Queensland Health

COVID-19 Comirnaty™ Vaccine (Pfizer®/BioNTech®) Protocol

V16 updated 24 December 2021

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Queensland Government

Scope

This protocol is applicable to those authorised to handle, prepare and/or administer the COVID-19 Comirnaty™ vaccine (Pfizer®/BioNTech®).

Legislation

- Medicines and Poisons Act 2019 (MPA)
- Medicines and Poisons (medicines) Regulation 2021
- Emergency Order Public Health Emergency – Pandemic Response to Coronavirus Disease (COVID-19)

Human Rights Act 2019

To the extent an act or decision under this document may engage human rights under the Human Rights Act 2019, regard will be had to that Act in undertaking the act or making the decision. For further information on the Human Rights Act 2019 see: https://www.forgov.qld.gov.au/humanrights

STAGE 1a: Assessment of the individual presenting for vaccination

ACTIVITY STAGE 1a:	**Assess the individual presenting for vaccination against the inclusion and exclusion criteria below. If they are not eligible for vaccination or need to return at a later date, advise them accordingly.**
Clinical condition or situation to which this Protocol applies	COVID-19 Comirnaty™ vaccine is indicated for the active immunisation of individuals for the prevention of coronavirus (SARS-CoV-2) infection and subsequent COVID-19, in individuals 5 years of age and older, in accordance with the National COVID-19 vaccination rollout. **This protocol pertains to the formulation approved for individuals aged 12 years and older. A separate protocol covers off on the formulation approved for individuals aged 5 years to under 12 years.** This protocol determines the situations which the vaccine can be used in Queensland Health vaccination locations as stipulated in the Emergency Order. It determines the prescribed indications for use of the vaccine within the Queensland Health List of Approved Medicines (LAM). Any deviations from this protocol may be in breach of the Medicines and Poisons Act and/or Regulations.
Criteria for inclusion	COVID-19 Comirnaty™ vaccine should be offered to individuals, aged 12 years or older, in accordance with the Commonwealth's national rollout strategy and ATAGI clinical advice, unless directed by the Queensland Health Director General. Implementation of the COVID-19 vaccination program should aim to achieve high vaccine uptake whilst prioritising those most at risk. Implementation should also involve flexibility in vaccine deployment at a local level. Operational considerations, such as minimising wastage, may require a flexible approach to prioritisation, where decisions are taken in consultation with national or local public health experts. However, the priority order as

	outlined by the Commonwealth above should be followed if it is reasonably practicable to do so.

Criteria for exclusion	Individuals who:
	• Have not consented
	• Are less than 12 years of age
	• Have experienced anaphylaxis to a previous dose of COVID-19 Comirnaty™ vaccine or to any component of the vaccine or residues from the manufacturing process. Excipients included in the vaccine are:
	  ○ ((4-hydroxybutyl)azanediyl)bis(hexane-6,1-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 dihydrate
	  ○ Sucrose
	  ○ Water for injection
	• Are suffering from acute severe febrile illness (the presence of a minor localized infection is not a contraindication for vaccination).
	• Have received a dose of COVID-19 vaccine in the preceding 21 days
	• Have completed a course (primary and booster series) of COVID-19 vaccinations as recommended by ATAGI. See also ATAGI guidance on vaccinations brands currently considered valid in Australia. Additional third doses as part of the primary dose series are recommended for severely immunocompromised individuals. Additional third (booster) doses of Comirnaty are being recommended by ATAGI following completion of primary series.
	• For Booster doses, are less than 18 years of age.
	For anyone who is unable to receive the vaccination, document the reason for exclusion and any action taken.
	See also Action to be taken if the patient is excluded and Drug Interactions

Criteria for medical referral	• Individuals for whom valid consent has not been obtained • Individuals with immediate (within 4 hours) and generalised symptoms of a possible allergic reaction (e.g. urticaria/hives) to a previous dose of a COVID-19 vaccine • Individuals with a generalised allergic reaction (without anaphylaxis) to any component of the COVID-19 vaccine to be administered (e.g. PEG in Comirnaty or polysorbate 80 in COVID-19 Vaccine AstraZeneca) • Individuals with a prior history of severe allergy and/or anaphylaxis to previous vaccines and/or multiple drugs (injectable and/or oral) • Individuals with a known systemic mast cell activation disorder with raised mast cell tryptase that requires treatment. • Individuals who have had any vaccination within the previous 7 days. Sites are responsible for determining this via Australian Immunisation Record, medical record and/or asking the patient. Note: shortening of this interval may be justified if adhering to the interval may result in non-adherence to the vaccination or if there is an imminent need to administer either of these vaccines because of the prevailing local epidemiological situation. If same day or reduced-interval vaccination is proposed, patients should be counselled about the possible adverse events from each vaccine and advised to report adverse events.

	• It is essential for consumer safety is that a history check is conducted by a vaccination provider to check when any previous doses of Covid-19 Vaccines or any other vaccines were given. It is best practice (and strongly recommended) to do an AIR history check prior to vaccination however this may not be practical or possible in certain settings and it is not mandatory at this stage. The mechanism to check this history could be any of or a combination of a medical record assessment, checking with a consumer directly, checking a consumer's My Health Record (MHR) record, Express Plus Medicare mobile app or checking AIR. It would be a local HHS decision of how to conduct this however clinical judgement should also be used if further validation of a consumer's verbal history is required with AIR records. Individuals who have had allergen immunotherapy (AIT) or venom immunotherapy (VIT) injections in the previous should 48 hours delay receiving the COVID-19 vaccine injection until the 48 hours has elapsed. • Immunocompromised individuals. See ATAGI Provider guide to COVID-19 vaccination of people with immunocompromise. • Individuals who are > 85 years of age. • Individuals with a history of recent (i.e. within the past 6 months) or current inflammatory cardiac illness (e.g, myocarditis, pericarditis, endocarditis), acute rheumatic fever or acute rheumatic heart disease, people aged 12-29 years with dilated cardiomyopathy, complex or severe congenital heart disease including single ventricle (Fontan) circulation, acute decompensated heart failure & cardiac transplant recipients. These individuals should consult a GP or cardiologist about the best timing of vaccination and whether any additional precautions are recommended. See joint ATAGI and the Cardiac Society of Australia and New Zealand (CSANZ) Guidance. • Individuals who develop myocarditis or pericarditis attributed to their first dose of Comirnaty™ are advised to defer further doses of mRNA vaccines till consultation with treating doctor. • ATAGI recommends completing the vaccination course with the same vaccine if available. Mixed (heterologous) schedules using 2 different vaccines to complete the primary vaccination course are can be used special circumstances such as for those with serious vaccine-attributed adverse events after the first dose, those who were partially vaccinated overseas with a brand not available in Australia or those unable to access or unwilling to accept the same brand. It is permissible to use an alternative brand if a patient is unable to access, or not accepting of a second dose of the same brand, since there are emerging data supporting the safety and efficacy of mixed schedules. See here for the ATAGI clinical advice on the use of a different COVID-19 vaccine as the second dose.
Cautions including any relevant action to be taken	**Specific allergies** The individuals with specific allergies listed above should be assessed for suitability for vaccination before being given a vaccine dose, if necessary, in consultation with an allergist/immunologist or specialist immunisation clinic. If people in these categories are vaccinated, they may require vaccination in a facility with medical staff in attendance, and to be observed for 30 minutes following administration of a COVID-19 vaccine dose. All other vaccine recipients, including those with a history asthma, atopic dermatitis (eczema) or allergic rhinitis (hay fever), should be observed for at least 15 minutes following administration of the vaccine at the clinic site **Have had any vaccination within the previous 7 days.** COVID-19 vaccines can be co-administered with an influenza vaccine if required.

For other vaccines, there are no data on the safety of co-administering COVID-19 vaccines, however, shortening of this interval may be justified if adhering to the interval may result in non-adherence to the vaccination or if there is an imminent need to administer either of these vaccines because of the prevailing local epidemiological situation or logistical issues. If same day or reduced-interval vaccination is proposed, patients should be counselled about the possible adverse events from each vaccine, increased likelihood to experience common adverse effects and advised to report adverse events.

Individuals with a bleeding disorder

This patient cohort may develop a haematoma at the injection site. Individuals with bleeding disorders may be vaccinated intramuscularly if, in the opinion of a doctor familiar with the individual's bleeding risk, vaccines or similar small volume intramuscular injections can be administered with reasonable safety by this route.

- If the individual receives medication/treatment to reduce bleeding, for example treatment for haemophilia, intramuscular vaccination can be scheduled shortly after such medication/treatment is administered.
- Individuals on stable anticoagulation therapy, including individuals on warfarin who are up to date with their scheduled INR testing and whose latest INR was below the upper threshold of their therapeutic range, can receive intramuscular vaccination. A fine needle (equal to 23 gauge or finer calibre such as 25 gauge) should be used for the vaccination, followed by firm pressure applied to the site (without rubbing) for at least 2 minutes. If in any doubt, consult with the clinician responsible for prescribing or monitoring the individual's anticoagulant therapy.

If the registered professional clinically assessing the individual is not the vaccinator, they must ensure the vaccinator is aware of the individuals increased risk of haematoma and the need to apply firm pressure to the injection site for at least 2 minutes. The individual/carer should be informed about the risk of haematoma from the injection.

Individuals who are Pregnant or breastfeeding

The Royal Australian and New Zealand College of Obstetricians and Gynaecologists (RANZCOG) and ATAGI recommend that pregnant women are routinely offered Cominarty™ at any stage of pregnancy. This is because the risk of severe outcomes from COVID-19 is significantly higher for pregnant women and their unborn baby. Global surveillance data from large numbers of pregnant women have not identified any significant safety concerns with mRNA COVID-19 vaccines given at any stage of pregnancy. Furthermore, there is also evidence of antibody in cord blood and breastmilk, which may offer protection to infants through passive immunity. Pregnant women are encouraged to discuss the decision in relation to timing of vaccination with their health professional. The Comirnaty™ vaccine is Australian category for prescribing medicines in pregnancy Category B1.

Women who are breastfeeding or who are planning pregnancy can receive COVID-19 vaccine. There are no theoretical concerns regarding the safety of Comirnaty™ in these groups.

	See the ATAGI Shared decision making guide for women who are pregnant, breastfeeding or planning pregnancy for more information. **Individuals who are immunocompromised** The efficacy of Comirnaty™ may be lower in immunosuppressed individuals. ATAGI has recommended the use of a 3rd primary dose of COVID-19 vaccine in individuals who are severely immunocompromised. mRNA vaccines (including Comirnaty™) are the preferred vaccine for this 3rd dose at an interval of 2 to 6 months following the 2nd vaccine dose. Immunocompromised individuals who have received 3 primary doses of a COVID-19 vaccine are also recommended to have a booster dose in line with the timing for the general population. Comirnaty™ is not a live-attenuated vaccine and is safe for people with immune system disorders such as allergy, primary or secondary immunodeficiency or autoimmune conditions, who are not considered to be at greater risk of vaccine allergy compared to the general population. It is important that regular treatments for immunodeficiencies and autoimmune conditions are continued, because stopping these treatments can place people with these conditions at greater risk from COVID-19. For people taking immunosuppressive therapies, the timing of vaccination should be discussed with their treating specialist, taking into account disease severity, characteristics of the immunosuppressive therapy, and patient preferences. Vaccination should occur on a different day (if possible) from regular infusion treatments, such as immunoglobulin (Ig) or immunosuppressant infusions. For example, people on monthly intravenous immunoglobulin (IVIg) may be advised by their specialist to be vaccinated two weeks after an IVIg infusion. This avoids confusion about the cause of side effects or allergic reactions, if they occur in response to the COVID-19 vaccine or the infusion treatment. See also ATAGI – Provider guide to COVID-19 vaccination of people with immunocompromise and ATAGI – COVID-19 vaccination decision guide for people with immunocompromise. **Individuals who have had allergen immunotherapy (AIT) or venom immunotherapy (VIT) injections in the previous should 48 hours of the COVID-19 vaccine injection.** It is important that regular hay fever (allergic rhinitis), eczema (atopic dermatitis) and asthma treatments are continued when having the COVID-19 vaccine. However, it is recommended that allergen immunotherapy (AIT) or venom immunotherapy (VIT) injections should not be given within 48 hours of the COVID-19 vaccine injection. This avoids confusion about the cause of side effects or allergic reactions, if they occur in response to the COVID-19 vaccine or immunotherapy. **Individuals with a past history of COVID-19 infection** It is possible for people who have already had COVID-19 to have the vaccine. The vaccine can offer more protection or boost any antibodies (immunoglobulins) that the body has already made in response to COVID-19. Vaccination is therefore recommended even if a person has already had COVID-19. There is no evidence of any safety concerns with vaccinating individuals with a history of COVID-19 infection, or with detectable COVID-19 antibodies.

	Vaccination of individuals who may be infected but asymptomatic or incubating COVID-19 infection is unlikely to have a detrimental effect on the illness. Vaccination should be deferred in those with confirmed infection to avoid onward transmission and confusing the differential diagnosis. As clinical deterioration can occur up to two weeks after infection, ideally vaccination should be deferred until clinical recovery to around four weeks after onset of symptoms or four weeks from the first confirmed positive specimen in those who are asymptomatic. The Queensland Health Covid-19 vaccination Taskforce's Clinical & Technical Advisory Group (CTAG) recommends vaccination of these consumers as soon as practical following the resolution of their acute symptoms. Consumers may choose to defer vaccination for up to six months after onset of the SARS-CoV-2 if they wish. ATAGI does recommend that vaccinations should be deferred for 90 days in people who have received anti-SARS-CoV-2 monoclonal antibody or convalescent plasma therapy. Having prolonged COVID-19 symptoms is not a contraindication to receiving a COVID-19 vaccine but if the individual is seriously debilitated, still under active investigation, or has evidence of recent deterioration, deferral of vaccination may be considered to avoid incorrect attribution of any change in the person's underlying condition to the vaccine. **Other considerations.** ATAGI COVID-19 vaccination decision guide for frail older people, including those in residential aged care facilities ATAGI COVID-19 vaccination decision guide for people receiving palliative or end-of-life care ATAGI Clinical guidance on use of an additional COVID-19 vaccine dose as a replacement dose for an invalid dose in specified scenarios of schedule deviation or vaccine administration errors ATAGI expanded guidance on acute major medical conditions that warrant a temporary medical exemption relevant for COVID-19 vaccines
Action to be taken if the patient is excluded	The risk to the individual of not being immunised must be considered. The indications for risk groups are not exhaustive, and the healthcare practitioner should consider the risk of coronavirus exacerbating any underlying disease that an individual may have, as well as the risk of serious illness from coronavirus itself. Where appropriate, such individuals should be referred for assessment of clinical risk. **Allergic reactions** Individuals who have had previous **anaphylaxis to a previous dose of Comirnaty™ or any component of the vaccine** should not receive further Comirnaty™. There will be at least three different types of vaccines available. This means that if someone is allergic to one type of vaccine, they may be able to have another type of vaccine, without having an allergic reaction. For these individuals, consultation with a clinical immunology/allergy specialist for assessment is recommended. **Pregnancy** If a pregnant woman declines to be vaccinated, the vaccination should be postponed. See also, COVID-19 vaccination decision guide for women who are pregnant, breastfeeding or planning pregnancy.

	Acute Severe Febrile Illness In case of postponement due to acute illness, advise when the individual can be vaccinated and, if possible, ensure another appointment is arranged. **Have received a dose of COVID-19 vaccine in the preceding 21 days** The Comirnaty™ vaccine requires at least 21 days between administration. If a patient presents earlier, they should be re-booked to ensure at least a 21-day lapse between doses. **Have completed a course of COVID-19 vaccination** Individuals who have completed a COVID-19 vaccination primary course (i.e. 2 doses of any vaccine or 3 doses for immunocompromised consumers), will be eligible for a booster vaccination dose 3 months (13 weeks) following their last dose. For anyone who is unable to receive the vaccination, document the reason for exclusion and any action taken.
Action to be taken if the patient or carer declines treatment	Informed consent, from the individual or a person legally able to act on the person's behalf, must be obtained for each administration and recorded appropriately. Advise the individual/carer about the protective effects of the vaccine, the risks of infection and potential complications if not immunised. Document advice given and the decision reached.

STAGE 1b: Description of treatment

ACTIVITY STAGE 1b:	**Consider any relevant cautions, interactions or adverse drug reactions.** **Provide advice to the individual and obtain informed consent.** **Record patient consent and ensure vaccinator, if another person, is informed of the vaccine product to be administered.**
Name, strength & formulation of drug	Comirnaty™ vaccine (BNT162b2[mRNA]) concentrate for solution for injection, presented as a multidose vial. Pack size: 195 vials. 2 mL clear multidose vial (Type I glass) with a stopper (synthetic bromobutyl rubber) and a flip-off plastic cap with aluminium seal. Each vial contains at least 5 doses.
Legal category	The COVID-19 Comirnaty™ vaccine is a Schedule 4 – Prescription Only Medicine. It has been provisionally approved by the TGA for therapeutic use. This decision was made based on short-term efficacy and safety data. Continued approval depends on the evidence of longer-term efficacy and safety from ongoing clinical trials and post-market assessment. Within Queensland Health Facilities and vaccination locations, the use of COVID-19 Vaccines is determined by the List of Approved Medicines (LAM) which is the official statewide formulary for medicines approved for use in all Queensland Health public hospitals and institutions. This is maintained and reviewed by the Queensland Health Medicines Advisory Committee (QHMAC). The LAM stipulates that the Covid-19 vaccines are for "use in accordance with the Emergency Order—Public Health Emergency—Pandemic Response to Coronavirus Disease (COVID-19)—Vaccination Service which in

	turn requires that a person authorised to administer a COVID-19 vaccine must "ensure all process (sic) are followed in accordance with the Queensland COVID-19 Vaccination Program Implementation Plan and Vaccine Protocols." Indications for use in this protocol generally align with ATAGI recommendations and clinical guidance, however there may be specific circumstances where deviations may be permissible indications. Currently approved deviations include, • **Heterologous (mixed) dosing in MMM 6 & 7 regions**. Instances where consumers in Modified Monash model (MMM) areas 6 & 7 (as defined by the Commonwealth) have had a specific vaccine brand for their first dose are either unable to access or unwilling to have the same brand for their second dose. In this instance, administering any available vaccine brand for a second dose (providing there is no clinical contraindication) is preferable to not providing any second dose. As of 29 October 2021 this is provisioned in the ATAGI Clinical Guideline. • **Inmates/prisoners within corrections facilities**. Instances where consumers who are inmates/prisoners have had a specific vaccine brand for their first dose are unable to access the same brand for their second dose due to their incarceration. In this instance, administration of another brand of vaccine could be considered to complete their primary vaccination schedule. As of 29 October 2021 this is provisioned in the ATAGI Clinical Guideline.
Black triangle ▼	This vaccine is subject to additional monitoring in Australia. This will allow quick identification of new safety information. Healthcare professionals are asked to report any suspected Adverse Events Following Immunisation (AEFI) via the Queensland COVID-19 Vaccine Management System (QCVMS).
Drug interactions	Immunological response may be diminished in those receiving immunosuppressive treatment, but it is important to still immunise this group. Although no data for co-administration of COVID-19 vaccine with other vaccines exists, in the absence of such data first principles would suggest that interference between inactivated vaccines with different antigenic content is likely to be limited. Based on experience with other vaccines, any potential interference is most likely to result in a slightly attenuated immune response to one of the vaccines. There is no evidence of any safety concerns, although it may make the attribution of any adverse events more difficult. It should not be routine to offer appointments to give this vaccine at the same time as other vaccines, however in certain circumstances, co-administration may be appropriate. **Scheduling should ideally be separated by an interval of at least 7 days to avoid incorrect attribution of potential adverse events**, however situations where shorter intervals may be acceptable include increased risk of COVID-19 or another vaccine-preventable disease or due to logistical or operational reasons. Where individuals in an eligible cohort present having received another inactivated or live vaccine, COVID-19 vaccination should still be considered. The same applies for other live and inactivated vaccines where COVID-19 vaccination has been received first or where an individual presents requiring two vaccines. In most cases, vaccination should proceed, and

	may be provided, to avoid any further delay in protection and to avoid the risk of the individual not returning for a later appointment. In such circumstances, individuals should be informed about the likely timing of potential adverse events relating to each vaccine.
Identification & management of adverse reactions	The most frequent adverse reactions in participants 16 years of age and older were pain at the injection site (> 80%), fatigue (> 60%), headache (> 50%), myalgia (> 30%), chills (> 30%), arthralgia (> 20%) and pyrexia (> 10%) and were usually mild or moderate in intensity and resolved within a few days after vaccination. Redness at the injection site, injection site swelling, and nausea are reported as common. Lymphadenopathy was reported in less than 1%. Particular adverse reactions in the 12-15 year old group are similar to the 16-25 age group however occur at a lower rate (0.6% in 12-15 year olds vs 1.7% in 16-25 year olds). This article provides more details for this age group and suggests injection site pain, fatigue, chills and headaches as the most common side effects. Individuals should be provided with the advice on adverse reactions and their management, such as with analgesic and/or antipyretic medication. Testing for SARS-CoV-2 infection or implementing (non-medically recommended) isolation of someone who develops symptoms of fever, headache, fatigue or other systemic symptoms within and lasting for <48 hours after receipt of a COVID-19 vaccine is not necessarily required. If a vaccine recipient develops typical vaccine-related adverse events (refer to Adverse events section) and there is complete absence of respiratory symptoms (including loss of smell), it is more likely that they have an expected vaccine response. However, vaccine-induced protection is not immediate, and it is possible that SARS-CoV-2 could be contracted within several days before or after vaccination (this would not constitute vaccine failure). A detailed list of adverse reactions is available in the Australian Product Information – Comirnaty™ (BNT162b2 [MRNA]) Covid-19 Vaccine. A tabulated comparison of adverse reactions vs. age can be found in Clinical guidance on use of COVID-19 vaccine in Australia in 2021 (v2.0). See also Clinical Incidents.
Reporting procedure of adverse reactions	The TGA will maintain surveillance and pharmacovigilance post deployment of COVID-19 vaccines in Australia. In response to any safety signals, the TGA may provide temporary advice or make substantive amendments to the authorised conditions of the vaccine product's supply in the Australia. Healthcare professionals should report any AEFIs via the QCVMS (once available) within 12 hours of presentation. Escalation of all severe AEFIs to the Queensland Health Vaccination Command Centre (QH VCC) are critical for state-wide of reporting AEFIs to the TGA and the Commonwealth Vaccine Operations Center. Severe AEFIs are defined as: • Death • Anaphylaxis or anaphylactic shock • Facial Drooping • Rash

	• Other AEFIs not defined in Australian Product Information – Comirnaty™ (BNT162b2 [MRNA]) Covid-19 Vaccine. • All other symptoms persisting longer than 24 hours Local AEFI reporting processes are to be used in the interim until the QCVMS is available. Individuals/carers with a suspected AEFI should contact their primary care health professional. Any AEFIs to a vaccine should also be documented in the individual's medical record and the individual's GP should be informed. Additional requirements, as dictated by local procedures for AEFIs should also be followed e.g. submitting a RiskMan report.
Written information available to be given to patient or carer	Ensure the individual can be provided with appropriate written information if requested: • COVID-19 Vaccine 2021 - Vaccination Information • COVID-19 Vaccine Record Card
Patient advice / follow up treatment	• As with all vaccines, immunisation may not result in protection in all individuals. Immunosuppressed individuals should be advised that they may not make a full immune response to the vaccine. Severely immunocompromised individuals should be offered a 3rd dose as part of their primary dosing schedule. Nationally recommended protective measures should still be followed. Individuals may not be fully protected until 14 days after their second dose of the Comirnaty™ vaccine. • Inform the individual/carer of possible side effects and their management. • The individual/carer should be advised to seek appropriate advice from a healthcare professional in the event of an AEFI. • Advise the individual/carer that they can report side effects directly to their primary care health professionals. Inform the patient an AusVaxSafety survey will be sent via text on days 3 and 8 after each dose and 42 days after the second dose (once the QCVMS functionality is available). • Vaccine recipients should be monitored for 15 mins after vaccination, with a longer observation period (30 minutes) when indicated after clinical assessment (see Cautions including any relevant action to be taken). • When applicable, advise the individual/carer when to return for vaccination or when a subsequent vaccine dose is due.
Special considerations / additional information	**Emergency kits** In existing Queensland Health clinical facilities, access to a facility's normal Medical Emergency Response Team (MERT), if available, is sufficient and appropriate to respond to a serious AEFI as required. A medical officer (at least PGY2) should be utilised for any other attendances in the clinic, including less serious AEFI. There is no specific requirement for a medical officer to be physically present in the clinic for the duration of operations providing they are readily accessible and can attend promptly if required. In vaccine locations where medical officers are not already working onsite or in close vicinity, other health professionals on site must be trained and capable of recognising an anaphylactic reaction and be familiar with techniques for resuscitation of an individual with anaphylaxis including providing Basic Life Support (BLS). Local systems

must be in place to transport patients with serious AEFI to appropriate health facilities as required.

Before each vaccination session, check that you have the protocols, equipment and medicines to manage anaphylaxis. Always keep an anaphylaxis response kit on hand. This kit should contain:

- adrenaline 1:1000 (at least 3 ampoules — check expiry dates)
- at least three drawing-up needles (19 gauge)
- at least three 1 mL syringes and 25 mm needles (22 or 23 gauge) for intramuscular injection
- cottonwool swabs
- pen and paper to record the time the adrenaline was administered
- laminated copy of Table. Doses of intramuscular 1:1000 adrenaline for anaphylaxis and Table. Recognising and treating anaphylaxis

A protocol for the management of anaphylaxis and an anaphylaxis pack must be readily available in case of an anaphylactic event prior to commencing a vaccination clinic. See Managing anaphylaxis. Sites must also have in place processes for checking the appropriate emergency equipment is in place. **Please see Appendix 1.**

In the event of anaphylaxis:

1. Call a CODE BLUE (hospital sites) or the Queensland Ambulance Service (QAS) emergency call (000) for community centres.
2. If any respiratory and/or cardiovascular symptoms or signs of anaphylaxis, give adrenaline 500microg* via the adrenaline (epinephrine) 1:1,000 ampoule by intramuscular injection into anterolateral thigh (not into the buttocks). Adrenaline (epinephrine) is NOT required for non-anaphylactic reactions (e.g. skin rash in isolation).
3. Lay the patient flat, with feet elevated, do not allow the patient to stand or walk. If breathing is difficult, allow the patient to sit, administer high flow oxygen by face mask (if available). If unconscious, use the recovery position.
4. Commence Basic Life Support.
5. If there is no improvement in condition 5 minutes post adrenaline (epinephrine) 1:1,000 ampoule administration, administer a second adrenaline (epinephrine) 500microg* dose with a 1:1,000 ampoule and document time of administration in an emergency response record.
6. Stay with the patient until the Medical Emergency Team – MET / Rapid Response Team – RRT or QAS arrives.
7. Record the incident, including doses of adrenaline given. In an acute facility, complete the relevant Code Blue documentation. Other sites see – Queensland Health Anaphylaxis Emergency Treatment Response Record Form.

*For a patient >50kg. For patient less than 50kg see dose advice below.
<50kg: 10 micrograms/kg = (0.01mL/kg).

Previous incomplete vaccination

	Other COVID-19 vaccines may become available after this protocol has been written. There is no evidence on the interchangeability of the COVID-19 vaccines although studies are underway. ATAGI has published clinical advice on use of a different COVID-19 vaccine as the second dose in special circumstances. A consumer should receive two doses of the same vaccine brand as part of their primary dosing schedule, however if they received two doses of any vaccine approved in Australia, they do not need additional doses to complete their primary course. This excludes severely immunocompromised consumers who are recommended to have three doses of any approved vaccines to complete their primary course. Specific ATAGI advice available here applies to consumers who receive a 1st dose of different vaccine brand overseas which are not approved in Australia (overseas 2 dose vaccines examples include Novavax, Sinovac/Sinopharma, Gamaleya, Sanofi/GSK, CureVac or Moderna). COVID-19 vaccines that are considered valid in Australia are those that have been assessed and included in the WHO Emergency Use Listing and/or approved by at least one of the 11 Stringent Regulatory Authorities. Any consumer who changes brands should be informed about the lack of interchangeability data and the immunogenicity risks and that their vaccinations may be considered off-label use of medications. Clinicians should ensure informed consent is obtained in these situations and have that discussion documented.

STAGE 2: Vaccine Preparation

ACTIVITY STAGE 2:	Vaccine preparation
Vaccine presentation	Comirnaty™ vaccine (BNT162b2[mRNA]) concentrate for solution for injection, presented as a multidose vial. Pack size: 195 vials. It is a white to off-white frozen suspension. 2 mL clear multidose vial (Type I glass) with a stopper (synthetic bromobutyl rubber) and a flip-off plastic cap with aluminum seal. Each vial contains 6 doses.* **The 6th dose may be dependent on the use of low dead space syringe / needle.* To enable timely distribution of COVID-19 vaccines, international labels will be used during the initial global rollout, including in Australia. The TGA has issued a labelling exemption for this product. Some information typically present on the Australian label (e.g. 'Keep Out of Reach of Children') may be absent and/or modified on the international label, as well as additional information present that is not relevant to the Australian context.
Supplies	Hubs will be allocated Comirnaty™ vaccine by the Queensland Health VCC.
Storage	The Comirnaty™ vaccine is a Schedule 4 medicine and must be stored in an area inaccessible by the public. Sites should consider implementing additional security measures as well. These measures need to minimize the chance the product could be stolen, diverted or tampered with as well as ensuring staff safety for those involved in the vaccine administration.

	Notify the QH VCC (who will notify the Australian Government) immediately if any doses are stolen, diverted, tampered with, substituted, or otherwise subjected to abuse or misuse. The Comirnaty™ vaccine is supplied from the manufacturer as a multiple-dose vial of frozen, preservative-free concentrate. Freezers and refrigerators utilised for vaccine management must have continuous temperature monitoring – see also Cold Chain Breaches or Wastage. The Comirnaty™ vaccine must be protected from light. Appropriate opaque containers should be utilised when removing vials from the original Pfizer tray. **Unopened vial** • 6 months at -90°C to -60°C. • Unopened vials may be stored and transported at -25°C to -15°C for a total of 2 weeks and can be returned to -90ºC to -60°C. • Once removed from the freezer, the unopened vial can be stored for up to 1 month at 2°C to 8°C. Within the 1-month (31 days) shelf-life at 2°C to 8°C, up to 12 hours may be used for transportation. • Prior to use, the unopened vial can be stored for up to 2 hours at temperatures up to 30°C. **If stored/defrosted in a refrigerator, they must be brought to room temperature before dilution.** **Once thawed, the Comirnaty™ vaccine should not be re-frozen.** **Thawed vials and syringes can be handled in room light conditions.** **Moving frozen vials** **Transfers of frozen vials stored at ultra-low temperature (<-60°C)** Closed-lid vial trays containing 195 vials removed from frozen storage (< -60 °C) may be at room temperature (< 25 °C) for up to 5 minutes for transfer between ultra-low-temperature environments. After vial trays are returned to frozen storage following room temperature exposure, they must remain in frozen storage for at least 2 hours before they can be removed again. Open lid and/or less than 195 vial trays removed from frozen storage (<-60°C) may be at room temperature for up to 3 minutes for transfer between ultra-low-temperature environments or to remove vials for use. After vial trays are returned to frozen storage following room temperature exposure, they must remain in frozen storage for at least 2 hours before they can be removed again. **Transfers of frozen vials stored at -25°C to -15°C** Closed-lid vial trays containing 195 vials removed from frozen storage (-25°C to -15°C) may be at temperatures up to 25°C for up to 3 minutes. Open-lid vial trays, or vial trays containing less than 195 vials, removed from frozen storage (-25°C to -15°C) may be at temperatures up to 25°C for up to 1 minute. **Diluted medicinal product**

	Chemical and physical in-use stability, including during transportation, has been demonstrated for 6 hours at 2ºC to 30ºC after dilution (in the vial) in sodium chloride 9 mg/mL (0.9%) solution for injection. ATAGI recommends that doses drawn up into a syringe must ideally be used within 1 hour if kept at room temperature, or 6 hours if stored at 2°C to 8°C to minimize risk of infection. From a microbiological point of view, the product should be used immediately. If not used immediately, in-use storage times and conditions are the responsibility of the user. Please refer to the ATAGI Guidance on the use of multi-dose vials for COVID-19 vaccination for further information. **Transportation** If local redistribution of unopened vials is needed, and full trays containing vials cannot be transported at -90°C to -60°C, available data support physical and chemical stability during transportation of 1 or more thawed vials at 2°C to 8°C for up to 12 hours. Any time used for transport of unopened vials at 2°C to 8°C are cumulative and count against the 12-hour limit for transportation time AND 1-month (31 days) limit for storage at 2°C to 8°C. If local redistribution of diluted medicinal product in vials is needed, available data support physical and chemical stability during transportation at 2°C to 30°C for up to 6 hours. Any hours used for transport of diluted medicinal product in vials at 2°C to 30°C count against the 6-hour limit for storage at 2°C to 30°C. Transport of vaccine already drawn into syringes must be at 2°C to 8°C and transport time counts against the 6 hour in-syringe time limit of the vaccine. Microbiological risks and package integrity, particularly for prepared dosing syringes, are the responsibility of the preparer during transportation of diluted medicinal product. **Each time a vaccine is moved, there is a risk of damage and/or a cold chain breach. Sites should limit vaccine movement as much as possible.**
Vaccine preparation	COVID-19 vaccine resources are scarce. Organisation and timing is critical to minimise wastage. Clear grouping of vaccinations, labelling and timers will be essential. Sites must have a workflow that shows the **clear separation of the vaccine preparation workflow, processes and governance to the area where administration of the vaccine will be conducted.** There needs to be a clearly delineated handover of prepared doses (including governance and accountability) from the preparation area staff to the administration area staff. Whilst discouraged, this does not preclude both areas co-habiting the same physical space. There must be a clear list of roles and responsibilities of staff in the vaccine preparation area, which includes cold chain management, dose preparation, tracking and record keeping, information entry into the QCVMS Vaccine stock management. A clear list of roles and responsibilities of staff in the vaccine administration area is also required. All staff directly involved in the preparation of vaccine must complete the Commonwealth COVID-19 Vaccination Training Program. Thawing vials for use • The multidose vial is stored frozen and must be thawed prior to dilution. Frozen vials should be transferred to an environment of 2 °C to 8 °C to thaw; a 195-vial pack may

	take 3 hours to thaw. Note: Vials do not need to be thawed a full tray at a time. Individual vials can be removed to be thawed. • Alternatively, frozen vials may also be thawed for 30 minutes at temperatures up to 30°C for immediate use. • Vaccine should be prepared in accordance with the product information and the standard operating procedures for the service using low dead-volume syringes and/or needles. The low dead-volume syringe and needle combination should have a dead volume of no more than 35 microlitres. • Using aseptic technique, thawed COVID-19 Comirnaty™ vaccine requires dilution in its original vial with 1.8mL of unpreserved sodium chloride 0.9% solution for injection, prior to withdrawing a 0.3mL dose for administration (Note - do not use bacteriostatic 0.9% sodium chloride). The top of the vial should be swabbed with an alcohol swab before inserting the needle. • Gently invert the diluted solution 10 times. Do not shake the vaccine. • The vaccine dose should be drawn up from the diluted vial immediately prior to administration. • It is essential the syringes be labelled with the batch number, date, time of reconstitution, expiry and the initials of the person who prepared the dose. Once diluted the syringe must be utilized within 6 hours (if stored at 2-8 degrees) or within 1 hour at room temperature. Each vial contains at least 5 doses (usually 6). It is normal for a small amount of liquid to remain in the vial after withdrawing the final dose. When low dead volume syringes and/or needles are used, the amount remaining in the vial after 5 doses have been extracted may be sufficient for an additional dose. If low dead volume syringes are not available, sites should utilise a 23G needle and a 1mL syringe. Note: the sixth dose may not be able to be extracted. Care should be taken to ensure a full 0.3mL will be administered. Where a full 0.3mL dose cannot be extracted the contents should be discarded. Discarded vaccine should be recorded in the QCVMS. The reason for discarding must be included. There is no specific restriction on using further doses (i.e. a 7th dose) which might be extracted from a diluted vial, however even if sufficient volume (0.3ml of vaccine in the syringe) is present, please ensure that there is a check conducted to ensure the vial had not been inadvertently overdiluted with dilutant or the preceding 6 syringe volumes have not been underdrawn. **Do NOT pool excess vaccine from multiple vials.** The vaccine should be ideally be diluted and drawn up by a different person to the person administering the dose. This is for infection control, to minimize distraction and the risk of inadvertent disposal of the vaccine after one dose (which is common with most vaccines) and streamlining the workflow. The vial used to prepare the doses must be defaced and discarded in an unrecoverable way as soon as possible after drawing up. Pre-drawn syringes should be taken into the administration area in, ideally an opaque container protected from light* with the expiry time clearly displayed on the outside of the container. There should be clear local procedures for transferring the vaccine to the

	vaccinator in a safe way, allowing for appropriate checks of vaccine particulars e.g. batch number and expiry, thaw date and expiry by both parties. It is the responsibility of the lead in the preparation area to determine the number of vials that should be opened. This decision must be made after considering the number of scheduled booking, number of pre-drawn syringes already in the administration area and the time left for the clinic. Sites should be gradually slowing dilution of vials as the end of the clinic approaches to minimise waste. *Note: the diluted product can be exposed to light conditions. However, it is suggested to minimize exposure as much as possible. See **Appendix 2** - COVID-19 Comirnaty™ Vaccine Preparation

STAGE 3: Vaccine Administration

ACTIVITY STAGE 3:	**Before administering the vaccine, ensure:** **1. the individual has been assessed in accordance with stage one of this protocol** **2. the vaccine to be administered has been identified, by the registered practitioner consenting the individual, as Comirnaty™ vaccine** **3. consent for vaccination has been provided and documented** **Administer the Comirnaty™ vaccine and provide post-vaccination written advice if requested.**
Consent	Informed consent is required before administering a COVID-19 vaccine. In Queensland health, the QCVMS system allows for paperless informed consent. Paper based forms for adults and young people are also available here for use in ICT downtime. Any use of these forms is to be subject to local HHS governance of clinical records and any data retention policies. The Queensland Health Guide to Informed Decision-making in Health Care is a useful reference. For young persons, please see the Queensland Health Guidance on Age of Consent for Vaccinations and the application of Mature Minor (or Gillick) Competence in Queensland. In Queensland, children and young persons under the age of 18 years are able to consent to health care where they have sufficient capacity to do so. In Queensland, there is no fixed lower limit below 18 years of age at which children or young persons are deemed to be able to consent to health care (i.e. Gillick Competent), however generally children over 16 would be deemed to have capacity to consent for vaccinations in the majority of cases. The clinician providing the vaccination at the vaccination centre will make this assessment and either refer them to a more experienced vaccinator (if they cannot assess capacity) or refer the child appropriately if they do not have capacity. Children 12 to 15 years will generally require a parent/legal guardian/other person to provide consent. For young people who are subject to child protection orders and/or placed in out of home care, please see this following guide from the Department of Child Safety in relation to specific consent requirements.

Vaccine to be administered	Comirnaty™ vaccine, COVID-19 mRNA vaccine BNT162b2 30micrograms in 0.3mL dose (embedded in lipid nanoparticles)
Dose and frequency of administration	The primary course series is a two-dose course which should be administered consisting of 30micrograms in 0.3mL followed by a second dose of 30micrograms in 0.3mL after an interval of at least 21 days. For operational purposes the second dose may be given between 21 and 42 days following the first dose. If an interval longer than the recommended interval is left between primary series doses, the second dose should still be given (using the same vaccine as was given for the first dose if possible). The course does not need to be restarted. Additional third doses as part of the primary course series are recommended for severely immunocompromised individuals with a time interval of 2 to 6 months after their second dose. Immunocompromised individuals who have received 3 primary doses of a COVID-19 vaccine are also recommended to have a booster dose (i.e a fourth dose) in line with the timing for the general population. Additional third (booster) doses of Comirnaty are being recommended by ATAGI following completion of primary course series with a time interval of 3 months (13 weeks) after completion of their last dose.
Route / method of administration	Comirnaty™ vaccine is for administration (after dilution) by intramuscular injection only, preferably into deltoid region of the upper arm. If you are not familiar with intramuscular injections at this site for adults, please review the in-depth information sheets and information available within the Australian Immunisation Handbook (AIH). Anatomical markers used to identify the deltoid injection site Below are some summary points on intramuscular (IM) administration: • The person's arm should be clean. If visibly dirty, ideally soap and water should be used to clean. There is no need to use an alcohol wipe as part of normal practice if the skin is visibly clean. If an alcohol wipe needs to be used for cleanliness, ensure the skin is fully dry before administering a vaccination as otherwise this may lead to increased injection site reactions. • In most cases, a 25mm length needle is recommended as per the AIH, however if the individual is obese then a 38mm length needle is recommended*. • The person should be sitting on a chair with their arm relaxed. • The vaccine should be inserted at a 90^{o} angle. • There is no need to withdraw to check your position during IM vaccinations. However, if a flash of blood is seen in the needle hub before injection, withdraw the needle and select a new site for injection. • The vaccine should be injected slowly over a count of 5 seconds. **If 38mm-length needles are absolutely unavailable, 32mm needles may be used for vaccine recipients who are of very large size or obese. However, 32mm-length needles are too short for morbidly obese recipients and a 38mm needle is the only suitable needle length for this group.* Do NOT inject Comirnaty™ vaccine intravascularly, subcutaneously or intradermally.

	The dose should be administered after being prepared in accordance with Stage 2 above. There must be a safe process in place for the person vaccinating to receive, check, and use the vaccine immediately after preparation (within the 6-hour time frame). Do not shake the vaccine. 1. Confirm patient identification (e.g. Photo ID / work ID badge, date of birth, first line of address). 2. Clean hands 3. Check product vial name and expiry and syringe date and time of vaccine expiry (6 hours after reconstitution) 4. Ensure a secure connection between the needle and syringe as is standard practice. 5. Inspect visually prior to administration and ensure appearance is an off-white solution with no particulates visible. Discard the vaccine if particulates or discolouration are present. 6. If the skin is visibly clean, there is no need to wipe it with an antiseptic (such as an alcohol wipe). If you use alcohol or other disinfecting agents to clean skin that is visibly dirty, the skin must be allowed to dry before injecting the vaccine. This reduces the likelihood of irritation at the injection site. 7. Administer vaccine into deltoid muscle (intramuscular). 8. Apply cotton wool to site and ask patient to hold for 1-2mins*. 9. Dispose of the needle / syringe into the sharps bin. 10. Ensure patient is comfortable and no immediate signs of side effects. 11. Discuss the importance of monitoring for 15 minutes and give the patient their completed record card (if one was requested). 12. Record administration details in the QCVMS. 13. Clean workspace 14. Clean hands with hand sanitiser or if soiled wash hands with soap and water. *Where the individual has been identified as being at increased risk of bleeding, a fine needle (equal to 23 gauge or finer calibre such as 25 gauge) should be used for the vaccination, followed by firm pressure applied to the site (without rubbing) for at least 2 minutes. The individual/carer should be informed about the risk of haematoma from the injection.
Disposal	The COVID-19 vaccine is categorised as a Schedule 4 drug under the Medicines and Poisons (Medicines) Regulation 2021 and is considered clinical waste under the Queensland Environmental Protection Regulation 2019. Therefore, all COVID-19 vaccines must be disposed of in accordance with the Queensland Department of Environment and Science Guideline: Clinical and related waste. The QCVMS must be used to account for the disposal of COVID-19 vaccines. All sharps must be discarded in a sharps bin. Please see Appendix 1 for specific guidance and requirements for disposal of used vials of vaccine once the vaccine has been drawn up into syringes. This is in relation to Patient Safety Alert (15/2021) issued 11/08/2021.
Vaccine Administration Errors	Vaccine Administration Errors (VAE) may occur from time to time. They must be reported to the VCC when they occur so that they can be reported, and appropriate clinical advice can be sought to ensure consumers are fully vaccinated. As a guide, ATAGI has published clinical guidance on use of an additional COVID-19 vaccine dose as a replacement dose for

	an invalid dose in specified scenarios of schedule deviation or vaccine administration errors.
Post-vaccination monitoring and advice	Vaccine recipients should be monitored for 15 mins (30 mins if high risk) after vaccination. Ensure the individual has been provided with the appropriate written information if requested, such as the: • COVID-19 Vaccination Record Card specifying which brand of vaccine they have received. • COVID-19 Vaccine 2021 - Vaccination Information prepared by the Commonwealth and ATAGI available here.

STAGE 4: Recording vaccine adminstration

ACTIVITY STAGE 4:	**Complete a record of vaccination for the individual**
Records	All details of the vaccination are to be kept in the state digital solution. There is no additional requirement for clinicians to upload information into the Australian Immunisation Register (AIR). This will be done at a state level, however it is the responsibility of the Hospital and Health Services to ensure any records entered in their vaccination clinics by their staff are entered correctly and errors are rectified in a timely manner to minimise the impact on consumers. Data quality issues must be rectified by clinic administration staff at the point of check in where possible, including the deactivation of duplicate client records and correction of client information. Hospital and Health Services must rectify any errors and discrepancies within 5 business days of the issue occurring, to enable time to meet legislative requirements to report the vaccination episodes to the AIR. Below is the minimum information to be entered into the state digital solution: • that valid informed consent was given • name of individual, address, date of birth and GP (or record where an individual does not have a GP and that appropriate advice has been given) • name of immuniser and, where different from the immuniser, ensure the professional assessing the individual, person preparing the vaccine, and person completing the vaccine record are identified • name and brand of vaccine • date of administration • dose, form and route of administration of vaccine • quantity administered • batch number and expiry date

	• anatomical site of vaccination • advice given, including advice given if excluded or declines immunisation • details of any adverse drug reactions and actions taken It is important that vaccinations are recorded in a timely manner on appropriate health care records for the individual. The vaccination record will be accessible by the individual and other primary care health professionals via My Health Record or My Gov.

Cold Chain Breaches or Wastage

In the event of a potential or actual wastage incident (e.g. damaged vials, breach of cold chain requirements) for Comirnaty™, that **exceeds the threshold (5 or more vials at a time)**, each Administration Site or other location which receives deliveries of Vaccines must **notify the QH VCC immediately** by calling 07 3608 5960. Sites must also submit this data using the state provided Excel template.

Clinical incidents

Any clinical incident must be reported via local processes. Any clinical incident involving the vaccine, dosage and/or administration must also be reported to the QH VCC: 07 3608 5960 (Mon-Fri: 8am-6pm) or QH.VCC@health.qld.gov.au.

Clinical queries can be directed to the Clinical line VCC.Clinical@health.qld.gov.au and AEFI enquiries to COVID_AEFI@health.qld.gov.au.

Acknowledgements

The Queensland Health Vaccine Taskforce greatly acknowledges Public Health England for their content utilized in this protocol.

Appendix

Appendix 1 – COVID-19 Mobile Clinic Emergency Response Equipment Guidance

Key principles:

- The following guidance has been drafted in response to enquiries regarding the emergency equipment required on-site to support mobile pop-up vaccination services.
- It is important to note that depending on the targeted cohort, the location of the service and availability of emergency response services, HHSs may need to adjust these requirements to suit their local context.
- Careful consideration should also be given to the adrenaline requirements. In accordance with the Australian Immunisation Handbook, three vials of 1:1000 is recommended however, HHSs may choose to carry additional quantities to ensure their vaccination clinic can continue post treatment of an anaphylaxis.

MANDATORY	
Adrenaline 1:1000 (minimum 3 vials)	3
1ml syringes (minimum 3)	3
23G 25mm (minimum 3)	3
Cotton balls	3
Notepad	1
Pen	1
Laminated copy of 'Doses of intramuscular 1:1000 adrenaline for anaphylaxis' (Australian Immunisation Handbook)	1
Laminated copy of 'Recognition and treatment of anaphylaxis' (Australian Immunisation Handbook)	1
RECOMMENDED	
Guedel airway size 2 - 70MM	1
Guedel airway size 3 - 80MM	1
Guedel airway size 4 - 90MM	1
Guedel airway size 5 - 100MM	1
Guedel airway size 6 - 110MM	1
Adult Bag-Valve-Mask (BVM) - Disposable Resuscitator	1
Paediatric Bag-Valve-Mask (BVM) - Disposable Resuscitator	1
Sphygmomanometer	1
Thermometer (including any disposable tips/sheaths if not infrared)	1
Pulse oximeter	1
Stethoscope	1
FOR CONSIDERATION BY HHS	
Suction unit	1
Yankauer suction tip	1
Suction catheters	various
Oxygen Cylinder (with regulator)	1
Adult oxygen mask (non-rebreather) tubing and bag	1
Adult oxygen nasal prongs	1
Paediatric oxygen mask (free-flowing) with tubing	1

Appendix 2 – COVID-19 Comirnaty™ Vaccine Preparation

Key principles:

- Use a new, sterile 23G or 25G 25mm length needle (or 23G/25G 38mm needle for people who are obese) and 1 mL syringe to draw up each new 0.3 mL dose by re-puncturing the bung.
- Ensure each re-puncture occurs at a *different* site on the bung (the Pfizer vial has small indentions around the silver seal of the vial which are indicators for puncture sites when withdrawing doses)
- Recap the clean needle using either a dedicated scoop dish, single-handed technique, forceps, or a suitable protective guard designed for re-sheathing. The needle must be properly recapped, and the sheath must not be held in the fingers.
- In the event of a needle stick injury during recapping, the needle and syringe must be discarded, and the incident recorded.
- PPE is to be worn as indicated in local and/or state guidelines: refer to Qld Health PPE guidelines.

Preparation process:

1	**Initial set up for aseptic prep space.** • Wipe down preparation area with Clinell™ wipes or similar • Perform hand hygiene • Remove a single vial from vaccine fridge or cooler confirming asset within temperature range • Ensure vial has come to room temperature • Inspect vial [prior to dilution the thawed suspension may contain white to off white amorphous particles] and place vial in a secure area on bench top • Quarantine any vials noted to have frothing, particulates, contamination or other concerns and report immediately to Preparation Lead (or nominated superior) • Only a single vial must be present on the bench top/vail preparation space to avoid any preparation errors. • Assemble required consumables, enough to prepare one vial • Complete information on label: Date/ Time reconstituted using 24-hour clock/ Initials. • Set the timer to 6 hours and press start
2	**Invert vial** • Slowly invert the vial 10 times to thoroughly mix theconcentrate suspension, **DO NOT SHAKE**.
3	**Diluting the vaccine** • Perform hand hygiene • Pop off the cap on the vial and disinfect the bung with an alcohol wipe (70% isopropyl alcohol) - a single swipe only and allow to dry for 30 seconds. Place upright on bench securely • Twist off the top of the sodium chloride 0.9% solution for injection ampoule with alcohol wipe and

	place securely upright on bench • Open the 3ml syringe and draw back air to 1.8ml • Luer lock the 3mL syringe to the saline ampoule → insert the 1.8mL of air into the vial, allow pressure to equalize, and draw back 1.8mL of saline. Ensure no air bubbles are present. • Get a second check on the saline volume. • Attach 21G or 23G needle to the 3mL syringe containing saline • Inject the 1.8mL of saline into the vaccine vial using the centre of the bung → bring the bevel of the needle up into the air space within the vial and equalise the vial pressure by removing 1.8mL of air. Remove the needle from the bung ensuring no liquid is withdrawn from the vial • Discard needle and syringe into sharps container • Invert the vial gently 10 times to mix. DO NOT SHAKE. • Inspect the vial again & quarantine any vials noted to have particulates or contamination and report immediately to Preparation Lead
4	**Drawing up vaccine doses** • **Perform hand hygiene. • Disinfect the bung on vaccine vial with alcohol wipe and let dry for at least 30 seconds • Attach a 23G or 25G to a 1mL syringe (LDS needle preferred option) • Pierce the bung aligning with one of the indentation indicators in the outside ring of the bung and withdraw a 0.3mL dose from the vial. Ensure no flicking of the syringe to remove air bubbles. • *** Remove needle from vial and carefully recap using no touch methods. Secure sheath onto needle and ensure needle is firmly attached to syringe. • Label prepared syringe using the flagging technique. Be sure not to cover the volume within the syringe or the number increments. • Place dose in a tray/container to the side. • Repeat steps ** to *** for all 6 doses ensuring each puncture is performed in a different location to previous punctures using indentations on silver vial capping as indicators. • If unable to extract a full 6th dose, place the syringe away from prepared doses for later recording as a wasted dose as per step 5 below. Each dose must be drawn from one vial only. Do not pool excess vaccine from multiple vials to make up a full dose. • Place labelled doses, vial and timer into a tray which is protected from light. • Obtain a second check on prepared syringes and vial they were drawn from. It is important the check includes volumes in each syringe, volume remaining in the vial, expiry date of the batch, expiry date of the vial since date of thawing, correct vaccine in syringe (and label) corresponding to vial label and vaccine appearance is appropriate (no frothing, clotting, particulates, contaminates). • Deface vial label to indicate it is used (with a black marker) and dispose of it into a sharp's container.

5	**Wastage** • DO NOT USE expired vials. Any wasted vials (e.g. not drawn up for administration before expiry time) must be recorded (including number of wasted vials, reason for wastage and batch number) as per reconciliation and disposal of wasted vials procedure. • Wasted syringes must be recorded and double-signed on wasted or discarded syringe recording tool before discarding in a sharps container. This should occur in an area that is separate to the preparation workstation.
6	**Cautions and disposal of vials following use.** • Please see Patient Safety Alert 15/2021: COVID-19 Vaccine Preparation issued 11/08/2021. All Queensland Health Vaccination locations and providers must be in compliance with this alert. • Adhere to the principal of "Prepare one vial at a time" : The vaccine preparation process is undertaken from beginning to end for one vaccine vial at a time. • Preparing more than one vial at a time carries a range of risks, including use of used vials (double dilution incidents), increased risk of microbial contamination (if preparing diluent in advance), incorrect diluent (if preparing diluent in advance in unlabeled syringes) amongst others. • Processes must be clearly defined to allow only one vial to be prepared at one time, with a new diluent ampoule, and for the vial to be discarded in an unrecoverable manner immediately after the verification of the syringes produced from the vial has been completed (i.e. 1 vial to 6 or 7 syringes).

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Version Control

Version	Date	Comments
1	21/2/2021	New document
2	3/3/2021	Update to allergy information, pregnancy and lactation information, medical officer requirements and wastage reporting requirements.
3	22/3/2021	Update to allergy & storage information
4	30/3/2021	Update to contraindications, link to ATAGI pregnancy and lactation advice, update to immunosuppression information
5	13/4/2021	Inclusion on advice for deltoid administration and preparation images.
6	12/5/2021	Minor grammatical updates, removal of incorrect contraindications (CVST)
7	2/6/2021	Update to brand interchangeability to align to ATAGI advice, update to storage conditions and cold chain reporting, link to Commonwealth stages, new preparation advice appendix
8	21.6.21	Reference to AstraZeneca in cold chain breaches removed. The word 'sterilised' removed in appendix 1. Pregnancy advice updated and duration between vaccine intervals aligned to ATAGI advice.
9	30.6.21	Rectified version error
10	26.08.21	Addition of new age 12-15 eligibility, adverse events, managing risk of myocarditis and pericarditis, new ATAGI resources and informed consent processes. Additional precautions on vaccine preparation are also included. Changes to Appendix 1 in accordance with PSA 15/2021.
11	21.10.2021	Updating clinical guidance's to align with new ATAGI recommendations. Stipulation of vaccine preparation staff minimum training. Change to legislative and regulation references to Medicines and Poisons Act (2021) including definition of indications for use as per LAM. Amendments to mixed dosing and VAE to align with ATAGI. Addition of Appendix to clarify emergency equipment. Enabling third doses for severe immunocompromised individuals.

Version	Date	Comments
12	27.10.2021	Addition of Booster doses information and approval from CHO for Covid-19 Designated hospital staff vaccination ahead of formal ATAGI advice. Other minor amendments included.
13	05.11.2021	Endorsement of off-label administration of Booster doses at 4 months (rather than 6) for certain consumer groups.
14	13.11.2021	Alignment of Booster dose timing (5 months/21 weeks) and mixed (heterologous) brand dosing to updated ATAGI clinical guidance.
15	13.12.2021	Alignment of Booster dose timing (5 months/21 weeks) to updated ATAGI clinical guidance. Updated advice on co-administration of COVID-19 vaccines and influenza and other vaccines.
16	24.12.2021	Updating New booster interval of 3 months as per ATAGI and enabling boosters for immunocompromised individuals.