# Kimberley Aboriginal Medical Services

# COVID-19 Vaccination Standard Operating Procedure

Version 2.4

Revision history

| Version | Date | Revised by | Changes |
|---|---|---|---|
| 2.4 | 13/07/2022 | Kimberley ACCHS COVID-19 Vaccine Management Group | • Updated COVID-19 vaccine eligibility |
| 2.3 | 10/06/2022 | Kimberley ACCHS COVID-19 Vaccine Management Group | • First booster dose in adolescents 12- 15 years<br>• Winter dose eligibility updated |
| 2.2 | 02/05/2022 | Kimberley ACCHS COVID-19 Vaccine Management Group | • Adult primary dose schedule<br>• Vaccination following positive COVID-19 infection |
| 2.1 | 07/04/2022 | Kimberley ACCHS COVID-19 Vaccine Management Group | • Paediatric Pfizer vaccine dose schedule<br>• Dose schedule updated<br>• Winter dose included |
| 2.0 | 04 February 2022 | Kimberley ACCHS COVID-19 Vaccine Management Group | • ATAGI advice on vaccination for those recently infected with COVID-19<br>• Change of age of boosters to 16+ |
| 1.16 | 11 January 2022 | Kimberley ACCHS COVID-19 Vaccine Management Group | • Cold-Chain management of Paediatric Pfizer<br>• Appendix X – vaccine comparison<br>• Change in recommendation to exclude AZ<br>• Cascades to illustrate dose intervals for immunocompromised and non-immunocomp.<br>• Appendix U – added Paediatric Pfizer chart as U2 |
| 1.15 | 7 January 2022 | Kimberley ACCHS COVID-19 Vaccine Management Group | • Updated recommendations for booster dose in immunocompromised (4th dose)<br>• Revision of Background section to incorporate updated ATAGI objectives<br>• Note of extra module (module 4) required for 5-12yo<br>• Change of booster dose interval to 4 months with reduction further in late January to 3 months flagged |
| 1.14 | 16 December 2021 | Kimberley ACCHS COVID-19 Vaccine Management Group | • Guidelines for Pfizer in 5-11 year olds<br>• RAT testing guidelines<br>• Co-administration with other vaccines<br>• Drawing up and administering Pfizer both age groups |
| 1.13 | 29 October 2021 | Kimberley ACCHS COVID-19 Vaccine Management Group | • Booster dose guidelines |
| 1.12 | 20 October 2021 | Kimberley ACCHS COVID-19 Vaccine Management Group | • AIR check prior to proceeding<br>• Medicare billing for 3rd dose |
| 1.11 | 13 October 2021 | Kimberley ACCHS COVID-19 Vaccine Management Group | • 3rd dose for immunocompromised |
| 1.10 | 6 October 2021 | Kimberley ACCHS COVID-19 Vaccine Management Group | • Useful Contacts |

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|---|---|---|---|
| | | | • Precautions for Comirnaty (Pfizer)<br>• Consent for mature minors<br>• Vaxtracker consent<br>• Wastage and disposal |
| **1.9** | 14 September 2021 | Kimberley ACCHS COVID-19 Vaccine Management Group | • Change in age eligibility for Pfizer to 12 and over<br>• Ordering vaccines<br>• TTS after AstraZeneca<br>• Myocarditis / Pericarditis precautions added<br>• Pfizer cold chain update (6 hours in cold chain after dilution) |
| **1.8** | 23 July 2021 | Kimberley ACCHS COVID-19 Vaccine Management Group | • Reporting cold-chain breaches and adverse events |
| **1.7** | 12 July 2021 | Kimberley ACCHS COVID-19 Vaccine Management Group | • COVID-19 vaccination in Pregnant and Breastfeeding Women advice<br>• COVID-19 vaccination timing with other vaccines<br>• New age recommendation for AstraZeneca<br>• Freezer management for Pfizer vaccine kept at -25 to -15◦C<br>• Appendix V: Do not unplug sign<br>• Appendix W: Freezer temperature log |
| **1.6** | 8 June 2021 | Kimberley ACCHS COVID-19 Vaccine Management Group | • Vaccine Information: Pfizer/BioNTech Vaccine<br>• COVID-19 Vaccine Contraindications and Precautions<br>• Very rare adverse events following immunisation<br>• Maintaining cold chain: Pfizer<br>• Vaccine preparation: Pfizer |
| **1.5** | 6 May 2021 | Kimberley ACCHS COVID-19 Vaccine Management Group | • Managing stock<br>• Consent<br>• Thrombosis with thrombocytopenia after COVID-19 vaccine AstraZeneca<br>• Disposal of vials |
| **1.4** | 12 April 2021 | Kimberley ACCHS COVID-19 Vaccine Management Group | • New safety recommendations from ATAGI regarding COVID-19 Vaccine AstraZeneca as of 8 April 2021<br>• Consent: safety investigation into thrombosis and thrombocytopenia<br>• Dealing with spillages of AstraZeneca vaccine<br>• MMEx template<br>• Appendix Q: COVID-19 Vaccine Checklist |
| **1.3** | 6 April 2021 | Kimberley ACCHS COVID-19 Vaccine Management Group | • Pre-vaccination checklist procedures<br>• Patient information leaflet<br>• AusVaxSafety (Vaxtracker surveillance tool) consent<br>• MBS key points |
| **1.2** | 26 March 2021 | Kimberley ACCHS COVID-19 Vaccine Management Group | • Stock acceptance procedure<br>• Contraindications (CVST and HITS) |
| **1.1** | 19 March 2021 | Kimberley ACCHS COVID-19 Vaccine Management Group | |

This document and appendices are available on the KAMS website at:

https://kams.org.au/covid-19-vaccine-clinical-resources/

Please ensure you are using the most recent version of the document available online.

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# 1 USEFUL CONTACTS

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|---|---|---|---|
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# 2 Background

Phase 1b of the national COVID-19 vaccine roll-out commenced in March 2021. This phase ensures access to COVID-19 vaccination to priority populations, including Aboriginal and Torres Strait Islander people through Aboriginal Community Controlled Health Services (ACCHS).

The overarching goal of Australia's COVID-19 vaccination program is to protect all people in Australia from the harm caused by SARS-CoV-2, primarily through preventing serious illness and death. As the virus that causes COVID-19, SARS-CoV-2, is likely to become endemic in Australia, ATAGI (Australian Technical Advisory Group on Immunisation) strongly advises that the highest priority for providing optimal community-wide protection against COVID-19 is achieving very high vaccination coverage for all eligible Australians.

It is recommended that all people aged 5 years and over have two doses of the COVID-19 vaccine to help protect individuals and the community.

ATAGI recommends a third booster dose of COVID-19 vaccine for all Australians aged 16 years or older, to mitigate against waning immunity to SARS-CoV-2 and emergence of SARS-CoV-2 variants. A first booster dose may be given to certain adolescents aged 12 – 15 years. In addition, a fourth 'winter' booster dose is recommended for certain population groups. The Pfizer vaccine is the only brand currently registered for use as a booster dose in this age group. ATAGI will update this advice if other vaccines are approved.

# 3 Scope

This document serves as a Standard Operating Procedure (SOP) to provide clear guidance on the operational and functional arrangements for Kimberley Aboriginal Medical Service (KAMS) remote clinics and headspace to effectively deliver COVID-19 vaccines in their communities. This guidance may also be utilised by Kimberley Renal Services (KRS) renal health centres and KAMS member services.

A suite of resources is provided as appendices to be used at the discretion of each clinic.

# 4 Preparation

This section details the preparation required for each site prior to commencing vaccine administration. Key information in this section is summarised in a site readiness checklist in Appendix A. Clinics are encouraged to print this checklist and ensure all requirements are met prior to vaccine arrival.

## 4.1 Workforce

Appendix B provides suggested workforce and patient flow mapping of COVID-19 vaccination at the vaccination site.

### 4.1.1 Leadership

Each clinic manager is responsible for ensuring adequate staffing of the clinic to facilitate administration of COVID-19 vaccinations alongside other clinic responsibilities. Concerns regarding staffing levels should be escalated to appropriate Executive Managers.

### 4.1.2 Surge vaccinators

Surge vaccinators will be available from other KAMS departments and external organisations. Surge vaccinators may be asked to assist clinics with clinic-based vaccination or vaccination outreach, depending on demand and staffing levels.

### 4.1.3 Authority to vaccinate

Immunisation providers can administer COVID-19 vaccinations independently:

- Doctors
- Registered Nurses (RNs) with immunisation provider qualifications
- Aboriginal Health Workers (AHWs) and Aboriginal Health Practitioners (AHPs) with immunisation provider qualifications

With an immunisation provider on site:

- RNs, Registered Midwives, Medication Competent Enrolled Nurses (ENs), AHPs, Medication Competent AHWs and Pharmacists are authorised to administer COVID-19 vaccines via the KAMS Structured Administration and Supply Arrangements (SASA) (Appendix C).

### 4.1.4 Non-clinical support staff

Non-clinical support staff may be required to assist in tasks including transport, re-stocking, cleaning, administration, waste removal and assisting with patient registration, direction and flow. Other staff that may be required to assist with non-clinical duties include Community Liaison Officers (CLOs) who may be required to assist with patient flow.

## 4.2 Training Requirements to vaccinate

- COVID-19 vaccine administrators **must** have completed the Department of Health's COVID-19 vaccination training program (available at https://covid19vaccinationtraining.org.au/), including;
    - Modules 1-6 AND
    - Additional Module 1: Pfizer/BioNTech vaccine
    - Additional Module 2: AstraZeneca vaccine
    - Additional Module 4: Pfizer (COMIRNATY) Paediatric COVID-19 vaccine (updated Jan 2022)

    https://covid19vaccinationtraining.org.au/login/index.php

- COVID-19 vaccine administrators must be competent in:
    - Cardiopulmonary resuscitation (CPR)
    - Diagnosis and management of anaphylaxis

- Vaccinators must have access to the Australian Immunisations Register (AIR) through PRODA, and the Western Australian Vaccine Safety Surveillance system (WAVSS).

## 4.3 Access

To ensure accessibility of COVID-19 vaccination to the community, vaccination can be provided in several ways;

- Clinic-based vaccination
- Vaccination outreach
    - Home visits
    - Community events

## 4.4 Layout and flow

The setup of the vaccination clinic site will vary by capacity and room layout but should have a logical one directional flow. The use of a standard clinic layout is recommended as much as possible to avoid confusion among rotating staff. See Appendix B for suggested workforce and patient flow mapping.

Space and staffing are required for:

- Pre-vaccination consultation: a private space to provide education and gain informed consent
- Vaccine draw up: a dedicated, well-lit and clean environment, with a second vaccinator to check dose drawn
- Vaccine administration: ideally, separate to the drawing up space
- Post-vaccination observation

## 4.5 Signage

### 4.5.1 Patient facing signage

KAMS develop posters and signs advising community members of vaccine availability. These are delivered directly to each clinic to be to displayed within the clinic and appropriate community locations.

### 4.5.2 Clinician facing signage

KAMS develop or endorse clinic prompts to be placed within the clinic to provide visual reminders and avoid errors. See Appendices D-W.

## 4.6 Physical environment

A COVID-19 vaccination clinic site must comply with a range of minimum requirements as outlined by the Australian Government. These are:

- Facilitate physical distancing and shelter from weather
- Private space for consultation with patients and vaccinator
- Dedicated, clean, well-lit space for administration of vaccine to patients

- Space for patients to wait and be observed post-vaccination, separate from area for administering the vaccine
- 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)
- Dedicated, clean, well-lit area where vaccines from multi-dose vials may be drawn up, labelled, and prepared for administration
- Adequate handwashing facilities, and antimicrobial hand sanitiser available
- Antimicrobial/disinfectant wipes to clean stations between patients
- Visual reminders and cues in place to reduce risk of errors
- Process to safely dispose of unused vaccines

## 4.7 Occupational health requirements

Clinics will comply with KAMS Occupational Health and Safety policies and procedures relevant to their scope of practice in immunisation and area health service including:

- Disposal of infectious waste including used needles and empty vaccine vials
- Occupational needle-stick injuries
- Safe work practices and reporting of potential hazards
- Incident management
- Managing violence and aggression
- Personal Protective Equipment

# 5 COVID-19 Vaccine Information

## 5.1 Pfizer/BioNTech Vaccine (COMIRNATY BNT162b2)

The TGA provisionally approved the Pfizer COVID-19 vaccine for **individuals 5 years of age and older**. Paediatric Pfizer is available for children 5 to 11 years of age. Pfizer vaccine product information can be viewed here.

### 5.1.1 Indications for use

The Pfizer vaccine is the **preferred vaccine** for **all people aged 5 and over** and can be used in **people with a past history of CVST, HIT, splanchnic vein thrombosis or antiphospholipid syndrome with thrombosis.** The Pfizer vaccine is not associated with a risk of TTS.

### 5.1.2 Dose and administration

#### *5.1.2.1 Adolescent / adult Pfizer for ages 12 and over (Purple top vials)*

- Intramuscular injection (IM) into deltoid muscle
- Dose schedule can be found at Appendix X
- 0.3mL each dose
- Preliminary data suggest that the increased antibody levels generated following a COVID-19 vaccine booster dose may offer improved protection against the Omicron variant. However,

the correlation between antibody levels in laboratory studies and protection against infection and severe disease is not yet established. Early indications around hospitalisation, ICU admission and death show that Omicron could be far less than Delta and other variants (COVID-19 Omicron update from CMO Prof Paul Kelly, 21st December 2021).

- A first booster dose of COVID-19 vaccine is recommended in adolescents aged 12 – 15 years who have completed a primary course of vaccination 3 or more months ago and fit the following criteria:
    - Those who are severely immunocompromised
    - Those who have a disability with significant or complex health needs
    - Those who have complex and/or multiple health conditions that increase the risk of severe COVID-19.
- A winter dose of COVID-19 vaccination is recommended for selected population groups:
    - Adults 50 years of age and over;
    - Residents of aged care or disability care facilities;
    - Aboriginal and Torres Strait Islander people aged 50 years and over;
    - People aged 16 years and over who are severely immunocompromised (fifth dose);
    - People aged 16-64 with a medical condition that increases the risk of severe COVID-19 illness (see ATAGI Statement – recommendations on winter COVID-19 booster doses 25 May 2022)
    - People aged 16-64 living with a disability with significant or complex health needs or multiple comorbidities with increased risk of poor outcome.
- The winter booster dose of COVID-19 is also available for adults aged 30 – 49 years of age.

  The winter dose can be given from 3 months after receiving the 3rd or last dose OR 3 months after a COVID-19 infection. ATAGI statement on recommendations on a winter booster dose of COVID-19 vaccine available here: https://www.health.gov.au/news/atagi-updated-recommendations-for-a-winter-dose-of-covid-19-vaccine

- The COVID-19 vaccine does not protect against influenza. See section 5.2.3.2 for more information.

ATAGI is not currently recommending booster doses for:

- people aged 5 to 15 years*
  *(refer to above regarding certain population groups 12 – 15 years).

#### *5.1.2.2 Paediatric Pfizer for ages 5 to 11 years (Orange top vials)*

1 IM injection into deltoid muscle
2 Dose schedule can be found at Appendix X
3 0.2mL each dose
4 See ATAGI recommendations https://www.health.gov.au/sites/default/files/documents/2021/12/atagi-recommendations-on-pfizer-covid-19-vaccine-use-in-children-aged-5-to-11-years_0.pdf

*List of ingredients*

- Tozinameran or BNT162b2 mRNA (the active ingredient)
- ((4-hydroxybutyl)azanediyl)bis(hexane6,1-diyl)bis(2-hexyldecanoate) (ALC-0315)
- 2-[(polyethylene glycol)-2000]-N, N-ditetradecylacetamide (ALC-0159)
- Distearoylphosphatidylcholine (DSPC)
- Cholesterol
- Potassium chloride
- Monobasic potassium phosphate
- Sodium chloride
- Dibasic sodium phosphate dehydrate
- Sucrose
- Water for injection

### 5.1.3 Cold chain management

Storage and transport of the Pfizer vaccine requires ultra-cold chain (UCC) management.

#### *5.1.3.1 Freezer management and monitoring*

- Ensure Pfizer storage container and freezer is clearly labelled with the date the vials entered the freezer, and when to be removed.
- Ensure there is a "Do Not Unplug" poster at the freezer's plug point! (Appendix V).
- Nuline Freezers are available in some clinics
  - Document the min/max temps *once* each workday, preferably in the morning
    a) Press Hi/low button and your max temperature will appear while flashing; repeat process to obtain min temperature
  - Check and record the current temperature of the freezer two times per day and document on temperature log (Appendix W)
  - If there are any temperatures out of range (not between -15 and -25) then alert your clinic manager immediately who should follow steps in SOP for cold chain breach
  - Take your time: check and record temperatures accurately
  - Make your mark: initial the log when recording temperatures
  - Leave it blank: if min/max temperatures were not recorded

#### *5.1.3.2 Storage*

- Pfizer vaccine should have minimal exposure to room light, and avoid exposure to direct sunlight. When possible, store Pfizer vaccine in the original boxed packaging / tray.
- Storage in a freezer – frozen vaccines should remain in the middle of the freezer leaving room for air to circulate around the vaccine
- Storage in vaccine fridge - defrosted vaccines should remain in a vaccine fridge
- Do not store any food or drink in vaccine freezer of fridge

#### *5.1.3.3 Cold chain process*

Pfizer vials must be thawed before use. Once thawed, Pfizer vaccine cannot be re-frozen. Thawing can occur by two methods:

- Place individual vials or whole vial pack into a cold chain (+2°C to +8°C) fridge – the full vial tray may take 3 hours to thaw;

- Place the individual vials on a workbench for 30 minutes at temperatures up to +30°C. The vials must then be used immediately (within 2 hours from being removed from fridge or freezer).

*Adolescent / adult Pfizer*

- Vials can be stored in a freezer between -**90°C and -60°C for up to 9 months**.
- Unopened vials may be stored and transported at **-25°C to -15°C for up to 2 weeks** (and can be **returned to UCC storage afterwards**). This frozen stock must be removed from the freezer and defrosted in the vaccine fridge.
- *Unopened thawed* vial can be maintained through **normal cold chain practices** (**+2°C to +8°C**) for a maximum of **31 days** (see TGA approval).
- *Diluted* vial can be stored for up to **6 hours** (including thawing time) in cold chain temperatures of **+2°C to +8°C** or up to **2 hours** (including thawing time) in room temperatures **+8°C up to +30°C**. The maximum time includes any time that the vial has spent outside the **+2°C to +8°C** (once thawed) which may include during stocktake time.

*Paediatric Pfizer*

- Vials can be stored in a freezer between -**90°C and -60°C for up to 6 months**.
- *Unopened thawed* vial can be maintained through **normal cold chain practices** (**+2°C to +8°C**) for up to **10 weeks**.
- *Diluted* vial can be stored for up to **12 hours** (including thawing time) in cold chain temperatures of **+2°C to +8°C** or up to **1 hour** (including thawing time) in room temperatures **+8°C up to +30°C**. The maximum time includes any time that the vial has spent outside the **+2°C to +8°C** (once thawed) which may include during stocktake time.

#### *5.1.3.4 Cold chain breach*

In the event of a potential or actual cold-chain breach (see Appendix G– "Strive for 5" Cold Chain Breach):

1. Immediately isolate the vaccines
2. Keep vaccines refrigerated between +2°C to +8°C, and label 'DO NOT USE'
3. Do not discard any vaccine until advised to do so by the VOC
4. Take steps to correct the problem and to prevent it from recurring
5. Notify the Department of Health immediately by calling the Vaccine Operations Centre (VOC) on 1800 318 208 and complete the Australian Government Vaccine Wastage Report online
6. Notify the KAMS medical director (0407 974 951)
7. Lodge a clinical incident through LogiQC

### 5.1.4 Pfizer resources

COVID-19 vaccination – patient resources

**Currently, Pfizer and AstraZeneca vaccines are not considered interchangeable. The two-dose course should be completed with the same vaccine.**

## 5.2 COVID-19 Vaccine Contraindications and Precautions

See ATAGI Clinical guidance on use of COVID-19 vaccine in Australia in 2021

See ATAGI Information for providers: COVID-19 Vaccination Consent & FAQs

### 5.2.1 Absolute Contraindications

All Types:

- Anaphylaxis after a previous dose of the same vaccine
- Anaphylaxis to any component of the vaccine, including to polyethylene glycol (PEG) for the Pfizer COVID-19 vaccine
- History of myocarditis and / or pericarditis with previous dose mRNA Covid 19 vaccine (Pfizer / Moderna).

See Very Rare Adverse Events Following Immunisation for Anaphylaxis Management Information

### 5.2.2 Precautions

#### *5.2.2.1 Circumstances where Pfizer is preferred over AstraZeneca*

KAMS recommends the use of Pfizer mRNA vaccine for all patients unless there is a contraindication or lack of supply. In these circumstances only should the use of AstraZeneca or other Covid-19 vaccines be considered.

In particular, the following situations would be indications for Pfizer mRNA vaccine and AstraZeneca should be avoided:

- People aged 5 years and over
- People with a past history of cerebral venous sinus thrombosis (CVST)
- People with a past history of heparin induced thrombocytopenia (HITS)
- Past history of idiopathic splanchnic (mesenteric, portal, splenic) vein thrombosis
- Antiphospholipid syndrome with thrombosis

#### *5.2.2.2 Specific allergies*

Assess the following individuals for vaccination suitability, if necessary in consultation with an allergist/immunologist or specialist immunisation clinic:

- People with immediate (within 4 hours) and generalised symptoms of a possible allergic reaction (e.g. urticarial/hives) to a previous dose of a COVID-19 vaccine
- People with a generalised allergic reaction (without anaphylaxis) to any component of the COVID-19 vaccine to be administered
- People with a history of anaphylaxis to previous vaccines and/or multiple drugs where ingredients such as PEG (mRNA vaccines) or polysorbate 80 (AZ vaccine) may conceivably be the cause
- People with a known systemic mast cell activation disorder associated with anaphylaxis with raised mast cell tryptase that requires treatment

People in these categories may require vaccination in a facility with medical staff in attendance, observation for at least 30 minutes following administration of a COVID-19 vaccine dose, or vaccination with an alternate brand of COVID-19 vaccine.
See ASCIA Guide: Allergy and COVID-19 Vaccination

#### *5.2.2.3 Acute illness*

- Defer vaccination in people with an acute illness e.g. temperature ≥ 38.5.

#### *5.2.2.4 People with bleeding disorders*

- Inform people with bleeding disorders or on anticoagulant therapy about the risk of haematoma with intramuscular injection

*5.3.2.5 People with specific heart conditions* can receive an mRNA vaccine in consultation with a GP or cardiologist about the best timing of vaccination and whether any additional precautions are recommended (see https://www.health.gov.au/sites/default/files/documents/2021/09/covid-19-vaccination-information-on-covid-19-pfizer-comirnaty-vaccine.pdf)

- Inflammatory cardiac illness e.g. myocarditis, pericarditis, endocarditis within the past 6 months
- *Current acute* rheumatic fever (with active myocardial inflammation), or acute Rheumatic Heart Disease
- *Acute decompensated* heart failure

People with the following stable heart conditions DO NOT NEED TO CONSULT with a specialist prior to being vaccinated with mRNA vaccine (e.g. Cominarty/Pfizer) and it is extremely important that these groups are vaccinated in a timely fashion:

- Chronic Rheumatic Heart Disease (RHD)
- Ischaemic Heart Disease (IHD)
- Congenital heart disease
- Cardiac transplant recipients
- Kawasaki Disease
- Arrhythmia
- Implantable cardiac devices
- Inflammatory cardiac illness > 6 months ago
- Cardiomyopathy

### 5.2.3 Special Circumstances warranting discussion before vaccination

#### *5.2.3.1 Pregnancy*

- It is recommended that pregnant women are routinely offered the Pfizer mRNA vaccine at any stage of pregnancy. Global surveillance data have not identified any significant safety concerns with mRNA COVID-19 vaccines given at any stage of pregnancy.
- There is evidence of antibody in cord blood and breastmilk, which may offer protection to infants through passive immunity.
- Women who are breastfeeding or planning pregnancy can receive the COVID-19 vaccine.

- See the KAMS COVID-19 and pregnancy information sheet for further information.

See RANZCOG statement COVID-19 Vaccination in Pregnant and Breastfeeding Women

#### *5.2.3.2 Co-administration with other vaccines*

- COVID-19 vaccines can be co-administered with an influenza vaccine or another vaccine if required.
- The COVID-19 vaccine does not protect against influenza. To reduce the likelihood of contracting both influenza and COVID-19 infection at the same time, it is recommended to get the influenza vaccine ahead of the influenza season. Any dose of the COVID-19 vaccine can be co-administered (given on the same day) with the annual flu vaccine. This is safe and produces a good immune response.
- New evidence demonstrates the safety and immunogenicity of co-administration of COVID-19 and influenza vaccines. There is limited data on the concomitant use of COVID-19 vaccines with other vaccines.
- There is a need to balance the need for co-administration with giving vaccines on separate visits. Co-administration or near administration of 2 or more vaccines can lead to a higher frequency of mild to moderate adverse events. It can also make it harder to attribute potential adverse events to specific vaccines.
- Inform the patient of the increased likelihood of experiencing common adverse effects. Encourage them to report any adverse events.
- Defer all vaccinations if the patient is acutely unwell. Wait until any short-term expected adverse events following vaccination (such as fever) have resolved before giving any other vaccines.

#### *5.2.3.3 People who are severely Immunocompromised*

- COVID-19 vaccination is recommended for people who are severely immunocompromised due to the increased risk of severe illness with COVID-19.
- There are no theoretical safety concerns for COVID-19 vaccination in people who are severely immunocompromised.
- ATAGI recommends a 3rd dose of COVID-19 vaccine as part of the primary course in individuals who are severely immunocompromised. This is to address the risk of suboptimal or non-response to the standard 2 dose schedule. The 3rd dose is scheduled 2 months after dose 2, and is intended to maximise the level of immune response to as close as possible to the general population. This recommendation applies to all individuals aged ≥12 years with certain conditions or on therapies leading to severe immunocompromise, as defined in **Box 1.** A minimum interval of 4 weeks may be considered in exceptional circumstances (e.g., anticipated intensification of immunosuppression, outbreaks). People who have had a second dose more than 6 months ago should receive a 3rd dose whenever feasible.
- People aged 12 and over with severe immunocompromise who have received the 3 dose primary course of a COVID-19 vaccine are recommended to receive a booster (i.e. 4th dose) 3 months after receiving their third dose as part of their primary course, in line with the timing of the general population.

- A 5th winter dose is recommended for people aged 16 and over who are severely immunocompromised. This will be 4 months after receiving their fourth booster dose (comparison with normal schedule illustrated in Figure 1 and Figure 2 Section 5.2.2). This is expected to improve the protection against symptomatic infection, serious illness or death from COVID-19 caused by Omicron variant.
- An individual with an unlisted condition should only be considered for a 3rd dose where the treating physician has assessed the patient as having a similar level of severe immunocompromise to the listed conditions in Box 1, and where the benefits of a 3rd dose of COVID-19 vaccine outweigh the risks.
- Individuals who currently are not severely immunocompromised but who will commence significant immunosuppressive therapy ≥ 2 weeks after their 2nd dose do not require a 3rd dose, as it can be expected that an adequate response to 2 primary doses will be achieved.

**Recommendations specific to the 3rd dose & booster doses (Immunocompromised – completion of primary course):**

An mRNA vaccine (Pfizer or Moderna) is preferred to Vaxzevria (AstraZeneca) for both the 3rd dose and the booster doses. *Note that KAMS no longer supplies Astra Zeneca vaccine.*

- AstraZeneca can be used for the 3rd dose for individuals who have received AstraZeneca for their first 2 doses if there are no contraindications or precautions for use, or if a significant adverse reaction has occurred after a previous mRNA vaccine dose which contraindicates further doses of mRNA vaccine (e.g., anaphylaxis, myocarditis).
- Antibody testing is not recommended to assess for immunity to SARS-CoV-2 following COVID-19 vaccination, including in immunocompromised individuals after a 2nd or 3rd dose. There are no serological assays that provide a definitive correlate of immunity to SARS-CoV
- There is currently no recommendation with regard to 3rd dose use for children 5 to 11 years (January 2022)
- Further information on these recommendations is available in the ATAGI Recommendations on the use of a 3rd primary dose of COVID-19 vaccine in individuals who are severely immunocompromised.

**People with the following immunocompromising conditions and therapies for which a 3rd primary dose is recommended:**

- Active haematological malignancy
- Non-haematological malignancy with current active treatment including chemotherapy, radiotherapy, and/or hormonal therapy, but excluding immunotherapy with immune checkpoint inhibitors
- Solid organ transplant with immunosuppressive therapy
- Haematopoietic stem cell transplant (HSCT) recipients or chimeric antigen receptor T-cell (CAR-T) therapy within 2 years of transplantation
- Immunosuppressive therapies
- Primary immunodeficiency
- Advanced or untreated HIV with CD4 counts <250/µL or those with a higher CD4 count unable to be established on effective antiretroviral therapy

- Long term haemodialysis or peritoneal dialysis

  https://www.health.gov.au/news/atagi-statement-on-the-use-of-a-3rd-primary-dose-of-covid-19-vaccine-in-individuals-who-are-severely-immunocompromised#:~:text=are%20severely%20immunocompromised.-,ATAGI%20recommendations,Long%20term%20haemodialysis%20or%20peritoneal%20dialysis,-Tags%3A%C2%A0

See ATAGI provider guide to COVID-19 vaccination of people with immunocompromise

#### *5.2.3.4 Past history of COVID-19 or ongoing illness from COVID-19*

- **People with COVID-19 infection should defer the next scheduled dose of COVID-19 vaccine for 3 months after onset of the infection. The next scheduled dose should be given as soon as possible after this period.** ATAGI has decreased the time allowable for deferral of vaccination after prior SARS-CoV-2 infection from 6 months to 4 months, due to the increased risk of re-infection with the Omicron variant, particularly for those who had a Delta variant infection in 2021.
- People who have received an anti-SARS-CoV-2 monoclonal antibody or convalescent plasma should defer future doses of COVID-19 vaccine for at least 90 days.
- Previously, past infection was shown to reduce the risk of reinfection for at least 6 months.[18-20] Early evidence from the Omicron wave shows there is increased risk of re-infection that was not present during the Beta and Delta variant waves. A 2-dose primary schedule and booster doses are recommended in previously infected people and is safe and well tolerated.[19,21,22] A 3-dose primary schedule is recommended in previously infected people aged ≥5 years who are severely immunocompromised.
- People who have prolonged symptoms from COVID-19 beyond 4 months after the initial illness can be vaccinated. Laboratory, PCR or Rapid Antigen Testing (RAT) to detect current or past infection with SARS-CoV-2 before vaccination is neither necessary nor recommended.
- https://www.health.gov.au/initiatives-and-programs/covid-19-vaccines/advice-for-providers/clinical-guidance/clinical-recommendations#:~:text=vaccine%20adverse%20events.%C2%A0-,People%20with%20a%20past%20SARS%2DCoV%2D2%20infection,after%20the%20first%20dose%2C%20but%20not%20after%20the%20second%20dose.,-23%C2%A0

## 5.3 Pre-vaccination checklist

A comprehensive COVID-19 Vaccination Checklist is available in Appendix Q. This document is to be used as a visual reminder of all the steps involved in processing a patient for vaccination.

- There is no need to print and complete a checklist for each patient, however this checklist should be used as a guide to ensure informed consent is obtained appropriately and all contraindications and precautions are checked and managed.
- Links to clinical decision-making tools are included in the checklist.

- Refer to COVID-19 vaccination – ATAGI clinical guidance on COVID-19 vaccine in Australia 2021 for further clinical guidance.

The checklist details the processes required during a COVID-19 vaccine clinical encounter, including;

- Checking on the Australian Immunisation Register for past vaccination – number, type and timing
- MMEx registration and confirmation of details
- Obtaining and documenting informed consent
- Checking for contraindications and precautions to vaccination
- Post-vaccination observation and tasks

If there are any concerns regarding possible contraindications or precautions to COVID-19 vaccination discuss this with on-site or on-call GP ***before*** proceeding with vaccination.

## 5.4 Consent

Providers should always ensure that informed consent is obtained and documented

### 5.5.1 General Consent Matters:

As with all other vaccines, informed consent is required before administering each COVID-19 vaccine dose. Verbal or written consent is acceptable (written consent is not mandatory).

Consider using an interpreter to assist in providing information and obtaining informed consent. Aboriginal language interpreters can be booked through Aboriginal Interpreting WA.

A vaccination information leaflet specific to each brand of vaccine (Appendix R1, Appendix R2) can be given to the patient at this stage to assist in decision-making.

If a patient declines COVID-19 vaccination after being informed, this should be documented in the clinical record via the *COVID-19 Vaccine Declined option in the drop down box on the MMEx progress note page.

All clinicians should refer to the ATAGI immunisation provider guide to obtaining informed consent for COVID-19 vaccine to guide consent discussions.

### 5.4.1 5.5.2 Consent for a Mature Minor:

In the case of a request for vaccination by an adolescent aged 12 to 16, there are guidelines outlined by headspace in the *document 526* (see hyperlink below) on LogiQc titled “Assessing the Mature Minor status of young people under 16’s Procedure”. This is a discussion on the principles of determining competency of a mature minor aged 12 to 16.

A minor may be legally competent to consent to treatment / engagement if they ‘achieve a sufficient understanding and intelligence to enable him or her to understand fully what is proposed’ (the Gillick test). The guiding principles are highlighted in the document (link below).

There should also be consideration given to cultural factors and to the mature minor's competency to appreciate all the elements involved in making the decision to have the vaccination without parental consent.

https://kamsc.logiqc.com.au//graphql/downloadFile/73c95491-028e-7e49-98a5-648f09fe384b?file=84921138-a50b-4d18-9020-ad0b00d749d1&filename=hs%20Broome%20Registration%20and%20Consent%20Form%20Doc_608.docx

### 5.4.2 Consent for people aged 5 – 11 years

For people aged 5 – 11 years, consent is required from a parent or guardian for COVID-19 vaccination. If a parent or guardian cannot attend, a nominated accompanying adult with verified identity can provide consent.

## 5.5 Adverse events following immunisation (AEFI)

An Adverse Event Following Immunisation (AEFI) is defined as
'an unwanted or unexpected event following the administration of a vaccine(s)'

An AEFI may be due to:

- A person's response to a vaccine
- Conditions that may occur following the incorrect handling or administration of a vaccine
- Coincidence, i.e. it would have occurred regardless of vaccination.

Completing a pre-vaccination screening checklist can reduce the chances of AEFI by identifying people with contraindications or at increased risk of AEFI before administration.

For advice on how to report an AEFI – see Reporting of adverse events after immunisation.

## 5.6 Common adverse effects following immunisation

Most common AEFIs are **mild and self-limiting** for 1 to 2 days. These can include:

- Site pain (>80%)
- Fatigue (>60%)
- Headache (>50%)
- Myalgia and chills (>30%)
- Arthralgia (>20%)
- Pyrexia (>10%)
- Injection site swelling (>10%)

## 5.7 Very rare adverse events following immunisation

### 5.7.1 Anaphylaxis

Anaphylaxis to vaccines is extremely rare. While rare, staff in charge of post-vaccination observation must be able to recognise the signs and symptoms of this medical emergency and provide appropriate management. Anaphylaxis usually occurs rapidly and within the first 15 minutes after administration (up to 6 hours).

**Severe cases can include:**

- Circulatory collapse
- Hypotension
- Weak or absent pulse
- Altered consciousness
- Marked respiratory compromise

**Early signs and symptoms can include:**

- Generalised erythema
- Urticaria
- Angioedema
- Diarrhoea
- Nausea and vomiting

Please refer to Appendices K and L for management of anaphylaxis and basic life support (CPR).

Important notes:

- It is NOT recommended to use antihistamines or hydrocortisone to treat anaphylaxis as this is a medical emergency. IM adrenaline is required (do not give IV).
- If a person has their own autoinjector with them, it is appropriate to use this as required to administer the adrenaline. The autoinjector should be administered in the mid-outer thigh.
- Any staff members who would like to refresh their understanding of the management of anaphylaxis are encouraged to complete an e-learning module on anaphylaxis management created by The Australasian Society of Clinical Immunology and Allergies.

### 5.7.2 Vasovagal episode

A vasovagal episode may occur following administration and can be a similar presentation to anaphylaxis. Therefore, it is important to be able to distinguish between these two medical events (see Appendix L – differences between anaphylaxis and vasovagal episode).

The **key differentiating sign between anaphylaxis and a vasovagal episode** is that the central (carotid) pulse is weak or absent during anaphylaxis but is strong during a vasovagal episode or convulsions

Fainting after vaccination can be serious and normally happens within 5 minutes of administration (up to 30 minutes).

#### *5.7.2.1 Management of vasovagal episode:*

1. Instruct the person to lie down somewhere safe if they are feeling dizzy or light-headed until they feel better.
2. Help them to loosen tight clothing and elevate their legs to promote venous return.

3. Monitor closely.
4. No other specific treatment is required until they feel better.

### 5.7.3 Bell's Palsy

Bell's Palsy has been reported as a rare side effect of the Pfizer vaccine.

### 5.7.4 Myocarditis / Pericarditis after COVID 19 mRNA vaccine (e.g. Pfizer Comirnaty or Moderna Spikevax)

See https://www.health.gov.au/sites/default/files/documents/2021/09/covid-19-vaccination-information-on-covid-19-pfizer-comirnaty-vaccine.pdf

- Symptoms typically appear within 1-5 days of vaccination
- Most cases linked to vaccination are mild and recover rapidly
- The risk in children aged 5 to 11 years is not yet known. The clinical trial in children aged 5 to 11 years did not have enough participants to assess rates of myocarditis or pericarditis following the Pfizer COVID-19 vaccine, but no specific safety concerns have been identified so far from millions of doses of this vaccine administered overseas to children aged 5 to 11 years. The benefits of vaccination outweigh this very rare risk, and vaccination is still recommended for all eligible age groups
- This condition can present with the following:
    - Chest pain
    - Palpitations (irregular heartbeat)
    - Syncope (fainting)
    - Shortness of breath
- Immediate Management
    - ED or cardiologist assessment or advice immediately on suspicion
    - Treatment specific to specific concerns may include antiarrhythmics, ACE inhibitors, diuretics, anti-inflammatories
- Clinical Investigations
    - ECG (ST or T wave abnormalities, premature atrial or ventricular complexes)
    - Troponin (usually elevated)
    - CXR
    - Echocardiogram or cardiac MRI if indicated clinically

# 6 Logistics and Supply

## 6.1 Ordering vaccines

Each service should have a designated staff member responsible for COVID-19 vaccine orders.

For KAMS Member Services, KAMS Remote Clinics, headspace and Kimberley Renal Service (KRS) Renal Health Centres, COVID-19 vaccine orders are the responsibility of the KAMS Vaccine Program Manager (currently Stefanie Faraone Stefanie.faraone@kamsc.org.au).

An order confirmation should be received, including the date of delivery.

Orders will need to include an authorised officer to be the point of contact for delivery acceptance and notifications.

- For KAMS Remote Clinics, headspace and KRS Renal Health Centres this will be the KAMS Medical Director (Lorraine Anderson (medicaldirector@kamsc.org.au ), KAMS Stores Officer, (Jake Coles storesofficer@kamsc.org.au ), and KAMS Vaccine Project Manager (Stefanie Faraone: Stefanie.faraone@kamsc.org.au ).

## 6.2 Accepting vaccines

When accepting the delivery of COVID-19 vaccines, the stock must be checked on arrival with clean hands, in a clean environment and as quickly as possible. This will include:

- Checking the package for signs of damage or tampering;
  Checking the temperature logger for indications of cold chain breach; and
- Visually inspecting the internal contents of the package.

If there is an issue with the delivery, sites will need to contact the VOC on **1800 318 208** immediately (within 2 hours of delivery)

Please also inform the KAMS medical director (0407 974 951) immediately

## 6.3 Managing stock

In order to ensure equitable and timely vaccine supply, it is important to have an accurate reporting system. A representative from each KAMS Remote Clinic is to update the KAMS Vaccine spreadsheet daily with the number of Pfizer vaccine vials currently in supply.

## 6.4 Non-vaccine stock

Clinic managers are responsible for ensuring adequate supplies of non-vaccine stock are available for ongoing COVID-19 vaccination. Lists of required stock can be found in Appendix P.

The non-vaccine stock that a clinic may require are defined under the following categories:

- **Patient facing vaccine consumables:** critical items required for the vaccinator to administer the COVID-19 vaccine. Each vaccine delivery will include syringes, needles and sharps waste disposal bin.
- **Personal Protective Equipment (PPE):** PPE is to protect health workers and those being vaccinated and is to be used in accordance with Infection Prevention and Control (IP&C) guidelines. Only examination gloves and hand sanitiser have been deemed as critical for the administration of the COVID-19 vaccine.
- **'Other' clinic equipment:** other equipment to support the implementation and ongoing running of a COVID-19 vaccination clinic.
- **ICT equipment and software**: this includes laptops, barcode scanners, and access to software and programs including MMEx.

## 6.5 Anaphylaxis Response Kits

Anaphylaxis Response Kits are to be used in the management of anaphylaxis. Clinic managers should ensure their site has adequate numbers of kits to support in-clinic and outreach vaccination (see Appendix P for list of items in Anaphylaxis Response Kits).

# 7 Clinic Operations

## 7.1 Documentation in MMEx

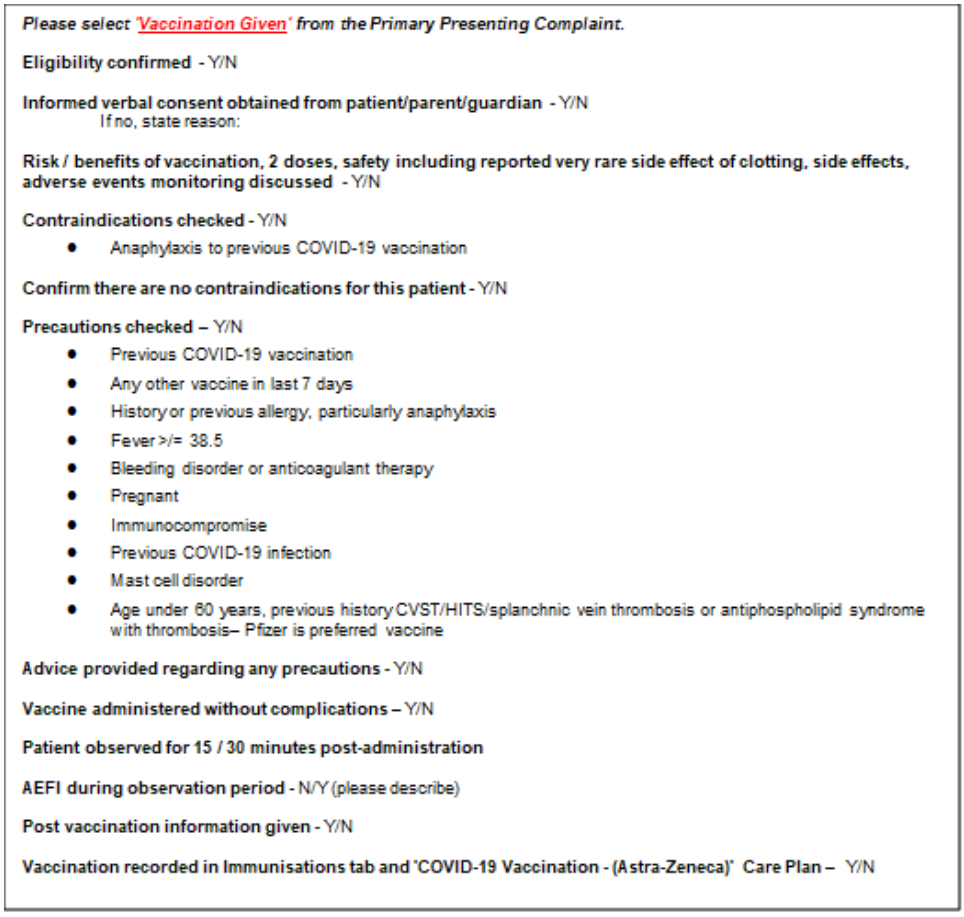
On presentation for COVID-19 vaccination, three steps must be completed for documentation within MMEx. A 4th procedure, addition of consent for side effect surveying by SMS (Vaxtracker) is highly recommended but not essential

1. **Check Australian Immunisation Register (AIR) for patient record of previous doses**
2. **Create Progress Note**

- **Primary presenting complaint:** "Vaccination given" if patient consents or "Vaccination not administered" if patient declines.
- **COVID-19 Dropdown:** Choose from one of the following:
    - "*COVID-19 Vaccine Given – Dose 1",
    - "*COVID-19 Vaccine Given – Dose 2"
    - "*COVID-19 Vaccine Given – Dose 3 Immunocompromised"
    - "*COVID-19 Vaccine Given – Booster"
    - "*COVID-19 Vaccine Given – Winter Dose)"
    - "*COVID-19 Vaccine Declined"

This is important to complete to enable accurate monitoring of vaccination rates.

- Use the pre-vaccination checklist which is available as a template in Progress Notes on MMEx ("COVID-19 Vaccine Consultation" – see below).



*Please select 'Vaccination Given' from the Primary Presenting Complaint.*

**Eligibility confirmed** - Y/N

**Informed verbal consent obtained from patient/parent/guardian** - Y/N
If no, state reason:

**Risk / benefits of vaccination, 2 doses, safety including reported very rare side effect of clotting, side effects, adverse events monitoring discussed** - Y/N

**Contraindications checked** - Y/N

- Anaphylaxis to previous COVID-19 vaccination

**Confirm there are no contraindications for this patient** - Y/N

**Precautions checked** – Y/N

- Previous COVID-19 vaccination
- Any other vaccine in last 7 days
- History or previous allergy, particularly anaphylaxis
- Fever >/= 38.5
- Bleeding disorder or anticoagulant therapy
- Pregnant
- Immunocompromise
- Previous COVID-19 infection
- Mast cell disorder
- Age under 60 years, previous history CVST/HITS/splanchnic vein thrombosis or antiphospholipid syndrome with thrombosis– Pfizer is preferred vaccine

**Advice provided regarding any precautions** - Y/N

**Vaccine administered without complications** – Y/N

**Patient observed for 15 / 30 minutes post-administration**

**AEFI during observation period** - N/Y (please describe)

**Post vaccination information given** - Y/N

**Vaccination recorded in Immunisations tab and 'COVID-19 Vaccination - (Astra-Zeneca)' Care Plan** – Y/N

Add template, ensure checklist is completed, and complete required fields (or choose Y/N option).

- Appendix Q (COVID-19 Vaccination Checklist) should be used alongside documentation in MMEx template for guidance on pre-vaccination screening.

3. Add COVID-19 Vaccination Care Plan (specific to vaccine brand)

- In "Care Plans" tab, click "Add New Care Plan".
- Select from the following:
  - "COVID-19 Vaccination – (AstraZeneca)"
  - "COVID-19 Vaccination – Comirnaty (Pfizer)"
  - "COVID-19 Vaccination – Comirnaty (Pfizer) (5-11 years)"
- Click "Choose This Care Plan For Patient" to generate the dose schedule.

4. Add Immunisation

- In "Immunisations" tab, click "Add Immunisation".
  - Type: choose
    - "COVID-19 Vaccine AstraZeneca Solution for injection"
    - "Comirnaty – Suspension for injection 30mcg – 0.3mL" (for adolescent / adult Pfizer)
    - "Comirnaty – Tris/Sucrose Presentation 10mcg – 0.2mL Dilute to use" (for paediatric Pfizer)
  - Site: document site of injection

- Batch No: record batch number (lot number) for vaccination
- Serial Number: record serial number for vaccination
- Expiry date: record expiry date for vaccination
- Dose: choose Dose 1, Dose 2, Dose 3, Booster, or Winter dose
- Reason: choose reason
- Patient education given: check box after patient education to obtain informed consent is given
- Consent received: tick box to confirm verbal consent received from patient
  - Consent Type: choose "COVID-19 Vaccination"
  - Consent Mode: choose written or verbal
  - Given by: choose who consent given by
- Click "Add"
- MMEx will automatically upload information to AIR **(DO NOT TICK "Don't send notifications" as this will mean the immunisation IS NOT uploaded to AIR)**

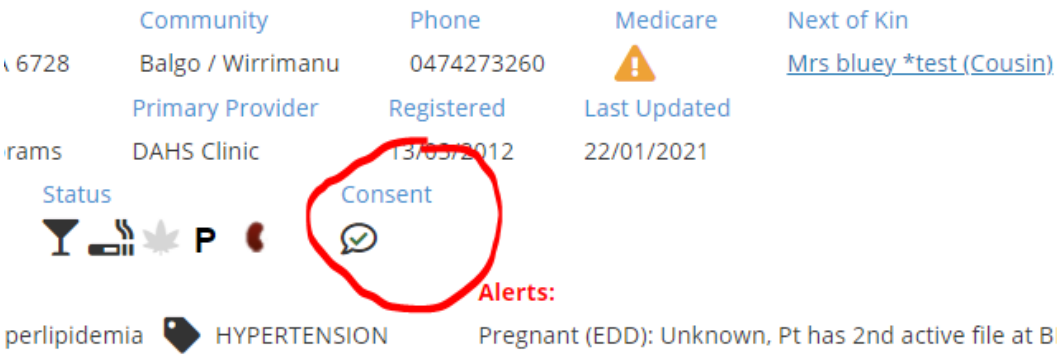
5. **Consent and Add Vaxtracker** (recommended but not essential).

### 7.1.1 AusVaxSafety

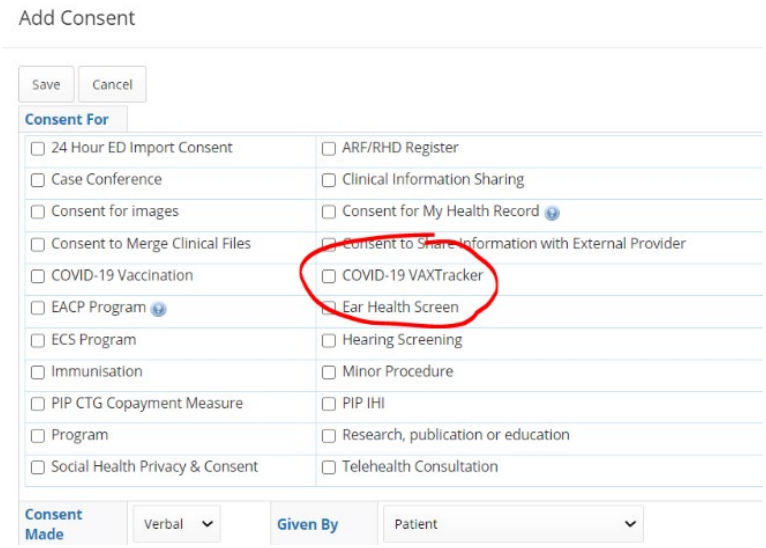
MMEx is linked with the Australian national vaccine safety system "AusVaxSafety". AusVaxSafety is the national safety surveillance initiative led by the NCIRS. It will automatically send an SMS to people who have received a vaccine to ask about their experience. The surveillance tool linked to MMEx is called Vaxtracker.

Ask each vaccine recipient if they **consent to receive SMS through clinical software**. To enable this function in MMEx:

Click on "Consent" Icon in patient file:




Click **"Add Consent"** and choose **"COVID-19 VAXTracker"**:




Ensure fields below are appropriately completed and click **"Save"**. This process will ensure patient is linked to the Vaxtracker surveillance tool.

## 7.2 COVID-19 vaccination checklist

### 7.2.1 Basic Principles

- All staff must complete COVID-19 Vaccination training including both Pfizer Modules – adolescent / adult and paediatric (available at https://covid19vaccinationtraining.org.au/login/index.php). For KAMS Remotes - certificates to be emailed to Carlinka Mackay (corporateservices@kamsc.org.au).
  The clinic manager or coordinator should ensure that all staff are adequately trained and supervised.
- Ensure different vaccines are stored in separate areas. For example, if one vaccine fridge is available store different vaccines on different shelves and ensure shelves are clearly labelled. Colour coded signage can be used. If two vaccine fridges are available, different vaccines should be stored in different fridges. When domestic freezers become available in clinic to store adolescent / adult Pfizer vaccine at -15 to -25 degrees C, ensure freezer is clearly labelled as Pfizer vaccine storage.

### 7.2.2 Pre-vaccination

- Always use the KAMS COVID-19 Vaccine checklist (Appendix Q) to check eligibility, contraindications and precautions to vaccination before vaccination (available at: https://kams.org.au/covid-19-vaccine-clinical-resources/). This checklist includes checks to ensure the correct vaccine is advised for each patient.
- Before opening a vial and preparing a dose of vaccine, check the vaccine type, dose and dosing interval with another colleague every time. Orange top vials are for 5 to 11 year olds, and purple top vials are for 12 and over (Pfizer).

- When labelling a vaccine vial, ensure the correct vaccine label is used to identify when the vial was opened (and diluted for Pfizer). Ensure the expiry time and date is clearly labelled. Specific labels for adolescent / adult Pfizer and paediatric Pfizer are available.

### 7.2.3 During vaccination

- Before administering a vaccine, check the vaccine type, dose and dosing interval with another colleague every time.

### 7.2.4 After vaccination

- Patients should be provided with vaccine information sheets specific to the brand they receive. Information for before and after each brand of vaccine is available with the KAMS COVID-19 vaccination SOP (appendices R1&2, S) at: https://kams.org.au/covid-19-vaccine-clinical-resources/
- Ensure correct vaccine brand is entered into MMEx in both the care plan and immunisations tabs.
    - COVID-19 Vaccination – Comirnaty (Pfizer) and Comirnaty suspension for injection 0.3mL
    - COVID-19 Vaccination – Comirnaty (Paediatric Pfizer) and Comirnaty Tris/Sucrose Presentation 0.2mL Dilute to use

### 7.2.5 AstraZeneca, adolescent / adult Pfizer and paediatric Pfizer: vaccine comparison

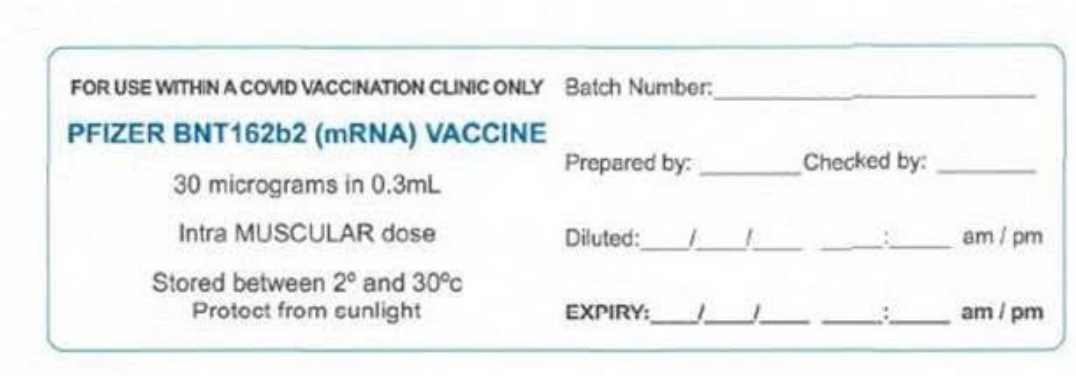
- Please see Department of Health website COVID-19 Vaccines in Australia.

### 7.2.6 Pfizer Vaccine Dose Preparation

#### *7.2.6.1 Pfizer for Ages 12 and over (PURPLE TOP)*

1. Perform hand hygiene
2. Follow instructions in Appendix U1.

Use the following label




#### *7.2.6.2 Pfizer for Ages 5-11 (ORANGE TOP)*

1. Perform hand hygiene

2. Follow instructions in Appendix U2.

## 7.3 Cleaning-up the work area

1. Discard the drawing up needle immediately into an approved sharps container. 2
2. Return the vial to the cold chain if there are remaining doses. Before returning the vial, ensure the date and time of opening are clear.
3. Clean and wipe the workbench.
4. Perform hand hygiene.
5. Ensure all syringes are labelled to identify contents if the preparer is not also administering the vaccine.
6. The vaccine should be administered as soon as possible after preparation and within the manufacturer's maximum recommendations.

## 7.4 Administering the vaccine

1. The vaccine should be administered immediately after preparation.
2. Must be administered as an IM injection into deltoid muscle.
3. The person's arm should be clean.
4. Use 25mm length needle (or 38mm length if obese person).
5. The person should be sitting on a chair with their arm relaxed.
6. The vaccine should be inserted at a 90° angle.
7. There is no need to withdraw to check your position during IM vaccinations. However, if blood is seen before injection, withdraw the needle and select a new site for injection.
8. The vaccine should be injected slowly over a count of 5 seconds.
   After administration, the vaccine dose administered including batch number must be entered into the Australian Immunisation Register (AIR) as described in section 4.

Refer to Appendix I.

**If an accidental overdose occurs:**

- Observe vital signs and, if symptomatic, treat the symptoms
- Lodge a clinical incident through LogiQC
- Contact the Poisons Information Centre on **131 126** for more information
- Contact on-site or on-call GP, who should also alert the KAMS medical director

## 7.5 Post-administration observation

After vaccination, the patient must be observed by a clinical staff member for a minimum of **15 minutes**.

These patients should be observed for **30 minutes:**

- Those with history to anaphylaxis to any substance AND/OR
- Those who have been prescribed an adrenaline autoinjector (i.e. Epipen)

During this time:

1. Observe the patient for adverse effects following immunisation (AEFI).
2. Provide patient with "KAMS COVID-19 Vaccine Information – After your vaccination" patient information sheet specific to the vaccine administered (see Appendix S).
3. Complete patient COVID-19 vaccine card and inform patient of brand of COVID-19 vaccine given, date of dose, and when the next dose is due.
4. If clinically appropriate, the patient may be offered light refreshments at the discretion of the clinic.

## 7.6 Reporting of adverse events after immunisation

AEFIs should be reported promptly as surveillance is an integral part of providing safe and trusted vaccines in Australia.

- Health professionals involved in the care of a vaccinated person who experience an AEFI can report an AEFI.
- Medical practitioners in WA have a statutory requirement to notify AEFIs to the WA Department of Health.

### 7.6.1 How to report an AEFI

In the event of an AEFI, staff should:

1. Submit an online report through: WAVSS at https://www.safevac.org.au/Home/Info/WA or call WAVSS on 6456 0208 (during business hours)
2. Inform KAMS Medical Director
3. Lodge a clinical incident report on LogiQC

For more information about WAVSS and reporting of AEFI visit WA Health – WAVSS.

Patients can also report adverse events directly to the TGA (see https://www.tga.gov.au/reporting-problems).

## 7.7 Wastage and disposal

### 7.7.1 Disposal

All sharps with syringes still attached (such as after administration) and vaccine vials for disposal should be discarded in a sharps waste container. The vials and other consumables should be disposed of in the clinical waste bin.

### 7.7.2 Wastage

In the event of a potential or actual wastage incident (e.g. damaged vials or breach of cold chain requirements):

**Involving five vials or more:**

1. Contact the KAMS Medical Director (0407 974 951)

2. Call the VOC on 1800 318 208
3. Submit an Australian Government Vaccine Wastage Report online
4. Lodge a clinical incident report on LogiQC

## 7.8 Medicare billing

New MBS item allow GPs and suitably qualified health professionals to assess if a patient is suitable to receive a COVID-19 vaccine. In cases where a patient is not suitable (and does not receive a vaccination), the GP can still bill Medicare for the vaccine assessment service.

Services must be billed in the name of the supervising GP, **who must be present at the location at which the vaccine suitability assessment service is undertaken** and must accept full responsibility for the service.

A Practice Incentive Program (PIP) is available when two vaccine suitability assessment services for the same patient are performed in a clinically appropriate timeframe.

### 7.8.1 MBS Item Numbers

| Vaccine suitability assessment services | Items (for VR GPs) | Rebate (paid at 85% of schedule fee) |
|---|---|---|
| FIRST DOSE | | |
| Practice located in MMM 2-7, in hours consultation | 93625 | $37.35 |
| Practice located in MMM 2-7, after hours consultation | 93635 | $49.50 |
| SECOND DOSE | | |
| Practice located in MMM 2-7, in hours consultation | 93645 | $27.55 |
| Practice located in MMM 2-7, after hours consultation | 93654 | $39.70 |
| THIRD & BOOSTER DOSES | | |
| Practice located in MMM 2-7, in hours consultation | 93645 | $27.55 |
| Practice located in MMM 2-7, after hours consultation | 93654 | $39.70 |

After Hours: Monday-Friday before 8am or after 8pm; Saturday before 8am or after 1pm; anytime Sunday or Public Holiday.

Some key points:

- If a patient declines COVID-19 vaccination, but returns on another day for further discussion and consents to vaccination, the same item code can be billed a second time.
- Vaccine and suitability assessments can be conducted by RANs and AHW/AHPs who have completed their online COVID-19 vaccine training, but there must be a GP on-site for these item numbers to be billed.
- These item numbers cannot be co-claimed with a 10988 (an immunisation service provided by an AHW/AHP) or a bulk bill item code (e.g. 10991).GPs can co-claim these item numbers with

general attendance item numbers (e.g. 3, 23, 36, 44, 721/732, 715 etc) if other issues are addressed at the same consult.

- Individuals who are severely immunocompromised should now receive a third dose of COVD-19 vaccine. Assessment of suitability for third doses are eligible for MBS reimbursement with the same rules as suitability assessments for second doses. The same second dose MBS items are used, including when a medical practitioner performs a suitability assessment for a patient and determines they are not suitable for a third vaccination dose.

## 7.9 Vaccine outreach

To ensure access to COVID-19 vaccination to all community members, vaccine outreach may take place. Options for vaccine outreach include:

1. Home visits
2. Community events

### 7.9.1 Key Principles

Please ensure these key principles are followed when preparing to deliver COVID-19 vaccine via outreach.

- Vaccines must be stored and transported within the recommended temperature range of +2°C to +8°C at all times — aim to store vaccines at 5°C.
- At least 24 hours before each mobile or outreach immunisation clinic, check the number of ice packs/gel packs in the freezer and replenish as needed.
- Plan the mobile or outreach immunisation clinic carefully. Take sufficient stock of vaccines, anaphylaxis kits, bubble-wrap, cold chain monitors and ice packs/gel packs.
- When using a cooler, store vaccines in their original packaging.
- If providing immunisations outdoors, choose a cool, shaded site.
- For a mobile service where there is no electric power supply or refrigerator, take an extra cooler containing additional ice packs/gel packs to replace melted ice packs/gel packs in the vaccine cooler.
- Take vaccines from the cooler only as required.
- When the vaccines are outside the vaccine cooler, keep them out of direct sunlight and away from other sources of heat and UV light.
- Avoid handling vaccines any more than absolutely necessary.
- During outreach immunisation clinic, monitor and record the current, minimum and maximum temperatures of the cooler every hour. Reset the thermometer after each reading.
- When the outreach immunisation clinic is over, return vaccines that have been continuously stored between +2°C and +8°C to the vaccine refrigerator as soon as possible.

See Appendix T for a checklist for mobile/outreach vaccination clinics and for a printable checklist and temperature chart to use during these clinics.

For detailed guidance please refer to and ensure compliance with the Australian Government Department of Health National Vaccine Storage Guidelines Strive for 5.

### 7.9.2 Coolers

Vaccines should be packed in coolers and monitored during transport and administration.

- Freezing episodes can occur, usually in the first 2 hours after packing.
- The minimum size cooler recommended for storing vaccines is 10 litres.
- Polystyrene coolers provide limited insulation and are only suitable for storing vaccines for short periods (up to 4 hours).

Refer to Appendix T for step by step process.

## 7.10 Infection prevention and control

Only standard precautions need to be followed when handling and administering COVID-19 vaccines. These include:

- Perform hand hygiene before and after every patient contact
- Where possible use disposable equipment
- Clean all shared patient equipment as per the KAMS cleaning guidelines
- Follow respiratory hygiene and cough etiquette
- Use PPE when at risk of body fluid exposure
- Use and dispose of sharps safely (see Appendix J – needle stick injury)
- Use Aseptic Non-Touch Technique (see Appendix E – ANTT poster)
- Perform routine environmental cleaning
- Handle and dispose of waste and used linen safely

# 8 Appendices

Appendices are available at the following link: http://kams.org.au/covid19/covid19_clinical/

List of Appendices:

- Appendix A – Site Readiness Checklist
- Appendix B – Suggested Workforce and Patient Flow Mapping
- Appendix C – KAMS COVID-19 Vaccination SASA
- Appendix D – Poster Clinical Prompts to Avoid Errors
- Appendix E – Poster Aseptic Non-Touch Technique (ANTT)
- Appendix F – Poster Strive for 5
- Appendix G – Poster Strive for 5 (cold-chain breach)
- Appendix H – Fridge sticker Strive for 5 “STOP”
- Appendix I – Poster Vaccine Administration
- Appendix J – Poster Needle-stick Injury
- Appendix K – Managing Anaphylaxis
- Appendix L – Anaphylaxis vs. Vasovagal Episode
- Appendix M – Basic Life Support
- Appendix N – Reporting Adverse Events

- Appendix O – Stock Management Spreadsheet
- Appendix P – Non-Vaccine Stock
- Appendix Q – COVID-19 Vaccination Checklist
- Appendix R1 – Pfizer Patient Information Before Vaccination
- Appendix R2 – Paediatric Pfizer Information Before Vaccination
- Appendix S – Pfizer Patient Information After Vaccination
- Appendix T – Checklist for Mobile/Outreach Immunisation Clinics
- Appendix U1 – Preparing Pfizer Vaccine for Administration in Adults
- Appendix U2 - Preparing Pfizer Vaccine for Administration in Children
- Appendix V – Do Not Unplug Freezer Sign
- Appendix W – Freezer Temperature Log
- Appendix X - Pfizer vaccine dose schedule