

Section C: Paediatric Pfizer COVID- 19 Vaccine (for ages 5 to 11 years)

Section C: Summary of Changes

Version	Date	Summary of Changes
31.0	22/12/21	New: Paediatric Pfizer COVID-19 Vaccines (for age 5 to 11 years)

Pathway to vaccination

Section guidance

This section is read in conjunction with Pfizer Vaccine section. This section provides additional operational guidance on the Paediatric Pfizer COVID-19 Vaccine vaccination pathway, from booking and scheduling to vaccine preparation onto vaccine administration and observation.

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.

The key safety points are:

- Use for children/tamariki aged 5 to 11 years
- The Paediatric Pfizer vaccine dose is different to the Pfizer dose for those 12 years and older (12+ Pfizer vaccine)
- There are 10 doses per vial
- Consumers receiving a Paediatric Pfizer first dose should finish their primary course with a Paediatric Pfizer second dose, regardless if they turn 12 years before the date of the second dose, unless clinically indicated.

This section is designed to be applicable to sites delivering the Paediatric Pfizer COVID-19 Vaccine and provides 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 *Immunisation Handbook 2020*, Ministry’s Policy Statements, 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)

Site readiness

If sites are new to vaccinating the Paediatric Pfizer vaccines (for ages 5 to 11 years) it is recommended a Paediatric Pfizer site, check list is completed

Paediatric Pfizer Site Checklist	Y / N
Site Workforce Police safety check are up to date	Y <input type="checkbox"/> N <input type="checkbox"/>
Vaccinators administering the Paediatric Pfizer vaccine must complete the Paediatric COVID-19 Vaccinator Education Course (IMAC link)	Y <input type="checkbox"/> N <input type="checkbox"/>
Child safe Environment	Y <input type="checkbox"/> N <input type="checkbox"/>
SOP preparation of Paediatric Pfizer doses	Y <input type="checkbox"/> N <input type="checkbox"/>
Child friendly resources available (such as distraction posters)	Y <input type="checkbox"/> N <input type="checkbox"/>
Paediatric Pfizer (age 5 to 11 years) collateral available	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"/>

Booking and scheduling

Arrangements for the booking and scheduling of the Paediatric Pfizer Vaccine can be found in the **National Immunisation Booking System**.

1 Booking second doses

Do not vaccinate less than 21 days

- The standard interval gap for the programme is 8 weeks. This interval is recommended as best practice.
- The administration of the Paediatric Pfizer COVID-19 Vaccine at an interval of less than 21 days is not approved by Medsafe and is considered off-label use and must be reported to CARM (unless clinically indicated).
- New bookings are made through bookmyvaccine.nz and the COVID-19 Vaccine Whakarongorau Aotearoa 0800 28 29 26.
- Consumers should select the appropriate age range when making an appointment.
- Doses can be booked for any time after 8 weeks.

2 Paediatric Pfizer Operational phase

- Please see the section Pfizer COVID-19 Vaccine Operational phase for detailed information
- Ensure the appropriate processes are in place to prevent vaccination of people under 5 years– **this is a never event**.
- Ensure the appropriate processes are in place to prevent vaccination of people under 12 years with the adult vaccine– **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**.

Note: The Paediatric Pfizer vaccine is offered as a first or second dose with a standard interval of 8 weeks. A shorter dosing interval is acceptable if for example the child is commencing significant immunosuppression treatment.

For information on informed consent please see section '**Obtaining informed consent**'.

3 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*.

Concomitant use with other vaccines

There are no interactions with other vaccines – It is considered safe to give the Paediatric Pfizer COVID-19 vaccine with any other paediatric vaccine. Vaccines on the Paediatric National Immunisation Schedule can be given before, after or at the same time as the COVID-19 vaccination.

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

IMAC and the Ministry are working on training and guidance material to support vaccinators to gauge a 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.

4 Paediatric Pfizer Preparation of doses

The Paediatric Pfizer COVID-19 Vaccine for children/tamariki aged 5 to 11 years comes as a concentrate and **must be diluted on site**, following the instructions provided by IMAC. These instructions are included in vaccine shipments and available on the **IMAC website**.

The dilution for the Paediatric Pfizer dose is different from the dilution for ages 12 years and older Pfizer dose.

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

BioNTech/Pfizer COVID-19 Vaccine 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.

Please note the BioNTech/Pfizer COVID-19 Vaccine is fragile and **must not be shaken** during preparation. However, once the vial has been fully thawed, it can be gently inverted ten times to reduce condensation.

Before preparation check:

- correct vaccine must be confirmed. The vial has an **orange-coloured cap** on top of the vial and the label has an orange border and orange writing 'mRNA-CV 10µg.
- manufacturer's vaccine expiry date
- the appropriate supplies are used:
 - 1mL syringe with 16mm or 25mm needles
 - syringe labels

It is recommended that a suitable covering is used when storing the drawn-up syringes. This is to ensure:

1. That at all times, **the vaccine is not exposed to direct sunlight or UV light** (both in the vial and in the drawn-up syringe).
2. To distinguish the used syringes from the unused syringes.

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 CIR.

Number the vaccine vial and enter the number into the vaccine log. Second person also cross 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 cross checks the numbering of the vial and documents these checks by signing/initialling the vaccine log.

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

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

Only draw up one vial at a time, each vaccine from that vial should go into one container with the original vial for vaccine delivery. **Do not mix doses from different vials.**

During the preparation of the vaccine standard local IPC policies should be followed.

Note: 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. Vaccines can be administered until the end of the expiry day.

4.1 Number of doses per vial for age 5 – 11 years

The number of doses from each vial is ten (10). Incorrect volume of diluent may be detected by identifying you have drawn up less or more than ten (10) doses from the vial. Should this occur, quarantine, and discard all doses from that vial. This error must be documented as waste in CIR and reported as an incident in the local organisation's quality and safety reporting system.

5 Paediatric Pfizer Vaccine administration and observation

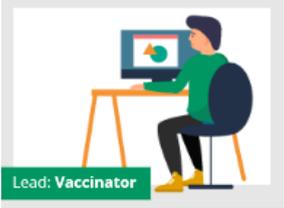
This section is read in conjunction with the Pfizer vaccine section (for ages 12 years and older). This section provides additional operational guidance on the Paediatric Pfizer Covid-19 vaccine for consumers aged 5 to 11 years.

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

For information on informed consent please see section '**Obtaining informed consent**'.

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>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>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> <p>Please note:</p> <ul style="list-style-type: none"> • People who have symptoms of COVID-19 should be advised to stay at home and get a PCR test. They can be vaccinated once they have a negative test result and symptoms are mild only. • People who have been to a current location of interest according to the Ministry's website, are advised to go home and follow the specific advice for the site of interest they attended. • 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 contra-indication. People in

	<p>this situation are advised to discuss their symptoms with their GP or vaccine provider.</p> <ul style="list-style-type: none"> • People who have been advised to self-isolate, stay at home 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>Lead: Vaccinator</p> <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 CIR. Check the consumer's DOB and ask their age. If underage (i.e., under five years of age) do not vaccinate.</p> <ul style="list-style-type: none"> • If the consumer has presented for their second vaccination and their first dose was given less than 21 days ago do not vaccinate. The standard interval for the Paediatric Pfizer vaccine is 8 weeks. <p>Note: Photo ID is not required to confirm the consumer's identity.</p>

*Especially those people who meet the New Zealand/Aotearoa Government 'higher index of suspicion' (HIS) criteria.

Table 23.2 – pre-vaccination provide collateral

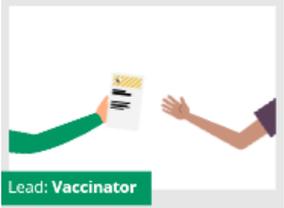
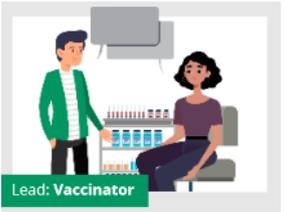
Step	Action
 <p>Lead: Vaccinator</p> <p>Provide collateral</p>	<p>The vaccinator/site administrator will provide the consumer with the COVID-19 vaccination information and consent pack, which includes the Getting your COVID-19 vaccine: What to expect factsheet, consent form, privacy statement, and after your immunisation factsheet.</p> <ul style="list-style-type: none"> • You may also choose to provide the COVID vaccine FAQs sheet, which is available on the Ministry's website. <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 the first dose of the COVID-19 vaccine, any current symptoms, and other relevant precautions. This includes checking the consumer's age and if the consumer has presented for their second vaccination dose and it has not been 8 weeks since their first vaccination dose.</p>

Step	Action
	<p>Concomitant use with other vaccines</p> <p>Vaccines on the Paediatric National Immunisation Schedule can be given before, after or at the same time as the COVID-19 vaccination.</p> <p>Note: Third primary additional doses for immunocompromised are NOT recommended for this age group.</p> <p>The outcome of this clinical assessment must be recorded in CIR (in the medical screening section).</p> <ul style="list-style-type: none"> • If you record the consumer as medically unfit to receive the vaccine, CIR will prompt you to either cancel or reschedule the immunisation event. If the consumer is temporarily unable to receive the vaccine (that is, they are unwell today), select reschedule to ensure you can use the same CIR case record in future to capture details of the first and second doses. • Only select cancel if the consumer will <i>never</i> be able to receive the vaccine. Cancelling the event record means you cannot go back to record a first or second dose on this record in future.

Table 23.4 – vaccination process: informed consent

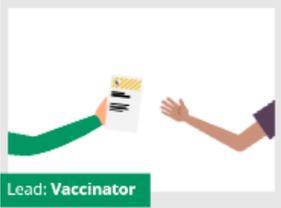
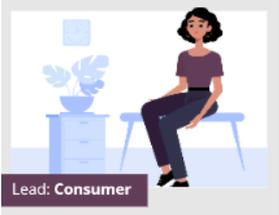
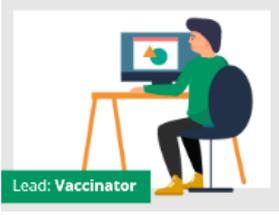
Step	Action
 <p>Lead: Vaccinator</p> <p>Obtain informed consent</p>	<p>Obtain informed consent before vaccine</p> <p>A parent, legal guardian, caregiver or person with an enduring power of attorney will need to accompany a child to their appointment(s) as the responsible adult and be able to provide consent for them to be immunised.</p> <p>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> <ul style="list-style-type: none"> • 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>Lead: Vaccinator</p> <p>Record consent in CIR</p>	<p>Consumer consent record</p> <p>The vaccinator or an administrative support person must record the consent to receive the vaccine in CIR.</p> <p>Do not vaccinate if the interval is less than 21 days.</p> <ul style="list-style-type: none"> • If the child's parent, legal guardian, or person with enduring power of attorney does not wish the child to receive the vaccine, record their decline in CIR.

Table 23.5 – vaccination process: administering the vaccination

Step	Action
 <p>Check Vaccine</p> <p>Check the Paediatric Pfizer Vaccine</p>	<p>Check the Paediatric Pfizer Vaccine is the correct vaccine for those age 5 to 11 years.</p> <p>Check:</p> <ul style="list-style-type: none"> • The label and confirm that the time after dilution (the recommended six-hour window) or the open vial expiry time (whichever is earliest) has not expired. • The vial and the 10-week expiry date. <p>Note: The Pfizer Vaccine can be administered until end of day/midnight on day of expiry</p>
 <p>Lead: Vaccinator</p> <p>Administer vaccination</p>	<p>Administer the vaccination</p> <ul style="list-style-type: none"> • Note: For children/tamariki under the age of 7 years a 16 mm length needle is recommended. For tamariki ages 7 to 11 years use your clinical judgement 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 <i>Immunisation Handbook</i>. • IMAC have clear preparation and administration guidance for this situation, including the importance of priming.
 <p>Lead: Vaccinator</p> <p>Record information</p>	<p>Record vaccination information in CIR</p> <p>Once the vaccination is complete the vaccinator or administrative support person must update the consumer's record in CIR with complete and accurate record of the vaccination event</p> <p>This enables accurate data for operational reports (such as number of vaccinations completed and other trend data).</p> <p>This must include:</p> <ul style="list-style-type: none"> • The batch and sub-batch number, for example AB1234-567 (the first part is the batch number, the second part is the sub-batch number; these are recorded on the vaccine box.) • Details of the injection site and the date and time of the vaccination event. <p>In situations where this is not possible, such as CIR being unavailable, or insufficient internet connectivity at the vaccinating location, ensure an administrative process is in place to enter information into CIR on the same day as the vaccination event. 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>Lead: Consumer</p> <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>Post-vaccination advice should be given to consumers both verbally and in writing. 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>
<p>Vaccination card</p>	<p>The vaccinator or site administrator must provide the consumer with a card to record the date/time of their vaccination and the date when they will be expected to receive their second dose.</p> <p>Note: The vaccination record card currently serves as an appointment reminder and must be provided to the consumer. Please encourage consumers to retain their record card and keep it somewhere safe or take a photo of the card.</p>
 <p>Lead: Vaccinator</p> <p>Record exit in CIR</p>	<p>Consumer exit time record</p> <p>The site administrator/vaccinator must record the time of the consumer's exit from the site in CIR.</p> <p>Any hard copy forms must be entered into CIR by close of business on the following day. Ensure any printed copies are locked away when not in use.</p>

Note: Children under the age of 12 years are not included in the vaccine mandate and therefore, do not need medical exemptions.