

## Statewide Protocol for the Supply or Administration of COVID-19 Vaccine

**Summary** This Policy Directive provides information on the administration of COVID-19 vaccines and if required, adrenaline (epinephrine) for anaphylaxis. These medications are administered for prevention of Severe Acute Respiratory Syndrome Coronavirus 2 (SARS-CoV-2) infection or COVID-19 disease resulting from infection with the SARS-CoV-2

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**Distributed to** Ministry of Health, Public Health System, Government Medical Officers, NSW Ambulance Service

**Audience** Pharmacy Departments and COVID-19 Vaccination Clinic Staff with Local Health Districts;Public Health Units;Nursing Administration

# STATE-WIDE PROTOCOL FOR THE SUPPLY OR ADMINISTRATION OF COVID-19 VACCINE

## POLICY STATEMENT

In NSW, COVID-19 vaccines are intended to be administered by Authorised Nurse Immunisers. In the event of insufficient workforce of Authorised Nurse Immunisers available to administer COVID-19 vaccines, the Policy Directive: *State-wide Protocol for the Supply or Administration of COVID-19 Vaccine* can be enacted. It allows a range of health practitioners and health practitioner students to administer the vaccine, providing they comply with the specified conditions of the Protocol.

Authorised health practitioners (other than medical practitioners or authorised nurse immunisers) and authorised health practitioner students employed in NSW public health facilities must follow the Protocol for the supply or administration of COVID-19 vaccines, as appropriate, when conducting vaccination within a NSW Health COVID-19 vaccination clinic.

The Protocol does not require further authorisation by local Drug and Therapeutics Committees nor endorsement or sign off by a medical officer (in addition to the Chief Health Officer).

## SUMMARY OF POLICY REQUIREMENTS

Authorised health practitioners and authorised health practitioner students are authorised to administer COVID-19 vaccines to those who meet the criteria for treatment under the Protocol.

Authorised health practitioners and authorised health practitioner students must ensure that informed consent has been obtained, including by providing relevant written information and the opportunity for the patient to ask questions or raise any relevant health concerns, and confirm and document this.

If the authorised health practitioner or authorised health practitioner student has any clinical concerns regarding patient safety or suitability for COVID-19 vaccination, they must refer the patient to a medical practitioner, authorised nurse (or midwife) immuniser or nurse practitioner (with appropriate scope of practice and experience in immunisation) for assessment.

A medical practitioner must be available to provide immediate advice and to address any concerns from the vaccine recipient that are unable to be addressed by the authorised nurse (or midwife) immuniser or nurse practitioner (with appropriate scope of practice and experience in immunisation).

Where a medical practitioner is not physically present, an authorised nurse (or midwife) immuniser or nurse practitioner (with appropriate scope of practice and experience in immunisation) must be available onsite to provide oversight of the clinic.

Public Health Organisations must have processes in place to periodically assess compliance with the Protocol and take appropriate action where non-compliance is identified.

Anaphylaxis must be managed as per the *Anaphylaxis after vaccination* guidance and the advice in the [Australian Immunisation Handbook](#) must be followed.

This policy must be read in conjunction with the NSW Health Policy Directive *Standard operating procedure for administration of COVID-19 vaccines in NSW vaccination clinics* ([PD2021\\_013](#)).

## REVISION HISTORY

Version	Approved by	Amendment notes
October – 2021 (PD2021_041)	Deputy Secretary, Population and Public Health and Chief Health Officer	Certain groups are recommended to receive a third dose in a primary course of COVID-19 vaccination. The Policy Directive has been updated to include reference to an additional dose and to refer to the updated Standard Operating Procedures PD2021_040.
September – 2021 (PD2021_038)	Deputy Secretary, Population and Public Health and Chief Health Officer	The key changes in this recent version include clarification on the roles and responsibilities of the authorised health practitioners and authorised health practitioner students, particularly in relation to informed consent; expansion of the authorised workforce to include VET qualified Aboriginal Health Workers; inclusion of the Spikevax (Moderna) vaccine to allow authorised health practitioners and health practitioner students to administer the vaccine and to refer to the updated Standard Operating Procedures PD2021_036.
September – 2021 (PD2021_034)	Deputy Secretary, Population and Public Health and Chief Health Officer	Key changes include expanding the protocol to allow additional authorised health practitioners to administer the vaccine under the conditions of the protocol. This includes Registered pharmacists, Registered Nuclear Medicine Technologists, Sonographers, Perfusionists, Exercise Physiologists, International Medical Graduates, Pharmacy Technicians, Dental Hygienists, Dental Therapists, VET qualified Allied Health Assistants, VET qualified Assistants in Nursing and specified previously registered health practitioner workforce.
August-2021 (PD2021_032)	Executive Director, COVID-19 response	Change to the recommended age range for people receiving the COVID-19 Pfizer (Comirnaty) vaccine to include people 12 years and over (from 16 years and over)
July-2021 (PD2021_028)	Deputy Secretary, Population and Public Health and Chief Health Officer	Inclusion of the Sydney Local Health District (SLHD) Vaccination Administration Practical Workshop' for employees of SLHD.
June-2021 (PD2021_019)	Deputy Secretary, Population and Public Health and Chief Health Officer	Key changes include expanding the protocol to allow additional authorised health practitioners to administer the vaccine under the conditions of the protocol. This includes dentists, paramedics, Aboriginal Health Practitioners, specified allied health professionals and students studying in approved medicine, nursing and specified allied health courses.  Specifying additional training requirements and competency assessment to enable these workforce groups to safely administer COVID-19 vaccines.  Amending the recommended age range for the AstraZeneca vaccine to include people aged 60 years and over, in accordance with recent ATAGI advice.

May-2021 (PD2021_015)	Deputy Secretary, Population and Public Health and Chief Health Officer	Key changes include allowing authorised pharmacists to supply or administer the vaccine; changes to authorised settings for administration; allowing medical officers to support clinics remotely rather than in person if an authorised nurse immuniser is on site; changes to requirements under section 2; and additions of contraindications and a precaution for the COVID-19 AstraZeneca (ChAdOx1-S) vaccine.
February-2021 (PD2021_004)	Deputy Secretary, Population and Public Health and Chief Health Officer	New State-wide Protocol for the Supply or Administration of COVID-19 Vaccine

## ATTACHMENTS

1. State-wide Protocol for the Supply or Administration of COVID-19 Vaccine.

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## 1 BACKGROUND

### 1.1 About this document

In NSW vaccination programs, generally vaccines are intended to be administered by Authorised Nurse (or Midwife) Immunisers. In the event of insufficient workforce of Authorised Nurse (or Midwife) Immunisers available to administer COVID-19 vaccines, this Protocol can be enacted. This Policy Directive: *State-wide Protocol for the Supply or Administration of COVID-19 Vaccine* and associated [Authorisation to Supply Poisons and Restricted Substances: COVID-19 Vaccine](#) authorises specific health practitioners and specific health practitioner students listed in section 1.3 to administer specified medications, providing they comply with the specified conditions.

It sets out procedures for administering medications for the purpose of prevention of Severe Acute Respiratory Syndrome Coronavirus 2 (SARS-CoV-2) infection, or COVID-19 disease resulting from infection with the SARS-CoV-2, and allows the use of adrenaline (epinephrine) by Registered Nurses, Registered Midwives and Authorised Pharmacist Immunisers if required, following vaccination.

This document is intended for use by authorised health practitioners and health practitioner students employed/engaged in a public health organisation for the administration of COVID-19 vaccines in NSW Health vaccination clinics, without the need for an order for each patient from a Medical Practitioner or Nurse Practitioner.

Health practitioners that are authorised under this policy directive are authorised separately from other authorised practitioners such as Authorised Nurse (or Midwife) Immunisers, Medical Practitioners or Nurse Practitioners (with appropriate scope of practice and experience in immunisation), who are authorised to supply or administer in their own right, and do not need the authorisation provided under this policy directive.

Authorised settings for administration are within a NSW Health COVID-19 vaccination clinic.

This state-wide protocol is similar in effect to a 'standing order', except that no signature of a medical practitioner is required.

A medical practitioner must be available to provide immediate advice to the authorised health practitioner and authorised health practitioner student, and to address any concerns from the vaccine recipient that are unable to be addressed by the authorised health practitioner or authorised health practitioner student. Where a medical practitioner is not physically present, an Authorised Nurse (or Midwife) Immuniser or Nurse Practitioner (with appropriate scope of practice and experience in immunisation) must be available onsite to provide oversight of the clinic.

Medical practitioners, Authorised Nurse (or Midwife) Immunisers and Nurse Practitioners (with appropriate scope of practice and experience) must familiarise themselves with the latest advice from the Australian Technical Advisory Group on Immunisation (ATAGI) and Therapeutic Goods Administration (TGA) regarding the COVID-19 vaccination program. Medical Practitioners must be available to support the clinic either onsite or remotely.

Clinics and hubs may have different structural requirements. LHDs should ensure that local considerations are reflected in the model that is developed. Each task of the

procedure must be completed by a person authorised to do so. This may not be the same person for each task. Appropriate levels of line of site supervision must be provided.

In a NSW Health vaccination clinic the authorised health practitioner and authorised health practitioner student must also follow the NSW Health Policy Directive *Standard operating procedure for administration of COVID-19 vaccines in NSW vaccination clinics (PD2021\_040)*.

Competency to administer medications by intramuscular (IM) injection is not routinely included in undergraduate or postgraduate studies for all health practitioners. Vaccinations may only be administered under this protocol by authorised health practitioners and authorised health practitioner students who hold competency in intramuscular (IM) administration of the vaccine, either through

1. entry level competency (included in curriculum), or
2. through completion of the *Sydney University COVID-19 Vaccination Administration Training*, or
3. When employed at Sydney LHD, through completion of the
  - a. *Sydney University COVID-19 Vaccination Administration* on-line modules (Module 1: Health Care Professionals as Vaccinators and Module 2: Vaccine Administration); AND
  - b. Sydney Local Health District (SLHD) Vaccination Administration Practical Workshop

and only in accordance with any practice conditions imposed by the person's place of employment and the endorsements, notations and conditions on the person's registration.

This protocol does not permit administration of vaccine where relevant precautions or contraindications to vaccine use apply. However, a Medical Practitioner or Nurse Practitioner (with appropriate scope of practice and experience) may direct an authorised health practitioner or authorised health practitioner student to administer a vaccine, separately to this protocol, and therefore under the Medical/Nurse Practitioner's authority.

This document contains state-wide protocols for:

- COVID-19 vaccines (authorised health practitioners and authorised health practitioner students)
- The subsequent use of adrenaline (epinephrine) by registered nurses, registered midwives and authorised pharmacist immunisers to treat anaphylaxis.

## 1.2 Key definitions

### **Authorised health practitioner and authorised health practitioner student**

An 'authorised health practitioner and authorised health practitioner student' is a person who has satisfactorily completed requirements outlined in section 1.3

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## **Medication**

Used singularly throughout the Policy to describe a drug, medicine, pharmaceutical preparation, therapeutic substance, and vaccine.

## **Authorised Pharmacist Immunisers**

Authorised pharmacist immunisers are pharmacists who have completed a training course that complies with the Australian Pharmacy Council 'Standards for the Accreditation of Programs to Support Pharmacist Administration of Vaccines' and conducted by an Australian Pharmacy Council accredited pharmacy education program provider, and are competent in the administration of adrenaline (epinephrine) in the management of anaphylaxis.

## **Public Health Organisation**

A local health district, or statutory health corporation, or an affiliated health organisation in respect of its recognised establishments and recognised services.

## **Supply**

Includes to administer medications to a group or a specific patient and is consistent with the definition of supply in section 4 of *the Poisons and Therapeutic Goods Act 1966*. Includes administration of a single dose for prophylaxis by an authorised health practitioner or authorised health practitioner student.

### 1.3 Authorised health practitioner and authorised health practitioner student

Authorised Health Practitioner or Authorised Health Practitioner Student	Training requirements
Registered nurse Registered midwife Authorised pharmacist immuniser	Must have: completed the core and elective COVID-19 vaccination training modules from the <i>COVID-19 Vaccination Training Program</i> developed by the Commonwealth Department of Health in partnership with the Australian College of Nursing — see <a href="#">COVID-19 vaccination training program</a> . completed the MyHealthLearning <i>Vaccine Storage and Cold Chain Management</i> module. current cardio-pulmonary resuscitation (Basic Life Support) competency. received prior training to recognise and manage anaphylaxis including the use of adrenaline (epinephrine). remain up to date on any new advice from the Australian Technical Advisory Group on Immunisation (ATAGI) or Therapeutic Goods Administration (TGA) regarding additional precautions or consent requirements for all the COVID-19 vaccines that are being administered at the vaccination clinic.
Registered: Aboriginal Health Practitioner Dental Hygienist Dental Therapist Dentist Enrolled nurse (under the supervision of a registered nurse) Nuclear Medicine Technologist Occupational Therapist Oral Health therapist Paramedic Physiotherapist Pharmacist	Must have: completed the core and elective COVID-19 vaccination training modules from the <i>COVID-19 Vaccination Training Program</i> developed by the Commonwealth Department of Health in partnership with the Australian College of Nursing — see <a href="#">COVID-19 vaccination training program</a> . completed MyHealthLearning <i>Vaccine Storage and Cold Chain Management</i> module. competency in intramuscular (IM) administration of the vaccine: <i>through entry level competency (where included in curriculum – includes dentists and podiatrists), or</i> through completion of the <i>Sydney University COVID-19 Vaccination Administration Training</i> ; or if the person is employed or engaged at Sydney Local Health District and is supplying the vaccine in that capacity, the:

<p>Podiatrist Radiation Therapist Radiographer</p>	<p><i>Sydney Local Health District (SLHD) Vaccination Administration Practical Workshop;</i> AND the <i>Sydney University COVID-19 Vaccination Administration on-line modules</i> completed the LHD competency assessment for intramuscular vaccine administration. current cardio-pulmonary resuscitation (Basic Life Support) competency. remain up to date on any new advice from the Australian Technical Advisory Group on Immunisation (ATAGI) or Therapeutic Goods Administration (TGA) regarding additional precautions or consent requirements for all the COVID-19 vaccines that are being administered at the clinic.</p>
<p>Dietitian who holds tertiary qualifications in Nutrition and Dietetics and who is eligible for full membership of the Dietitians Association of Australia Speech Pathologist who holds a bachelor or post graduate degree in speech pathology and who is eligible for membership of Speech Pathology Australia Sonographer who holds relevant and accredited postgraduate qualifications and is eligible for full membership with Australian Sonography Association Perfusionist who holds a certificate of Clinical Perfusion awarded by the Australasian Board of Cardiovascular Perfusion Exercise physiologist who holds tertiary qualifications in Exercise Physiology and who is eligible for full membership of Exercise &amp; Sports Science Australia Pharmacy Technician who holds a Certificate III or IV issued by a Registered Training Organisation in Hospital and Community Pharmacy or equivalent (To be considered as a Pharmacy Technician Grade 1 or 2); AND be employed by NSW Health as a Drawing Up Officer in a COVID-19 vaccination clinic; AND obtain approval to be trained as a Vaccination Worker by their line manager</p>	<p>Must have: completed the core and elective COVID-19 vaccination training modules from the <i>COVID-19 Vaccination Training Program</i> developed by the Commonwealth Department of Health in partnership with the Australian College of Nursing — see <a href="#">COVID-19 vaccination training program</a>. completed MyHealthLearning <i>Vaccine Storage and Cold Chain Management</i> module. competency in intramuscular (IM) administration of the vaccine, through completion of the <i>Sydney University COVID-19 Vaccination Administration Training</i>; or if the person is employed or engaged at Sydney Local Health District and is supplying the vaccine in that capacity, the: <i>Sydney Local Health District (SLHD) Vaccination Administration Practical Workshop;</i> AND the <i>Sydney University COVID-19 Vaccination Administration on-line modules</i> completed the LHD competency assessment for intramuscular vaccine administration. current cardio-pulmonary resuscitation (Basic Life Support) competency. remain up to date on any new advice from the Australian Technical Advisory Group on Immunisation (ATAGI) or Therapeutic Goods Administration (TGA) regarding additional precautions or consent requirements for all the COVID-19 vaccines that are being administered at the clinic.</p>
<p>International Medical Graduate who holds a primary qualification in medicine and surgery awarded by a training institution recognised by both the Australian Medical Council (AMC) and the World Directory of Medical Schools (WDOMS); AND provide</p>	<p>Must have: completed the core and elective COVID-19 vaccination training modules from the <i>COVID-19 Vaccination Training Program</i> developed by the Commonwealth Department</p>

<p>evidence of passing the AMC Computer Adaptive Test (CAT) MCQ Examination</p>	<p>of Health in partnership with the Australian College of Nursing — see <a href="#">COVID-19 vaccination training program</a>.          completed MyHealthLearning <i>Vaccine Storage and Cold Chain Management</i> module.          competency in intramuscular (IM) administration of the vaccine,          through completion of the <i>Sydney University COVID-19 Vaccination Administration Training</i>; or          if the person is employed or engaged at Sydney Local Health District and is supplying the vaccine in that capacity, the:  <i>Sydney Local Health District (SLHD) Vaccination Administration Practical Workshop</i>;          AND          the <i>Sydney University COVID-19 Vaccination Administration on-line modules</i>          completed the LHD competency assessment for intramuscular vaccine administration.          completed the MyHealthLearning 'Aseptic Technique' online training module.</p>
<p>Vocational Education and Training (VET) qualified Allied Health Assistant who holds a certificate IV in Allied Health Assistance; AND demonstrate relevant clinical experience in NSW Health          Vocational Education and Training (VET) qualified Assistants in Nursing who holds a certificate III Health Service Assistance (Assisting in Nursing Work in Acute Care); AND demonstrate relevant clinical experience in NSW Health          Vocational Education and Training (VET) qualified Aboriginal Health Worker (AHW) who holds          Certificate III Aboriginal Primary Health Care; OR          Certificate IV Aboriginal Primary Health Care; OR          Diploma of Aboriginal Primary Health Care; AND          Demonstrate relevant experience in NSW Health.</p>	<p>Must have:          completed the core and elective COVID-19 vaccination training modules from the <i>COVID-19 Vaccination Training Program</i> developed by the Commonwealth Department of Health in partnership with the Australian College of Nursing — see <a href="#">COVID-19 vaccination training program</a>.          completed MyHealthLearning <i>Vaccine Storage and Cold Chain Management</i> module.          competency in intramuscular (IM) administration of the vaccine,          through completion of the <i>Sydney University COVID-19 Vaccination Administration Training</i>; or          if the person is employed or engaged at Sydney Local Health District and is supplying the vaccine in that capacity, the:  <i>Sydney Local Health District (SLHD) Vaccination Administration Practical Workshop</i>;          AND          the <i>Sydney University COVID-19 Vaccination Administration on-line modules</i>          completed the LHD competency assessment for intramuscular vaccine administration.          completed the MyHealthLearning 'Aseptic Technique' online training module.</p>
<p>Formerly Registered Health Practitioner that has been previously registered in the National Registration and Accreditation Scheme for health professionals within the last 10</p>	<p>Must have:          completed the core and elective COVID-19 vaccination training modules from the <i>COVID-19 Vaccination Training Program</i> developed by the Commonwealth Department</p>

<p>years in one of the following professions: Registered Nurse, Registered Midwife, Enrolled Nurse, Aboriginal Health Practitioner, Dentist, Paramedic, Podiatrist, Oral Health Therapist, Radiographer, Radiation Therapist, Occupational Therapist, Physiotherapist, Pharmacist, Nuclear Medicine Technologist, Dental Hygienist, and Dental Therapist; AND must make a declaration about any adverse findings by a scheme entity when registered such as conditions placed on registration, suspension or cancellation.</p>	<p>of Health in partnership with the Australian College of Nursing — see <a href="#">COVID-19 vaccination training program</a>.                  completed MyHealthLearning <i>Vaccine Storage and Cold Chain Management</i> module.                  competency in intramuscular (IM) administration of the vaccine,                  through completion of the <i>Sydney University COVID-19 Vaccination Administration Training</i>; or                  if the person is employed or engaged at Sydney Local Health District and is supplying the vaccine in that capacity, the:  <i>Sydney Local Health District (SLHD) Vaccination Administration Practical Workshop</i>;                  AND                  the <i>Sydney University COVID-19 Vaccination Administration on-line modules</i>                  completed the LHD competency assessment for intramuscular vaccine administration.                  completed the MyHealthLearning 'Aseptic Technique' online training module.</p>
<p>Student in Dentistry, Medicine, Paramedicine, Pharmacy, Podiatry, Radiation Therapy, Radiography, Physiotherapy, Occupational Therapy, Oral Health Therapy or Nuclear Medicine Technology who is:                  entered on the student register in an approved program of study under the Health Practitioner Regulation National Law; AND                  where they have undertaken at least one clinical placement of the relevant qualification.                  A nursing or midwifery student who is:                  currently enrolled in a recognised course leading to registration as a nurse (division 1) or midwife, with the Nursing and Midwifery Board of Australia; AND                  where they have undertaken at least one clinical placement of the relevant qualification.                  An enrolled nurse student currently enrolled in a Nursing and Midwifery Board of Australia approved Diploma of Nursing course leading to registration as an enrolled nurse (division 2); AND where they have undertaken at least one clinical placement of the relevant qualification.</p>	<p>Must have:                  completed the core and elective COVID-19 vaccination training modules from the <i>COVID-19 Vaccination Training Program</i> developed by the Commonwealth Department of Health in partnership with the Australian College of Nursing — see <a href="#">COVID-19 vaccination training program</a>.                  completed MyHealthLearning <i>Vaccine Storage and Cold Chain Management</i> module.                  competency in intramuscular (IM) administration of the vaccine,                  through completion of the <i>Sydney University COVID-19 Vaccination Administration Training</i>; or                  if the person is employed or engaged at Sydney Local Health District and is supplying the vaccine in that capacity, the:  <i>Sydney Local Health District (SLHD) Vaccination Administration Practical Workshop</i>;                  AND                  the <i>Sydney University COVID-19 Vaccination Administration on-line modules</i>                  completed the LHD competency assessment for intramuscular vaccine administration.                  completed the MyHealthLearning 'Aseptic Technique' online training module (unless employed as a vaccination worker prior to publication of the 1 October version of this Policy Directive).</p>

<p>A speech pathology student who is enrolled in a course accredited by Speech Pathology Australia; AND where they have undertaken at least one clinical placement of the relevant qualification.</p> <p>A nutrition and dietetics student enrolled in a course accredited by Dietitians Australia; AND where they have undertaken at least one clinical placement of the relevant qualification.</p> <p>A sonography student enrolled in a course accredited by the Australian Sonographer Accreditation Registry AND where they have undertaken at least one clinical placement of the relevant qualification.</p> <p>An exercise physiology student enrolled in a course accredited by Exercise and Sports Science Australia; AND where they have undertaken at least one clinical placement of the relevant qualification.</p>	
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## 1.4 Legal and legislative framework

Clauses 170 and 171 of the *Poisons and Therapeutic Goods Regulation 2008* allow the Secretary of the NSW Ministry of Health to authorise (for the purposes of section 10 of the Act) a particular person (by means of an instrument in writing given to the person) or a specified class of persons (by means of an instrument published in a manner approved by the Secretary) to supply (which includes administer) restricted substances (Schedule 4 medicines) according to clause 53 of the Regulation and Schedule 3 medicines such as adrenaline accordance to clause 17).

The authorisation only applies to authorised health practitioners and authorised health practitioner students listed in section 1.3 who are employed by a public health organisation and working in an authorised setting, for the medications listed in this Policy.

## 2 IMPLEMENTATION OF STATE-WIDE PROTOCOL

### 2.1 Prerequisites for authorised health practitioners and authorised health practitioner students

Authorised health practitioners and authorised health practitioner students operating under this protocol must:

- Have completed the training requirements outlined in section 1.3
- Have read and understood the authority attached to this Policy Directive
- Practice in accordance with any practice conditions imposed by the person's place of employment and the endorsements, notations and conditions on the person's registration
- Practice according to the NSW Health Policy Directive *Standard operating procedure for administration of COVID-19 vaccines in NSW vaccination clinics* ([PD2021\\_040](#)) and its [supporting documents](#), which describe specific procedures for each vaccine.
- Ensure records relating to the administration of vaccine are retained in accordance with the State Records Authority General Retention and Disposal Authority for Public Health Services: Patient / Client Records (GDA 17).
- Informed consent can only be obtained by specified authorised health practitioners as per section 5.

Authorised health practitioner students must work in line of sight supervision of a Medical/Nurse practitioner, Authorised Nurse/Midwife Immuniser or Registered Nurse (year 2 and above).

### 2.2 Public Health Organisations

Public Health Organisations must ensure there is a nominated medical practitioner available to provide immediate advice to authorised health practitioners and authorised health practitioner students during operational hours of the vaccination clinic. Where a Medical Practitioner cannot be physically present, an Authorised Nurse (or Midwife) Immuniser or Nurse Practitioner (with appropriate scope of practice and experience in

immunisation) must be available onsite to provide oversight of the clinic. A Medical Practitioner must be available remotely to support the clinic.

Public Health Organisations must ensure there is a

- Medical Practitioner, Authorised Nurse Immuniser, Authorised Midwife Immuniser, Registered Nurse (year 2 and above) or Nurse Practitioner (with appropriate scope of practice and experience in immunisation) available to provide line of sight supervision and general oversight of the work of an eligible health practitioner student
- nominated Registered Nurse available to supervise any Enrolled Nurse.

Public Health Organisations must have processes in place to periodically assess compliance with the Protocol and take appropriate action where any aspect of non-compliance is identified.

### 3 ADRENALINE (EPINEPHRINE) FOR ANAPHYLAXIS

Anaphylaxis must be managed as per the *Anaphylaxis after vaccination* guidance, found in [supporting documents](#) to the NSW Health Policy Directive *Standard operating procedure for administration of COVID-19 vaccines in NSW vaccination clinics* (PD2021\_040). In addition, advice in the [Australian Immunisation Handbook](#) must be followed. In addition to Medical Practitioners, Authorised Nurse (or Midwife) Immunisers and Nurse Practitioners (with appropriate scope of practice and experience in immunisation), only Registered Nurses, Registered Midwives and Authorised Pharmacists are authorised to administer adrenaline.

### 4 RECORD OF SUPPLY / ADMINISTRATION

Follow the procedures in the NSW Health Policy Directive *Standard operating procedure for administration of COVID-19 vaccines in NSW vaccination clinics* (PD2021\_040) regarding eMR and / or other specific vaccination record for loading the information up to the Australian Immunisation Register.

### 5 VACCINATION FOR PROPHYLAXIS AGAINST COVID-19

Authorised health practitioners and authorised health practitioner students are authorised to administer the vaccine to those who are presenting for COVID-19 vaccination as prophylaxis against COVID-19, where there is no precaution or contraindication to treatment (as per protocol), and when employed by a public health organisation and working in an authorised setting.

Authorised health practitioners and authorised health practitioner students are authorised to supply/administer the vaccine, but only specified health practitioners are authorised to obtain informed consent i.e. following provision of information on benefits and harms of vaccination, gain agreement to treatment.

Informed consent can be obtained by Dentists, Dietitians, Occupational Therapists, Physiotherapists, Pharmacists, Podiatrists, Radiation Therapists, Radiographers and Speech Pathologists, provided that:

- they are confident that the patient/parent/guardian understands the information that they have been provided regarding the risks and benefits of vaccination;
- no barriers to understanding the information have been identified such as language or communication barriers;
- the patient/parent/guardian do not have any outstanding questions;
- a relevant history has been taken and no medical contraindications or precautions have been identified.

If any issues, concerns, barriers or questions are identified or raised by the consenting individual, they must be referred to one of the following to obtain informed consent:

- Medical practitioner
- Authorised Nurse Immuniser
- Registered Nurse/Midwife
- Pharmacist Immuniser
- Nurse Practitioner (with appropriate scope of practice and experience in immunisation).

All other authorised health practitioners and all authorised health practitioner students must ensure that the person has undergone an informed consent process with an authorised health practitioner listed above.

If any authorised health practitioner or authorised health practitioner student identifies any clinical concerns at any time regarding patient safety or suitability for provision of the vaccine, they must arrange for the patient to be reviewed by a Medical Practitioner, Authorised Nurse (or Midwife) Immuniser or Nurse Practitioner (with appropriate scope of practice and experience in immunisation).

### 5.1 Protocol for administration of the COVID-19 Pfizer (Comirnaty) vaccine in authorised settings

TITLE	Protocol for BNT162b2 [mRNA] (COVID-19 Pfizer (Comirnaty) vaccine)
Drug(s)	BNT162b2 [mRNA]
Presentation <sup>1</sup>	Multidose vial which must be thawed then diluted before use. After reconstitution one vial of 2.25 mL provides 5 or 6 doses of 0.3 mL. Store diluted vials at two to eight degrees Celsius. (Refrigerate. Do not freeze.) <b>Always maintain cold chain storage and protect from light.</b>
Indication	Active immunisation to prevent coronavirus disease 2019 (COVID-19) caused by SARS-CoV2, in individuals 12 years of age and older. People requiring a third dose as part of their primary course are recommended to receive Pfizer (Comirnaty) or Moderna (Spikevax) 2 to 6 months after the second dose (minimum interval of 4 weeks in accordance with ATAGI advice).
Contraindications <sup>1</sup>	<ul style="list-style-type: none"> <li>• Do not use diluted vaccine products after expiry date on label.</li> <li>• Do not use diluted vaccine beyond 6 hours after dilution.</li> </ul>

	<ul style="list-style-type: none"> <li>• Hypersensitivity, anaphylaxis or generalised allergic reaction to the active substance or to any of the excipients listed in the list of excipients in the <a href="#">product information</a>, including polyethylene glycol (PEG).</li> <li>• People should not receive COVID-19 Vaccine Pfizer (Comirnaty) if they experienced anaphylaxis or any other serious adverse event following a previous dose of an mRNA COVID-19 vaccine (Comirnaty).</li> <li>• People should not receive COVID-19 Vaccine Pfizer (Comirnaty) if they have been diagnosed with myocarditis and/or pericarditis attributed to a previous dose of either COVID-19 Vaccine Moderna (Spikevax) or COVID-19 Vaccine Pfizer (Comirnaty).</li> </ul>
<p><b>Precautions<sup>1</sup></b></p>	<ul style="list-style-type: none"> <li>• The efficacy, safety and immunogenicity of COVID-19 Pfizer (Comirnaty) vaccine has not been assessed in immunocompromised individuals, including those receiving immunosuppressant therapy. For immunocompromised individuals, a medical practitioner must review the suitability of administration.</li> <li>• People with a history of anaphylaxis to previous vaccines and/or multiple drugs (injectable and/or oral) where ingredients such as PEG may conceivably be the cause.</li> <li>• People with a known systemic mast cell activation disorder with raised mast cell tryptase that requires treatment.</li> <li>• Adrenaline (epinephrine) must be available for the authorised healthcare professional to administer if anaphylaxis occurs.</li> <li>• Patients must be closely observed for at least 15 minutes for the occurrence of adverse reactions.</li> <li>• Vaccination is to be postponed in individuals suffering from acute severe febrile illness or acute infection.</li> <li>• The preferred minimum interval between receipt of a COVID-19 vaccine and any other vaccine, including influenza vaccine, is 7 days. A shorter interval (i.e. less than 7 days, including co-administration) may be acceptable.</li> <li>• COVID-19 Pfizer (Comirnaty) vaccine must be given with caution in individuals receiving anticoagulant therapy or those with thrombocytopenia or any coagulation disorder (such as haemophilia).</li> <li>• It is unknown whether BNT162b2 [mRNA] is excreted in human milk.</li> <li>• Very rare events of myocarditis and pericarditis have been reported following vaccination with COVID-19 Vaccine Pfizer (Comirnaty). Data suggests these conditions are causally related to vaccination with a COVID-19 mRNA vaccine, with the risk highest in young people (&lt;30 years and adolescents), more often after second dose and predominantly in men. As with other vaccines, the benefits and potential risks of vaccinating individuals with COVID-19 Vaccine Pfizer (Comirnaty) should be considered.</li> <li>• People with a history of any of the following conditions can receive COVID-19 Vaccine Pfizer (Comirnaty) but advice should be sought from a GP, immunisation specialist or cardiologist about the best timing of vaccination and whether any additional precautions are recommended:             <ul style="list-style-type: none"> <li>○ Recent (i.e., within the past 6 months) inflammatory cardiac illness e.g., myocarditis, pericarditis, endocarditis</li> <li>○ Acute rheumatic fever (i.e., with active myocardial inflammation) or acute rheumatic heart disease</li> <li>○ People aged 12-29 years with dilated cardiomyopathy</li> <li>○ Complex or severe congenital heart disease including single</li> </ul> </li> </ul>

	<ul style="list-style-type: none"> <li>○ ventricle (Fontan) circulation</li> <li>○ Decompensated heart failure</li> <li>○ Cardiac transplant recipients.</li> </ul>
<b>Dose<sup>1</sup></b>	0.3 mL (following dilution) for patients 12 years and older.
<b>Dose frequency<sup>1</sup></b>	A course of 2 doses 21 to 42 days apart. A third dose as indicated in the TGA approved product information or ATAGI recommendations
<b>Administration<sup>1</sup></b>	Administer intramuscularly (after dilution). The preferred site of administration is the deltoid muscle of the upper arm. Inject 0.3 mL using a standard needle and syringe for intramuscular injection, or low dead-volume syringe and/or needles when available.
<b>Drug Interactions<sup>1</sup></b>	No interaction studies have been performed. Concomitant administration of COVID-19 Pfizer (Comirnaty) vaccine with other vaccines has not been studied.
<b>Adverse effects<sup>1</sup></b>	For information on adverse effects, please refer to the <a href="#">product information</a> .
<b>Documentation<sup>2</sup></b>	Explain risks and possible adverse effects, provide patient information sheet on the Pfizer (Comirnaty) COVID-19 Vaccine and obtain informed consent.

<sup>1</sup> The drug information provided in this protocol is to act as a guide only. Always refer to and comply with the latest ATAGI and TGA advice as this is regularly updated. For comprehensive information, refer to the latest manufacturer's [product information](#). If any contraindications, precautions or other concerns in relation to suitability for treatment are identified, refer to a Medical Practitioner or Authorised Nurse Immuniser before administration.

<sup>2</sup> Informed consent must be obtained by a specified authorised health practitioner as per section 5. Eligible health practitioner students are authorised to administer the vaccine but not authorised to assess patients for suitability to receive the vaccine (including precautions and contraindications) or to obtain informed consent.

## 5.2 Protocol for administration of the COVID-19 AstraZeneca (Vaxzevria) vaccine in authorised settings

TITLE	Protocol for COVID-19 AstraZeneca ChAdOx1-S (Vaxzevria) vaccine
<b>Drug(s)</b>	<b>ChAdOx1-S</b>
<b>Presentation<sup>1</sup></b>	<p>Multidose vial (10 dose-vial) containing <math>5 \times 10^{11}</math> viral particles of (ChAdOx1-S<sup>a, b</sup>) in 5 mL.</p> <p>One dose (0.5 mL) contains <math>5 \times 10^{10}</math> viral particles of (ChAdOx1-S<sup>a, b</sup>).</p> <p><sup>a</sup> Recombinant, replication-deficient chimpanzee adenovirus vector encoding the SARS-CoV-2 Spike glycoprotein.</p> <p><sup>b</sup> The vaccine is manufactured using material originally sourced from a human embryo (Human Embryonic Kidney cells: HEK293).</p>
<b>Indication</b>	Active immunisation of individuals $\geq 18$ years old for the prevention of coronavirus disease 2019 (COVID-19) caused by SARS-CoV-2.
<b>Contraindications<sup>1</sup></b>	<ul style="list-style-type: none"> <li>• Do not use product beyond recommended storage times. The vial can be re-refrigerated, but after first opening the cumulative storage time at room temperature must not exceed 6 hours, and the total cumulative storage time must not exceed 48 hours. After this time, the vial must be discarded.</li> </ul>

	<ul style="list-style-type: none"> <li>• People should not receive COVID-19 Vaccine AstraZeneca (Vaxzevria) if they have had heparin induced thrombocytopenia in the past.</li> <li>• People should not receive COVID-19 Vaccine AstraZeneca (Vaxzevria) if they have had cerebral venous sinus thrombosis in the past.</li> <li>• People should not receive COVID-19 Vaccine AstraZeneca (Vaxzevria) if they have a history of splanchnic vein thrombosis (clots in the portal, splenic or mesenteric veins); or the Budd-Chiari Syndrome.</li> <li>• People should not receive COVID-19 Vaccine AstraZeneca (Vaxzevria) if they have a history of anti-phospholipid syndrome with clots.</li> <li>• People should not receive COVID-19 Vaccine AstraZeneca (Vaxzevria) if they have a hypersensitivity or anaphylaxis to the active substance or to any of the excipients listed in the list of excipients of the product information, including polysorbate 80.</li> <li>• People should not receive COVID-19 Vaccine AstraZeneca (Vaxzevria) if they experienced anaphylaxis or other serious adverse event, such as thrombosis with thrombocytopenia, following a previous dose of the vaccine.</li> </ul>
<p><b>Precautions<sup>1</sup></b></p>	<ul style="list-style-type: none"> <li>• ATAGI have recommended that the COVID-19 Pfizer (Comirnaty) vaccine or COVID-19 Moderna (Spikevax) vaccine are preferred in persons <b>aged under 60 years</b>. Very rare events of vaccine-induced prothrombotic immune thrombocytopenia have occurred. If a first dose of the COVID-19 AstraZeneca (Vaxzevria) vaccine has been given without a serious adverse event, then the course should be completed using the AstraZeneca (Vaxzevria) vaccine.</li> <li>• The immunogenicity, efficacy and safety of COVID-19 Vaccine AstraZeneca (Vaxzevria) has not been assessed in immunocompromised individuals, including those receiving immunosuppressive therapy. For immunocompromised individuals, a medical practitioner must review the suitability of administration.</li> <li>• People with a history of anaphylaxis to previous vaccines and/or multiple drugs (injectable and/or oral) where ingredients such as polysorbate 80 may conceivably be the cause.</li> <li>• Pregnancy Category B1.</li> <li>• People with a known systemic mast cell activation disorder with raised mast cell tryptase that requires treatment.</li> <li>• Adrenaline (epinephrine) must be available for the authorised healthcare practitioner to administer if anaphylaxis occurs.</li> <li>• Vaccination should be postponed in individuals suffering from acute severe febrile illness or acute infection.</li> <li>• The preferred minimum interval between receipt of a COVID-19 vaccine and any other vaccine, including influenza vaccine, is 7 days. A shorter interval (i.e. less than 7 days, including co-administration) may be acceptable.</li> <li>• COVID-19 Vaccine AstraZeneca (Vaxzevria) should be given with caution to individuals with thrombocytopenia, any coagulation disorder or to persons on anticoagulation therapy, because bleeding or bruising may occur following an intramuscular administration in these individuals.</li> </ul>

	<ul style="list-style-type: none"> <li>Very rare events of demyelinating disorders have been reported following vaccination with COVID-19 Vaccine AstraZeneca (Vaxzevria). A causal relationship has not been established. As with other vaccines, the benefits and potential risks of vaccinating individuals with COVID-19 Vaccine AstraZeneca (Vaxzevria) should be considered.</li> <li>An mRNA vaccine (Pfizer Comirnaty or Moderna Spikevax) is preferred to AstraZeneca Vaxzevria for this 3rd dose. Vaxzevria vaccine can be used for the 3rd dose for individuals who have received Vaxzevria 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).</li> </ul>
<b>Dose<sup>1</sup></b>	0.5 mL
<b>Dose frequency<sup>1</sup></b>	A course of 2 separate doses of 0.5 mL each between 4 and 12 weeks (28 – 84 days apart). A third dose as indicated in the TGA approved product information or ATAGI recommendations.
<b>Administration<sup>1</sup></b>	Administer intramuscularly, preferably in the deltoid muscle.
<b>Drug Interactions<sup>1</sup></b>	The safety, immunogenicity and efficacy of co-administration of COVID-19 Vaccine AstraZeneca (Vaxzevria) with other vaccines have not been evaluated.
<b>Adverse effects<sup>1</sup></b>	For information on adverse effects, please refer to the <a href="#">product information</a> .
<b>Documentation<sup>2</sup></b>	Explain risks and possible adverse effects, provide patient information sheet on the COVID-19 Vaccine AstraZeneca (Vaxzevria) and obtain informed consent.

<sup>1</sup> The drug information provided in this protocol is to act as a guide only. Always refer to and comply with the latest ATAGI and TGA advice as this is regularly updated. For comprehensive information, refer to the latest manufacturer's [product information](#). If any contraindications, precautions or other concerns in relation to suitability for treatment are identified, refer to a Medical Practitioner or Authorised Nurse Immuniser before administration.

<sup>2</sup> Informed consent must be obtained by a specified authorised health practitioner as per section 5. Eligible health practitioner students are authorised to administer the vaccine but not authorised to assess patients for suitability to receive the vaccine (including precautions and contraindications) or to obtain informed.

### 5.3 Protocol for administration of the COVID-19 Spikevax (Moderna) vaccine in authorised settings

<b>TITLE</b>	<b>Protocol for COVID-19 Spikevax (Moderna) vaccine</b>
<b>Drug(s)</b>	<b>Elasomeran [mRNA-1273]</b>
<b>Presentation<sup>1</sup></b>	Multidose vial (10 dose-vial) which contains 10 doses of 0.5mL which must be thawed before use.  One dose (0.5mL) contains 100 micrograms of messenger RNA (mRNA) (embedded in SM-102 lipid nanoparticles) that encodes for the full-length SARS-CoV-2 spike protein.
<b>Indication</b>	Active immunisation to prevent coronavirus disease 2019 (COVID-19) caused by SARS-CoV-2 in individuals ≥12 years old.

	<p>People requiring a third dose as part of their primary course are recommended to receive Pfizer (Comirnaty) or Moderna (Spikevax) vaccine 2 to 6 months after the second dose (minimum interval of 4 weeks in accordance with ATAGI advice)</p>
<p><b>Contraindications<sup>1</sup></b></p>	<ul style="list-style-type: none"> <li>• Do not use product beyond recommended storage times. Once thawed, the unpunctured vial may be stored refrigerated at 2°C to 8°C, protected from light, for maximum 30 days. Once thawed the vaccine must not be re-frozen. The unpunctured vial may be stored at 8°C to 25°C up to 24 hours after removal from refrigerated conditions. The punctured vial can be held at 2°C to 25°C, but after first opening must be discarded after 19 hours.</li> <li>• People should not receive COVID-19 Vaccine Spikevax if they have a hypersensitivity or anaphylaxis to the active substance or to any of the excipients listed in the list of excipients of the <a href="#">product information</a>, including polyethylene glycol (PEG).</li> <li>• People should not receive COVID-19 Vaccine Spikevax if they experienced anaphylaxis or any other serious adverse event following a previous dose of an mRNA COVID-19 vaccine (Spikevax or Comirnaty).</li> <li>• People should not receive COVID-19 Vaccine Spikevax if they have been diagnosed with myocarditis and/or pericarditis attributed to a previous dose of either COVID-19 Vaccine Pfizer (Comirnaty) or COVID-19 Vaccine Spikevax.</li> </ul>
<p><b>Precautions<sup>1</sup></b></p>	<ul style="list-style-type: none"> <li>• The immunogenicity, efficacy and safety of COVID-19 Vaccine Spikevax has not been assessed in immunocompromised individuals, including those receiving immunosuppressive therapy. The efficacy of COVID-19 Vaccine Spikevax may be lower in immunosuppressed individuals. For immunocompromised individuals, a medical practitioner must review the suitability of administration.</li> <li>• People with a history of anaphylaxis to previous vaccines and/or multiple drugs (injectable and/or oral) where ingredients such as PEG may conceivably be the cause.</li> <li>• People with a known systemic mast cell activation disorder with raised mast cell tryptase that requires treatment.</li> <li>• Adrenaline (epinephrine) must be available for the authorised healthcare practitioner to administer if anaphylaxis occurs.</li> <li>• Vaccination should be postponed in individuals suffering from acute severe febrile illness or acute infection.</li> <li>• The preferred minimum interval between receipt of a COVID-19 vaccine and any other vaccine, including influenza vaccine, is 7 days. A shorter interval (i.e. less than 7 days, including co-administration) may be acceptable.</li> <li>• COVID-19 Vaccine Spikevax should be given with caution in individuals receiving anticoagulant therapy or those with thrombocytopenia or any coagulation disorder (such as haemophilia) because bleeding or bruising may occur following an intramuscular administration in these individuals.</li> <li>• Pregnancy Category B1.</li> </ul>

	<ul style="list-style-type: none"> <li>It is unknown whether COVID-19 Vaccine Spikevax is excreted in human milk.</li> <li>Very rare events of myocarditis and pericarditis have been reported following vaccination with COVID-19 Vaccine Spikevax. Data suggests these conditions are causally related to vaccination with a COVID-19 mRNA vaccine, with the risk highest in young people (&lt;30 years and adolescents), more often after second dose and predominantly in men. As with other vaccines, the benefits and potential risks of vaccinating individuals with COVID-19 Vaccine Spikevax should be considered.</li> <li>People with a history of any of the following conditions can receive COVID-19 Comirnaty (Pfizer) or Spikevax (Moderna) vaccine but advice should be sought from a GP, immunisation specialist or cardiologist about the best timing of vaccination and whether any additional precautions are recommended:             <ul style="list-style-type: none"> <li>Recent (i.e., within the past 6 months) inflammatory cardiac illness e.g., myocarditis, pericarditis, endocarditis</li> <li>Acute rheumatic fever (i.e., with active myocardial inflammation) or acute rheumatic heart disease</li> <li>People aged 12-29 years with dilated cardiomyopathy</li> <li>Complex or severe congenital heart disease including single ventricle (Fontan) circulation</li> <li>Decompensated heart failure</li> <li>Cardiac transplant recipients.</li> </ul> </li> </ul>
<b>Dose<sup>1</sup></b>	0.5 mL
<b>Dose frequency<sup>1</sup></b>	A course of 2 separate doses of 0.5 mL each. The second dose should be administered 28 to 42 days (4 to 6 weeks) after the first dose. A third dose as indicated in the TGA approved product information or ATAGI recommendations
<b>Administration<sup>1</sup></b>	Administer intramuscularly, preferably in the deltoid muscle.
<b>Drug Interactions<sup>1</sup></b>	The safety, immunogenicity and efficacy of co-administration of COVID-19 Vaccine Spikevax with other vaccines have not been evaluated.
<b>Adverse effects<sup>1</sup></b>	For information on adverse effects, please refer to the <a href="#">product information</a> .
<b>Documentation<sup>2</sup></b>	Explain risks and possible adverse effects, provide patient information sheet on the COVID-19 Vaccine Spikevax and obtain informed consent.

<sup>1</sup> The drug information provided in this protocol is to act as a guide only. Always refer to and comply with the latest ATAGI and TGA advice as this is regularly updated. For comprehensive information, refer to the latest manufacturer's [product information](#). If any contraindications, precautions or other concerns in relation to suitability for treatment are identified, refer to a Medical Practitioner or Authorised Nurse Immuniser before administration.

<sup>2</sup> Eligible health practitioner students are authorised to administer the vaccine but not authorised to assess patients for suitability to receive the vaccine (including precautions and contraindications) or to obtain informed consent.

## 6 PROCEDURE FOR VACCINE ADMINISTRATION AND CLINICAL ROLES

## 6.1 Procedure for preparing for vaccine administration

This protocol allows for administration of the vaccine under the attached authority ONLY where the patient does not have a relevant precaution or contraindication to treatment. Where a relevant precaution or contraindication exists, treatment (COVID-19 vaccination) can only proceed under the direct authority of a Medical Practitioner, Authorised Nurse Immuniser or Nurse Practitioner (with appropriate scope of practice and experience in immunisation).

The following steps must be followed when preparing for vaccine administration. It is important to note that each step may involve several distinct tasks, and the same person may not be authorised to perform each task. For more information about which person is authorised to perform specific tasks, please refer to Section 6.2: Clinical roles.

All assessments and details relating to the administration of a vaccine must be documented.

Procedure:

- Practice according to the NSW Health Policy Directive *Standard operating procedure for administration of COVID-19 vaccines in NSW vaccination clinics* ([PD2021\\_040](#)) and its [supporting documents](#), which describe specific procedures for each vaccine.
- Arrange the supply of vaccine from the designated supply point. Ensure an anaphylaxis kit is available. The Medical Practitioner, Authorised Nurse (or Midwife) Immuniser, Nurse Practitioner (with appropriate scope of practice and experience in immunisation), Registered Nurse, Registered Midwife or Authorised Pharmacist authorised to administer adrenaline (epinephrine) must ensure an anaphylaxis kit is available. This includes adrenaline (epinephrine), 1mL syringes, 23g needles and cotton swabs. They must also be familiar with the adrenaline (epinephrine) treatment protocol, found in the online version of [The Australian Immunisation Handbook](#)
- Provide the patient with the relevant Patient Information Sheet:
  - Australian Government [COVID-19 vaccination – Information on COVID-19 Pfizer \(COMIRNATY\) vaccine](#)
  - Australian Government [COVID-19 vaccination – Information on COVID-19 AstraZeneca vaccine](#)
  - [Australian Government COVID-19 vaccination – Information on COVID-19 Moderna \(Spikevax\) vaccine](#)
- Determine whether the patient meets the criteria for the Protocol by:
  - undertaking a medical history (note the use of a patient-completed screening tool may assist but does not replace relevant history taking by the practitioner, including ensuring the patient/parent/guardian understands the questions that are asked, and identifying any language or communication barriers that may prevent informed consent, before proceeding). Refer the patient for further assessment should any health concerns or questions be identified

- assessing the medical history, in particular, in relation to precautions or contraindications to treatment, and whether there are any known allergies or a hypersensitivity to the vaccine. Should the patient have a contraindication or precaution to the vaccine, refer the patient to a Medical Practitioner, Authorised Nurse/Midwife Immuniser or Nurse Practitioner (with appropriate scope of practice and experience in immunisation) for assessment. In this situation the vaccination may be administered ONLY where the Medical Practitioner, or Nurse Practitioner (with appropriate scope of practice and experience in immunisation) has re-assessed the patient history, discussed the benefits and risks, and gives a verbal direction to administer the vaccine or is assessed and the vaccine administered by the Authorised Nurse/Midwife immuniser directly. This assessment should be documented.
- checking if they are currently using any relevant medications or have received any recent vaccinations.
- checking the patient is currently well.
- providing information in relation to the benefits and risks of the specific vaccine. Explain the rationale and purpose of the vaccine to the patient/parent/guardian. Provide written patient information. Ensure the patient/parent/guardian has had the opportunity to discuss benefits and risks with a Medical Practitioner, Authorised Nurse (or Midwife) Immuniser or Nurse Practitioner (with appropriate scope of practice and experience in immunisation), Registered Nurse or Midwife or Authorised Pharmacist), using the latest available benefits and risks information and advice from the Australian Technical Advisory Group on Immunisation (ATAGI) and the Therapeutic Goods Administration (TGA).
- discussing the decision to treat and document the patient/parent/guardian decision to consent to treatment. This can only be undertaken by specified health practitioners as per section 5.
- documenting all assessments and details relating to the administration of the vaccine.
- Explain the expected adverse effects of the vaccine and the use of simple over the counter medication in the 24-48 hours following vaccination if required. Provide post-vaccination care advice as per the latest ATAGI or TGA advice, including the period during which symptoms should be carefully monitored, symptoms to look out for, and when to seek medical attention. In particular, provide advice to immediately seek medical review for any new or unexpected or severe symptoms, severe or persistent headache, stomach (abdominal) pain, chest pain, vomiting or visual symptoms, bruising or petechial haemorrhages, difficulty breathing, wheezing, a fast heartbeat or collapsing, chest pain, pressure or discomfort, irregular heartbeat, skipped beats or 'fluttering', fainting, shortness of breath or pain with breathing up to 6 weeks after vaccination with COVID-19 Vaccine.
- Provide written post-vaccination advice using the:
  - Australian Government: [COVID-19 vaccination – After your AstraZeneca vaccine](#); OR

- Australian Government: [COVID-19 vaccination – After your Pfizer \(COMIRNATY\) vaccine](#); OR
- Australian Government: [COVID-19 vaccination – After your Moderna \(Spikevax\) vaccine](#).
- For each person, document the following details:
  - Name
  - Address
  - Date of birth
  - Sex
  - Phone number
  - Whether the person has any relevant conditions, including precautions or contraindications, established above
  - That they have received the relevant information sheet and appropriate post-immunisation advice.
- Following vaccination, observe the patient for the required period, and check the patient has no signs or symptoms requiring clinical review prior to discharge.
- Record the administration of each vaccine according to the [supporting documents](#) to the NSW Health Policy Directive *Standard operating procedure for administration of COVID-19 vaccines in NSW vaccination clinics* ([PD2021\\_040](#)).

## 6.2 Clinical roles

Task	Practitioners who may undertake the task, where training, supervision and other prerequisites are met
<p>To suitably screen individuals prior to vaccination by checking that the responses to the screening questions provided by patients are complete. Screening patients does not replace the process of obtaining informed consent.</p> <p>Using a patient-completed screening tool, take a medical and allergy/hypersensitivity history relevant to COVID-19 vaccination, to identify any relevant health concerns, precautions or contraindications. The use of a patient-completed screening tool may assist but does not replace relevant history taking by the practitioner, including ensuring the patient understands the questions that are asked, and identifying any language or communication barriers.</p>	<ul style="list-style-type: none"> <li>● All Authorised Health Practitioners</li> <li>● Authorised Health Practitioner Students (under line of sight supervision)</li> </ul>

<p>Assess medical and allergy/hypersensitivity history to identify precautions and contraindications to vaccination and suitability for treatment (vaccination), and determine appropriate management, according to an escalation pathway, including for any other health concerns identified and referred by other practitioners. Determine appropriate observation period following vaccination.</p>	<p>Medical Practitioner (PGY4 and above).                  Authorised Nurse (or Midwife) Immuniser                  Nurse Practitioner (with appropriate scope of practice and experience in immunisation)</p>
<p>Obtain informed consent by:</p> <ul style="list-style-type: none"> <li>Ensuring that the patient/parent/guardian is able to understand the information on risk and benefits of vaccination that has been provided and has had the opportunity to ask any questions.</li> <li>The use of a patient-completed screening tool may assist but does not replace relevant history taking by the authorised health practitioner</li> <li>Ensuring the patient/parent/guardian understands the medical history screening questions that have been asked, and identifying any language or communication barriers that may prevent informed consent</li> <li>Ensuring the patient/parent/guardian has had the opportunity to discuss benefits and risks of vaccination using the latest available information from the Australian Technical Advisory Group on Immunisation (ATAGI) and the Therapeutic Goods Administration (TGA).</li> </ul> <p>If the patient/parent/guardian have further questions or concerns regarding the benefits and risks of vaccination or if any other issues or barriers are identified, refer the them to:</p> <ul style="list-style-type: none"> <li>Medical practitioner</li> <li>Authorised Nurse Immuniser</li> <li>Registered nurse/midwife</li> <li>Pharmacist Immuniser</li> <li>Nurse Practitioner (with appropriate scope of practice and experience in immunisation).</li> </ul>	<p>Informed consent can be obtained by Dentists, Dietitians, Occupational Therapists, Physiotherapists, Pharmacists, Podiatrists, Radiation Therapists, Radiographers and Speech Pathologists, provided that:</p> <ul style="list-style-type: none"> <li>they are confident that the patient/parent/guardian understands the information that they have been provided regarding the risks and benefits of vaccination;</li> <li>no barriers to understanding the information have been identified such as language or communication barriers;</li> <li>the patient/parent/guardian do not have any outstanding questions;</li> <li>a relevant history has been taken and no medical contraindications or precautions have been identified.</li> </ul> <p>If the patient/parent/guardian have further questions or concerns regarding the benefits and risks of vaccination or if any other issues or barriers are identified, the patient/parent/guardian must be referred to one of the following health practitioners to obtain informed consent:</p> <ul style="list-style-type: none"> <li>Medical practitioner.</li> <li>Authorised Nurse Immuniser</li> <li>Registered nurse/midwife</li> <li>Pharmacist Immuniser</li> <li>Nurse Practitioner (with appropriate scope of practice and experience in immunisation)</li> </ul>
<p>Provide information in relation to the benefits and risks of the specific vaccine, gain patient agreement to treatment, document informed consent</p>	<p>Medical Practitioner                  Authorised Nurse (or Midwife) Immuniser</p>

<p>Refer patients with any health concerns, precautions or contraindications; or other queries regarding suitability for vaccination to a Medical Practitioner, Authorised Nurse/Midwife Immuniser or a Nurse Practitioner (with appropriate scope of practice and experience in immunisation)</p>	<p>Nurse Practitioner (with appropriate scope of practice and experience in immunisation) Registered Nurse or Registered Midwife Pharmacist Immuniser</p>
<p>Ensure the 'Rights' of vaccine administration: Right patient, right drug, right route/site</p>	<p>All authorised health practitioners and authorised health practitioner students</p>
<p>Administer vaccine by IM injection</p>	<ul style="list-style-type: none"> <li>• Authorised Nurse (or Midwife) Immuniser</li> <li>• Nurse Practitioner (with appropriate scope of practice and experience in immunisation)</li> <li>• Registered Nurse (RN) or Registered Midwife</li> <li>• Enrolled Nurse (under supervision of an RN)</li> <li>• Pharmacist Immuniser</li> <li>• Aboriginal Health Practitioner</li> <li>• Podiatrist</li> <li>• Paramedic</li> <li>• Dentist</li> <li>• Radiation Therapist</li> <li>• Radiographer</li> <li>• Speech Pathologist</li> <li>• Physiotherapist</li> <li>• Dietitian</li> <li>• Occupational Therapist</li> <li>• Oral Health Therapist</li> <li>• Pharmacist (who is not a pharmacist immuniser)</li> <li>• Nuclear Medicine Technologist</li> <li>• Sonographer</li> <li>• Perfusionist</li> <li>• Exercise physiologist</li> <li>• International Medical Graduates</li> <li>• Pharmacy Technician</li> <li>• Dental Hygienist</li> <li>• Dental Therapist</li> <li>• VET qualified Allied Health Assistants</li> <li>• VET qualified Assistants in Nursing</li> </ul>

	<ul style="list-style-type: none"> <li>• VET qualified Aboriginal Health Worker</li> <li>• Previously registered health practitioner (within the last 10 years)</li> </ul> <p>Authorised health practitioner students operating under the line of sight supervision of an Authorised Nurse (or Midwife) Immuniser, Registered Nurse, Registered midwife, Nurse Practitioner (with appropriate scope of practice and experience in immunisation) or Medical Practitioner:</p> <ul style="list-style-type: none"> <li>• Students in Medicine, Nursing, Midwifery, Enrolled Nursing, Dentistry, Paramedicine, Pharmacy, Podiatry, Radiation Therapy, Radiography, Speech Pathology, Physiotherapy, Occupational Therapy, Nuclear Medicine Technology, Dietitian, Sonography, Oral Health Therapy or Exercise Physiology who have completed the relevant training requirements and clinical placements.</li> </ul>
Record patient details at time of vaccine administration	All authorised health practitioners and authorised health practitioner students
Provide verbal post-vaccination information (including the period over which symptoms should be carefully monitored, symptoms to look out for, and when to seek medical attention). Refer any queries in relation to post-vaccine care to a Medical Practitioner, Authorised Nurse/Midwife Immuniser, Registered Nurse, Registered Midwife, Pharmacist Immuniser, or Nurse Practitioner (with appropriate scope of practice and experience in immunisation)	All authorised health practitioners and authorised health practitioner students
Provide written post-vaccination advice using the: <ul style="list-style-type: none"> <li>• Australian Government: <a href="#">COVID-19 vaccination – After your AstraZeneca vaccine</a>; OR</li> <li>• Australian Government: <a href="#">COVID-19 vaccination – After your Pfizer (COMIRNATY) vaccine</a>; OR</li> <li>• Australian Government: <a href="#">COVID-19 vaccination – After your Moderna (Spikevax) vaccine</a>.</li> </ul>	All authorised health practitioners and authorised health practitioner students.
Provide post-vaccination observation and care  Observe all patients for any signs or reported symptoms of adverse effects following vaccination for the required period  Refer any patients under observation with observed signs or reported symptoms to a Registered Nurse, Registered Midwife,	All authorised health practitioners and authorised health practitioner students

<p>Authorised Nurse/Midwife Immuniser or appropriate Medical/Nurse Practitioner (where the observation was performed by a practitioner of another kind)</p>	
<p>Assess adverse effects following vaccination, and administer adrenaline if required</p> <p>Refer patients assessed as suspected potential allergic reaction or other more serious adverse event to an Authorised Nurse/Midwife Immuniser or appropriate Medical Practitioner for further management (where the initial assessment was performed by a practitioner of another kind)</p>	<p>Medical Practitioner (PGY4 and above).                  Authorised Nurse (or Midwife) Immuniser                  Nurse Practitioner (with appropriate scope of practice and experience in immunisation)                  Registered Nurse or Registered Midwife                  Pharmacist Immuniser</p>