

Section B: Pathway to COVID-19 vaccination

Section B: Pathway to COVID-19 vaccination - summary of changes

Version	Date	Section	Summary of Changes
59.0	30/04/24	Section 16	Updated section to reflect unavailability of Novavax vaccine from 1 May 2024 until Novavax XBB.1.5 is Medsafe approved
		Section 22	Updated section to reflect unavailability of Novavax vaccine from 1 May 2024 until Novavax XBB.1.5 is Medsafe approved
		Table 22.1	Updated section to reflect unavailability of Novavax vaccine from 1 May 2024 until Novavax XBB.1.5 is Medsafe approved

Section guidance

This section provides operational guidance on the vaccination pathway COVID-19 vaccines, from booking and scheduling to vaccine preparation onto vaccine administration and observation. The first line vaccines where there are no contraindications is the Pfizer-BioNTech Comirnaty vaccines.

Purpose

The purpose of this section is guiding the vaccinating workforce to *do the right thing* and have the right resources and information available to provide a safe quality vaccination journey for every consumer. It is designed to be applicable to all sites delivering the COVID-19 vaccine and provide guidance and assistance to providers, to maintain public safety and ensure consistent and equitable vaccination practices are in place across New Zealand/Aotearoa.

This section should be read and interpreted alongside the **COVID-19 immunisation policy**, **Immunisation Handbook 2020**, the Standards, and **IMAC resources**.

Appendices relevant to this section

- **Appendix G: Vaccination site screening questions**
- **Appendix H: Supported decision-making process**
- **Appendix I: Serious Adverse Event Process** (process steps, SAC examples, notification form)

1 Booking and scheduling

The National Immunisation Booking System known as *Book My Vaccine* (BMV) supports a national-led approach to immunising New Zealand/Aotearoa against COVID-19 and some additional vaccinations. *Book My Vaccine* supports vaccination sites down to Community Hub level. Use by primary care sites is optional where they only service their own enrolled populations.

For more information, see **Section C: Additional Programme Guidance, Variations, and Incidents**.

Ensure that the scheduling of vaccination appointments avoid over-crowding and allow for physical distancing and other IPC measures. Also, limit the number of accompanying people to only those who need assistance, whether physical or psychosocial.

1.1 Booking doses

Booking vaccinations

- **Consumers next COVID-19 vaccine depends on the date of their last COVID-19 vaccine or infection.**
- **It is recommended to wait 6 months after testing positive for COVID-19 before getting any COVID-19 vaccination.**
- **Consumers can check when their last vaccine was administered by logging into My Covid Record.**
- **The number of doses required depends on age and other clinical circumstances.**
- **New bookings can be made through bookmyvaccine.nz and the COVID-19 Vaccination Healthline 0800 28 29 26 between 8am to 6pm Monday to Friday.**
- **Consumers should select the appropriate age range when making an appointment.**

Note: A prescription from an authorised prescriber is required when using Nuvaxovid as a second primary dose following a non-Nuvaxovid COVID-19 vaccine for a first primary dose, in accordance with Section 25 of The Medicines Act 1981, as it is considered off-label use. This must be documented clearly including the rationale and the informed consent process.

For more information on dose intervals please see **COVID-19 Vaccines** and the **COVID-19 Immunisation policy statement on the Ministry of Health website**.

2 Protecting security and privacy

The vaccination process requires personal, identifying information be collected. In the health sector, NHIs are considered identifiable information as well as standard identifiers such as name, address, and date of birth.

Protecting and treating sensitive health information with respect is important.

- All medical records (such as written consent forms) at vaccination sites are required to be securely stored out of the sight (for example, in a drawer).
 - It is preferable this storage area is locked, or in the constant presence of an authorised person, such as an administrator, a security guard, or a vaccinator.
- At the conclusion of the vaccination event, the Programme recommends that the personal information documentation is taken directly (that is, no transit points) by an authorised person (such as an administrator, a security guard, or a vaccinator) to the site where the record will be held.

In addition to ensuring the security of health records as per above, the following security and privacy factors should be considered:

- Informing consumers why their information is being collected and what it will be used for. For example, that it will not be used for immigration or law-enforcement purposes.
- Consider who may be able to see computer screens that are likely to be used to input personal information.
- Ensure passwords and log-in details are kept confidential.
- In the event of a likely security or privacy breach advise the relevant Health District or provider privacy officer or contact the Programme's Privacy team as soon as possible
- Securely dispose unnecessary duplicate information.
- Ensure confidential conversations occur away from areas where other consumers or members of the public might also access.
- Ensure staff accessing consumer data have completed the appropriate privacy training (e.g., see the **Privacy Commissioner courses link**).

Note: Use secure methods when transferring information outside of the core vaccine systems such as USB encryption or accredited online services. Data should be password protected.

3 COVID-19 vaccines operational phase

- Use a daily checklist to monitor and ensure IPC and other safety measures are adhered to.
- Consider a daily 'huddle' to enhance teamwork and to highlight any IPC issues.
- Screen all staff for signs and symptoms of COVID-19 at the start of each shift.
- Screen all people arriving for vaccination for COVID signs and symptoms. For additional screening questions see **Appendix G**.
- Ensure the scheduling of vaccination appointments avoids over-crowding and allows for physical distancing and other IPC measures. Also, limit the number of accompanying people to only those who need assistance, whether physical or psychosocial.
- Ensure the appropriate processes are in place to prevent under-age vaccinations – **this is a never event**.
- Ensure the appropriate processes are in place to prevent second dose vaccinations earlier than 21 days – **this is a never event**.
- **Ensure the appropriate processes are in place to ensure consumers are receiving the age-appropriate vaccine.**

Note: In the rare occurrence where an authorised prescriber deems the vaccine clinically indicated for a consumer, the authorised prescriber can prescribe the vaccine as off label/unapproved use. This must be documented clearly including the rationale for early second dose and the informed consent process. Written consent is advised.

Key IPC measures to implement

Prepare each injection in a clean, designated area.

Hand hygiene

- At the start of the shift, all vaccination team members are required to wash their hands thoroughly with soap and water and dry them thoroughly or use hand sanitiser.
- Facilitate attending consumers' hand hygiene (as above).
- Vaccinators should perform hand hygiene before putting on and removing PPE, before preparing the vaccine, and between each vaccine administration, preferably using alcohol-based hand sanitisers.
- Gloves are not required and, if used, do not replace the need for hand hygiene between each vaccine administration and for other indications. The use of alcohol hand sanitisers on gloves is strongly discouraged.

PPE

- PPE is to be selected based on risk assessment as a part of standard precautions.
- In the context of the COVID-19 pandemic, vaccinators should wear PPE appropriate to the area they are working in. For more information visit the **Te Whatu Ora website** .

Preparation and administration IPC

- Sterile, single use syringes and needles should be used. These should only be removed from their packaging immediately before use.
- Perform hand hygiene before preparing vaccine for delivery.
- Prevent contamination of the vials by wiping the access diaphragm (septum) with 70% alcohol (isopropyl alcohol or ethanol) on a swab or cotton wool ball before piercing the vial and allow to air dry. If the top of the vial is accidentally touched during drawing up it must be re-wiped (repeat this step).
- Adhere to IMAC guidance for the drawing up of vaccine and skin preparation at the site of injection.
- Discard used syringes and needles as a single unit into a sharps container immediately after administering the vaccine.

4 Obtaining informed consent

Prior to administering the vaccination, the registered health professional must obtain informed consent, per the *Code of Health and Disability Services Consumers' Rights* (the Code). The steps to recording the outcome of the informed consent question is:

- The vaccinator or an administrative support person must record in the AIR vaccinator portal or PMS the consumer's consent to approve or decline administration of vaccine.
- The Programme assumes verbal consent is agreeable in most situations.
- Written consent can be considered in the following situations below:
 - a. where there are significant risk of adverse effects to the consumer, per **clause 7(6c) of the Code**
 - b. if it is being prescribed. For more information, please refer to the below 'Prescription' section.
 - c. if this is the provider's or vaccinator's preference, for example, in aged residential care settings.
- Where written consent is recorded under points a. b. and/or c. above, the provider is responsible for ensuring the forms are archived as a part of the consumer's clinical record.
- Please always use the most up to date consent form.

Where a consumer is not competent to make an informed choice and give consent for their vaccine, someone who has the legal right can make decisions on the consumer's behalf; namely a legal guardian or someone who currently holds Enduring Power of Attorney for personal care and welfare.

See **Appendix H** which displays the process for consumers requiring support to consent to the COVID-19 Vaccination. . For more information regarding obtaining informed consent, see the *Immunisation Handbook, chapter 2*.

For more information regarding supported decision making, or to access the training module specific to COVID-19 Vaccine Supported Decision Making, see IMAC Learning Courses at **IMAC Learning**.

Obtaining written consent for the Nuvaxovid vaccine

The Programme requires written consent to be obtained before administering the Nuvaxovid vaccine as a second primary dose after a non-Nuvaxovid vaccination.

Please note: Nuvaxovid 0.5mL multi-dose vial vaccine (12+ years) will not be available from 1 May 2024. There will be no Novavax vaccine available until the Nuvaxovid XBB.1.5 vaccine is Medsafe approved.

Informed consent for consumers aged 12 to 15 years

Under the code of rights, every consumer, including a child, has the right to the information they need to make an informed choice or to give informed consent. Therefore, a young person aged 12-15 years can provide their own informed consent or refusal to consent if they are deemed competent to give consent, and a parent or guardian does not need to provide consent or be present. Some of these young people may choose to have their parent or guardian consent on their behalf and that is fine.

Verbal or written consent for consumers aged 12 to 15 years

Informed consent for consumers aged 12-15 years can be verbal, however, written consent can be obtained if it is the provider's or vaccinator's preference.

4.1 Prescription

A prescription from an authorised prescriber is required when a vaccine is being administered off-label under **Section 25 of The Medicines Act 1981**, such as when a Medsafe approved medicine is being used for an un-approved use. However, no prescription from an authorised provider is required if the administration is authorised under **section 34A of The Medicines Act 1981** which empowers the Director-General of Health to authorise, by Notice, the use of a consented COVID-19 vaccine otherwise than in accordance with the approved data sheet.

For the list of authorised prescribers please refer to the **Medsafe website**.

When a prescription is used, it is recommended that written consent is completed. In this instance it means that the prescriber completes and signs the written consent form. However, if the prescriber is not available to sign the written consent form, the Clinical Lead can complete the form.


Written consent forms:

Written consent forms must be managed on-site or by a centralised administration team. Given the information on the written form contains personal information, **forms must be always held and transported securely** (for example, in a locked cabinet/drawer, a tracked courier bag, or other secure container when transported between locations). The consumer may also decide to take the written consent form with them.


4.1.1 Vaccine safety and additional considerations for consumers aged 12 to 15 years

Similarly, as with consumers over the age of 16 years, it is important to assess the administration site and select the correct needle length. Most commonly, the same needles used for adults would be used for consumers aged 12-15 years.

5 **Comirnaty 15/15mcg Original/ Omicron BA.4/5 grey cap COVID-19 vaccine (for ages 16 years and over) - Discontinued.**

	<p>As of 7 March 2024, Comirnaty 15/5mcg Original/Omicron BA.4/5 grey cap will no longer be available in Aotearoa New Zealand.</p> <p>Comirnaty 30mcg Omicron XBB.1.5 vaccine is available for 12 years and over. See section 19 for operational guidance.</p>
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6 **Comirnaty 30mcg Original grey cap COVID-19 vaccine (for ages 12 years and over) - Discontinued.**

	<p>As of 7 March 2024, Comirnaty 30mcg Original grey cap will no longer be available in Aotearoa New Zealand.</p> <p>Comirnaty 30mcg Omicron XBB.1.5 vaccine is available for 12 years and over. See section 19 for operational guidance.</p>
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7 Comirnaty 30mcg Omicron XBB.1.5 vaccine (12+ years): Multi-dose vial dark grey cap and Single dose vial light grey cap

The key safety points are:



- As of 7 March 2024, Comirnaty Omicron 30mcg XBB.1.5 supersedes the previous 12+ years Comirnaty vaccines.
- The vaccine is available as multi-dose vials (dark grey cap) and single-dose vials (light grey cap).
- There are 6 doses per vial in the multidose vial.
- One dose (0.3mL) contains 30mcg of Raxtozinameran.
- Approved for use for consumers aged 12 + years as a primary course.
- Approved for use as additional doses if eligible.
- The Comirnaty 30mcg Omicron XBB.1.5 (12+ years) vaccine **does not require** dilution.
- For all vaccinator resources and materials related to Comirnaty vaccines please refer to the **IMAC website**.

For more **details on recommended groups, spacing and eligibility**, see the Immunisation Handbook or the COVID vaccine eligibility table_V3 in the National Immunisation **dropbox**.

8 Comirnaty 10mcg vaccine (5-11 years): orange cap

The key safety points are:



- Approved for use for children/ tamariki aged 5 to 11 years.
- Comirnaty 10mcg orange cap (5-11 yrs) vaccine needs to be diluted with 1.3mL of 0.9% NaCl before use.
- There are 10 doses per vial.
- One dose contains 10mcg of Raxtozinameran.
- If consumer receives Comirnaty 10mcg dose (5-11 years) and turns 12 before their second dose, they will require a Comirnaty 30mcg XBB.1.5 dose at least 3 months after first dose to complete primary course and subsequent doses if eligible. See Immunisation Handbook for details.

For all vaccinator resources and materials related to Comirnaty 10mcg vaccine please refer to the **IMAC website**.

8.1 Site readiness

It is recommended sites providing Comirnaty childhood vaccines complete the following checklist.

Checklist	Y / N
Site Workforce Police vetting safety check is up to date	Y <input type="checkbox"/> N <input type="checkbox"/>
Vaccinators administering the Comirnaty 10mcg and/or 3mcg vaccine must complete IMAC's Paediatric COVID-19 Vaccinator Education Course.	Y <input type="checkbox"/> N <input type="checkbox"/>
Child safe environment	Y <input type="checkbox"/> N <input type="checkbox"/>
SOP preparation of Comirnaty 10mcg and/or 3mcg doses	Y <input type="checkbox"/> N <input type="checkbox"/>
Child friendly resources (distraction posters can be found on IMAC website)	Y <input type="checkbox"/> N <input type="checkbox"/>
Child-suitable bag valve mask (BVM or 'ambu bag') resuscitator is required, airways (optional) and any other emergency equipment to respond to a serious adverse event. Note: See A4.6. Minimum staff and equipment requirements for vaccination services in Appendix 4 of the Immunisation Handbook (2020)	Y <input type="checkbox"/> N <input type="checkbox"/>
Consumer collateral	Y <input type="checkbox"/> N <input type="checkbox"/>
Dry Run	Y <input type="checkbox"/> N <input type="checkbox"/>
Wet Run	Y <input type="checkbox"/> N <input type="checkbox"/>

8.2 Vaccine safety and additional considerations for consumers aged 5 to 11 years

With consumers the age of 5 to 11 years, it is important to use the correct needle length. For children/tamariki under the age of 7 years a 16 mm length needle should be used. For children/tamariki ages 7 to 11 years clinical judgement should be used to determine if a longer needle is required (25mm). Use of a shorter needle risks delivering the vaccine subcutaneously as opposed to intramuscularly, which has the potential to underdose. For more information on needle length, refer to the *Immunisation Handbook*.

Ensuring young people have adequate understanding of the vaccine and can provide informed consent

Training and guidance material are available to support vaccinators to gauge consumer's ability to provide informed consent. It is important that a robust conversation occurs prior to vaccination, where the child or their parent/ legal guardian/ enduring power of attorney has an opportunity to have any questions answered and concerns addressed.

9 Comirnaty 3mcg (6 months -4 yrs): maroon cap

The key safety points are:



- Approved for use for children/tamariki aged 6 months to 4 years.
- The Comirnaty 3mcg vaccine (6 months to 4 yrs) vaccine needs to be diluted with 2.2mL of 0.9% NaCl before use. There are 10 doses per vial.
- One dose contains 3mcg of Raxtozinameran.
- If the consumer receives the Comirnaty 3mcg dose (for ages 6 months – 4 years) and then turns 5 before their second dose, they will receive the Comirnaty10mcg dose for subsequent doses. See Immunisation Handbook for details.
- For all vaccinator resources and materials related to Comirnaty 3mcg vaccine please refer to the **IMAC website**.

9.1 Vaccine safety and additional considerations for consumers aged 6 months to 4 years

With consumers the age of 6 months to 4 years, it is important to use the correct needle length for the child being vaccinated as well as the area of their body the vaccine is to be given into (ie deltoid vs vastus lateralis). For more information on needle length, refer to the *Immunisation Handbook*.

Ensuring young people have adequate understanding of the vaccine and can provide informed consent

Training and guidance material are available to support vaccinators to gauge consumer's ability to provide informed consent. It is important that a robust conversation occurs prior to vaccination, where the child or their parent/ legal guardian/ enduring power of attorney has an opportunity to have any questions answered and concerns addressed.

10 Nuvaxovid COVID-19 vaccine (12+yrs) – Unavailable.



As of 1 May 2024, Nuvaxovid (12+ years) will no longer be available in Aotearoa New Zealand.

There will be no Novavax COVID-19 vaccine available until the Nuvaxovid XBB.1.5 vaccine is Medsafe approved.

Supply of the Pfizer XBB.1.5 COVID-19 vaccine (branded as Comirnaty) is unaffected and continues to be available.

Please see IMAC website for vaccinator advice
<https://www.immune.org.nz/vaccine/nuvaxovid>

11 Preparation of Doses

Follow the IMAC vaccine preparation instructions for vaccine preparation. These instructions are included in vaccine shipments and are available on the **IMAC website**.

Note: These instructions are regularly updated. Please ensure you are using the most recent version.

Table 22.1

Vaccine type	Dilution required?	Draw up	Doses per vial
Comirnaty 30mcg/0.3mL Omicron XBB.1.5 multi-dose vial (dark-grey cap) 12+ years	NO	0.3mL	6
Comirnaty 30mcg/0.3mL Omicron XBB.1.5 single-dose vial (light-grey cap) 12+ years	NO	0.3mL	1
Comirnaty 10mcg/0.2mL (orange cap) 5-11 years	YES	0.2mL	10
Comirnaty 3mcg/0.2mL (maroon cap) 6 months – 4 years	YES	0.2mL	10
Nuvaxovid (blue cap) 12+ years Note: Nuvaxovid (blue cap) 12+ years will not be available from 1 May 2024. There will be no Novavax vaccine available until the Nuvaxovid XBB.1.5 vaccine is Medsafe approved.	NO	0.5mL	10

For vaccines that **do not** require dilution:

Incorrect volume of vaccine may be detected by identifying you have drawn up less or more than the indicated number of doses listed in **Table 22.1**.

Should this occur, immediately quarantine the vaccines and discard all doses from that vial if it is clear why the mistake has occurred.

If it is unclear why the error has occurred, keep the vaccines in quarantine and contact IMAC for clinical guidance. This error must be documented as waste in the Inventory

portal and reported as an incident in the local organisation's quality and safety reporting system.

For vaccines **that require dilution** (Comirnaty 10mcg orange cap and 3mcg maroon cap only):

Comirnaty vaccines should be brought to room temperature prior to dilution, as noted in IMAC's preparing vaccine instructions. It should not feel cold to the touch. The actual time to get the vial to room temperature will vary depending on when you take vials out of the fridge and the temperature of the room. Approximately 30 minutes should be sufficient time.

Comirnaty 10mcg/0.2mL multi-dose vial (dilute to use) orange cap vaccine (5-11 yrs) contains ten (10) doses per vial.

Comirnaty 3mcg/0.2mL multi-dose vial (dilute to use) maroon cap vaccine (6 months – 4 yrs) contains ten (10) doses per vial.

To avoid the Comirnaty vaccine being under or over diluted it is recommended that all doses are drawn up into syringes following dilution and double-checked by a second appropriately trained vaccinator.

If the number of doses drawn from the vial are not in line with expected number, this will immediately alert to the vial having not been correctly diluted. If this occurs, the vial should be quarantined. Use of the IMAC dilution record spreadsheet will also provide an additional check.

Please discuss with IMAC on 0800 466 863 and if advised to discard, this must be documented as waste in the Inventory Portal as per guidelines and reported as an incident in the local organisation's quality and safety reporting system.

Before preparation of vaccine check:

- **That it's the right vaccine**
- Manufacturer's vaccine expiry date
- Appropriate supplies are used. **Please refer to Section 9: Vaccine and consumables ordering and delivery** for ordering consumables.

Number the vaccine vial and enter the number into the Comirnaty Orange cap **dilution record** or Comirnaty Maroon Cap **dilution record**. Second person independently checks that the correct vaccine has been selected, by confirming the product name on the vial and checking the expiry date printed on vial by manufacturer. Second person also independently checks the numbering of the vial and documents these checks by signing/initialling the **dilution record**.

Vaccine labels are used to help differentiate between vaccines. Please see **table 8.2** for the different labels available to order.

During the preparation of the vaccine both expiry dates must be double checked. This includes the vial and the 10-week removal from ULT expiry date (in-use' expiry date label on the vaccine pack). Vaccines can be administered until the end of the expiry day.

For quality and safety purposes, it is recommended that each vial and/or syringes (made from that vial), are labelled with the:

- date and time
- expiry time

For vaccines that require dilution:

- diluent name
- date and time of dilution
- expiry time after dilution

Vaccine preparation precautions

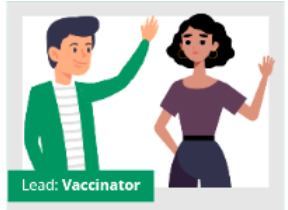
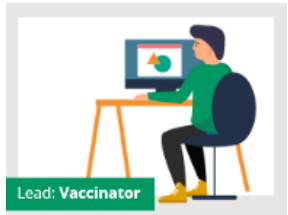
- Draw up from one vial at a time. Each vaccine dose from that vial should go into one kidney dish/ container with the empty vial for vaccine administration.
- It is recommended that a suitable covering is used when storing the drawn-up syringes. This is to ensure that **the vaccine is not exposed to direct sunlight or UV light** (both in the vial or in the drawn-up syringe) and that used syringes will not be put back with the unused syringes.
- During the preparation of the vaccine standard local IPC policies should be followed.
- **Any vaccine not used within the expiry time outlined above must be discarded.**
- The vaccine must not be shaken during preparation.
- Some liquid may remain in the vial after withdrawing the final dose. The leftover vaccine must be discarded. **Do not mix doses from different vials.**
- If during the preparation of the vaccine a foreign body (such as a black particle) or discolouration is identified, the vial should be discarded and recorded as an open vial-quality issue in the inventory portal. The vaccine will appear colourless to slightly yellow, clear to mildly opalescent.
- **Note:** Call IMAC for clinical advice if required at any stage of preparation.

12 COVID-19 vaccine pathway to vaccination

For more information see **IMAC guidelines** found on the IMAC website and the **Immunisation handbook Section 2.2** for the correct vaccine administration process.

Please refer to the '7 Rights of Vaccine Administration' on the **IMAC website**.

Table 23.1 – pre-vaccination greeting and verify identity

Step	Action
 <p>Greet consumer, conduct COVID-19 health check</p>	<p>On arrival at the vaccination site, the vaccinator/site administrator will greet the consumer and ask whether they have any COVID-19 symptoms as per standard site practices.</p> <p>If the consumer is underage, a parent, legal guardian, caregiver, or person with an enduring power of attorney will need to accompany a child to their appointment(s) as the responsible adult and be able to provide consent for them to be immunised.</p> <p>Please note:</p> <ul style="list-style-type: none"> • People who have a confirmed COVID-19 infection, should not be vaccinated until they have had the appropriate recovery period • People who have symptoms of COVID-19 should be advised to stay at home and get a test. They can be vaccinated once they have a negative test result and symptoms are mild only. • People who live with someone who has COVID-19 are a household contact and are advised to follow the specific advice public health advice for testing and isolating. • People who are significantly unwell are advised to wait until they are better before getting the vaccine; however, note that mild symptoms are not a contraindication. People in this situation are advised to discuss their symptoms with their GP or vaccine provider. • People who have been advised to self-isolate, stay at home, are under an isolation order or are waiting on a test result, should have their appointment deferred. • Please see the Vaccination Site screening questions below for questions related to clinical assessment.
 <p>Verify consumer's identity</p>	<p>The vaccinator/site administrator will also verify the consumer's identity using name, DOB, address, and locate their record in the AIR vaccinator portal or PMS. This should be done in a private and confidential manner and should not be overheard or viewed by other consumers.</p> <p>Check the consumer's DOB and confirm age and what vaccine they will be receiving. If underage do not vaccinate.</p> <ul style="list-style-type: none"> • Check with the consumer to ensure they are eligible for their vaccine today.

	<ul style="list-style-type: none"> • Check the dose interval and timing is correct for the vaccine the consumer is receiving. For more information see the COVID-19 immunisations policy statement. <p>Note: Photo ID is not required to confirm the consumer’s identity.</p> <p>Use the 7 rights of vaccine administration resource available on the IMAC website.</p>
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Table 23.2 – pre-vaccination provide collateral

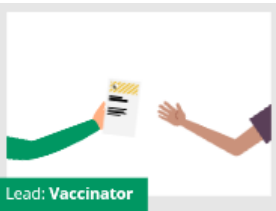
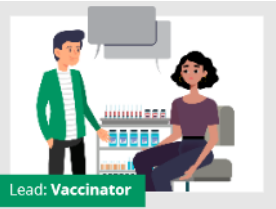
Step	Action
 <p>Lead: Vaccinator</p> <p>Provide collateral</p>	<p>The vaccinator/site administrator will provide the consumer with the COVID-19 vaccination information and consent pack, which includes:</p> <ul style="list-style-type: none"> • What you need to know about the COVID-19 vaccination • After the COVID-19 vaccination <p>Ensure the consumer retains this information in either paper form or by taking a photo.</p> <p>You may also choose to provide the COVID vaccine FAQs sheet, which is available on the Ministry’s website.</p> <p>You may also display the privacy statement in the reception area as well as supplying the information in hard copy.</p>

Table 23.3 – vaccination process: pre-vaccination clinical assessment

Step	Action
 <p>Lead: Vaccinator</p> <p>Complete a pre-vaccination clinical assessment</p>	<p>Pre-vaccination clinical assessment</p> <p>The vaccinator undertakes a pre-vaccination clinical assessment. This encompasses whether the consumer has medical reasons why they should not receive the vaccine, any history of allergy, whether they had an adverse event after receiving a previous dose of the COVID-19 vaccine, any current symptoms, are pregnant or breastfeeding, and other relevant precautions.</p> <p>This includes checking that the consumer is not underage for the vaccine they will be receiving, and they have scheduled the correct interval between doses.</p> <p>For more information on dose intervals and timing see the COVID-19 immunisation policy statement.</p> <p>Interaction with other vaccines</p> <p>The safety and efficacy of administering two adjuvanted vaccines together is not yet established. Shingrix and Nuvaxovid (adjuvanted recombinant COVID-19 vaccine) utilise novel adjuvants to gain a good immune response. Patients should be informed of the possibility of a stronger post-vaccination response, where two or more of these are administered together. Other vaccines on the</p>

Step	Action
	<p>National Immunisation Schedule can be given before, after or at the same time as the COVID-19 vaccination.</p> <p>Boosters</p> <p>If the consumer has presented for a COVID-19 vaccine booster, they must meet the eligibility criteria available on the Ministry of Health website.</p>

Table 23.4 – vaccination process: informed consent

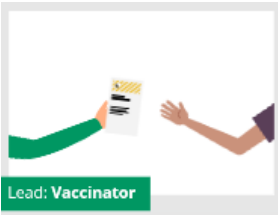
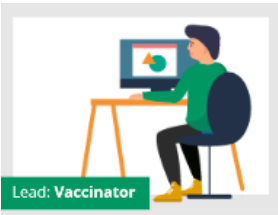



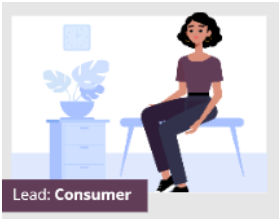
Step	Action
 <p>Lead: Vaccinator</p> <p>Obtain informed consent</p>	<p>Obtain informed consent before administering the vaccine</p> <p>The vaccinator (or vaccinator support person) must obtain the consumer’s informed consent to receive the vaccine prior to the administering of the vaccine.</p> <p>Where appropriate, consent may be given by a proxy such as a guardian or person with power of attorney.</p> <p>A parent, legal guardian, caregiver, or person with an enduring power of attorney will need to accompany a child to their appointment(s) as the responsible adult and be able to provide consent for them to be immunised.</p> <ul style="list-style-type: none"> • If a child presents to their vaccination with whānau who cannot provide consent for the child to be immunised, written or verbal consent should be obtained from a parent, legal guardian, or person with an enduring power of attorney prior to administration of the paediatric vaccine. <p>If off-label use of the vaccine, obtain written informed consent before administering the vaccine.</p> <p>Note: IPC guidance must be observed when dealing with hard-copy consent forms and obtaining consent. For example, consumers should use hand-sanitiser before or after handling a pen to sign the form or bring along their own pen.</p>
 <p>Lead: Vaccinator</p>	<p>Consumer consent record</p> <p>The vaccinator or an administrative support person must record the consumer’s consent.</p> <ul style="list-style-type: none"> • Check vaccination spacing interval before administration. • Do not vaccinate with Nuvaxovid if the child is under the age of 12 years. • Nuvaxovid vaccine is not recommended for pregnant people due to lack of safety data and requires a prescription and written consent before administration.

Table 23.5 – vaccination process: administering the vaccination

Step	Action
 <p data-bbox="264 465 432 506">Check Vaccine</p> <p data-bbox="260 517 485 546">Check the vaccine</p>	<p data-bbox="571 338 807 367">Check the vaccine</p> <p data-bbox="571 400 655 430">Check:</p> <ul data-bbox="600 465 1318 757" style="list-style-type: none"> • The label and confirm that you have the correct vaccine, and that the vaccine has not expired. • The opened/punctured diluted vial is used within the appropriate time frame before expiry. Refer to the IMAC vaccine preparation sheets for vial expiry times after opening. • The unopened vial fridge expiry date (in-use' expiry date label on the vaccine pack).
 <p data-bbox="264 947 395 965">Lead: Vaccinator</p> <p data-bbox="260 1003 405 1066">Administer vaccination</p>	<p data-bbox="571 792 927 822">Administer the vaccination</p> <p data-bbox="571 837 1331 936">Before administering the vaccine verbally check the vaccine type with the consumer. Please refer to the '7 Rights of Vaccine Administration' on the IMAC website.</p> <p data-bbox="571 952 1337 1086">When administering concomitant vaccines, the vaccinator should ensure that the vaccines do not require any spacing and there is no specific information required to be given to consumers regarding this.</p> <p data-bbox="571 1102 1350 1236">Note: Vaccinators should ensure the correct needle length is used for the administering the vaccine based on individual consumers being vaccinated. This includes considering body size and site vaccine will be administered (e.g., deltoid or vastus lateralis).</p> <p data-bbox="571 1252 1182 1314">For more information on needle length, refer to the Immunisation Handbook.</p>
 <p data-bbox="264 1512 395 1529">Lead: Vaccinator</p> <p data-bbox="264 1565 512 1594">Record information</p>	<p data-bbox="571 1357 991 1386">Record vaccination information</p> <p data-bbox="571 1402 1342 1536">Once the vaccination is complete the vaccinator or administrative support person must update the consumer's record in the AIR vaccinator portal or PMS with complete and accurate record of the vaccination event.</p> <p data-bbox="571 1552 1259 1615">This enables accurate data for operational reports (such as number of vaccinations completed and other trend data).</p> <p data-bbox="571 1630 783 1659">This must include:</p> <ul data-bbox="619 1675 1342 1966" style="list-style-type: none"> • The batch, sub-batch number and expiry date for the vaccine (for example AB1234-567 the first part is the batch number, the second part is the sub-batch number) these are found on the vaccine pack. • The batch number and expiry date for the diluent, if used (these are found on the diluent vial/ampoule). • Details of the injection site and the date and time of the vaccination event. <p data-bbox="571 1982 1310 2080">In situations where this is not possible, such as AIR vaccinator portal being unavailable, or insufficient internet connectivity at the vaccinating location, ensure an administrative process is in</p>

Step	Action
	<p>place to enter information into the relevant system on the same day as the vaccination event.</p> <p>This is essential clinical information; it is a requirement to ensure it is not lost and that it is transcribed correctly.</p>

Table 23.6 – vaccination process: after vaccination

Step	Action
 <p>Consumer waits 15 minutes in observation area</p>	<p>Observation</p> <p>The consumer must remain on site under observation for at least 15 minutes. If the vaccinator determines it necessary, they may ask the consumer to wait for longer than 15 minutes, for example, if the individual is in a rural or remote area or has a history of anaphylaxis.</p> <p>Consumers may also be required to stay for a longer length of time (20 mins) if a non-COVID-19 vaccine is to be administered at the same time eg a childhood vaccine such as MMR, shingles or tetanus booster,</p> <p>Post-vaccination advice should be given to consumers both verbally and in writing. Site Clinical Leads should ensure the latest leaflets are being used (these can be downloaded from the drop box). More information and resources can be found on the Ministry's 'COVID-19 vaccine: After your vaccination' poster found on the Ministry's website.</p> <p>For further information on post vaccination, see section 2.3 in the <i>Immunisation Handbook</i>.</p>

12.1 Sharing information on the vaccine

The Medicines Regulations 1984 requires written information is provided in the form of a data sheet, available at <https://www.medsafe.govt.nz/medicines/infosearch.asp>; the COVID-19 vaccine data sheet can be found by searching 'COVID-19'. There is no legal requirement for any hard copy data sheets or medicine packaging inserts to be provided on site.

12.2 Observation following vaccination

Consumers should remain under observation for at least 15 minutes following vaccination in an observation area. This is to ensure that any adverse reactions that may occur can receive prompt treatment.

Consumers may also be required to stay for a longer length of time (20 mins) if a non-COVID-19 vaccine is to be administered at the same time e.g., a childhood vaccine, shingles or tetanus booster,

All vaccinators must be able to distinguish anaphylaxis from fainting, anxiety, immunisation stress-related responses, and breath-holding spells and seizures. For further information on post-vaccination procedures, see **section 2.3** in the *Immunisation Handbook*.

12.3 Consumers' record of vaccination

Consumers may be supplied with a COVID-19 Vaccination record card detailing the vaccine administered and the date their next dose is due. This card is not designed as a vaccination certificate – and as such, may not be recognised as proof of vaccination by other countries.

International Travel Vaccination Certificate

Consumers can request an International Travel Vaccination Certificate required when travelling overseas. This certificate can also be requested through **My Covid Record** or calling 0800 222 478.

For more information please see the **Ministry's website**.