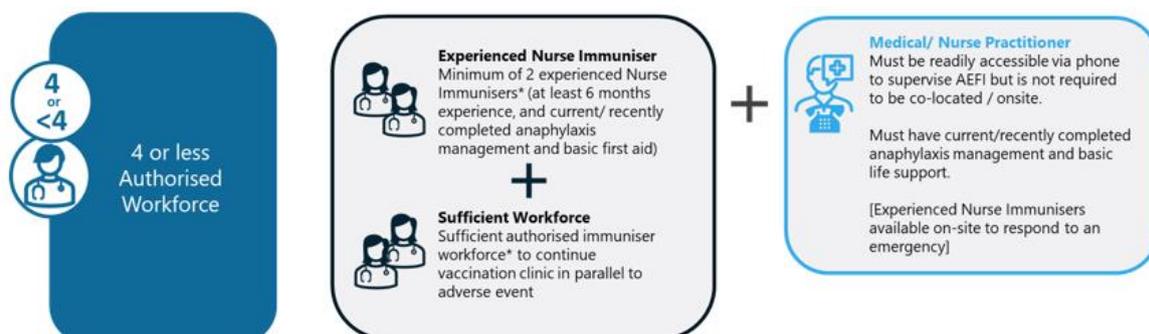
Following a medical emergency, WH OHS should be advised and a WH Riskman should be documented by the Team Leader.

6. Workforce

The workforce required to operationalise the Port of Melbourne Outreach Model includes

Role	Per 4 vaccination spaces
Team Lead (Certified Immuniser)	1
Vaccinator (pre- immunisation health assessment check & consent, administers vaccine)	4
Pharmacy Vaccination Preparation	2
Cleaner	1
Site security	1
Administration	1
Total workforce – head count	10

The [Victorian COVID-19 Vaccination Guidelines](#) requires the following minimum workforce for outreach:



*Sites must adhere to required supervision ratios at all times.

7. Information and Communication Technology (ICT)

The Department has engaged Microsoft® in the development of a COVID Vaccine Management System (CVMS) platform – the platform will enable registration capabilities for vaccine recipients and provider. The ICT hardware required to support a Vaccination Hub includes:

Hardware	Number required
Laptop – CVMS data entry	5
Laptop – pharmacy inventory management	1
Mobile phones / phone access	1

8. Equipment

Minimum equipment requirements are outlined in the *ATAGI recommended vaccine equipment checklist* found in the hub site's [Quick Reference Guide section](#).

Equipment to operationalise the outreach service also includes:

- First Aid kit including an Anaphylaxis response kit
- Portable Automatic External Defibrillator (AED)
- CVMS Down time kit
- Stainless steel trolley for vaccine preparation
- Table and Chairs for vaccination team
- 12 chairs for vaccine cubicles and observation area
- Privacy screens
- Hospital scrubs
- Cleaners trolley

9. Communication

The Department will continue to provide communication material to ensure consistent communication across all COVID Vaccination Hubs.

As suite of documents will be accessible through the Western Health [COVID Vaccination Hub Microsite](#).

10. Appendices

10.1 ATAGI Site Requirements Form

The following site readiness requirements for COVID-19 vaccination clinics have been developed by the Australian Government in consultation with expert advice from the Australian Technical Advisory Group on Immunisation (ATAGI) and standards outlined in the Australian Immunisation Handbook. Pfizer vaccination site sites must confirm compliance with the minimum requirements outlined below (as well as the declaration in relation to Pfizer Vaccination Site Requirements) prior to taking delivery of Pfizer vaccine doses.

1.0 Physical environment	Yes / No	Comments
1.1 Access to toilets for patients (separate to usual practice or clinic toilet) and staff	Yes / No	
1.2 Have adequate space for patients waiting to be vaccinated that is not congested, observes physical distancing requirements, and is sheltered from weather elements.	Yes / No	
1.3 Have a private space for consultation with patients and vaccinator (including obtaining informed consent, answering patient questions and assessment of any conditions that may preclude vaccination or require further assessment and administration of vaccine)	Yes / No	
1.4 Have a dedicated area, separate from areas that provide other clinical services at the same time, where vaccines from multi-dose vials may be drawn up, labelled, and prepared for administration	Yes / No	
1.5 Have a dedicated, clean, well-lit space for administration of the vaccine to patients, including a desk and chairs for patients and vaccinator(s).	Yes / No	
1.6 Have adequate space for patients to wait and be observed post-vaccination that observes physical distancing requirements (note this may be the same as the waiting area however will still require sufficient physical distancing, and post-vaccine observation cannot take place with patients in cars)	Yes / No	
1.7 Have safe, risk free and directed access in clinical areas to allow movement of staff between areas while minimising the risk of workplace incidents (e.g., moving doses from preparation area to patient administration area, accessing refrigerators or cool boxes, etc.).	Yes / No	
1.8 Adequate handwashing facilities for staff, and antimicrobial hand sanitisers available. Have visual reminders and cues in place to reduce the risk of errors.	Yes / No	

COVID-19 VACCINATION HUB

1.9	Have a process in place to safely dispose of unused vaccines, in accordance with TGA and other regulatory requirements.	Yes / No	
1.10	Have adequate sharps disposal bins, appropriate for the volume of patients, and securely placed and spaced to mitigate the risk of needle stick injuries.	Yes / No	
1.11	Appropriate security provisions to ensure no unauthorised access to vaccine doses	Yes / No	
2.0 Physical location		Yes / No	Comments
2.1	Close proximity to sufficient car parking	Yes / No	
2.2	Close proximity to public transport (where relevant)	Yes / No	
2.3	Accessible by other patient transport services (including ambulance)	Yes / No	
3.0 Infrastructure		Yes / No	Comments
3.1	Reliable water and electricity supply	Yes / No	
3.2	Access to telephone and computer networks and internet	Yes / No	
3.3	Ability to maintain room temperatures between 19 – 25 degrees	Yes / No	
4.0 Workforce requirements		Yes / No	Comments
4.1	Adequate number of appropriately trained staff to ensure clinical safety including:		
4.1.1	Vaccinators to prepare and administer vaccines	Yes / No	
4.1.2	Authorised immunisation provider (e.g. medical officer or fully trained immunisation registered nurse/nurse practitioner to assess patients and authorise other appropriately trained clinical staff (vaccinator) to administer the vaccine)	Yes / No	
4.1.3	Concierge or team leader (to direct clinic flow)	Yes / No	
4.1.4	Clerical staff	Yes / No	
4.1.5	First aid staff, additional to vaccinating staff as per jurisdictional requirements	Yes / No	
4.1.6	Security staff (if/ when required)	Yes / No	
4.1.7	Medical officer (may be the same as the authorised immunisation provider)	Yes / No	
4.2	Note that everyone administering vaccines must have appropriate training and/or qualifications in line with jurisdictional requirements, and have received adequate specific training in AZ's COVID-19 vaccination, including regarding the use of multi-dose vials and, to the extent relevant, low-dead volume syringes	Yes / No	

4.3	Have documented procedure for managing and recording training of staff handling vaccine doses	Yes / No	
5.0 Cold chain management		Yes / No	Comments
5.1	Have adequate number and capacity of refrigerators to store vaccines, with refrigerators to be maintained and monitored at 2 – 8 degrees Celsius	Yes / No	
5.2	Have appropriate refrigerators and opaque containers to store vaccine syringes that have been prepared for administration under appropriate temperature conditions and protected from light from the time they are prepared until the time they are administered	Yes / No	
5.3	Have specific procedures in place associated with receipt of vaccine doses including unloading, acceptance, temperature checks, inspection, unpacking and storage to ensure compliance with the AZ Vaccine Acceptance Checklist .	Yes / No	
5.0 Cold chain management (cont.)		Yes / No	Comments
5.4	Sites must be able to adhere to the Strive for 5 guidelines ¹ and will need to have or be able to develop policies for cold chain management including:		
5.4.1	Able to continuously monitor the temperatures of the freezers and/or refrigerator(s) where vaccines are stored	Yes / No	
5.4.2	Have an appropriate policy and protocol in place to respond to temperature breaches, including relocating vials to another refrigerator (or freezer, where relevant) and responding at times where the AZ vaccine site may not have any staff present.	Yes / No	
6.0 Technology and Record Keeping		Yes / No	Comments
6.1	Access to patient management system and Australian Immunisation Register via Provider Digital Access (PRODA)	Yes / No	
6.2	There will be a requirement for connectivity to support integration with a National booking system. <i>More information will be circulated regarding integration to current practice management systems.</i>	Yes / No	
6.3	Ability to meet mandatory requirements regarding reporting of all vaccine administration into AIR within 48 hours	Yes / No	

¹ Australian Government Department of Health. National Vaccine Storage Guidelines – **Strive** for 5. Canberra ACT: Department of Health; 2019. Available from: <https://www.health.gov.au/sites/default/files/documents/2020/04/national-vaccine-storage-guidelines-strive-for-5.pdf>.

	Have a process of obtaining and recording informed consent.	Yes / No	
6.5	<i>Further information regarding consent relating to COVID-19 vaccination will be provided by the Commonwealth.</i>		
6.6	Be able to develop policies and procedures for:		
6.6.1	Identifying individual vaccine recipients, checking to confirm any record of previous receipt of any COVID-19 vaccine doses (including date and brand of product received), and recording immunisation encounters (electronic records are preferable)	Yes / No	
6.6.2	Labelling syringes when they are drawn up from multi-dose vials, including date and time of preparation and of expiry	Yes / No Yes / No	
6.6.3	Recording and reporting of vaccines used and stock on hand and any doses discarded, including reasons for discarding, and vaccine wastage	Yes / No	
6.7	Ability to monitor, manage and report adverse events following immunisation, including anaphylaxis	Yes / No	
7.0 Waste disposal		Yes / No	Comments
7.1	Facilities to dispose of all waste, including sharps and unused vaccine appropriately in accordance with local requirements for disposal of Schedule 4 medication, the Product Information and Safety Data Sheet for the AZ Vaccine and any other instructions given by the Australian Government	Yes / No	
8.0 Personal protective and other equipment		Yes / No	Comments
8.1	Appropriate PPE, as per requirements in the Product Information for the AZ Vaccine, Australian Immunisation Handbook and jurisdictional requirements – option available for this to be supplied by the Commonwealth	Yes / No	
8.2	Adequate supplies of other medical equipment e.g. stethoscopes, examination tables, diagnostic testing equipment	Yes / No	
8.3	Labels for syringes (if filling in advance)	Yes / No	
8.4	Antimicrobial /disinfectant wipes to clean stations between patients.	Yes / No	
8.5	Sanitation equipment for administration site	Yes / No	
9.0 Accreditation and other regulatory requirements		Yes / No	Comments
9.1	Able to claim MBS item numbers for billing	Yes / No	

9.2	Have the appropriate accreditation required for the relevant clinic or practice, as advised by the Commonwealth (noting that accreditation will inform funding arrangements)	Yes / No	
9.3	Willingness to comply with compulsory infection control training and external quality assurance procedures	Yes / No	
9.4	All immunisers to be authorised under the relevant state or territory's Public Health Act to provide vaccines	Yes / No	
10.0 Accessibility and cultural safety		Yes / No	Comments
10.1	Will need to be able to develop policies and procedures for ensuring services are culturally safe for Aboriginal and Torres Strait Islander peoples	Yes / No	
10.2	Will need to have arrangements for identification of and assistance for those with additional or specific needs, including: <ul style="list-style-type: none"> - Ensuring culturally appropriate policies and procedures for multicultural communities - Qualified interpreters available when needed - Translations to languages other than English 	Yes / No	
10.3	Will need to have arrangements to provide accessibility to those with Disability (including intellectual disability)	Yes / No	
11.0 Management of the clinic		Yes / No	Comments
11.1	Standardised screening process to exclude patients who display symptoms of COVID-19, and refer for appropriate assessment for COVID-19 or other conditions (as per guidance provided in the ATAGI Guiding Principles for Maintaining Immunisation Services During the COVID-19 Pandemic)	Yes / No	
11.2	Standardised screening process for contraindications, receipt of previous doses of COVID-19 vaccines and/or receipt of other vaccines (observing any interval requirements).	Yes / No	
11.3	Clear assignment of duties and responsibilities of all staff and clear plan of workflow, particularly regarding drawing up from a multi-dose vial and administering individual vaccine doses drawn from a particular vial for each clinic session.	Yes / No	
11.4	Incident management in place, with staff knowledgeable about relevant procedures and able to report any clinical incident (e.g. injury in workplace) to the appropriate health authorities.	Yes / No	
11.5	Has process in place to manage injuries to workforce or patients (e.g. needle stick injury).	Yes / No	
11.5	Has process in place to any adverse reaction to administration of a vaccine.	Yes / No	



11.6	Process in place to prevent and manage violence or aggression in the clinic.	Yes / No	
12.0 Vaccine administration equipment requirements for each patient vaccination - the Commonwealth will provide some consumables if sites are unable to access supply through existing mechanisms			
Ability to procure and securely store items listed below sufficient for the administration of the AZ vaccine doses the AZ vaccine site will administer:			
12.1	Sterile 1mL, 2mL or 3mL syringes	Yes / No	
12.2	Sterile syringes with 0.1mL graduation	Yes / No	
12.3	21 gauge bevel or narrower	Yes / No	
12.4	Sterile drawing up needle (19 or 21 gauge recommended to reduce risk of coring)	Yes / No	
12.5	Sterile administration needle (22-25 gauge), 25mm for adults, 38mm for very large or obese person	Yes / No	
12.6	Alcohol wipe (for vials)	Yes / No	
12.7	Cotton wool ball	Yes / No	
12.8	Hypoallergenic tape or latex free band aid	Yes / No	
12.9	Dish for drawn up vaccine (kidney dish)	Yes / No	
12.10	Sharps containers	Yes / No	
12.11	Containers for disposal of biohazardous waste	Yes / No	
12.13	Adrenaline 1:1000	Yes / No	
12.14	1mL 'single use only' syringes, with 23 gauge needle	Yes / No	
12.15	Paediatric and adult size Guedel airways	Yes / No	

Declaration

Pfizer vaccine site: _____

Organisation responsible for the AZ vaccine site: _____

Address of Pfizer vaccine site: _____

By signing this declaration, the signatory warrants that the signatory is duly authorised to make this declaration on behalf of the organisation responsible for the Pfizer vaccine site and, having considered the matters set out in this document, that the responses set out above are true and correct. The signatory confirms that the Pfizer vaccine site will implement the procedures described in this document and follow any directions of the Australian Government in relation to the acceptance, management, storage and administration of the Pfizer vaccines. If any information in this declaration or any circumstances relevant to the ability of the Pfizer vaccine site to administer Pfizer vaccines changes, the signatory undertakes to immediately notify the Australian Government.

SIGNED by _____

Print name in capitals: _____

Role or Title: _____

As authorised representative for the organisation running AZ vaccination site (identified above).

Date: _____

COVID-19 VACCINATION HUB

10.2 Operational Readiness Checklist

VIC Health COVID Vaccine Hub	Sunshine Hospital – Outreach
Business name	COVID 19 VACCINE HUB VIC001
AIR Provider Number (Pfizer & Astra Zeneca)	V97571W
SAEFVIC reporting	Username: SAEFVIC.WesternHub@dhhs.vic.gov.au Password: pfizerhub1
Sub-Hub Location: Address & phone number	
Authorised Contact Contact email & phone number:	
Site Manager Contact email & phone number:	
ATAGI Site requirements for COVID-19 vaccination clinics completed	Yes / No
Copy provided to WHCVH	Yes / No
Forms available	
Astra Zeneca Acceptance Form	Yes / No
Vaccine Stock Management Form	Yes / No
Vaccine Wastage Report Form	Yes / No
Summary of Wastage Form	Yes / No
Authorised contact confirming preparedness	
Authorised contact signature	
Date:	
Authorised WHCVH Contact reviewing:	
Date:	

COVID-19 VACCINATION HUB

Equipment	All equipment is set up and in correct location			
	Equipment tagged, tested and working			
	Staff working familiar with equipment			
	Emergency routes confirmed & tested			
	Anaphylaxis Kits stocked and available in planned location			
	Staff familiar with anaphylaxis kits			
	Emergency equipment hats, vests etc. set up			
OH&S Safety Checks	New equipment risk assessments complete			
	Area OH&S risk assessment completed			
	OH&S signage visible			
	COVID safe signage visible			
	Evacuation exits identified			
	Evacuation kits in area			
	Emergency manual in area			
	Break glass alarms / Fire alarms identified			
	Position of WIP known			
	Area warden training complete by your area leads			
	Complete workplace inspections if required			
Pharmacy	Pharmacy Preparation Zone set up – consumables, ICT, labelling			
	Vaccine transport receptacle checked			
ICT	Computers in place in all designated areas			
	Staff access to ICT software programs confirmed			

1. Wastage Report <https://consultations.health.gov.au/covid19-vaccine-taskforce/3a45a6a3>
2. Stock Management Report - <https://consultations.health.gov.au/covid19-vaccine-taskforce/dadfe24a>
3. AstraZeneca Vaccine Acceptance Form (<https://consultations.health.gov.au/covid19-vaccine-taskforce/f361b0a4/>)

COVID-19 VACCINATION HUB

10.3 Daily Reporting Template

Date:	6pm to 6pm				Data description
Site name					The name of the location where the vaccinations occurred
Vaccine type	Pfizer		Astra Zeneca		
Dose number	Dose 1	Dose 2	Dose 1	Dose 2	
Total doses administered					Please include data for all outreach, sub-hubs or other locations in your LPHU that you are managing or distributing vaccine to.
Breakdowns by 1a priority group					
- Quarantine workers					Workers employed in the Hotel Quarantine program, including those directly employed by CQV, medical and support staff who work in quarantine and Health Hotels, workers involved in transporting people to and within the hotel quarantine program, security and other staff supporting the hotel quarantine program including ADF and Victoria Police. This category includes CQV staff stationed at Melbourne Airport.
- Border workers					Workers vaccinated because of their high-risk status at an airport or marine port. This category will primarily apply to people working in or traversing the Red Zone at Melbourne Airport, and high-risk workers at Geelong and Portland marine ports in the early weeks of the program. For example, Authorised Officers, Australian Border Force, COVID testing staff, Melbourne Airport and airline employees who work in the Red Zone. This category captures all airport and marine port staff NOT categorised as quarantine workers (above).
- Front line healthcare workers					All other healthcare workers in phase 1a
- Residential aged care (public sector) – Staff					RACS Staff
- Residential aged care (public sector) – Resident					RACS Residents
- Other (wastage prevention)					Any other doses administered to prevent doses being discarded at the end of the clinic
Breakdowns by 1b priority group					

COVID-19 VACCINATION HUB



- Other Healthcare workers					<p>All those employed or otherwise engaged by a healthcare setting including all employees, contractors, visiting medical officers, students and volunteers performing clinical and non-clinical roles.</p> <p>People employed on a paid or voluntary basis who are directly involved in the care of clients who are eligible under Phase 1b and are working within 1.5 metres of clients for over 15 minutes.</p>
- Critical and high-risk workforces					<ul style="list-style-type: none"> • Emergency workforce personnel (e.g. ADF, VicPol, VicSES, ESTA etc.) • Corrections/detention: all staff, prisoners in custody, and detainees • All staff working in licenced meat processing centres • Public transport workers (client facing), ride share and taxi drivers • Workers manufacturing/ delivering AstraZeneca COVID-19 vaccine • Members of households of 1a cohorts; hotel quarantine, ports of entry, border workers • Residents of high-risk accommodation • WorkSafe inspectors
- Age-related					Any person whose primary eligibility as a priority vaccination group is age-related.
- People with a pre-existing medical condition					See list in guidelines
- People with a disability					All those covered under NDIS or receiving TAC disability payments.
- Aboriginal and Torres Strait Islander people					Self-identified as Aboriginal and/or Torres Strait Islander (may be verbal)
Medically attended AEFI (number only, no detail required)					Any Adverse Event Following Immunisation (AEFI) which occurred during your clinic time that results in attendance of/by a hospital medical officer, GP, paramedic or transfer to the Emergency Department, direct hospital admission or death.
Immunisers used					Clinical immunisation workforce utilised (excluding administrative and support staff)

10.4 ATAGI requirements

ATAGI checklist of minimum equipment requirements to administer COVID-19 vaccines

One each of the following is required for each patient administration:

Vaccine administration equipment

- Adequate stock of unexpired vaccines (with diluents and sterile dilution equipment, i.e. needles 21 gauge bevel or narrower, and 2mL or 3mL syringes, if applicable)
- Sterile syringes with 0.1mL graduation: 2mL or 3mL syringes are preferred for drawing up dose volumes of 0.5mL or greater; 1mL syringes may be preferable for drawing up dose volumes smaller than 0.5mL (specifically 0.3mL of the vaccine sponsored by Pfizer Australia Pty Ltd, COMIRNATY BNT162b2). Use of a 1mL syringe with a Luer lock is highly preferred over those without a Luer lock.
- Sterile drawing up needle – 19 or 21 gauge bevel are strongly recommended to reduce the risk of coring
- Sterile administration needle (22–25 gauge): 25mm for infants, children or adults, 16mm for preterm infants, 38mm for very large or obese person *
- Alcohol wipe (for vials)
- Cotton wool ball
- Hypoallergenic tape or latex-free bandaid
- Dish for drawn up vaccine (e.g. kidney dish) Note the TGA approved Product Information for the vaccine sponsored by Pfizer Australia Pty Ltd (COMIRNATY BNT162b2) states that low dead-volume syringes and/or needles should be used in order to extract six doses from a single vial. The low dead-volume syringe and needle combination should have a dead volume of no more than 35 microlitres. Additionally, the following is required in the clinic:
- PPE for staff, as per requirements in the Australian Immunisation Handbook and jurisdictional/institutional requirements (see notes in section below)
- Labels for syringes (if filling them in advance of administration)
- Materials to sanitise worktop and equipment
- Clean opaque labelled containers to store prepared doses

Additional stock of each of the above should be available in case of need to discard equipment.

Sites may also consider having the following available:

- • Safety needles (strongly recommended)
- • Digital thermometers
- • Blood pressure monitor
- • Stethoscope
- • Disposable gloves (latex free) of varying sizes suitable for use by immunising staff (see notes in section below), noting that gloves may not be recommended for use during vaccine administration due to increased risk of needlestick injury

*As per recommendations on needle size, length and angle for administering vaccines in the Australian Immunisation Handbook <https://immunisationhandbook.health.gov.au/resources/handbook-tables/tablerecommended-needle-size-length-and-angle-for-administering-vaccines>

COVID-19 VACCINATION HUB

- Masks for patients, as per jurisdictional/institutional requirements (see notes in section below)
- Labels for multi-dose vials to record date/time vial first accessed

Cold chain Sites must be able to adhere to the Strive for 5 guidelines**

- Portable cooler
- Frozen ice packs/gel packs
- Battery operated digital thermometers to monitor temperatures
- Purpose built vaccine refrigerator set at 2–8 C refrigerator
- Temperature data logger
- Waste disposal • Sharps container (one per vaccinator)
- Containers for infectious waste (biohazard, non-sharps)
- Provisions for general waste
- Rubbish bags
- Emergency equipment

Resuscitation Kit, including:

- Adrenaline 1:1000
- 1mL 'single use only' syringes (not Insulin syringes) with 0.1mL graduation, with needles 22 or 23 gauge x 25mm
- Paediatric and adult size Guedel airways
- Laerdal resuscitator with paediatric and adult masks
- Copy of 'Recognition and Treatment of Anaphylaxis' from the Australian Immunisation Handbook and "Doses of IM adrenaline"
- Documentation to record treatment of anaphylaxis
- Clock (for timing of adrenaline)
- Address of venue(s)

** Australian Government Department of Health. National Vaccine Storage Guidelines – Strive for 5. Canberra ACT: Department of Health; 2019. Available from: <https://www.health.gov.au/sites/default/files/documents/2020/04/national-vaccine-storage-guidelines-strive-for-5.pdf>

10.5 Pre-Vaccination Screening – Outreach Reference Guide

The following questions will help us determine if there is any reason the vaccine recipient should not have the COVID-19 vaccine today. **If they answer “yes” to any question, it does not necessarily mean they should not be vaccinated.** It just means additional questions and medical officer review may be required.

Pre Vaccination Question	If Yes	Further Information
<p>1. Have you ever received a COVID-19 vaccine?</p>	<p>Which product?</p> <p>Date?</p>	<p>Confirm that second dose is required and within correct timeframe.</p>
<p>2. Have you had an allergic reaction to a vaccine or medication or other allergen in the past?</p> <p><i>* includes anaphylaxis requiring adrenaline and/or hospitalisation OR an allergic reaction within 4 hours causing hives, swelling or respiratory distress.</i></p>	<p>What was the allergic reaction to?</p> <p>(a) Previous COVID-19 vaccine? Which one? Pfizer or Astra Zeneca?</p> <p>(b) Polyethylene glycol (PEG), which is found in some medications, such as laxatives and preparations for colonoscopy procedures?</p> <p>(c) Polysorbate</p> <p>(d) Other vaccine?</p> <p>(e) Other injectable therapy (intramuscular, intravenous or subcut).</p> <p>What was the severity?</p>	<p>If (a), (b), (c) or (d) defer vaccination today and refer to the Western Health Specialist Immunisation Clinic (SIC) at Sunshine Hospital.</p> <p>Contact SH hub’s HMO on 0478 908 746 to complete & email a referral form as per the ViCSIS guidelines</p> <p>If (e) Vaccine not to be given at outreach hub, defer to SH hub’s HMO. HMO to refer to SIC if concern or counsel about potential risk and observe for 30 minutes post vaccination (vaccination to only be undertaken at Sunshine).</p> <p>Allergic reactions, including severe allergic reactions that are NOT related to vaccines or injectable therapies, components of mRNA COVID-19 (Pfizer) vaccines (including PEG), or polysorbates are NOT contraindications or precautions for currently authorised COVID-19 vaccines.</p>

Pre Vaccination Question	If Yes	Further Information
		<p>HOWEVER, individuals who have had severe allergic reactions to anything, regardless of cause, should be observed for 30 minutes after vaccination at the Sunshine Hub.</p> <p>All others, including those with immediate allergic reactions that were not severe, should be observed for 15 minutes.</p>
<p>3. Have you ever had a positive test for COVID-19 or has a doctor ever told you that you have COVID-19?</p>	<p>When was the last time you had a positive test?</p> <p>Have you been cleared by DH and have clearance letter?</p>	<p>If within 3 weeks of last positive test and/or cannot provide a clearance letter, defer vaccination today and ask to reschedule (could still be shedding virus).</p>
<p>4. Do you have a bleeding disorder/currently taking anticoagulants?</p>	<p>If on anticoagulant therapy (not just aspirin), defer vaccination.</p> <p>Direct the vaccine recipient to discuss this with their treating doctor and reschedule appointment if cleared by treating doctor to receive vaccine.</p>	<p>If they have discussed this with their treating doctor and they have been deemed suitable, they may proceed with their vaccination today.</p> <p>Vaccinations should be administered via intramuscular injection, using a 25 gauge needle (if suitable).</p> <p>Ask vaccine recipient to apply firm pressure on injection site without rubbing for 2 to 5 minutes post injection to reduce bleeding and swelling.</p> <p>Advise they may have local bruising.</p>

Pre Vaccination Question	If Yes	Further Information
5. Are you immunocompromised?	Counsel vaccine recipient on unknown vaccine safety and effectiveness on immunocompromised people	<p>Vaccines may be administered to persons with underlying medical conditions who have no contraindications to vaccination.</p> <p>Vaccine recipients should be counselled about the unknown vaccine safety profile and effectiveness in immunocompromised populations, as well as the potential for reduced immune responses.</p> <p>Immunocompromised people should be advised to continue to follow all current guidance to protect themselves against COVID-19, including wearing a mask, social distancing, and washing hands frequently.</p>
6. Are you pregnant?	<p>If pregnant, defer appointment and ask person to speak with their GP or obstetrician.</p> <p>If remain anxious, refer women to WH SIC.</p>	<p>Vaccination in pregnancy is not routinely recommended, but is not contraindicated.</p> <p>There is no data on the safety of this vaccine in pregnancy and on pregnancy outcomes.</p> <p>Refer to the ATAGI COVID-19 vaccination decision guide for women who are pregnant, breastfeeding, or planning pregnancy for very helpful guidance.</p>
7. Are you breastfeeding?	If breastfeeding, reassure, can proceed with vaccination today.	Refer to the ATAGI COVID-19 vaccination decision guide for women who are pregnant, breastfeeding, or planning pregnancy for very helpful guidance.

Pre Vaccination Question	If Yes	Further Information
8. Are you feeling sick today, and/or have a temperature $\geq 38.5^{\circ}\text{C}$?	Defer vaccination today and reschedule appointment. Direct to nearest Respiratory Assessment Clinic to get tested for COVID-19 and isolate until result received.	If the vaccine recipient has a temperature and has had a negative COVID result they are still required to defer vaccination until they have recovered from their acute febrile illness. This is a general precaution for all vaccines and will also avoid misattribution of acute symptoms from the acute illness as being due to the vaccine or vice-versa.
9. Have you received any vaccines in the previous 14 days?	Confirm vaccination that has been received in the previous 14 days. Defer vaccination today and reschedule appointment.	Best practice is to separate COVID-19 vaccine and any others vaccines by 14 days.
10. Is the vaccine recipient < 16 years of age?	Cancel vaccination appointment.	Inform vaccine recipient that the vaccine is currently not approved for administration to people < 16 years of age.
11. Known systemic mast cell activation disorder with raised mast cell tryptase that requires treatment?	Defer vaccination today. Inform the vaccine recipient they require referral to the SIC.	Complete referral form and email to COVIDvaccinationSIS@wh.org.au
Pre Vaccination Question	If Yes	Further Information
12. Have you had cerebral venous sinus thrombosis (a type of brain clot) in the past?	Defer vaccination today. Inform the vaccine recipient they require referral to the SIC.	Complete referral form and email to COVIDvaccinationSIS@wh.org.au

<p>13. Have you had heparin-induced thrombocytopenia (a rare reaction to heparin treatment) in the past?</p>	<p>Defer vaccination today.</p> <p>Inform the vaccine recipient they require referral to the SIC.</p>	<p>Complete referral form and email to COVIDvaccinationSIS@wh.org.au</p>
<p>14. Are you under 50 years of age?</p>	<p>Proceed with appointment when Pfizer is available.</p> <p>Defer vaccination today if Pfizer is currently unavailable.</p>	<p>ATAGI recommends that the COVID-19 vaccine by Pfizer (Comirnaty) is preferred over COVID-19 Vaccine AstraZeneca in adults aged under 50 years. This recommendation is based on the increasing risk of severe outcomes from COVID-19 in older adults (and hence a higher benefit from vaccination) and a potentially increased risk of thrombosis with thrombocytopenia following AstraZeneca vaccine in those under 50 years.</p> <p>COVID-19 Vaccine AstraZeneca can be used in adults aged under 50 years where the benefits clearly outweigh the risk for that individual and the person has made an informed decision based on an understanding of the risks and benefits.</p> <p>People who have had the first dose of COVID-19 Vaccine AstraZeneca without any serious adverse effects can be given the second dose, including adults under 50 years.</p>