State-wide 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, COVID-19 disease resulting from infection with the SARS-CoV-2, or prophylaxis as a result of exposure to SARS-CoV-2.

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**Branch contact** (02) 9391 9606

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**Functional group** Clinical/Patient Services - Infectious Diseases, Pharmaceutical Population Health - Communicable Diseases

**Applies to** Public Health Units, Local Health Districts, Board Governed Statutory Health Corporations, Specialty Network Governed Statutory Health Corporations, Public Health System Support Division, Government Medical Officers, Public Hospitals

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

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

Secretary, NSW Health

This Policy Directive may be varied, withdrawn or replaced at any time. Compliance with this directive is mandatory for NSW Health and is a condition of subsidy for public health organisations.
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. However, in the event of insufficient workforce of Authorised Nurse Immunisers available to administer COVID-19 vaccines, this Protocol can be enacted. This allows registered nurses and midwives to administer the vaccine, providing they comply with the specified conditions.

Registered nurses and registered midwives employed in NSW public health facilities must follow this state-wide protocol for the supply or administration of COVID-19 vaccine when conducting vaccination within a NSW Health COVID-19 vaccination clinic.

This Policy Directive does not require further authorisation by any local Drug and Therapeutics Committees, nor does it require endorsement or sign off by any additional medical officer (in addition to the Chief Health Officer).

SUMMARY OF POLICY REQUIREMENTS

A registered nurse or registered midwife is authorised to administer the vaccine to those who fit an agreed case definition.

Registered nurses or registered midwives must check that consent has been obtained or checked verbally on presentation to the clinic.

If the registered nurse/midwife has any clinical concerns regarding patient safety for provision of the medication, they must arrange for the medical officer or emergency department to review.

The medical officer must be available on site to provide immediate advice to the registered nurse/midwife, to supervise the vaccination program and to address any concerns from the vaccine recipient that are unable to be addressed by the registered nurse/midwife.

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 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_003).
REVISION HISTORY

<table>
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<th>Version</th>
<th>Approved by</th>
<th>Amendment notes</th>
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<td>February-2021 (PD2021_004)</td>
<td>Deputy Secretary, Population and Public Health and Chief Health Officer</td>
<td>New State-wide Protocol for the Supply or Administration of COVID-19 Vaccine</td>
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1 BACKGROUND

1.1 About this document

In NSW, COVID-19 vaccines are intended to be administered by Authorised Nurse Immunisers. However, in the event of insufficient workforce of Authorised Nurse Immunisers available to administer COVID-19 vaccines, this Protocol can be enacted. This allows registered nurses and midwives to administer the vaccine, providing they comply with the specified conditions.

This Policy Directive and associated Authorisation to Supply Poisons and Restricted Substances: COVID-19 Vaccine authorises a registered nurse or registered midwife to administer the specified medications. It sets out procedures for administering medications for the purpose of prevention of Severe Acute Respiratory Syndrome Coronavirus 2 (SARS-CoV-2) infection, COVID-19 disease resulting from infection with the SARS-CoV-2, or prophylaxis as a result of exposure to SARS-CoV-2, and allows the use of adrenaline (epinephrine) if required, following vaccination.

This document is intended for use by registered nurses and registered midwives employed in a public health organisation for the administration of COVID-19 vaccines in all settings designated by the Chief Health Officer, without the need for an order for each patient from a medical officer or nurse practitioner. It is not mandatory for the registered nurse to be an Authorised Nurse Immuniser. Settings may include health facilities, residential care facilities, airports, seaports, schools, or workplaces.

This state-wide protocol is equivalent to a ‘standing order’, except that no signature of a local medical officer is required.

The medical officer must be available on site to provide immediate advice to the registered nurse/midwife, to supervise the vaccination program and to address any concerns from the vaccine recipient that are unable to be addressed by the registered nurse/midwife.

Competency to administer medications is included in the qualifications of registered nurses, and registered midwives who have undertaken vaccination training but 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 document contains state-wide protocols for:

- COVID-19 vaccines
- The subsequent use of adrenaline (epinephrine) to treat anaphylaxis.

1.2 Key definitions

Medication

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

Registered Nurse

Includes nurses and midwives registered with the Nursing and Midwifery Board of Australia. For this Policy it excludes an Enrolled Nurse.

Supply

Includes to administer medications to a group or a specific patient and is consistent with the definition of supply in section 3 of the Poisons and Therapeutic Goods Act 1966. Includes administration of a single dose for prophylaxis by a registered nurse or registered midwife.

1.3 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 clauses 17 and 53 of the Regulation.

The authorisation only applies to registered nurses and registered midwives employed by a public health organisation for the medications listed in this Policy.

2 IMPLEMENTATION OF STATE-WIDE PROTOCOL

2.1 Registered nurses and registered midwives

Registered nurses and registered midwives operating under this protocol must:

- Determine whether the patient meets the criteria for the Protocol and explain the treatment and its purpose to the patient (or guardian).

- Check that the patient is not showing signs and symptoms requiring immediate medical review and contact the medical officer or refer to the emergency department for immediate review as required.

- Determine any known allergies, hypersensitivity to the medication or contraindications to treatment and contact the medical officer to discuss how to proceed.

- Check that consent has been obtained or checked verbally on presentation to the clinic. Nurses or midwives who are authorised to initiate vaccines have the same obligations as medical practitioners when obtaining consent for the procedures which they are authorised to perform.

- Document all assessments and details relating to the administration of vaccine.

- Have current cardio-pulmonary resuscitation certification and be competent in the administration of adrenaline (epinephrine) for the management of anaphylaxis.
• Practice according to the NSW Health Policy Directive Standard operating procedure for administration of COVID-19 vaccines in NSW vaccination clinics (PD2021_003) and its supporting documents, which describe specific procedures for each vaccine.

• Record the administration of each medication 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_003).

• 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).

### 2.2 Public Health Organisations

Public Health Organisations must ensure there is a nominated medical officer available to provide immediate advice to registered nurses and registered midwives working in the organisation’s vaccination clinic, at all times during the vaccination program.

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_003). In addition, advice in the Australian Immunisation Handbook must be followed.

### 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_003) regarding eMR and / or other specific vaccination record and loading the information up to the Australian Immunisation Register.

### 5 VACCINATION FOR PROPHYLAXIS OF COVID-19

A registered nurse or registered midwife is authorised to administer the vaccine to those who fit an agreed case definition. If the registered nurse/midwife has any clinical concerns regarding patient safety for provision of the medication, they must arrange for the Medical Officer or emergency department to review so the administration of vaccine can occur as soon as possible.

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

<table>
<thead>
<tr>
<th>TITLE</th>
<th>Protocol for BNT162b2 [mRNA] (COVID-19 Pfizer (Comirnaty) vaccine)</th>
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<tbody>
<tr>
<td>Drug(s)</td>
<td>BNT162b2 [mRNA]</td>
</tr>
</tbody>
</table>
**Presentation**

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.)

**Indication**

Active immunisation to prevent coronavirus disease 2019 (COVID-19) caused by SARS-CoV2, in individuals 16 years of age and older.

**Contraindications**

- Do not use diluted vaccine products after expiry date on label.
- Do not use diluted vaccine beyond 6 hours after dilution.

**Precautions**

- 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 officer must review the suitability of administration.
- Adrenaline (epinephrine) must be available for the registered nurse or registered midwife to administer if anaphylaxis occurs.
- Patients must be closely observed for at least 15 minutes for the occurrence of adverse reactions.
- Vaccination are to be postponed in individuals suffering from acute severe febrile illness or acute infection.
- 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).
- Pregnancy Category B1
- It is unknown whether BNT162b2 [mRNA] is excreted in human milk.

**Dose**

0.3 mL (following dilution) for patients 16 years and older.

**Dose frequency**

A course of 2 doses at least 21 days apart.

**Administration**

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.

**Drug Interactions**

No interaction studies have been performed. Concomitant administration of COVID-19 Pfizer (Comirnaty) vaccine with other vaccines has not been studied.

**Adverse effects**

- Very common (≥ 1/10): headache (>50%), myalgia and chills (>30%), arthralgia (>20%), injection site pain (>80%), fatigue (>60%), pyrexia and injection site swelling (>10%) and were usually mild or moderate in intensity and resolved within a few days after vaccination. A slightly lower frequency of reactogenicity events was associated with greater age. A higher frequency of pyrexia was observed after the 2nd dose.
- Common (≥ 1/100 to < 1/10): nausea, injection site redness
- Uncommon (≥ 1/1,000 to < 1/100): lymphadenopathy, insomnia, pain in extremity, malaise, injection site pruritus
- Rare (≥ 1/10,000 to < 1/1,000): Acute peripheral facial paralysis
- Not known (cannot be estimated from the available data): Anaphylaxis; hypersensitivity
Obtain consent, explain possible adverse effects and provide patient information sheet

1 The drug information provided is to act as a guide only. For comprehensive information, refer to the full manufacturer’s product information. If contraindications, precautions or interactions are present, refer to medical officer before administration.

5.2 Protocol for administration of the COVID-19 AstraZeneca (ChAdOx1-S) vaccine

<table>
<thead>
<tr>
<th>TITLE</th>
<th>Protocol for COVID-19 AstraZeneca (ChAdOx1-S) vaccine</th>
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<tbody>
<tr>
<td>Drug(s)</td>
<td>ChAdOx1-S</td>
</tr>
<tr>
<td>Presentation1</td>
<td>Multidose vial (10 dose-vial) containing contains 5x10^{11} viral particles of (ChAdOx1-S a b) in 5 mL. One dose (0.5 mL) contains 5x10^{10} viral particles of (ChAdOx1-S a b). a Recombinant, replication-deficient chimpanzee adenovirus vector encoding the SARS-CoV-2 Spike glycoprotein b The vaccine is manufactured using material originally sourced from a human embryo (Human Embryonic Kidney cells: HEK293)</td>
</tr>
<tr>
<td>Indication</td>
<td>Active immunisation of individuals ≥18 years old for the prevention of coronavirus disease 2019 (COVID-19) caused by SARS-CoV-2.</td>
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</table>

Contraindications1

- 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.

Precautions1

- The immunogenicity, efficacy and safety of COVID-19 Vaccine AstraZeneca has not been assessed in immunocompromised individuals, including those receiving immunosuppressive therapy.
- Adrenaline (epinephrine) must be available for the registered nurse or registered midwife to administer if anaphylaxis occurs.
- Vaccination should be postponed in individuals suffering from acute severe febrile illness or acute infection.
- COVID-19 Vaccine AstraZeneca 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.
- Very rare events of demyelinating disorders have been reported following vaccination with COVID-19 Vaccine AstraZeneca. A causal relationship has not been established. As with other vaccines, the benefits and potential risks of vaccinating individuals with COVID-19 Vaccine AstraZeneca should be considered.

Dose1

- 0.5 mL

Dose frequency1

- A course of 2 separate doses of 0.5 mL each. The second dose should be administered between 4 and 12 weeks after the first dose.

Administration1

- Administer intramuscularly, preferably in the deltoid muscle.
Drug Interactions¹ | The safety, immunogenicity and efficacy of co-administration of COVID-19 Vaccine AstraZeneca with other vaccines have not been evaluated.

| Adverse effects¹ | ¹ Very common (≥ 1/10): injection site tenderness (>60%); injection site pain, headache, fatigue (>50%); myalgia, malaise (>40%); pyrexia, chills (>30%); arthralgia, nausea (>20%), injection site warmth, itch (>10%). The majority of adverse reactions were mild to moderate in severity and usually resolved within a few days of vaccination. When compared with the first dose, adverse reactions reported after the second dose were milder and reported less frequently. ² Common (≥ 1/100 to < 1/10): injection site swelling, injection site redness, pyrexia |

| Documentation | Obtain consent, explain possible adverse effects and provide patient information sheet |

¹ The drug information provided is to act as a guide only. For comprehensive information, refer to the full manufacturer’s product information. If contraindications, precautions or interactions are present, refer to medical officer before administration.
6 ATTACHMENTS

6.1 Procedure for preparing for vaccine administration

Step 1: Arrange the supply of vaccine from the designated supply point.

Step 2: Ensure access to an anaphylaxis kit (adrenaline (epinephrine), 1mL syringes, 23g needles and cotton swabs) and be familiar with the adrenaline (epinephrine) treatment protocol, found on the back cover of the current edition of The Australian Immunisation Handbook.

Step 3: Explain the rationale and purpose of the vaccine to the patient (or parent / guardian).

Step 4: Check with the patient (or parent / guardian) if they:

- Are pregnant or breastfeeding
- Have any known allergies
- Are currently taking any interacting medications, or
- Have pre-existing medical condition(s) where the use of the vaccine may be contraindicated or precautions may be required.

Should the patient have a contraindication or precaution to the vaccine, contact the Medical Officer.

Step 5: Explain the adverse effects of the vaccine.

Step 6: Ensure the patient has received the Patient Information Sheet available in supporting documents to the NSW Health Policy Directive Standard operating procedure for administration of COVID-19 vaccines in NSW vaccination clinics (PD2021_003), and has had the opportunity to ask any questions. Should the patient have further questions regarding the vaccination, contact the Medical Officer.

Step 7: For each person, document the following details:

- Name
- Address,
- Date of birth
- Sex
- Phone number
- Whether the person has any relevant conditions established above
- That information has been given.