Operating Guidelines for DHBs & Providers

COVID-19
Vaccine Immunisation Programme

Version 42.0

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New Zealand Government

Unite against COVID-19

MINISTRY OF HEALTH
MANATŪ HAUORA

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Section A: Summary of Changes

Version	Date	Section	Summary of Changes
42.0	11/07/22		No changes

Section B: Summary of Changes

Version	Date	Section	Summary of Changes
42.0	11/07/22	Table 18.3	Wording updated for clarity Note about AstraZeneca as a booster removed

Section C: Summary of Changes

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Section D: Summary of Changes

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42.0	11/07/22	Table 26.3	Wording updated for clarity

Section E: Summary of Changes

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Section F: Summary of Changes

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Appendices: Summary of Changes

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Document Approval

National Immunisation Programme	Date	Signature
Astrid Koornneef (Director)	11/07/22	Electronic

Contents

Introduction

These Operating Guidelines provide guidance on establishing and managing a COVID-19 vaccination site, including guidelines for the vaccination workforce and how to provide a clinically safe and quality vaccination service.

Purpose

The Operating Guidelines are designed to assist District Health Boards and providers to maintain public safety and to ensure consistent and equitable COVID-19 vaccination practices are established and maintained throughout New Zealand/Aotearoa. The Operating Guidelines are to be read and interpreted in conjunction with the **Aotearoa New Zealand COVID-19 Vaccine Immunisation Service Standards (the Standards).**

The Operating Guidelines are published on the **Ministry of Health's website** for DHBs and providers. We expect regular iterations based on learnings from the delivery of the COVID-19 vaccine programme. Please ensure the most updated version is used.

Notes on guidance:

- The Operating Guidelines provide operational guidance for the COVID-19 vaccination programme. Clinical guidance is available in the Immunisation Handbook, available at: **https://www.health.govt.nz/publication/Immunisation-Handbook-2020**.
- See in particular **Chapter 2 Processes for Safe Immunisation** and **Chapter 5 Coronavirus disease (COVID-19)**.

Whakatauki

Me mahi tahi tātou mō te oranga o te katoa

We should work together for the wellbeing of everyone

Current version focus

The Operating Guidelines are designed for administering the BioNTech/Pfizer COVID-19 Vaccine (Pfizer COVID-19 Vaccine) and will be updated as other vaccine types become available and approved for administration to consumers.

Abbreviations

Abbreviation	Full Name
A&I	Adoption and Improvement
AEFI	Adverse Event Following Immunisation
BWTR	Border Worker Testing Register
CARM	Centre for Adverse Reactions Monitoring
CICS	COVID-19 Immunisation Consumer Support
CVIP	COVID-19 Vaccination Immunisation Programme
CIR	COVID-19 Immunisation Register
DHB	District Health Board
DNS	Did not show
IMAC	Immunisation Advisory Centre
IPC	Infection prevention and control
MIQF	Managed isolation and quarantine facility
Ministry	Ministry of Health
NHI number	National Health Index number
NIBS	National Immunisation Booking System (Book my Vaccine)
ULT	Ultra-low temperature (-90°C to -60°C)

Key contacts

Issue Type	When to Contact	Contact Details	Hours of Operation
IT hardware or non-CIR software issues	Logging technology hardware or software issues that aren't CIR-related	Contact your local IT ServiceDesk	Ensure after-hours support is available for sites operating outside of business hours
CIR issues	For help on using CIR Logging-in issues, password resets, or after hours help	Refer to the *Where to get help* poster*	8am-5.30pm, weekdays and weekends
Vaccine or consumables supply issues	To raise an issue with supplies	Refer to the *Where to get help* poster*	Email: 9am-5pm, weekdays Phone: 8am-8pm, weekdays and weekends
Clinical vaccine queries	To receive clinical advice on the vaccine or vaccination process	**0800 IMMUNE (466 863)**, option 1 (health professionals) and then option 2 (COVID-19 vaccinator support)	Available during site operating hours
Order vaccination collateral	To request additional pamphlets or other collateral	The DHB communications manager	
Privacy Incident or Concern	In the event of a known or suspected privacy breach	Refer to the *Where to get help* poster*	9am-5pm weekdays
Adverse Event Following Immunisation (AEFI)	Reporting an adverse reaction to the vaccine	**https://report.vaccine.covid19.govt.nz** Phone: (03) 479 7247 Email: **carmnz@otago.ac.nz**	
Interwaste vial disposal bin requests/collection	To arrange first delivery of vial disposal bin and collection of full bins	Phone: 0800 102 131	8am-5pm, weekdays
Programme Incidents	See serious adverse event process **Appendix I**	**nip.incidentnotification@health.govt.nz**	

A ***Where to get help poster is available in the Ministry's drop box for vaccination sites. The poster includes the CIR helpdesk number and email address details, and the Ministry's logistics team's contact number and email address.

Roles and responsibilities

Activity	Ministry of Health	DHBs & Providers	Group 1 Employers	IMAC	CARM	Distribution Provider
Purchasing	• Purchase vaccine from Pfizer • Purchase consumables including PPE	N/A	N/A	N/A	N/A	N/A
Distribution	• Arrange distribution of vaccine and consumables to vaccination sites/DHB facilities	• If needed, arrange secure distribution from DHB facility to vaccination site	N/A	N/A	N/A	• Thaw and repack vaccine into sub-batches as needed • Distribute vaccine & consumables
Inventory Management	• Coordinate allocation schedule • Order vaccine & consumables for DHBs	• Plan vaccine demand to minimise wastage • Report stock on hand, stock movement & exceptions • Ensure vaccine handling & storage requirements are met	N/A	N/A	N/A	• Perform QA checks on receipt of vaccine from Pfizer • Ensure secure storage of vaccine prior to distribution
Workforce & Training	• Provide guidance on workforce model and training requirements • Provide access to CIR for vaccinators & admin staff • Provide CIR support/factsheets	• Hire and roster vaccinators and required site support staff • Provide info to MoH and IMAC for user on-boarding & provision of training • Ensure staff are appropriately trained	N/A	• Provide vaccine preparation & delivery training • Provide CIR training	N/A	N/A
Site Operations	• Provide guidance on preparing and running vaccination sites • Disseminate process improvements (e.g., via updated Operating Guidelines)	• Prepare & run vaccination sites, incl. providing IT equipment and disposing waste • Work with Group 1 employers to schedule vaccinations of staff • Schedule appts for household contacts • Engage with Māori & Pacific Island partners around vaccination of household contacts	• Liaise with DHBs if vaccination site is on employer premises to ensure site is set-up and secured	• Provide clinical support to vaccinators as needed	N/A	N/A
Post-Event	• Monitoring adverse event data	• Dispose of expired, empty, or broken vaccine vials and used consumables • Pack down site as needed	• Where vaccination on employer premises, support pack down of site • Provide employee support	N/A	• Receive and investigate adverse event reports	N/A
Comms & Engagement	• Coordinate national vaccine engagement campaign • Provide key messages to DHBs to share with Group 1 employers • Engage with household contacts • Provide collateral files to DHBs/providers & distribute site banners/cards • Manage adverse event comms	• Engage with Group 1 employers re: sites & schedule • Print and circulate collateral to vaccination sites as required • Engage with household contacts	• Engage with employees re: vaccination plan	N/A	N/A	• Include 'Instructions for the Pfizer Vaccine – Preparation and Administration' info sheet in vaccine shipments
Reporting	• Produce programme and operational reporting	• Complete weekly stock on hand and stock movements reporting • Report exceptions to plan, as they occur	N/A	• Provide data on vaccinators trained to date	• Provide adverse event data to Medsafe	• Provide stock on hand and orders out reporting to MoH

Section A:
Ready to vaccinate

Section A: Summary of Changes

Version	Date	Section	Summary of Changes
42.0	11/07/22		No changes

Section guidance

This section should be read and interpreted in conjunction with **the Standards**. For onboarding sites, this section should be used alongside the Ministry's **Onboarding Guidelines**.

This section provides operational guidance, including equity, site considerations, onboarding, vaccination workforce, IPC guidance, ordering, planning, vaccine handling and storage, logistics, and site closure; to ensure consistent, equitable and quality vaccination.

Purpose

This section is designed to be applicable from the preparation of a vaccination site (from the selection and setting up of a suitable site), through to the closing of a site.

Appendices relevant to this section

- **Appendix A: Site checklist**
- **Appendix B: New facility/site setup**
- **Appendix C: Facility/site closure**
- **Appendix D: Logistics and Inventory Management**
- **Appendix E: CVIP logistic overview/ cheat sheets**

1 Equity

Providers must ensure vaccination sites are accessible to all members of the community and there is equitable opportunity for Māori and Pacific people, other ethnic communities, and disabled people.

1.1 Equitable access

Reasonable steps must be taken to improve access and reduce potential inequalities. Steps to enable equitable access may include:

- Providing access to translation and interpretation services to support the consent and immunisation processes. For more information on interpreter services see **https://www.healthnavigator.org.nz/languages/i/interpreter-services/**
- Ensuring key written material and any signage is in easy-to-read formats.
- Providing supporting literature available in a range of languages and resources/support for those who have low health literacy. This may include access to New Zealand Sign Language (NZSL) if needed.
  Note: The Ministry has prepared translations of COVID-19 vaccine information (see section **Ordering site collateral** below).
- Considering how the service delivery model caters for the support people consumers may bring to the vaccination event (such as friends, whānau, carers).
- Encouraging site staff to greet consumers in Te Reo or the language the consumer uses where possible.

1.2 Te Tiriti and Māori

Actively incorporate Te Tiriti o Waitangi considerations, including:

- ensuring Māori are not disadvantaged
- mitigating the impact to Māori as a result of COVID-19
- establishing and maintaining effective partnerships with Māori stakeholders including iwi, hapū and whānau
- seeking Māori-specific advice from the outset
- resourcing and investing where it is required the most
- starting and ending the day with a karakia.

1.3 Māori and Pacific peoples

- Ensure as far as reasonably practicable, the site workforce reflects the demographic make-up of the likely consumer group or local area.
- Consider which site locations can best meet the community's needs in terms of both ease of access and comfort or familiarity with the location (such as marae, churches).
- Where drive-in sites are planned, ensure consumers can attend the site if they do not have a car or have access to a non-drive-in site.
- Build early and regular engagement with Māori and Pacific partners into the service delivery model to ensure design to the community's needs.

1.4 Disability and/or Impairments

Ensure access for disabled consumers and others, including venue accessibility and accessible information. For more information on venue accessibility, see the **Ministry's website**. Equity steps and processes to follow include:

- Designing site support processes to support consumers with visual or hearing impairments. For example, providing a card to ask consumers advise site staff if they have a hearing impairment to ensure their needs can be met during the vaccination or any follow up interactions.
- For Deaf or hard of hearing consumers, there may be a need to arrange a New Zealand Sign Language (NZSL) Interpreter. Information on working with NZSL Interpreters can be found at **https://www.odi.govt.nz/nzsl/tools-and-resources/**
- Ensuring staff are educated in disability equity issues and know how to employ a rights-based approach. A 30-minute Disability Equity eLearn is available through the **Ministry's LearnOnline website**.
- Enabling consumers to access appropriate support and accommodations they may need for a successful vaccination, for example, are there any measures as a site or team that can be implemented to support mobility constraints, or accommodate individuals, families and whānau if a consumer has an anxiety or phobia, or may need a quiet and low stimulation environment?
- Supported decision-making is an important process for consumers needing support to make decisions. This may be due to a consumer's communication needs, learning disability, acquired brain injury, neurodiverse needs, mental health issues or other cognitive or physical condition.
- Supported decision-making is a way for consumers to make their own decisions based on their will and preferences, so they have control of their life, ensuring the consumer needing support is at the centre of decision making that concern them. Training on supported decision making is available on **IMAC's website**.

2 Site considerations

2.1 Environmental considerations and safety controls at the vaccination site

Assess the layout of the building or area identified for vaccination delivery to ensure the following features are in place supporting appropriate IPC implementation:

- Clearly marked one-way foot traffic flow, with clear entry and exit areas through the vaccination clinic; these should be separate when the vaccination area or clinic is in a health care facility.
- Adequate screening area (ideally, private spaces) at the entry where consumers are assessed, including questioning for signs/symptoms of COVID-19 and other criteria for inclusion.
- Sufficient space to allow **at least** one metre of physical distancing between all staff and individuals; including between health workers and at all stations – at the entrance, at the screening stages, while waiting to be vaccinated, and during the observation period post-vaccination.
- Adequate ventilation (mechanical, natural or hybrid) of all areas, including the screening, waiting, post-vaccination observation, and vaccination areas. Where a mechanical ventilation system is operating in these areas, the ventilation rate should be six air changes per hour or according to national or local requirements for healthcare facilities.
- A medically equipped post-vaccination observation area for dealing with possible vaccine adverse reactions.
- Adequate number of hand hygiene stations in strategic areas supporting appropriate hand hygiene for public and staff (such as, at entrance and exit areas, in the waiting areas, and in each vaccination station).
- Laminated signage/posters including reminders regarding:
  - reporting COVID-19 signs and symptoms
  - hand and respiratory hygiene
  - physical distancing (including floor markings, seating arrangements, tapes, ropes, and cones).
- Adequate space for vaccine storage and preparation – a clean and hygienic environment, with adequate ventilation and equipment to adhere to specific COVID-19 vaccine cold chain requirements.
- Vaccination stations **at least** one metre apart, ideally with installation of physical barriers between the vaccination stations.
- Adequate cleaning ability for screening areas, vaccination stations, waiting areas (such as removing items that cannot be readily decontaminated and minimising clutter to aid effective cleaning).
- Appropriate waste management systems, including safe disposal of waste (such as vials and masks) and sharps at each vaccination station (see also the **Disposal of consumables, vaccine, and vaccine packaging** section below).

2.2 Business continuity

A business continuity plan is required for each site to guide recovery from events that may interrupt service delivery such as a power failure.

Hard copies of the following forms and documents should be available on site in the event of the CIR being unavailable:

- **Consent form** (required consumer data fields that will need to be added to CIR are included on the back of the form)
- **COVID-19 Vaccine Adverse Event Report form.** This form is used to submit adverse event information to the Centre for Adverse Reactions Monitoring (CARM). If CIR is unavailable this form may be used to capture relevant information; noting on-site adverse events must in any event be reported in CIR as soon as practicable (in addition to submitting the form to CARM).
- **Reviewing early COVID-19 AEFIs** (found on the **IMAC website**)
- **Reviewing late onset AEFIs** (found on the **IMAC website**)

See the **Ordering site collateral** section below for obtaining these forms.

Note: Any hard copy forms must be entered into CIR as soon as practicable and in any event by close of business on the **following day**. Ensure any printed copies of information are locked away when not in use.

2.3 Site access and traffic management

Waka Kotahi NZ Transport Agency has provided the following advice to support site location and traffic management planning.

In addition to the considerations below, the **Waka Kotahi Journey Planner** is useful for assessing how people will safely access your sites. Similarly, regional council websites also contain valuable information about local public transport provision.

Access considerations

When choosing your location, consider how easily people might be able to access the site. For example, consider the following:

- How easily people with mobility issues can access your site
- Is a public transport stop within 500m of your site?
- Are there multiple routes and/or multiple modes of public transport within 500m?
- Does the site provide cycling or walking access?
- Is adequate parking available for people using a private vehicle?
- Are there opportunities to locate the site in place that will reduce the number of additional trips people need to make?
- Is any additional signage required to direct people to the location of the centre?
- How would consumers living in areas not serviced by public transport reach your site?
- How would a change in alert levels affect the site?

Traffic management considerations

Consider how the numbers of people receiving vaccines increases will impact the traffic network. For example, consider:

- How will the increase in road users impact vehicle congestion?
- How many different routes can consumers use to access the site?
- The impact to current levels of congestion at different times of the day.
- Is the site close to major arterial roads or state highways, which may give greater access?
- Does your site location provide easy access to public transport to mitigate impacts on road congestion?
- Are there any planned roadworks, road closures, or events that may impact access?
- Will any potential queues to your facility affect access to key services such as emergency services, health centres or schools?
- Could you provide multiple small sites instead of a few major locations servicing large numbers of people to better disperse demand across the transport system?
- Can your booking system be used to manage demand on the facility and consider peak traffic times?

2.4 Site physical security

To ensure the safety of consumers and staff, all vaccination sites should have a security presence to control access and to be available to support in the event of attempted unauthorised access, such as queue jumping to obtain a vaccination, or protest action.

Vaccinators will not require security to travel to the immunisation sites but secure parking and how vaccinators gain access to the site should be considered (such as separate access from the public).

Site security assessment

Each vaccination site must provide for:

- Staff safety
- Consumer safety
- Visitor safety
- Vaccine security including storage facilities and in-transit
- Information security – particularly paper-based information such as spreadsheets
- Contingency plans addressing a disturbance/potential protest event.

A documented risk assessment should be conducted for every individual vaccination site. This should include, but is not limited to, the following considerations:

- How will staff travel to the vaccination location?
- Will secure parking be provided for vaccinators and administrators?
- How is site access controlled?
- How is the vaccine transported to and from the vaccination site?
- How is the vaccine securely stored at the vaccination site?

- How are consumables, including items such as needles, securely stored at the vaccination location?
- How is hard copy information (if any) securely stored at the vaccination site?
- How staff respond to disruptions (such as attempted unauthorised access like queue jumping to obtain a vaccination, or to protest action).

2.5 Planning for adverse events

Some consumers who have a history of allergy or hypersensitivity, following administration of vaccines or injectable medicines, will require additional monitoring at the time of receiving their first vaccine dose. Similarly, consumers who experienced an adverse event after receiving their first dose of the vaccine may require clinical monitoring at the time of the second dose.

The Ministry expects vaccination sites to have appropriate protocols, equipment, settings, and workforce in place to support those who may require enhanced care following vaccination. Consider arranging any enhanced or additional consumer care requirements at the time of booking, or prior to these consumers attending a vaccination site.

It is recommended simulation scenarios are used to prepare staff to respond to adverse events.

2.6 Mobile vaccination set up

Mobile vaccination teams may be established to attend several different locations rather than being based at a single site. For example, this may be how vaccinations are delivered to aged residential care settings or workplaces. Mobile teams may be useful in the outreach setting with difficult to reach vulnerable families or small communities.

When setting up a mobile vaccination team, provide for the following:

- **Equipment and connectivity:** Ensure mobile vaccination teams have the required equipment, both medical equipment and technology, to enable the use of CIR onsite. Check the connectivity at the site before attending.
- **CIR recording:** Ensure the mobile team know the name of their facility and team (site) to select in CIR.
- **Planning:** Establish a location plan for the mobile team with the logistics required for vaccine stock. Ensure a record is kept of where and when the mobile team has been vaccinating.
- **Vaccine storage and transport:** All appropriate and standard cold chain requirements must be met when transporting and storing vaccine. See guidance on transporting and storing vaccine in the **Vaccine storage and handling** section below for more information.
- **Business continuity:** Ensure a business continuity plan is in place for the team to manage unexpected events and appropriately record vaccination events, such as having a stock of printed event forms on hand if access to CIR is unavailable.
- **Site readiness:** Refer to the **Site readiness and closure** section below for completing a dry run with your mobile team before commencing vaccinations.

3 Preparing the vaccination workforce

3.1 Vaccinating the workforce

Before commencing vaccinations, the Ministry recommends all vaccination site staff have an opportunity to receive a COVID-19 vaccination. This includes all staff who have contacts with consumers, from health professionals to receptionists and security staff.

3.2 Clinical leadership

Every multi-vaccinator vaccinator site should have a named lead clinician each shift. The onsite lead clinician should be an appropriately experienced clinician who is able to lead the vaccination team, manage and investigate adverse events and incidents, and provide onsite clinical advice.

3.3 Preparation and planning phase

- Appoint a facility IPC lead for the planning, deployment, and monitoring of the vaccination activities.
- Identify an adequate number of vaccinators to ensure sufficient staff and time is available to support correct implementation of IPC practices required to safely administer the vaccine.
- Identify trained staff to deliver IPC training to others involved in vaccination activities (including managers, logistical support vaccinators, cleaners and health workers dedicated to screening), and to provide information to consumers to be vaccinated.
- Identify health workers for the supervision of vaccination activities and define a monitoring and evaluation process of IPC practices, including providing feedback to vaccinators and other staff as required.

3.4 Quality and safety

There is an expectation that each DHB region has quality and safety oversight of the vaccination programme rollout through their existing quality and safety and/or clinical governance mechanisms. For clarity, this includes adverse events, complaints, and incident management. **Note:** In this context, 'adverse event' does not refer to an adverse reaction following immunisation.

3.5 Occupational health and safety requirements

Appropriate occupational health and safety policies and procedures are required for each site. This will include an accessible needlestick injury protocol which staff are familiar with.

3.6 Staff training and reference materials

Training will be provided to CIR users and vaccinators through a combination of eLearning Modules and quick step guides. The quick step guides will be available within the eLearning system, as well as within the knowledge tab of the CIR for continued availability and reference.

The eLearning modules and quick step guides include:

- Working with the COVID-19 Immunisation Register (eLearning)
- COVID-19 vaccinator education course (eLearning)
- COVID-19 vaccination for prescriber health professionals (eLearning)
- CIR quick step guides: reception, vaccination, recovery, quick adverse event, adverse event
- Inventory management (eLearning)

In addition to these training materials, staff have access to a range of reference materials. Please refer to the IMAC website for vaccinator training materials. These include:

- IMAC written resources: **https://covid.immune.org.nz/faq-resources/written-resources**. This includes COVID-19 vaccinator guidelines and instructions for preparing doses.
- IMAC video resources: **https://covid.immune.org.nz/faq-resources/video-resources**
- IMAC FAQs: available on the IMAC website at: **https://covid.immune.org.nz/faq**
- ***The Immunisation Handbook***: provides clinical guidance for administering vaccines. IMAC has also prepared a COVID-specific chapter in the Handbook. This information is updated regularly. See **https://www.health.govt.nz/publication/immunisation-handbook-2020**

See the **Ordering site collateral** section below for details regarding collateral to be given to consumers.

3.7 Access to training, CIR classroom, and CIR

Staff are required to complete the IMAC training by registering at **lms.immune.org.nz**. Users will complete CIR and/or Pfizer eLearning modules. CIR users will also be invited to attend a drop-in session where they can ask any CIR questions they may have.

To support their training, CIR users will be granted access to CIR classroom to practice using the system. To gain access to CIR classroom, the DHB or provider workforce lead must send a list of all staff requiring CIR Classroom access to the Ministry.

Once staff have completed the required training, the DHB or provider workforce lead must confirm to the Ministry that the staff member is 'approved'; the Ministry will then provide access to the live CIR environment.

Note: An organisation email address must be supplied for any CIR user to obtain access to the live CIR environment.

3.8 On site functions

The Ministry has identified the following functions for the onsite team. Note that someone with a clinical role (such as a vaccinator) may perform non-clinical functions, particularly in smaller sites.

The list below outlines the functions required to assist workforce planning. It is not intended to be a prescriptive list of all functions and expectations of different roles.

Clinical functions

- Preparing the vaccination dose
- Obtaining consent to receive the vaccination
- Asking health questions prior to administering the vaccine
- Vaccinating the consumer
- Monitoring consumers in an observation area for any adverse events
- Attending to adverse events and recording them

Staff performing clinical functions must be appropriately trained by **the Immunisation Advisory Centre (IMAC)**.

Non-clinical functions

- Greeting consumers and answering questions
- Identifying any accommodations and additional support consumers may require, such as mobility support, low sensory/quiet spaces, interpreters (including New Zealand Sign Language interpreters)
- Confirming consumer identity
- Entering consumer information into CIR
- Providing COVID-19 factsheets and FAQs
- Directing the consumer to the Privacy Statement
- Recording the vaccine details in CIR

- Advising the consumer when they can depart the observation area
- Providing the vaccination record card
- Capturing household contact information from Border and managed isolation and quarantine facility MIQF workers where this information has not already been provided
- Completing or arranging daily cleaning of the site
- Arranging collection of medical waste
- Decommissioning the site when it is no longer needed
- Providing reporting back to the ministry or DHB or provider leads as needed.

3.9 Workforce modelling

The size of the vaccination site and volume of vaccinations expected to be delivered on site will determine the size of the workforce required. The following tables outline staffing models for consideration as the vaccination workforce is planned.

Note: The framework below is only a suggestion and site workforce requirements will depend on matters such as expected site volumes, the service delivery model adopted and the likely needs of the consumers (for example, low health literacy or low English skills), more support throughout the process may be required which may in turn affect timing and resourcing.

Refer to **Appendix 4** in the ***Immunisation Handbook*** for further guidance on criteria for authorised vaccinators and minimum staff and equipment requirements for the provision of vaccination services.

Table 3.1 – activities and associated staffing

Waiting room	Immunisation event	After the event
Activity • Consumer checked in; may watch a consent video in the waiting room (~10mins)	• Consumer and vaccinator will have a clinical conversation about the vaccination and consumer will provide consent • Immunisation occurs • Administrator will enter details into CIR as the vaccinator performs the vaccination	• Consumers must remain onsite for 15 mins after the event for monitoring.
Staffing • 1 x Administrator	**Staffing** • 1 x Administrator • 1 x Vaccinator	• 1 x Registered health professional **minimum specifications in Appendix 4.2** of the ***Immunisation Handbook*.** • 1 x support person with CPR training

Based on the activities and staffing numbers above, the Ministry recommends the following site staffing numbers:

Table 3.2 – site staffing number recommendations

If 20 vaccinations/day	If 120 vaccinations/day	If 360 vaccinations/day
Staffing • **2 x vaccinators working at the site who will undertake all roles**	**Staffing** • 1 x Admin in waiting room • 3 x Vaccinators • 3 x Admin support • 1 x Vaccinator drawing up • 1 Registered Health Professional and 1 x Support person monitoring during observative period	**Staffing** • 1 x Admin in waiting room • 9 x Vaccinators • 9 x Admin support • 3 x Vaccinators drawing up • 2 x Registered Health Professionals and 1 x Support person monitoring during observative period
Note 1: If COVID-19 vaccinators are being used, there must be one (1) dedicated vaccination clinical supervisor for every six (6) COVID-19 vaccinators. **Note 2:** Dedicated vaccination clinical supervisors are not simultaneously responsible for any other roles or processes that prevent them from being immediately available while supervising COVID-19 vaccinators. **Note 3:** DHBs and providers will need to be prepared to adjust their site staffing requirements as administering the COVID-19 vaccine will likely vary from these assumptions as delivery progresses and lessons learned		

3.10 Mobile and home vaccinator workforce

For fixed sites, providers should consider the number of vaccinators and administrators that are needed for home or mobile vaccinations to ensure safety of both consumers and staff. Staff delivering home vaccination will need to meet the standards as set out in the **COVID-19 Vaccine and Immunisation Programme Service Standards** and have completed the required training.

4 Infection prevention and control (IPC)

The key IPC principles to consider and the precautions for safely delivering COVID-19 vaccines are described below. These principles and recommendations have been derived from the World Health Organization (WHO) guidance.[1] For the latest Ministry guidelines on IPC please see the following **link**.

This guidance is intended for policy makers, immunisation programmes and IPC Lead for vaccination delivery venues. This section covers the IPC measures required to support all vaccination activities, and as such, some aspects may also be covered in other sections of the operating guidelines.

4.1 Key IPC principles for COVID-19 vaccine deployment

Standard precautions to be applied during any vaccination activity are also valid for COVID-19 vaccine delivery, considering the population to be vaccinated consists of individuals **not** presenting signs and symptoms of infection.

Perform regular environmental cleaning and disinfection of areas and sites where vaccination occurs at least twice daily with special attention to high touch surfaces. Use recommended detergent and disinfectant products.

Additional IPC precautions may be necessary in the context of the COVID-19 pandemic to reduce the risk of transmission (such as PPE usage in line with IPC guidelines per the protection framework).

It is imperative health workers are provided with specific training and the public is provided with targeted information regarding IPC measures for safe COVID-19 vaccine delivery.

A clean, hygienic, and well-ventilated environment, with appropriate waste management and adequate spaces to facilitate best IPC practices (such as physical distancing) are necessary for safe COVID-19 vaccination activities.

National guidance and protocols for IPC measures should be consulted and adhered to.

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[1] Aide-Memoire Infection prevention and control (IPC) principles and procedures for COVID-19 vaccination activities, 15 January 2021. ***https://apps.who.int/iris/handle/10665/338715***

Local IPC guidance

Include the following details, when developing your local IPC guidance and standard operating procedures for COVID-19 vaccination:

- Screening policies for COVID-19 signs and symptoms for staff and consumers arriving for vaccination along with clear exclusion criteria.
- Key IPC measures to be taken by anyone in the vaccination area or clinic.
- Key IPC measures for safely administering COVID-19 vaccines.
- Cleaning and disinfection of the environment.
- Appropriate waste management, taking into consideration the increase of waste associated with COVID-19 vaccination activities. Where possible, include environmentally sound approaches to manage both general and medical waste at point of use, segregation, disposal, and collection.
- Visual reminders emphasising hand hygiene, safe injection practices, respiratory hygiene, and other IPC measures.
- Training materials for relevant staff.
- Communication material to inform and educate consumers.

IPC supplies

Ensure there is a continuous and sufficient supply of the following:

- PPE, including eye protection and long-sleeve fluid resistant gowns and gloves for the vaccination team's protection in the event of dealing with a vaccine adverse event or other incidents such as support to an unwell consumer or clean-up of body fluids.
- Other IPC supplies including alcohol-based hand sanitisers, thermo-scans for temperature screening, tissues, waste bins and bin liners, sharps disposal bins, cleaning and disinfection products, visual reminders, and signage and physical barriers to aid spatial separation.

Identify a suitable secure area for storage of supplies.

5 COVID-19 Immunisation Register

The COVID-19 Immunisation Register (CIR) is a centralised, browser-based system used to record all vaccination details. CIR uses email address, phone number and six identifiers to match consumer records with NHI records.

Once a site has joined the COVID Vaccination Immunisation Programme (CVIP), request access to CIR for vaccinators and administrators, following the process outlined below.

For any questions or support on new user onboarding, the regional account manager should be contacted.

5.1 Logging in to CIR

Access request is made to the CIR location and inventory portal by contacting the Ministry, email **help@C-19imms.min.health.nz** or call **0800 223 987**.

- To access to the live CIR Location and Inventory portal follow the link **https://ncts.force.com/cir/s/**
- Email **help@C-19imms.min.health.nz** or call **0800 223 987**, for assistance with forgotten passwords or logging in problems.

Further details regarding how to log into the CIR can be found in the quick guides, videos, and detailed training guide at **https://circlassrm-ncts.cs116.force.com/cir/s/article/CIR-Inventory-Orders-Portal-Quick-Step-Guide**.

5.2 Pre-loading immunisation event records in CIR

CIR is linked to consumers' NHI numbers, meaning any consumer with an NHI will automatically be available in CIR (they will have a CIR profile). Where consumers are in the border worker testing register (BWTR), the Ministry will extract that information to create immunisation event records (or cases) and add these to the consumer's CIR profile.

If consumers aren't in the BWTR, vaccinators or site administrators can add the immunisation event record/case to the consumer's profile on site at the time of vaccination.

5.3 Where the consumer does not have an NHI number

Where a consumer does not have an NHI in CIR, confirm the consumer is in the eligible cohort to receive their vaccine, then create a new NHI number for that consumer. If you do not have the ability to create an NHI number in Health UI, contact the Ministry contact centre on 0800 855 066 to request an NHI number be set up.

When making contact with the centre:

- Provide the payee number for the DHB or hospital
- Identify the COVID-19 vaccination clinic
- Provide the name of the consumer
- Once the NHI is created, make sure it is linked to CIR using the NHI retrieval function. Retrieving the NHI will create a person profile in CIR which can then be used to create immunisation case records as normal.

Note: It is not mandatory to collect information on the consumer's residency status when setting up new NHI numbers. Experience has demonstrated that collecting residency information can be a barrier for consumers both in their uptake and receipt of healthcare services.

5.4 Recording vaccine waste

It is important for vaccine sites to record vaccine waste in the CIR Logistics Portal, but only to the unopened vial level (the recording of vaccine wasted at the opened vial level is yet to be determined). This is so that vaccine vial waste can be tracked at a local, regional, or national level.

Further details regarding how to log into the CIR can be found in the quick guides, videos, and detailed training guide at **https://circlassrm-ncts.cs116.force.com/cir/s/article/CIR-Inventory-Orders-Portal-Quick-Step-Guide.**

See the Standard operating procedure (SOP) for inventory management on this **SOP for inventory management CIR link**

5.5 CIR support

If the site team requires CIR support, they should contact their super user in the first instance or join a drop-in session before contacting the CIR ServiceDesk.

CIR eLearning modules and quick step guides are available to all staff (see the **Staff training and reference materials** section above).

5.6 Recording in CIR

CIR reports

The CIR portal provides a centralised place for operational reporting, including demand forecast, inventory management (including stock on hand), and orders approved for sites.

These operational reports can be generated for providers by the Ministry of Health CVIP logistics customer services team and will be made available to providers in the future.

Available hard copies

Hard copies of the following forms should be available on site, in the event of CIR being unavailable:

- **Consent forms**
  the required consumer data fields that need to be added to CIR are included on the back of the form
- **COVID-19 Vaccine Adverse Event Report**
  this is the form used to submit adverse event information to CARM. In the event of CIR being unavailable, this form can be used to capture relevant information, noting that on-site adverse events must be reported in CIR as soon as practicable (as distinct from submitting the form to CARM).

See the **Ordering site collateral** section below regarding obtaining these forms.

6 Logistics

6.1 Logistics

The Ministry will maintain the COVID-19 Immunisation Register (CIR) logistics module to support ongoing monitoring of inventory and demand. **Appendix D** shows the current process for distributing the vaccine to vaccination sites. **Appendix E** provides CVIP logistics overview/ cheat sheets.

Logistics support

The Ministry provides two levels of customer support.

- Level one is the Ministry's IT helpdesk.
  The helpdesk deals with log-in and access issues and can be contacted by emails: **help@C-19imms.min.health.nz** or by phone on **0800 223 987**.
- Level two is the CVIP logistics customer services team.
  This team can assist with support for order placing and approval, inventory management, and use of the CIR inventory portal. Once the vaccination site has been onboarded, contact details for this team will be provided.

Quality Assurance Approval Step of Orders

Supplier orders made by Inventory users at a DHB level will be sent to their Quality Assurance (QA) user to be reviewed and approved before being sent to the Ministry for approval. The QA user can add and remove products from the order as well as edit the quantity of these products in the order. The QA user can also reject the order or accept the order. Accepting the order will send it through to the Ministry's Logistics team for approval. Each DHB and Provider using the inventory portal will need to have dedicated QA users to review these orders. If a supplier order is created by a QA user, it will go straight to the Ministry's logistics team for approval.

Further detail about how to log into the CIR can be found in the quick guides, videos, detailed training guide on **https://circlassrm-ncts.cs116.force.com/cir/s/article/CIR-Inventory-Orders-Portal-Quick-Step-Guide**

7 Equipment ordering and demand planning

7.1 Ordering IT equipment

Provide the IT requirements, outlined in table 7.1 below, at vaccination sites to ensure staff can access the COVID-19 Immunisation Register. Before starting vaccinations, ensure all IT equipment has been tested, and all staff have received the necessary training to use the devices and CIR. Advise each site team where they can access additional IT support (for non-CIR issues such as hardware issues), including after-hours support if your vaccination site is operating outside standard business hours.

Table 7.1 – IT requirements

Requirement	Details
Network	• A secure network (Wi-Fi, hard wired, or 4G) with connectivity to the device running CIR, and to the user's mobile phone or computer. • Site Wi-Fi specifications: Coverage ranging to reception, vaccination and waiting areas Highly available network (such as fibre and 4G backup)
Internet Browser	• Chrome is the recommended internet browser. Other browsers support CIR, but Internet Explorer is not supported (use Microsoft Edge if needed). For further information see: **https://help.salesforce.com/articleView?id=sf.getstart_browsers_sfx.htm&type=5**
Computer or Tablet Device	• Any laptop from the last five years should be compatible with CIR providing it has the appropriate browser access. • For further information see: **https://help.salesforce.com/articleView?id=sf.getstart_browser_recommendations.htm&type=5**
Mobile Phone	• CIR users require an iOS or Android mobile phone to download the Salesforce Authenticator application. This can be downloaded from the App Store on iOS and the Play Store on Android. • You can scan the QR code on the right to locate the Salesforce Authenticator app in the relevant App Store.

COVID-19 Tracer App QR codes

The Ministry recommends using posters that have a site-specific COVID-19 vaccination Tracer App QR code.

- QR code posters can be created using the current **self-service webform**.
  More information about QR code posters is available on the **Ministry's website.**

7.2 Ordering personal protective equipment (PPE)

Table 7.2 – information required when ordering PPE

Details	Process
• **PPE provided will be based on the current COVID-19 Alert Level settings**	• Order via the existing PPE portal via HealthCare Logistics or Onelink
• **Healthcare providers should hold contingency stock of PPE which can be used in the event of Alert Level changes**	• If you are a new provider or currently do not hold contingency stock, please contact **COVID.healthsupplychain@health.govt.nz** to discuss your requirements

7.3 Ordering site collateral

The Ministry has prepared the following collateral to support the vaccination programme. Files will be shared with DHB communications managers via an existing All of Government (AoG) Dropbox or via a Ministry weblink. These can then be printed and supplied to sites.

Translations are now available in the following languages on the Ministry's website; additional languages will be added:

- Māori
- Hindi
- Samoan
- Simplified Chinese
- Tongan
- Cook Island Māori
- Fijian
- Tagalog
- Niuean
- Tokelauan

IMAC has also prepared a consent video which can be displayed in site reception areas if desired. This video is available on the **IMAC website**.

Note: A translator may be arranged to be available on site to assist consumers who speak languages other than English, including New Zealand/Aotearoa Sign Language. See the **Equitable access** section above for more information about translators.

Table 7.3 – site collateral ordering and purpose

Collateral	Purpose	How to Order
COVID-19 Vaccine Information and Consent Pack, which includes: • **Getting your COVID-19 Vaccine: What to Expect** • **Consent form** • **After your immunisation** • **Privacy statement**	To share with consumers on site or before attending the vaccination site	Contact the DHB communications manager
COVID-19 Vaccine FAQs	To provide answers to FAQs	Available on the **Ministry's website**
Vaccination record card	To provide appointment information after the consumer has been vaccinated	The Ministry will arrange distribution of physical cards to sites.
Household contacts of Border workers form	To collect household contact information on site (only to be used if consumers cannot access the online form or 0800 number)	Contact the DHB communications manager
Consent form (which includes fields to capture required consumer data)	For use if CIR is unavailable	Contact the DHB communications manager
COVID-19 Vaccine Adverse Event Report	To provide information, and to enable accurate record keeping	Available on the Centre for Adverse Reactions Monitoring (CARM) website: **https://report.vaccine.covid19.govt.nz**
Vaccine Error Reporting Form	To enable accurate record keeping	Contact the DHB communications manager
Pull-up banners for site (2 designs: 'Vaccinations here' and 'Protecting our people')	To be displayed on site	The Ministry will arrange distribution of banners to sites.
Teardrop flag for outside site	Visibility to consumers	The Ministry will arrange distribution of flags to sites.
COVID-19 vaccine posters (A3/A4 size)	Provide information to consumers	Contact the DHB communications manager
Large vaccination site poster (A0 size)	To provide information simply and quickly	The Ministry will arrange distribution of these large posters to sites.
Instructions for the BioNTech/Pfizer COVID-19 Vaccine – Preparation and Administration	For vaccinators and staff on site	Included in vaccine shipments and are available on the **IMAC website**.
'Where to get help' poster	To provide information simply and quickly	• Contact the DHB communications manager • Also available via the CIR homepage

7.4 Vaccine ordering/demand planning

Table 7.4 – site and facility set up for vaccine delivery

Information required	Details	Process
Site and facility set up information	• Site and facility information must be provided to the Ministry five (5) days in advance of any initial deliveries.	• Use the **New facility site set up form (found in Appendix B)** to submit site or facility details • Return the completed form via email to **help@c-19imms.min.health.nz**

Table 7.5 – demand planning

Information required	Details	Process
Demand plan – appropriate to cater for the upcoming four weeks	• The plan should represent the expected number of vials to be consumed each day, in each location, for the upcoming four-week period. • The plan should be maintained at the facility level on the vial's product. • 21 days of demand forecast must be loaded for a location to place an order.	• Upload and maintain the plan in the CIR Inventory Portal using the demand upload functionality. • Please update forward forecasts on a weekly basis.

7.5 Ordering Interwaste vial disposal bins

As part of site preparations, Interwaste must be contacted to arrange the delivery of an Interwaste vial disposal bin (see the **Disposal of consumables, vaccine, and vaccine packaging** section below).

Contact Interwaste on 0800 102 131 (business hours) as soon as the site is approved. Provide at least five business days' notice before the container is required to arrive.

Interwaste will collect the relevant details such as the site manager's name and contact details, the delivery date for the first container, and the site delivery address information.

7.6 Ordering other Ministry supplied consumables

Table 7.6 – other consumables

Information required	Details	Process
Order for other consumables (such as sharps bins, bio bags for waste disposal, or 21G 38mm needles)	• This stock will be shipped through a standard courier network, expect delivery between two and four days from the time of order.	• Order consumables via the CIR Portal.
Order for other individual items (such as boxes of plasters).	• This stock will be shipped through a standard courier network, expect delivery between two and four days from the time of order.	• Order consumables via the CIR Portal.

7.7 CIR and inventory management

The COVID-19 Immunisation Register (CIR) provides a centralised place for vaccine and consumables orders, managing stock on hand (SOH), arranging transfers, and recording consumption and wastage of unopened vaccine vials.

The CIR inventory module is where movement (transactions) and use of stock is managed and recorded. (The term inventory is used to describe how much product or stock (in this case vaccine and consumables) is at a location at any point in time.) These records provide effective stock management at each location, ensuring optimum use – and minimum wastage – of vaccines and consumables.

The Ministry's logistics team will continue to monitor demand and allocation using data from CIR along with information provided by DHBs or providers. DHB and provider logistics leads must supply daily reporting (as required) on:

- Stock on hand (daily stock takes)
- Stock movements, including ordering, transfers, wastage, consumption, and stock adjustments
- Stock consumption
- Stock waste
- Quarantine of and repacking of stock.

The Ministry's logistics team will liaise with logistics leads to collect this information through an agreed mechanism.

DHBs or providers may wish to collate daily reporting back from sites on inventory and/or operations to aid the supply of information back to the Ministry.

Please contact your regional liaison if you have feedback on the immunisation process or recommendations for operational improvements.

7.8 Operational reporting

DHBs or providers need to report significant events on sites such as a significant adverse reaction, or a protest to the Ministry on a daily basis.

8 Vaccine storage and handling

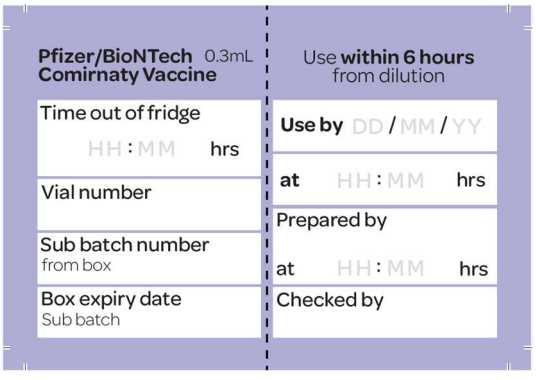
8.1 Vaccine security

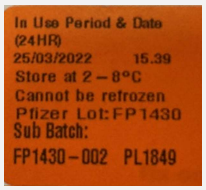
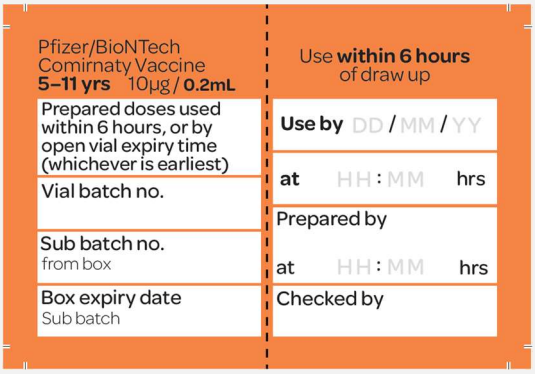
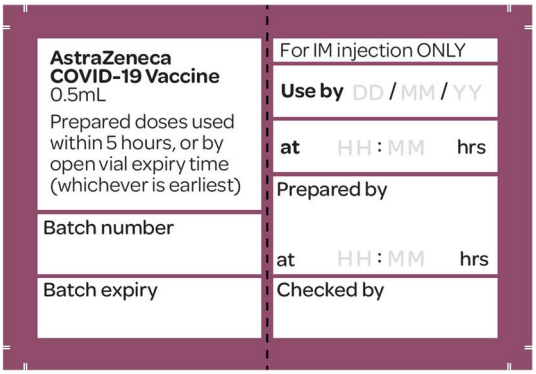
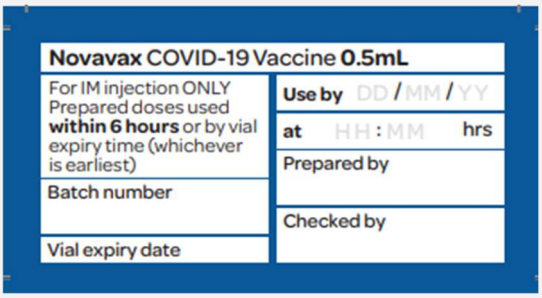
To ensure the security of the vaccine, the following minimum standards must be met:

- Vaccines must be stored in a work area that has the constant presence of an authorised person (such as an administrator, or security guard or vaccinator) during the hours of operation.
- If the vaccine is to be stored overnight at the vaccination site, the building should be in a controlled-access environment (such as Maritime Port or MIQF).
- If the building is not in a controlled-access environment (such as a community hall), the building should be able to be secured and have a monitored alarm.
- In the event of the vaccines being stored at a vaccination site without controlled access and not a building (such as a tent), an overnight onsite security guard must be present.

8.2 Differentiation of Vaccines

Syringe labels have been introduced to help differentiate between vaccines as per the table below. A roll of 500 stickers can be ordered as a standalone product through the CIR inventory.

Syringe Labels	
Syringe Label for the Pfizer Adult Vaccine (12+ years)	

Syringe Label for the Pfizer Paediatric Vaccine (5-11yrs) **Note:** the sub-batch labels on the box for the Paediatric Vaccine (5-11year olds) is also orange to assist with differentiation.  	
Syringe Label for the AstraZeneca Vaccine	
Syringe Label for the Novavax Vaccine	

8.3 Cold chain storage

All facilities must hold cold chain accreditation as per the ***National Standards for Vaccine Storage and Transportation for Immunisation Providers* 2017** (the National Standards). The cold chain accreditation expiry date and back up fridge for each facility must be recorded in the CIR.

Vaccine must be stored and transported in cold chain accredited conditions. The Ministry requires any individuals responsible for handling the vaccine to have completed the appropriate cold chain training.

Further information on cold chain management is available in **section 2.1** of the ***Immunisation Handbook***. See also the manufacturer's specifications for approved product handling, available at: **https://www.medsafe.govt.nz/profs/datasheet/c/comirnatyinj.pdf**.

See shelf life of vaccines in the table below. Storage should protect from light.

Table 8.1 – vaccine shelf life of vaccines

	State	At +2°C to+8°C	At ambient temperature
Pfizer (12+yrs)	Undiluted	**Up to 31 days** after removal from the ULT freezer. **Note:** Please always follow the 'in-use' expiry date label on the vaccine box. Vaccines can be administered on day of expiry (up to midnight). Please note the expiry date on **the vial** is only relevant to ULT freezer storage. Transportation time at +2°C to +8°C is included in the 31-day limit.	**Up to 2 hours** (up to 30°C including any breaches above +8°C that occur during storage in the vaccine refrigerator)
	Diluted	**Up to 6 hours**	**Up to 6 hours** (up to 30°C)
Paediatric Pfizer (5-11yrs)	Undiluted	**Up to 10 weeks** after removal from the ULT freezer. **Note:** Please always follow the 'in-use' expiry date label on the vaccine box. Vaccines can be administered on day of expiry (up to midnight). Please note the expiry date on **the vial** is only relevant to ULT freezer storage.	**Up to 2 hours** (up to 30°C) **Note:** there is up to 12 hours allowed however, keeping it at 2 hours as a precautionary measure to align with the 12+ Pfizer
	Diluted	**Up to 12 hours in vial** (or until the end of the day it was prepared on)	**Up to 6 hours when drawn up into syringe or by time written on the vial (whichever is earliest)** (up to 30°C) **Note:** there is up to 12 hours allowed however, keeping it at 6 hours as a precautionary measure to align with the 12+ Pfizer
AstraZeneca **DO NOT DILUTE**	Unopened	**Up to 6 months** Please check the box label for expiry date. Or if opened 48hrs cumulative storage time. **DO NOT FREEZE.**	**Up to 12 hours** (up to +30°C) including unforeseen excursions from refrigerated storage (2°C – 8°C) for a single period. **Note:** Return unopened vials to the refrigerator (at 2°C to 8°C) following an unforeseen temperature excursion. **Note: 72 hours** (down to -3°C) including unforeseen excursions from refrigerated storage (2°C – 8°C) for a single period.
	Opened/ Punctured	No more than **48 hours** cumulative storage time.	No more than **5 hours** (up to +30°C) **Note:** 5 hours is the recommended time at room temperature as a precautionary measure as it is a **6 hour** cumulative storage period. Any vaccine remaining in vials or syringes must be discarded after six hours.

				Also, the total cumulative storage time must not exceed 48 hours.
Novavax	**DO NOT DILUTE**	Unopened	**Up to 9 months**	**Up to 6 hours** (up to 25°C)
		Punctured vial or drawn up syringe	**Up to 6 hours**	**Up to 6 hours** (up to 25°C)

8.3.1 Process for Refrigeration Failure or Temperature Excursion.

In the event of refrigeration failure which results in a temperature excursion of the vaccine, follow the steps below.

Table 8.2 – refrigeration failure procedure

Step 1	
Label the vaccines 'not for use' and in the event:	
• The refrigerator is currently running within the +2°C to +8°C range, the labelled vaccines are to be retained in your refrigerator.	• The refrigerator is not within the +2°C to +8°C range, reversible causes should be considered (door open, power interruption). If no cause found, the labelled vaccines are to be packed into a chilly bin, with a temperature monitoring device and transported to the nearest back-up provider (details for this are in your cold chain policy and in the CIR).

Step 2	
Contact your local immunisation coordinator for advice and further actions.	
• Email is monitored from 8.30am to 5.00pm weekdays or contact the Clinical Advice line on **0800 IMMUNE (466 863)** for guidance up to 8.00pm weekdays or on weekends.	• Northern: Lisa Box (**lisa.box@auckland.ac.nz**) • Midland: Olivia Haslam (**Olivia.Haslam@auckland.ac.nz**) • Central: Melanie Miller (**Melanie.Miller@auckland.ac.nz)** • Southern: Sue Rogers (**Sue.Rogers@auckland.ac.nz**)

Step 3
Document the steps and actions taken.

8.4 Movement of vaccine

Vaccine can be moved around a vaccination facility carefully if required (for example, walking vaccine from one floor to another within a facility if required carefully is acceptable, but running with it is not). Avoid any unnecessary movement or handling.

The vaccine must not be shaken at any stage of transportation, preparation, or administration.

Note: If vials are dropped, or there is another reason for concern about whether the vaccine is still viable, contact **IMAC for advice on 0800 IMMUNE (466 863),** option 1 (health professionals) and then option 2 (COVID-19 vaccinator support).

8.5 Repacking vaccine at DHB facilities

Re-packing only applies to Pfizer vaccines that come in different size packs.

- **Who can re-pack vaccines?**
  Only a DHB hospital pharmacy department can repack the vaccine packs down to distribute to a vaccinator or site. This function is actioned under their hospital pharmacy licence and only able to do so for supply within their DHB. In this circumstance, DHB means within the DHB legal entity.
- **Who cannot re-pack vaccines?**
  DHB hospital pharmacy departments are not able to re-pack the vaccine packs for supply to providers outside of their DHB.
- **What if a hospital pharmacy is required to repack the vaccine packs?**
  The DHB hospital pharmacy department will need a packing licence issued to them by Medicines Control.

8.6 Transportation of vaccine to other locations

8.6.1 Permissible Stock Movement

Sites who have received their vaccine stock from a DHB Pharmacy can contact the pharmacy to organise a stock movement. The DHB Pharmacy can move whole packs, under their wholesale license. Note: all movements must comply with the **National Standards for Vaccine Storage and Transportation for Immunisation Providers 2017**.

This has significant resource implications for the DHB Pharmacy therefore tight stock management is important to minimise waste, and if a stock transfer is necessary please plan ahead to provide maximum time to support DHB Pharmacy processes.

A provider may take their own vaccine offsite for outreach/home visiting purposes. All cold chain requirements must be met.

No other transportation of vials is permissible.

8.6.2 Restrictions on Transport Durations

For Pfizer (aged 12+ years) vaccine:

The total allowable transit time of an unopened vial is at 2°C to 8°C is **12 hours**. This includes the original transit from our warehouse to you, and any further transport the vial undertakes after that.

For Paediatric Pfizer (age 5 to 11 years) vaccine:

There is no limit on the transit time of an unopened vial of the Paediatric Pfizer vaccine transported at 2°C to 8°C however, normal shelf-life limits apply.

For AstraZeneca vaccine:

Where possible, transport the vial at 2-8°C. Providing cold chain has been maintained and the shelf life of the vaccine is not affected, there is no limit on travel time.

Opened vials may travel by car as long as the transportation time does not exceed 30 minutes and the other vaccine storage requirements outlined in Table 8.3 (and stated on the product label) are satisfied.

For Novavax vaccine:

There is no limit on the transit time of an unopened vial of the Novavax vaccine transported at 2°C to 8°C however, shelf-life limits apply.

Please note:

- Transit time limits for all vaccines when transporting different types together.

8.7 Transportation of diluted or drawn-up vaccine

8.7.1 Transportation of pre-drawn syringes

The syringes must be appropriately labelled (content, volume, batch, and expiry).

8.7.2 Bulk preparation of pre-drawn syringes

The bulk preparation of pre-drawn vaccine to be transported to another location is regarded as compounding and is not permitted unless it is undertaken in an approved facility (such as a hospital pharmacy aseptic unit, or a third-party commercial compounder) with appropriate checks, documentation, and regulator audit.
Note: diluted Pfizer vaccine can be in transit for up to six hours at 2°C to 30°C.

8.7.3 Transport time is Included in Storage Limits

In all circumstances for Pfizer (12+ years Pfizer), any hours used for transportation counts against the six-hour expiry limit for storage for undiluted vaccine at 2°C to 30°C.

Note: Microbiological risks and package integrity, particularly for prepared dosing syringes, are the responsibility of the preparer during transportation of diluted vaccine.

9 Vaccine ordering and delivery

9.1 Vaccine ordering

9.1.1 Inventory order

Vaccine stock (inventory) can be ordered using the CIR in two ways:

- Direct from the national distribution hubs using a supplier order (see section below),

  or

- From another vaccine site using a **transfer order** (see section below).

See the Standard Operating Procedure (SOP) for order fulfilment at this **SOP for order fulfilment CIR link**

9.1.2 Supplier order

This is an order where the stock will come directly from a national distribution hub and the order must be approved by the Ministry's team. Users must be associated with a location to place a supplier order.

Further details regarding how to log into the CIR can be found in the quick guides, videos and detailed training guide at this **link**.

See the Standard Operating Procedure (SOP) for order fulfilment at this **SOP for order fulfilment CIR link**

Cancelling orders

Orders can be cancelled before they are approved by the Ministry. This is to allow corrections to an order that might be incorrect or orders that are no longer required.

9.1.3 Transfer orders

This is a transfer between two locations. It is used routinely to transfer stock between DHB Hospital Pharmacies and mobile vaccination sites. For fixed vaccination sites, the transfer order process is only used for surge/back-up transfers for delivery from DHB Hospital Pharmacies, or end of day returns between two locations. Users must be associated with a location to place a transfer order.

See the Standard operating procedure (SOP) for inventory management on this **SOP for inventory management CIR link**

Table 9.1 – ordering information required

Details	New Process
• **Each site will be allocated a day of the week for delivery. High volume sites may have more than one designated delivery day per week** • **Vaccine orders must be submitted before 10am the day before your allocated delivery day.** • **For the Pfizer Vaccine: a facility should consider the size of the packs they are ordering and their ability to break down packs to avoid unnecessary vaccine movement or wastage.**	• Vaccine orders must be made through the CIR inventory portal. • The CIR inventory portal will only allow orders for deliveries on the allocated delivery day(s). • If an order is **not placed before** 10am the day before your allocated delivery day, the DHB will need to submit a request for an 'out-of-cycle' delivery to the Ministry's CST Logistics Desk.

9.1.4 Vaccine delivery schedule

- **How often will I receive vaccine deliveries?**
  The frequency will depend on your typical volume and frequency. For example, a site with higher volumes can receive more regular shipments while lower volume sites or sites only operating on one day a week may choose to receive only one shipment per week.
- **Can my delivery schedule change?**
  The schedule will be discussed and agreed with DHBs or providers and can be reviewed when required.
- **What if I miss the cut off (by 10am the day before) for ordering vaccines?**
  If you need to order vaccine urgently prior to your next designated delivery day, notify your DHB and they will need to send an 'out-of-cycle' delivery request to the CST Logistics Desk.
- **Where will the vaccine be shipped to?**
  To the location agreed with the DHB or provider.
- **How will I know what vaccines I am due to receive?**
  Each site receiving shipments from the Ministry will receive a notification containing details of the amount of vaccine and/or consumables due to be delivered the following day.
- **What if I don't receive a shipment when I am expecting one?**
  Delivery tracking will be managed centrally by the Ministry. Please contact the Ministry's logistics customer services team.
- **What support can the designated receiver expect?**
  There is a 30-minute call made to the designated receiver to support the delivery process.

9.1.5 Vaccine Unit sizes and Dimensions

	Unit Size	Unit Dimensions
Pfizer Adult (12+years)	Full tray (195 multidose vials)	290mm x 290mm x 40 mm
	15 multidose vial pack	130mm x 130mm x 45mm
	5 multidose vial pack	130mm x 65mm x 45mm
Paediatric Pfizer (15-11 years)	10 multidose vial packs	84mm x 37mm x 37mm
Astra Zeneca	10 multidose vial packs	137mm x 53mm x 53mm
Novavax	10 multidose vial packs	92mm x 36mm x 62mm

9.1.6 Consumables Kits

There are two kits available based on the size of the vaccine order

- Kit 1 for 100 doses
- Kit 2 for 700 doses

Table 9.2 – consumable kits

Item	Material number	Notes	100 Dose Kit	700 Dose Kit
Nipro 25G Standard Needle (supplied by DHL)	1170095	Drawing-up needle for saline – 1 syringe per vial dilution	20 (partial pick)	200 (2 cartons)
BD 3 mL Syringe	1165009	Drawing syringe for saline – 1 syringe per vial dilution	20 (partial pick)	100 (1 carton)
Vernacare LDS Needle	1165446	Administering needle – 1 per dose	100 (1 carton)	700 (7 cartons)
Unifix 1 mL Syringe	1169565	Administering syringe – 1 per dose	100 (1 carton)	700 (7 cartons)

Table 9.3 – order as required

Item	Purpose	Carton size
Biohazard Yellow Bags	Disposal of waste	50
Sharps Containers – 15 L (5 pack)	Disposal of sharps	5 x 15L
Antiseptic Swabs	Vial disinfectant	200
Non-Woven Swab	Swab	100
Dermaplast Sensitive Injection Plaster	Plaster	250
10 mL Saline (1.8mL per vial)	Diluent	100 x 10mL
SOL-M 1ml syringe + 25Gx16mm needle	Administration needle for smaller arms	100
Vernacare LDS Blue Needle 23G 38mm Pk/100	Administration needle for larger arms	100

Table 9.4 – consumables kits sizes and weights:

Kit Type	Carton Size	Carton Weight
Kit 1 – 100 dose kit – via HCL	250 x 250 x 200mm	1.6kg
Kit 2 – 700 dose kit – via HCL	455 x 305 x 305mm	6.4kg
Kit 1 – 100 dose kit – via DHL	255 x 250 x 250mm	1.57kg
Kit 2 – 700 dose kit – via DHL	520 x 290 x 385mm	6.405kg

Table 9.5 – AstraZeneca

Item	Material number	Carton size
MOH-Flu+ Syringe 0.25-1ML 25Gx1"	1165003	200

Table 9.6 – Novavax

Item	Material number	Carton size
BD Flu Plus 0.1-1mL and 23G 1" LDS needle	1173501	200

9.2 Delivery to sites

Figure 9.1 – delivery security

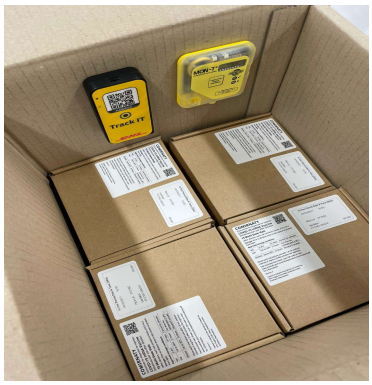
 **Warehouse/distribution provider**	 **DHB facility or vaccination facility**	 **Vaccination site**
Role of the Ministry	**Role of DHB**	**Vaccine handover**
The Ministry will arrange secure transportation of the large quantities of vaccine from the vaccine distribution provider to the cold chain storage facility (such as DHB facility or vaccination site) using a Ministry-contracted courier and security firm.	• If the vaccine is transported to a DHB cold chain storage facility, secure transportation of the vaccines from that facility to the vaccination sites becomes the responsibility of the relevant DHB or provider. • In the event vaccines are to be transported from a local facility to the vaccination site, the unique circumstances of such transportations should be considered in the site risk assessment. • In the event couriers or authorised personnel (such as vaccinators, administrators, or security) are conducting the transport, the Ministry recommends there should be direct travel to the vaccination site (that is, no transit points).	**Note:** There should be a local procedure in place to ensure the person responsible for transporting the vaccine can be identified. This is to ensure the DHB, or provider has complete confidence they are handing over the vaccine for delivery to the appropriate person. There is no requirement for the person to be a vaccinator.

Shipper boxes that may be used for transportation from warehouse/distribution provider

Credo Cube

Cool Green Cell

Please note the placement of the MonT2 temperature tracking device used in the shipping box is now placed on the side of the box beside the TrackIT temperature logger (see below):



9.2.1 Delivery temperature and expiry dates

Check the sub batch label on the box for the expiry date of the vaccine.

9.2.2 Vaccine stock/inventory management

- Stock should be used on a **first to expire first out** (FEFO) basis, to ensure waste due to expiry is minimised.
- If there is any concern that a site has excess stock, this should be reported to the DHB who can arrange redistribution.
- Sites should hold two weeks of stock cover.

Process

Site stock on hand should be managed through the CIR Inventory.

1. Once stock is delivered to a site:
    - Check and verify batch details against details on the order record. Report any discrepancy to the CVIP logistics team.
    - Mark stock as receipted in the CIR Inventory once the site has accepted the stock
2. A physical record should also be kept of any vials consumed or wasted
3. Check the vial and 31-day removed from ULT expiry dates:
    - During the preparation of doses and document this on the drawn-up doses label
    - Before administration of the vaccine
    - At the end of the day check stock
4. Discard any expired vaccines and record this as waste in the CIR Inventory (see section '**Recording vaccine waste**').
5. Any consumption and wastage must be recorded in the CIR Inventory daily.
6. Once consumption is recorded in the CIR Inventory, all remaining stock on site must be checked against the stock showing in the CIR Inventory to ensure that there are no discrepancies.

7. Any discrepancies must be investigated and captured in the CIR Inventory as stock adjustment.

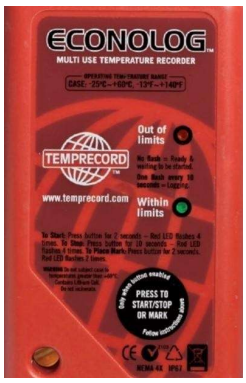
For more detail see the Standard operating procedure (SOP) for inventory management on this **SOP for inventory management CIR link**

Table 9.5 – site delivery and receipt process

Step	Action
 **DHB/provider logistics lead provides site contact and delivery details**	**Site checklist** The site checklist must be completed prior to the site commencing vaccinations (see **Appendix A**).

	Site contact
	• The DHB or provider logistics lead must provide the Ministry with:
	  ○ a site contact (a named role and a phone/mobile number)
	  ○ detailed delivery instructions, including address and any special instructions (such as separate entrances and so on).
	• Submit this information using the New facility/ site set-up form (**Appendix B**) *at least 5 days prior* to ordering vaccines for that site.

	Availability of site contact • The site contact should be regularly available on site to accept deliveries. This will minimise the administration involved changing the site contact person, for example. • Please notify **urgent** site contact changes to the Ministry's logistics team.
	Cold chain accreditation • The Ministry recommends individuals handling vaccines are cold chain accredited; however, this is not a requirement.
 **Vaccine distribution provider packs and ships vaccine**	**Ship under cold chain conditions** • The vaccine distribution provider will pack and ship the vaccine under cold chain conditions in shipping boxes, depending on delivery destination, at +2°C to+8°C.
 **Site contact receives the package**	The courier will hand the package to the site contact. Before signing for the package, the site contact will: • Confirm the shipping box is addressed to them/their site • Provide their identification to the courier for the courier's confirmation • Conduct a check of the order immediately while the courier is present (see below)

Step	Action
 **Site contact checks the temperature logger**	**Check for a temperature excursion** The site contact must check the temperature datalogger included in the shipping box to confirm whether a temperature excursion has occurred in transit. The site contact must follow the process below: • Retrieve the temperature logger immediately • Do not attempt to stop the temperature logger • Check the temperature logger as soon as you remove it before any other action (such as removing vials). Checking the temperature datalogger needs to happen immediately as the box containing the vials is opened.
If the temperature datalogger shows: **Green light** flashing once every 10s • The temperature has remained within limits **Red light** flashing once every 10s • Excursion has occurred	**Temperature excursion** When an excursion occurs, a photo should be taken of the datalogger showing the excursion and emailed to the Ministry's logistics team. ***Quarantining a shipment*** Where an excursion has occurred, the site contact must quarantine the shipment in cold chain conditions while the logger is returned to the vaccine distribution provider for reading. The site contact must call the Ministry's logistics team.
 **Note:** A tick in the area indicated means the temperature has remained within limits. A cross means that a temperature excursion has occurred.	**Temperature excursion – next steps** The Ministry's logistics team will talk the site contact through the actions to be taken, such as urgent orders being placed and what will happen once the temperature data has been read.


Site contact conducts visual check
	Visual check
	• The site contact will open the shipping box and the internal vaccine packaging and conduct a visual check of the outer packaging to check for damage and/or leakage. If there is no damage store directly in the fridge.
	• Each site should check the packing slip to make sure all vaccines have been received
	• If there are any signs of damage to the outer container, inspect the vials inside the package:
	  • Broken vials or waste needs to be recorded in the CIR logistics module, but only to the unopened vial stage
	  • Vaccine wasted in opened vials is not required to be recorded in the CIR logistics module.

Step	Action
	• Please see the **Standard Operating Procedures** in the **Inventory orders** section regarding how to record vial consumption and waste.
 **Site contact signs for vaccine package**	**Vials intact** • Where the vials are intact and there are no concerns, the site contact will sign for the package.
 **Site contact stores vaccine in cold chain accredited conditions**	**Store vaccine** The site contact will then store the vaccine at cold chain conditions in the internal packaging carton it arrived in (not the *Credo Cube/Cool Green Cell* box, but the white vaccine box) until the expiry date and time marked on the vaccine box is reached. Any vials no longer viable must be disposed of following the disposal process detailed below.
 **Receipting orders**	When a vaccine or consumables order is received, it must be receipted into the CIR. This enables the movement of the stock from in transit to available for use in the stock on hand. Further details regarding how to log into the CIR can be found in the quick guides, videos, and detailed training guide at **https://circlassrm-ncts.cs116.force.com/cir/s/article/CIR-Inventory-Orders-Portal-Quick-Step-Guide.** See the Standard Operating Procedure (SOP) for order fulfilment at this **SOP for order fulfilment CIR link**

Equipment returns

Table 9.6 – temperature monitoring, *Shipping boxes* equipment return

Details	Process
***Shipping* boxes and temperature monitoring equipment should be returned in a timely manner – preferably on the same day as receipt – to ensure there are no interruptions of subsequent vaccine deliveries.**	• Pre-paid stickers will be included with the delivery for returns. • The number on the instructions should be called to arrange collection. • Any fault or damage to the packaging equipment should be reported at the time of return. • **Note:** Ensure correct removal or crossing-out of the original courier label and original address details to avoid any confusion.

Table 9.7 – daily reporting information required

Vaccination events	Significant events	Stock on hand / stock movements
• Sites must ensure vaccination events are recorded in CIR at the time of administration. This enables accurate data for operational reports, such as number of vaccinations completed and other trends.	• Providers need to report significant events on sites such as a significant adverse reaction, or a protest to the Ministry daily as required.	Providers must ensure the following information is recorded in the CIR inventory portal daily as required: • Facility stock on hand • Stock movements from facility to facility • Stock movements from facility to site

Table 9.8 – asset management recommended practice

Recommended practice	Details
Collation of site inventory and operations	DHBs or providers may wish to collate daily reporting back from sites on inventory and/or operations to aid the supply of information back to the Ministry.
Demand planning	Maintain a 4-week forward demand plan.
Continuous process improvement	The Ministry welcomes feedback on the immunisation process or recommendations for operational improvements. Please contact your regional liaison to pass on your feedback

9.3 Reports available to DHBs

- **What information is available in reports?**
  As the COVID-19 vaccine reporting is linked to the NHI database, requesting any existing NHI data fields (such as ethnicity) to track vaccination rates and meet other reporting needs is valid.
- **How do I request reports?**
  Contact your DHB or provider reporting team, who will then submit your request to the Ministry's reporting team.
- **Where can I find my reports?**
  Once the report is prepared, it will be available in CIR as both a dashboard and downloadable report.
- **Will my reports be refreshed?**
  Reports will be updated in real-time.
- **What if I want reports for multiple DHBs?**
  Please specify this at the time of requesting the report.

9.4 Vaccine and consumables assets and asset management

An asset is an instance of vaccine stock and vaccine consumables, such as: five pack of vaccine, 15 pack of vaccine, 195 pack of vaccine, or consumable kit.

Assets at a location can be updated through:

- Stock re-work
- Stock adjustment
- Quarantine stock
- Recording consumption, or
- Stock on hand.

Further details regarding how to log into the CIR can be found in the quick guides, videos, and detailed training guide at **https://circlassrm-ncts.cs116.force.com/cir/s/article/CIR-Inventory-Orders-Portal-Quick-Step-Guide.**

See the Standard operating procedure (SOP) for inventory management at this **SOP for inventory management CIR link**

Recording consumption

It is important to record the consumption of vaccine stock and consumables as stock in consumed or, as a minimum, as part of the daily stocktake. The purpose of this is to give an accurate local, regional, and national view of vaccine stock on hand.

Consumption can be recorded in two ways:

1. Consumption – entering directly what has been consumed
2. Stock on hand – entering a physical count of the stock on hand as part of the daily stock take

Further details regarding how to log into the CIR can be found in the quick guides, videos, and detailed training guide at **https://circlassrm-ncts.cs116.force.com/cir/s/article/CIR-Inventory-Orders-Portal-Quick-Step-Guide**.

See the Standard operating procedure (SOP) for inventory management at this **SOP for inventory management CIR link**

Recording vaccine waste

It is important for vaccine sites to record vaccine waste in the CIR Logistics Portal, but only to the unopened vial level (the recording of vaccine wasted at the opened vial level is yet to be determined). This is so that waste can be tracked at a local, regional, or national level.

Further details regarding how to log into the CIR can be found in the quick guides, videos, and detailed training guide at **https://circlassrm-ncts.cs116.force.com/cir/s/article/CIR-Inventory-Orders-Portal-Quick-Step-Guide.**

See the Standard operating procedure (SOP) for inventory management at this **SOP for inventory management CIR link**

10 Disposal of consumables, vaccine, and vaccine packaging

Vaccine disposal and other inventory management topics (outlined below) are available as eLearning modules.

10.1 Disposal of consumables

DHBs and providers are responsible for the disposal of consumables. Consumables should be disposed of according to existing procedures (such as disposal into sharps bin and/or biohazard bags). Local procedures are to be followed to arrange collection of the sharps bin and other medical waste.

10.2 Disposal of damaged, empty, and expired vaccine vials

When a possible cold chain breach occurs providers must contact their immunisation coordinator before disposing of any vaccines as per the **National Standards for Vaccine Storage and Transportation for Immunisation Providers 2017**.

The process for destruction and disposal of expired vials is as follows:

1. Remove the lid
2. Deface the vial
3. Place the vial(s) in the Interwaste vial disposal bin
4. Record the wastage in the CIR Inventory

As part of site preparations, Interwaste must be contacted at least 5 business days in advance of your site going live to request a vial disposal bin to be delivered to the site. Contact Interwaste on 0800 102 131 (their call centre is available from 8am-5pm weekdays). For more information see the **Ordering Interwaste vial disposal bin** section above.

Interwaste will provide a 20-litre sized container in which to dispose expired (full), empty, broken, or damaged vials. Please note, expired vials should be defaced before disposal. When the container is almost full, contact Interwaste on 0800 102 131 to arrange its pick-up. Interwaste will deliver a new disposal container at the same time they remove the existing container. Interwaste will destroy the vials in an appropriate manner.

Ensure the lid of the Interwaste disposal container remains closed when not in use.

Figure 10.1 – disposal bin

10.3 Disposal of vaccines drawn up but not administered and empty vaccine syringes

Vaccine doses that have been drawn up but not administered must be disposed of in the sharps bin provided. Similarly, empty/used vaccine syringes should be disposed of in the sharps bin. Seal and remove sharps bins when filled and stored in a secure area for transportation and final disposal

Manage sharps waste as per NZS 4304:2002 *Management of Healthcare Waste*.

10.4 Vaccine packaging disposal

Ensure all packaging that the vaccine is sent in is appropriately destroyed to ensure packages cannot be replicated.

Once all vials in a packet have been used, black-out all vaccine-related information on the label, using a permanent marker. The vaccine box must be securely destroyed. It can be disposed of in a secure document destruction bin if one is available or a biohazard bag. Packaging must not be disposed of in household waste collection or recycling centres. If additional biohazard bags are required, please advise Ministry logistics when placing the next consumables order.

11 Site readiness and closure

11.1 Site setup form and site checklist

Complete the site checklists included in **Appendix A** to assess whether the vaccination site is ready to commence vaccinations. Site checklists, upon completion, must be signed by the DHB or provider chief executive, or their delegate, to approve the site is ready. The checklist is then submitted to either the regional account manager or the Ministry's logistics team. Primary care providers may be asked to submit site checklists to their DHB rather than the Ministry directly.

The new facility/ site set up form (v1.4) form (see **Appendix B**) must be submitted ***at least five days prior*** to the site commencing vaccinations. This information is used to set up the facility or site in CIR and ensure deliveries are made to the correct address. Care is required to provide accurate information on this form.

11.2 Completing a dry run

The Ministry recommends a site trial or dry run before beginning vaccinations on site to ensure staff are familiar with their roles and consumer flow can be tested. The Ministry's logistics team do not provide dry run packs however, an optional order of consumables can be ordered from the Ministry's logistics team which can be used to complete a dry run.

11.3 Facility/site closure form

Complete the **facility/site closure form** (see **Appendix C)** as a part of the site and facility closure protocol, and to assess and return stock.

A stocktake of all consumables relating to the COVID-19 Vaccination Rollout must be completed upon site/facility closure. Submit the completed facility and site closure form to the Ministry's logistics team and your DHB logistics Lead. This should be submitted a week before the closure or as soon as the closure of the location is known.

11.4 Site moving location

If a site needs to move their physical location, the site closure and the new site set-up will be required in order to ensure quality assurance meeting the cold-chain accreditation standards. This includes:

- Complete the **Site Closure Form** and associated procedures.
- Complete the new **Site Set-up Form** and **associated procedures** which will allow the site to be set up in the CIR for delivery to the new address.
- Cold chain accreditation for the new location must be assessed and approved.

The only circumstance where vaccines can be delivered to an alternative address to that already set up in the CIR, is where it is delivered to the nominated address for cold chain back-up in the CIR.

12 Becoming a COVID-19 Vaccination site

12.1 Onboarding

Becoming a COVID-19 vaccination site can be complex, involving engagement with both your local DHB and/or PHO and the Ministry. To ensure consumer safety, vaccination sites will need an appointed Clinical Site Lead to navigate the onboarding process. The Clinical Site Lead is accountable for meeting **clinical safety and quality standards** at their site, as well as supporting **planning, clinical governance, quality, and safety management** processes.

Primary Care providers are a critical component of the New Zealand COVID-19 vaccination rollout.

The Ministry-prepared Primary Care Onboarding Guide provides simple step-by-step guidance on how to become a COVID-19 vaccination site. Specifically, the guide incorporates:

- A sequential view of the steps required to set-up a COVID-19 vaccination site
- Links to supporting documents for each step of the process
- Contact details for support and assistance for each step of the process
- A simple checklist to track progress.

12.2 Additional resources

The following supporting documents found on the Ministry's website sit alongside the Primary Care Onboarding guide:

- **Technology, User Roles, and Training Matrix**
- **User Onboarding Journey for Book My Vaccine** (also known as NIBS)
- **User Onboarding Journey for COVID-19 Immunisation Register (CIR)**

Section B: BioNTech/Pfizer COVID-19 Vaccine

Pathway to vaccination

Section B: Summary of Changes

Version	Date	Section	Summary of Changes
42.0	11/07/22	Table 18.3	Wording updated for clarity Note about AstraZenica as a booster removed

Section guidance

This section provides operational guidance on the vaccination pathway for the BioNTech/Pfizer COVID-19 Vaccine, from booking and scheduling to vaccine preparation onto vaccine administration and observation. The first line vaccine where there are no contraindications is the Pfizer vaccine. The AstraZeneca vaccine is available as second line vaccine for consumers who meet the eligibility criteria.

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 ***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)

13 Booking and scheduling

Arrangements for the booking and scheduling of Group 1 consumers, including household contacts, will take place at the DHB or provider level. This will include booking and scheduling appointments for consumers to receive their second dose of the BioNTech/Pfizer COVID-19 Vaccine. This should also include rescheduling second dose visits, if required, and providing a mechanism for people to reconfirm their appointment time (for example, if they lose their record card).

It is a requirement that electronic booking systems are used by providers to book consumer vaccination appointments alternatively consumers can book appointments via Whakarongorau Aotearoa on 0800 28 29 26. Where a provider (including general practice, hauora providers, urgent care (primary care/hauora providers) and community pharmacy) does not have an operational electronic booking system, the provider must book appointments through the National Immunisation Booking System (NIBS).

While providers with existing electronic booking systems may continue to book vaccination appointments through their own electronic booking systems, they may choose to opt-in to the NIBS. The Ministry will support NIBS onboarding and training for providers planning to use the NIBS.

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

- Affected persons under the Vaccinations Order
- Vaccinating Household Contacts
- National Immunisation Booking System (NIBS)

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.

13.1 Booking second doses

Do not vaccinate less than 21 days
• The administration of the BioNTech/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. • In the context of the current Delta outbreak, the Ministry recommends receiving the second dose as soon as practical after the minimum 21 days. • New bookings made through bookmyvaccine.nz and the COVID-19 Vaccine Whakarongorau Aotearoa 0800 28 29 26 is set to three weeks between the two doses. • If consumers have existing vaccination bookings, they can keep their second appointment as it is, or choose to change it. Either way the important thing is that consumers receive two doses of the vaccine to be fully vaccinated. • Doses can be booked for any time after day 21.

Administering leftover vaccines

To minimise wastage, the Ministry recommends the preparation of a back-up/stand-by list of consumers aligning to the sequencing framework. Leftover diluted and/or drawn vaccine unused at the end of the shift that would expire before the next clinic, may be administered to consumers on the back-up/stand-by list.

The Ministry does not require visibility of the back-up/stand-by list; use best judgement to manage this list as to align with the sequencing framework.

14 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 Ministry 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 the 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 DHB or provider privacy officer or contact the Ministry'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.

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

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. A CARM report does not need to be completed if the vaccine has been prescribed by an authorised prescriber. 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 public health risk and current COVID-19 Alert Level settings.

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

Vaccination Practice in COVID-19 Alert levels

Generic risk mitigations for vaccination sites (applicable to any Alert level) can be found in **Appendix J.**

Vaccination practice variation according to COVID-19 Alert level changes can be found in **Appendix K**. All guidance will be regularly reviewed. This should be read in conjunction with COVID-19 Readiness Plans, **Community Response Framework (PDF, 422 KB)** and **Primary care quick reference guide.**

16 Vaccinating consumers aged 12 to 15 years

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

16.1 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.

Interaction with other vaccines

If possible, the COVID-19 vaccination should be given 7-days before or after administering the live-attenuated shingles vaccine (Zostavax). Other vaccines on the 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

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 consumer has an opportunity to have any questions answered and concerns addressed.

17 Pfizer Preparation of doses

The BioNTech/Pfizer COVID-19 Vaccine 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**.

- **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.

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.

Once the vaccine has been diluted, it **must be administered within six hours**. Any prepared doses not used within this time period must be discarded. Prepared doses cannot be transported to other sites.

Before preparation check:

- it is the right vaccine
- the 'in-use' **expiry date label on the vaccine box**. Vaccines can be administered on day of expiry (up to midnight)

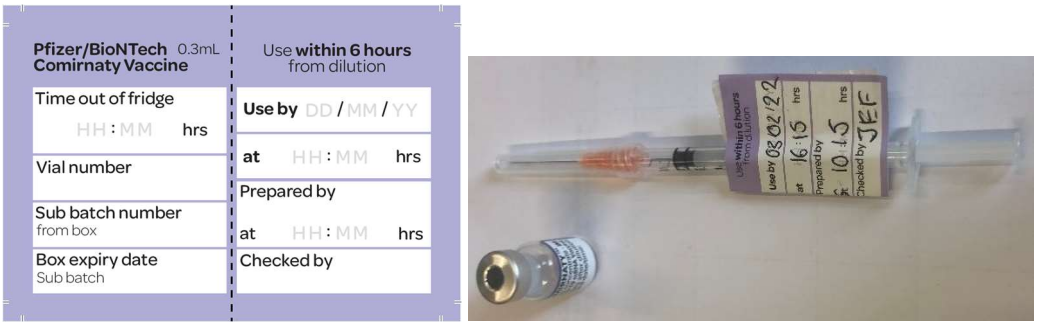
Number the vaccine vial and enter the number into the vaccine log. Second person also checks that the correct vaccine has been selected, by confirming the product name on the vial and checking the expiry date printed on vial by manufacturer. Second person also checks the numbering of the vial and documents these checks by signing/initialling the vaccine log.

For quality and safety purposes, after diluting the vaccine, it is recommended that all doses are drawn after dilution and each vial and/or syringes, are labelled with the:

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

Syringe labels have been introduced to help differentiate between vaccines.

- The syringe label for Pfizer Adult Vaccine (12+ years) and an example on how the label could be used is below:



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

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. 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.

Note: During the preparation of the vaccine both expiry dates must be double checked. This includes the vial and the 31-day removal from ULT expiry date. Vaccines can be administered until the end of the expiry day.

17.1 Number of doses per vial

The expected number of doses from each vial remains at six, but there is technically enough vaccine in a vial to draw up seven doses using LDS needles. It is safe to use the vaccine in the seventh dose providing you are totally confident that you have measured the saline correctly for dilution, that each dose of vaccine has the full 0.3mls, and that you are drawing up and giving the vaccine using the same needle as instructed.

To avoid the Pfizer 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.

Note: Incorrect volume of diluent may be detected by identifying you have drawn up less than six or more than seven 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.

For more information on vaccine policy statements and clinical guidance, refer to the **Ministry's website**.

18 Pfizer Vaccine administration and observation

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 COVID-19 Vaccine Administration' on the **IMAC website**.

Table 18.1 – pre-vaccination greeting and verify identity

Step	Action
 **Greet consumer, conduct COVID-19 health check**	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*. **Please note:** • 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-19are a household contact and are advised to go home and follow the specific advice public health advice for testing. • 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 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. • If a provider wishes to vaccinate a higher risk consumer (someone who answered yes to the screening questions), providers should follow the 'vaccination in high-risk or screen 'positive' consumers' section in the Operating Guidelines.

 **Verify consumer's identity**	The vaccinator/site administrator will also verify the consumer's identity using name, DOB, address, and locate their record in CIR. This should be done in a private and confidential manner and should not be overheard or viewed by other consumers. Check the consumer's DOB and confirm age. If underage do **not** vaccinate. • Check with the consumer to ensure they are eligible for their vaccine today. **Note:** Photo ID is not required to confirm the consumer's identity.

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

Table 18. 2 – pre-vaccination provide collateral

Step	Action
 **Provide collateral**	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. • You may also choose to provide the COVID vaccine FAQs sheet, which is available on **the Ministry's website.** You may also display the privacy statement in the reception area as well as supplying the information in hard-copy.

18.1 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.

Table 18.3 – vaccination process: pre-vaccination clinical assessment

Step	Action
 **Complete a pre-vaccination clinical assessment**	**Pre-vaccination clinical assessment** 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 that the consumer is not underage or if the consumer has presented for their second vaccination dose and it has not been 21 days since their first vaccination dose. **Interaction with other vaccines** If possible, the COVID-19 vaccination should be given 7-days before or after administering the live-attenuated shingles vaccine (Zostavax). Other vaccines on the National Immunisation Schedule can be given before, after or at the same time as the COVID-19 vaccination. **Vaccine booster** If the consumer has presented for the adult Pfizer vaccine booster, they must meet the eligibility criteria in the **Programme's Booster Vaccination Policy Statement**. The outcome of this clinical assessment must be recorded in CIR (in the medical screening section). • If recording the consumer as medically unfit to receive the vaccine, CIR will prompt 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 *never* be able to receive the vaccine. Cancelling the event record means it will not be possible to go back to record a first or second dose on this record in future.

Table 18.4 – vaccination process: informed consent

Step	Action
	**Obtain informed consent before vaccine** The vaccinator (or vaccinator support person) must obtain the consumer's informed consent to receive the vaccine prior to the administering of the vaccine. Where appropriate, consent may be given by a proxy such as a guardian or person with power of attorney.

Step	Action
Obtain informed consent	• **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.
 **Record consent in CIR**	**Consumer consent record** The vaccinator or an administrative support person must record the consumer's consent to receive the vaccine in CIR. Do not vaccinate if the interval is less than 21 days. • If the person does not wish to receive the vaccine, record their decline in CIR.

18.2 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 CIR the consumer's consent to approve or decline the administration of the 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 forms do not need to be uploaded to CIR; rather, the provider is responsible for ensuring the forms are archived as a part of that consumer's clinical record.
- If written consent forms are unable to be archived in the consumer's clinical record, then this must be uploaded onto CIR. Once this is complete the record can be destroyed.

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. Any supported decision-making conversations should be

documented in the notes section of CIR. 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**.

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 required if it is the provider's or vaccinator's preference, and like with all consumers, must be obtained if there is significant risk of adverse effects.

18.3 Prescription

A prescription from an authorised prescriber is required when a vaccine is being administered off-label in accordance with **Section 25 of The Medicines Act 1981** (that is, when a Medsafe approved medicine is being used for an un-approved use) and the administration is not authorised under section 34A of the Medicines Act 1981, that 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. The prescription and written consent form can be uploaded in the CIR.

18.3.1 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.

If providers choose to upload written consent forms the person uploading, for example the administrator, must scan each form to their computer, locate the consumer's CIR record, then upload the scanned form/s to the consumer's CIR record; delete the local copy and securely destroy the written form. When necessary, the written form may be kept for a few days or weeks to check for inaccuracies in transcribing before the written forms are destroyed.

Note: Instructions for uploading files to CIR are included in the CIR eLearning module.

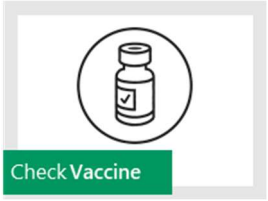
18.3.2 Variations to consent forms

As of 6 May 2021, there is now only one Ministry of Health consent form (the Group 1a version m has been withdrawn). This is available via the Ministry's Dropbox.

Where a variation of the Ministry's consent form is used, it must still include the standard information, *please let your vaccinator know* bullet points and the *informed consent* declarations.

- **Note**: Modified consent forms must be submitted to the Ministry for review and approval before making it available for use.

Table 18.5 – vaccination process: administering the vaccination

Step	Action
 **Check the Pfizer Vaccine**	**Check the Pfizer Vaccine** Check: • Vaccine syringe label and confirm that the time after dilution (a six-hour window) has not expired • The box expiry date on the syringe label • The amount of reconstituted vaccine in the syringe **Note:** The Pfizer Vaccine can be administered until end of day/midnight on day of expiry
 **Administer vaccination**	**Administer the vaccination** Before administering the vaccine verbally check the vaccine type with the consumer. Please refer to the '7 Rights of COVID-19 Vaccine Administration' on the **IMAC website**.**Note**: Use your clinical judgement to determine if a longer needle is required (38mm). 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.*** IMAC have clear preparation and administration guidance for this situation, including the importance of priming.

Step	Action
 **Record information**	**Record vaccination information in CIR** 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 This enables accurate data for operational reports (such as number of vaccinations completed and other trend data). This must include: • 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 box. • The batch number and expiry date for the diluent (these are found on the diluent vial/ampoule). • Details of the injection site and the date and time of the vaccination event. 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.

Table 18.6 – vaccination process: after vaccination

Step	Action
 **Consumer waits 15 minutes in observation area**	**Observation** 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. If a consumer is required to wait 30 minutes the vaccinator should record this on the CIR so that the staff member observing is aware. 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.** For further information on post vaccination, see **section 2.3** in the ***Immunisation Handbook***.

Step	Action
Vaccination card	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. **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. Once the vaccine course is complete the consumer can download their vaccine pass, some consumers may need support to complete this.
 **Record exit in CIR**	**Consumer exit time record** The site administrator/vaccinator must record the time of the consumer's exit from the site in CIR. If the consumer insists on leaving early the Site Clinical Lead must be notified and discuss this with the consumer to understand possible implications. A note should be added to the CIR to document the consumer leaving early and the advice given. 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.

18.4 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.

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***.

Active monitoring: Post Vaccine Symptom Check

As part of the pharmacovigilance activities for the Pfizer Vaccine, the Ministry is conducting active monitoring for side effects after vaccination. This is called Post Vaccine Symptom Check and will be sent to up to 25% of consumers (or their caregiver). This is being rolled out for booster doses in adults, and the 5-to-11-year age group for the primary course.

The Post Vaccine Symptom Check, enquiring if the consumer has experienced side effects since the vaccination, is via an SMS text-based survey to a randomly selected sample of the vaccinated population. The consumer can reply YES or NO – or STOP should they wish to opt out of the survey. Where the consumer replies with YES, a unique and secure link to a mobile-friendly survey form that will capture the side effect/s experienced is sent.

- Post Vaccine Symptom Check will provide additional understanding of the vaccine side effects. The results will be published on the Medsafe website.

18.5 Consumers' record of vaccination

Consumers should be supplied with a COVID-19 Vaccination record card detailing the vaccine administered and the date their second 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.

My Vaccine Pass

My Vaccine Pass is a domestic vaccination certificate for consumers to access places in Aotearoa New Zealand that require proof of vaccination status. Consumers can request the My Vaccine Pass through the **My Covid Record** website or calling 0800 222 478.

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**.

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

Section C: Summary of Changes

Version	Date	Section	Summary of Changes
42.0	11/07/22		No changes

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 ☐ N ☐
Vaccinators administering the Paediatric Pfizer vaccine must complete the Paediatric COVID-19 Vaccinator Education Course (IMAC link)	Y ☐ N ☐
Child safe Environment	Y ☐ N ☐
SOP preparation of Paediatric Pfizer doses	Y ☐ N ☐
Child friendly resources (distraction posters can be found on the IMAC website)	Y ☐ N ☐
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 ☐ N ☐
Paediatric Pfizer (age 5 to 11 years) collateral	Y ☐ N ☐
Dry Run	Y ☐ N ☐
Wet Run	Y ☐ N ☐

19 Booking and scheduling

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

19.1 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.**

20 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**'.

21 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

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.

22 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. That used syringes will not be put back with 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

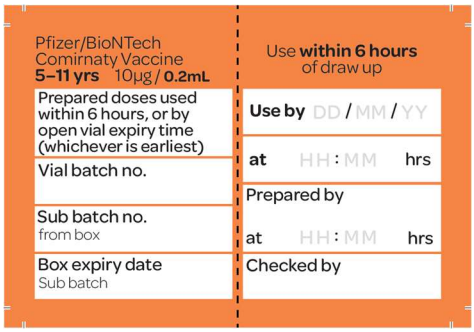
also cross checks the numbering of the vial and documents these checks by signing/initialling the vaccine log.

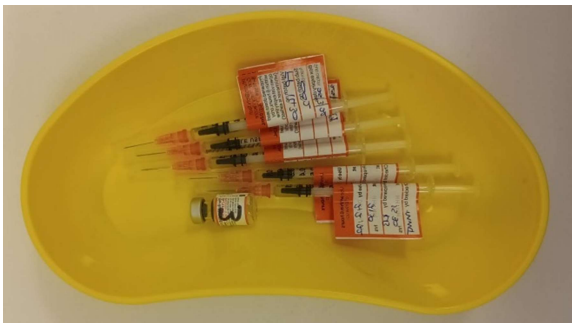
For quality and safety purposes, after diluting the vaccine, it is recommended that each vial and/or syringes (made from that vial), are labelled with the:

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

Syringe labels have been introduced to help differentiate between vaccines.

- The syringe Label for Pfizer Paediatric Vaccine (5-11 years) and an example on how the labels could be used is below:





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.

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

The Medsafe data sheets confirms ten (10) doses per vial however, there is technically enough vaccine in a vial to draw up eleven (11) doses using Low Dead Space (LDS) syringes. It is safe to use the vaccine in the 11th dose providing that you are totally confident that you have measured the saline correctly for dilution, that each dose of vaccine has the full 0.2mLs, and that the drawing up and administration of the vaccine uses the same needle as instructed.

LDS syringes are to be used with the Paediatric Pfizer vaccine. If LDS syringes are not available for use, contact IMAC on 0800 466 863 for advice.

To avoid the Paediatric Pfizer 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. Any vial where doses drawn up are less than ten (10) or more than eleven (11) in number, 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 CIR as per guidelines and reported as an incident in the local organisation's quality and safety reporting system.

23 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'**. Please refer to the '7 Rights of COVID-19 Vaccine Administration' on the **IMAC website**.

Table 23.1 – pre-vaccination greeting and verify identity

Step	Action
 **Greet consumer, conduct COVID-19 health check**	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*. 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. 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. **Please note:** • 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-19are a household contact and are advised to go home and follow the specific advice public health advice for testing. • 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 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. • If a provider wishes to vaccinate a higher risk consumer (someone who answered yes to the screening questions), providers should follow the 'vaccination in high-risk or screen 'positive' consumers' section in the Operating Guidelines.
 **Verify consumer's identity**	The vaccinator/site administrator will also verify the consumer's identity using name, DOB, address, and locate their record in CIR. This should be done in a private and confidential manner and should not be overheard or viewed by other consumers. Check the consumer's DOB and ask their age. If underage (i.e., under five years of age) do **not** vaccinate. • 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. **Note:** Photo ID is not required to confirm the consumer's identity.

*****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
 **Provide collateral**	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. • You may also choose to provide the COVID vaccine FAQs sheet, which is available on **the Ministry's website.** You may also display the privacy statement in the reception area as well as supplying the information in hard copy.

Table 23.3 – vaccination process: pre-vaccination clinical assessment

Step	Action
 **Complete a pre-vaccination clinical assessment**	**Pre-vaccination clinical assessment** 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. **Note:** Please refer to the '**COVID-19 Vaccine for Children Aged 5-11 years Policy Statement**'. **Concomitant use with other vaccines** Vaccines on the Paediatric National Immunisation Schedule can be given before, after or at the same time as the COVID-19 vaccination. **Note:** For severely immunocompromised individuals please see the '**COVID-19 vaccine third primary dose**'. The outcome of this clinical assessment must be recorded in CIR (in the medical screening section). • If recording the consumer as medically unfit to receive the vaccine, CIR will prompt 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 *never* be able to receive the vaccine. Cancelling the event record means it will not be possible to go back to record a first or second dose on this record in future.

Table 23.4 – vaccination process: informed consent

Step	Action
 **Obtain informed consent**	**Obtain informed consent before vaccine** 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. 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

Step	Action
	person with an enduring power of attorney prior to administration of the paediatric vaccine. • **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.
 **Record consent in CIR**	**Consumer consent record** The vaccinator or an administrative support person must record the consent to receive the vaccine in CIR. Do not vaccinate if the interval is less than 21 days. • 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

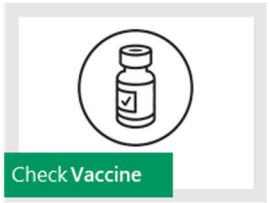
Step	Action
 **Check the Paediatric Pfizer Vaccine**	**Check the Paediatric Pfizer Vaccine is the correct vaccine for those age 5 to 11 years.** Check: • Syringe label and confirm that the time after dilution (the recommended six-hour window) or the open vial expiry time (whichever is earliest) has not expired. • The box expiry date. **Note:** The Pfizer Vaccine can be administered until end of day/midnight on day of expiry
 **Administer vaccination**	**Administer the vaccination** Before administering the vaccine verbally check the vaccine type with the consumer. Please refer to the '7 Rights of COVID-19 Vaccine Administration' on the **IMAC website**. **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 ***Immunisation Handbook***. IMAC have clear preparation and administration guidance for this situation, including the importance of priming.
 **Record information**	**Record vaccination information in CIR** 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 This enables accurate data for operational reports (such as number of vaccinations completed and other trend data). This must include: • 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 can be found on the vaccine box. • The batch number and expiry date for the diluent (these are found on the diluent vial/ampoule). • Details of the injection site and the date and time of the vaccination event. 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.

Table 23.6 – vaccination process: after vaccination

Step	Action
 **Consumer waits 15 minutes in observation area**	**Observation** 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. If a consumer is required to wait 30 minutes the vaccinator should record this on the CIR so that the staff member observing is aware. 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.** For further information on post vaccination, see **section 2.3** in the ***Immunisation Handbook***.
Vaccination card	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. **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. Once the vaccine course is complete the consumer can download their vaccine pass, some consumers may need support to complete this.
 **Record exit in CIR**	Consumer exit time record The site administrator/vaccinator must record the time of the consumer's exit from the site in CIR. If the consumer insists on leaving early the Site Clinical Lead must be notified and discuss this with the consumer to understand possible implications. A note should be added to the CIR to document the consumer leaving early and the advice given. 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.

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

Section D: AstraZeneca COVID-19 Vaccine

Section D: Summary of Changes

Version	Date	Section	Summary of Changes
42.0	11/07/22	Table 26.3	Wording updated for clarity

Pathway to vaccination

Section guidance

This section is read in conjunction with Pfizer Vaccine section. This section provides additional operational guidance on the AstraZeneca 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:

- Approved for use for people aged 18 years or over
- AstraZeneca COVID-19 Vaccine **does not need** to be diluted on site
- There are 10 doses per vial

The Ministry recommends vaccination to everyone of eligible age in Aotearoa New Zealand. The first line vaccine where there are no contraindications is the Pfizer vaccine. The AstraZeneca vaccine is available as second line vaccine for consumers who meet the eligibility criteria. A prescription from an authorised prescriber is required when using the AstraZeneca vaccine as a booster dose or dose 2 of their primary course (i.e., following a non-AstraZeneca COVID-19 vaccine for dose 1), in accordance with **Section 25 of The Medicines Act 1981**, as it is considered off-label use. Written consent is required for all consumers receiving a dose of the AstraZeneca vaccine. This Programme requirement will be regularly reviewed.

This section is designed to be applicable to sites delivering the AstraZeneca 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***, **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)

24 Booking and scheduling

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

24.1 Booking second doses

Do not vaccinate less than 28 days
• **The administration of the AstraZeneca COVID-19 Vaccine at an interval of less than 28 days is not approved by Medsafe and is considered off-label use and must be reported to CARM.** • **New bookings made through bookmyvaccine.nz and the COVID-19 Vaccine Whakarongorau Aotearoa 0800 28 29 26.** • **Doses can be booked for any time after day 28.**

25 AstraZeneca Operational phase

- Please see the section Pfizer Operational phase for detailed information
- Ensure the appropriate processes are in place to prevent vaccination of people under 18 years– **this is a never event**.
- Ensure the appropriate processes are in place to prevent second dose vaccinations earlier than 28 days – **this is a never event**.

Note: A prescription from an authorised prescriber is required when using the AstraZeneca vaccine as a booster dose or a second primary dose (i.e., following a non-AstraZeneca COVID-19 vaccine for dose 1), 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. A CARM report does not need to be completed if the vaccine has been prescribed by an authorised prescriber.

Written consent is required for all consumers receiving a dose of the AstraZeneca vaccine. This Programme requirement will be regularly reviewed.

26 AstraZeneca Preparation of doses

The AstraZeneca COVID-19 Vaccine does **not need to be diluted,** please follow the instructions provided by IMAC. These instructions are included in vaccine shipments and available on the **IMAC website**. **Note:** These instructions are regularly updated. Please ensure you are using the most recent version.

Each multi-dose vial contains 10 doses of 0.5mL.

Once the vial is opened/punctured the AstraZeneca Vaccine can be stored at **2°C-8°C** and must be used within **48 hours**. Opened/punctured vials must be returned to the fridge. Any vaccine not used within this time period must be discarded. Vaccines should be prepared as close to administration as possible, ideally as needed.

If multiple vaccines are needed, there is an option to draw up several doses from the vial, but they must be used within **5 hours** and can be stored either in the fridge or at room temp (**max. of 30°C**). Any vaccine not used within this time period must be discarded.

The AstraZeneca vaccine is fragile and must not be shaken during preparation. The AstraZeneca vaccine **does not** need to be at room temperature prior to administration. Some liquid may remain in the vial after withdrawing the final dose. The leftover vaccine must be discarded.

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.

Before preparation check:

- it is the right vaccine
- manufacturer's vaccine expiry date

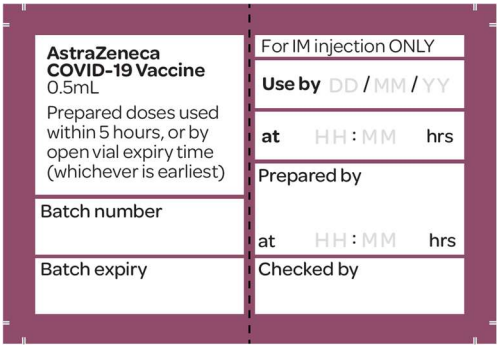
Number the vaccine vial and enter the number into the vaccine log. Second person also checks that the correct vaccine has been selected, by confirming the product name on the vial and checking the expiry date printed on vial by manufacturer. Second person also checks the numbering of the vial and documents these checks by signing/initialling the vaccine log.

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

Syringe labels have been introduced to help differentiate between vaccines.

- The syringe Label for the AstraZeneca Vaccine and an example of how the labels could be used is below:



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**.

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

26.1 Number of doses per vial

Incorrect volume of vaccine may be detected by identifying you have drawn up less or more than 10 from a vial. Should this occur, quarantine, and discard all doses from that vial. If it is unclear why the error has occurred contact IMAC for clinical guidance. This error must be documented as waste in CIR and reported as an incident in the local organisation's quality and safety reporting system.

The **Vaccine Use and Waste Policy Statement Version 2.0** has been updated to reflect the introduction of AstraZeneca as a second line vaccine into the Programme and to record that the rate of wastage of AstraZeneca will be higher than for Pfizer.

27 AstraZeneca Vaccine administration and observation

This section outlines the administration of the AstraZeneca vaccine. Please read this section with the Pfizer section above. 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 COVID-19 Vaccine Administration' on the IMAC website.

Table 26.1 – pre-vaccination greeting and verify identity

Step	Action
 **Greet consumer, conduct COVID-19 health check**	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*****. **Please note:** • 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-19are a household contact and are advised to go home and follow the specific advice public health advice for testing. • 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 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. • If a provider wishes to vaccinate a higher risk consumer (someone who answered yes to the screening questions), providers should follow the 'vaccination in high-risk or screen 'positive' consumers' section in the Operating Guidelines.

 **Verify consumer's identity**	The vaccinator/site administrator will also verify the consumer's identity using name, DOB, address, and locate their record in CIR. This should be done in a private and confidential manner and should not be overheard or viewed by other consumers. Check the consumer's DOB and confirm age. If the consumer is under the age of 18 do not vaccinate with AstraZeneca. • If the consumer has presented for their second AstraZeneca vaccination and their first dose was given less than 28 days ago do **not** vaccinate. **Note:** Photo ID is **not** required to confirm the consumer's identity.

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

Table 26.2 – pre-vaccination provide collateral

Step	Action
 **Provide collateral**	The vaccinator/site administrator will provide the consumer with the AstraZeneca COVID-19 vaccination information and consent pack. You may also display the privacy statement in the reception area as well as supplying the information in hard-copy.

Table 26.3 – vaccination process: pre-vaccination clinical assessment

Step	Action
 **Complete a pre-vaccination clinical assessment**	**Pre-vaccination clinical assessment** 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, are pregnant, and other relevant precautions. Check that the consumer meets the AstraZeneca eligibility criteria. For more information see the **AstraZeneca Vaccine Policy Statement Clinical Criteria and Guidance**. If the consumer has presented for their second AstraZeneca vaccination dose and it has not been **28 days** since their first vaccination dose, **do not vaccinate.**

Step	Action
	Vaccine booster Adult Pfizer is the preferred and first-line vaccine for a booster. Consumers should discuss optimal timing for an AstraZeneca booster dose with an authorised prescriber. Advice for clinicians is also available from IMAC. A prescription from an authorised prescriber is required when using the AstraZeneca vaccine as a booster dose or a second primary dose (i.e., following a non-AstraZeneca COVID-19 vaccine for dose 1), in accordance with **Section 25 of The Medicines Act 1981**, as it is considered off-label use. Written consent is required for all consumers receiving a dose of the AstraZeneca vaccine. This program setting will be reviewed regularly. **Interaction with other vaccines** If possible, the COVID-19 vaccination should be given 7-days before or after administering the live-attenuated shingles vaccine (Zostavax). Other vaccines on the National Immunisation Schedule can be given before, after or at the same time as the COVID-19 vaccination. The outcome of this clinical assessment must be recorded in CIR (in the medical screening section). If recording the consumer as medically unfit to receive the vaccine, CIR will prompt 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 *never* be able to receive the vaccine. Cancelling the event record means it will not be possible to go back to record a first or second dose on this record in future.

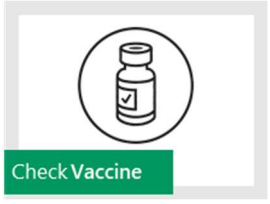
Table 26.4 – vaccination process: informed consent

Step	Action
 **Obtain written consent**	**Obtain written consent before administering the vaccine. This program setting will be reviewed regularly.** The vaccinator (or vaccinator support person) must obtain the consumer's written consent to receive the vaccine prior to the administering of the AstraZeneca vaccine. Where appropriate, consent may be given by a proxy such as a guardian or person with power of attorney. **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.
 **Record consent in CIR**	**Consumer consent record** The vaccinator or an administrative support person must record the consumer's consent to receive the vaccine in CIR. Do not vaccinate if the interval is less than **28 days**. Do not vaccinate if the consumer is under the age of 18 years. If the person does not wish to receive the vaccine, record their decline in CIR.

27.1 Obtaining written consent for the AstraZeneca Vaccine

The Programme requires written consent to be obtained before administering the AstraZeneca Vaccine. See section '**Obtaining informed consent**' for more information on written consent.

Table 20.5 – vaccination process: administering the vaccination

Step	Action
 **Check vaccine**	**Check vaccine** Check: • The label and confirm that you have the correct vaccine, and that the vaccine has not expired.

Step	Action
	• The opened/punctured vial (fridge (48 hours) or room temperature (5 hours)) expiry date. Whichever one comes first. • The unopened vial fridge expiry date (6 months)
 **Administer vaccination**	**Administer the vaccination** Before administering the vaccine verbally check the vaccine type with the consumer. **Note:** Use your clinical judgement to determine if a longer needle is required (38mm). 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***. IMAC are creating clarified preparation and administration guidance for this situation, including the importance of priming.
 **Record information**	**Record vaccination information in CIR** 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. This enables accurate data for operational reports (such as number of vaccinations completed and other trend data). This must include: • 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). • Details of the injection site and the date and time of the vaccination event. 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.

Table 26.5 – vaccination process: after vaccination

Step	Action
 **Consumer waits 15 minutes in observation area**	**Observation** 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. If a consumer is required to wait 30 minutes the vaccinator should record this on the CIR so that the staff member observing is aware. 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.** For further information on post vaccination, see **section 2.3** in the ***Immunisation Handbook***.
Vaccination card	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. **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. Once the vaccine course is complete the consumer can download their vaccine pass, some consumers may need support to complete this.
 **Record exit in CIR**	**Consumer exit time record** The site administrator/vaccinator must record the time of the consumer's exit from the site in CIR. If the consumer insists on leaving early the Site Clinical Lead must be notified and discuss this with the consumer to understand possible implications. A note should be added to the CIR to document the consumer leaving early and the advice given. 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.

Section E: Novavax (Nuvaxovid) COVID-19 Vaccine

Section E: Summary of Changes

Version	Date	Section	Summary of Changes
42.0	11/07/22	Table 26.3	Information added about Novavax as a booster

Pathway to vaccination

Section guidance

This section is read in conjunction with Pfizer Vaccine section. This section provides additional operational guidance on the Novavax 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:

- Approved for use for people aged 18 years or over
- Novavax COVID-19 Vaccine **does not need** to be diluted
- There are 10 doses per vial

The Ministry recommends vaccination to everyone of eligible age in Aotearoa New Zealand. The first line vaccine where there are no contraindications is the Pfizer vaccine. The Novavax vaccine is available as a second line vaccine for consumers who meet the eligibility criteria. A prescription from an authorised prescriber is required when using the Novavax vaccine as dose 2 of their primary course (i.e., following a non-Novavax COVID-19 vaccine for dose 1), in accordance with **Section 25 of The Medicines Act 1981**, as it is considered off-label use. Written consent is required for all consumers receiving an 'off label' dose of the Novavax vaccine.

This section is designed to be applicable to sites delivering the Novavax 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 Aotearoa New Zealand.

This section should be read and interpreted alongside the ***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)

28 Booking and scheduling

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

29 Booking second doses

Do not vaccinate less than 21 days
• **The administration of the Novavax COVID-19 Vaccine at an interval of less than 21 days must be reported to CARM.** • **New bookings made through bookmyvaccine.nz and the COVID-19 Vaccine Whakarongorau Aotearoa 0800 28 29 26.** • **Doses can be booked for any time after day 21.**

30 Novavax Operational phase

- Please see the section Pfizer Operational phase for detailed information
- Ensure the appropriate processes are in place to prevent vaccination of people under 18 years– **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: A prescription from an authorised prescriber is required when using the Novavax vaccine as a second primary dose (i.e., following a non-Novavax COVID-19 vaccine for dose 1), 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. A CARM report does not need to be completed if the vaccine has been prescribed by an authorised prescriber.

Written consent is required for all consumers receiving an 'off-label' dose of the Novavax vaccine.

31 Novavax Preparation of doses

The Novavax COVID-19 vaccine does **not need to be diluted,** please follow the instructions provided by IMAC. These instructions are included in vaccine shipments and available on the **IMAC website**. **Note:** These instructions are regularly updated. Please ensure you are using the most recent version.

Each multi-dose vial contains 10 doses of 0.5mL.

Once the vial is opened/punctured the Novavax vaccine can be stored at **2°C-25°C** and must be used within **6 hours**. Opened/punctured vials must be returned to the fridge. Any vaccine not used within this time period must be discarded. Vaccines should be prepared as close to administration as possible, ideally as needed.

If multiple vaccines are needed, there is an option to draw up several doses from the vial, but they must be used within **6 hours** and can be stored either in the fridge or at room temp (**max. of 25°C**). Any vaccine not used within this time period must be discarded.

The Novavax vaccine must not be shaken during preparation. The Novavax vaccine **does not** need to be at room temperature prior to administration. 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 CIR. The vaccine will appear colourless to slightly yellow, clear to mildly opalescent.

Before preparation check:

- it is the right vaccine
- manufacturer's vaccine expiry date

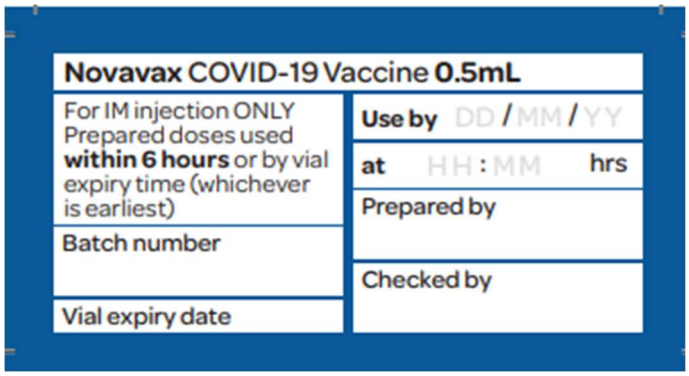
Number the vaccine vial and enter the number into the vaccine log. Second person also checks that the correct vaccine has been selected, by confirming the product name on the vial and checking the expiry date printed on vial by manufacturer. Second person also checks the numbering of the vial and documents these checks by signing/initialling the vaccine log.

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

Syringe labels have been introduced to help differentiate between vaccines.

- The syringe Label for the Novavax Vaccine is below:



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.

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

32 Number of doses per vial

Incorrect volume of vaccine may be detected by identifying you have drawn up less or more than 10 doses from a vial. Should this occur, quarantine, and discard all doses from that vial. If it is unclear why the error has occurred contact IMAC for clinical guidance. This error must be documented as waste in CIR and reported as an incident in the local organisation's quality and safety reporting system.

33 Novavax Vaccine administration and observation

This section outlines the administration of the Novavax vaccine. Please read this section with the Pfizer section above. 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 COVID-19 Vaccine Administration' on the **IMAC website**.

Table 26.1 – pre-vaccination greeting and verify identity

Step	Action
 **Greet consumer, conduct COVID-19 health check**	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*****. **Please note:** • 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-19are a household contact and are advised to go home and follow the specific advice public health advice for testing. • 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 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. • If a provider wishes to vaccinate a higher risk consumer (someone who answered yes to the screening questions), providers should follow the 'vaccination in high-risk or screen 'positive' consumers' section in the Operating Guidelines.

 **Verify consumer's identity**	The vaccinator/site administrator will also verify the consumer's identity using name, DOB, address, and locate their record in CIR. This should be done in a private and confidential manner and should not be overheard or viewed by other consumers. Check the consumer's DOB and confirm age. If the consumer is under the age of 18 do not vaccinate with Novavax. • If the consumer has presented for their second Novavax vaccination and their first dose was given less than 28 days ago do **not** vaccinate. **Note:** Photo ID is **not** required to confirm the consumer's identity.

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

Table 26.2 – pre-vaccination provide collateral

Step	Action
 **Provide collateral**	The vaccinator/site administrator will provide the consumer with the Novavax COVID-19 vaccination information and consent pack. You may also display the privacy statement in the reception area as well as supplying the information in hard-copy.

Table 26.3 – vaccination process: pre-vaccination clinical assessment

Step	Action
 **Complete a pre-vaccination clinical assessment**	**Pre-vaccination clinical assessment** 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, are pregnant or breastfeeding, and other relevant precautions. Check that the consumer meets the Novavax eligibility criteria. If the consumer has presented for their second Novavax vaccination dose and it has not been **21 days** since their first vaccination dose, **do not vaccinate.** A prescription from an authorised prescriber is required when using the Novavax vaccine as a second primary dose (i.e.,

Step	Action
	following a non- Novavax COVID-19 vaccine for dose 1), in accordance with **Section 25 of The Medicines Act 1981**, as it is considered off-label use. **Vaccine booster** **Adult Pfizer is the preferred and first-line vaccine for a booster. Novavax can be offered if eligibility criteria are met. The eligibility criteria and further details can be found in the** Programme's Booster Vaccination Policy Statement**. Interaction with other vaccines** If possible, the COVID-19 vaccination should be given 7-days before or after administering the live-attenuated shingles vaccine (Zostavax), and 3-days before or after the Shingrix or Fluad Quad vaccines. Other vaccines on the National Immunisation Schedule can be given before, after or at the same time as the COVID-19 vaccination. The outcome of this clinical assessment must be recorded in CIR (in the medical screening section). If recording the consumer as medically unfit to receive the vaccine, CIR will prompt 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 *never* be able to receive the vaccine. Cancelling the event record means it will not be possible to go back to record a first or second dose on this record in future.

Table 26.4 – vaccination process: informed consent

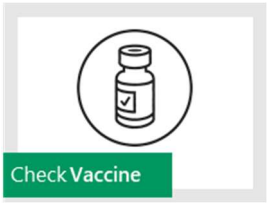
Step	Action
 **Obtain written consent**	**If off-label use of the vaccine obtain written consent before administering the vaccine.** The vaccinator (or vaccinator support person) must obtain the consumer's consent to receive the vaccine prior to the administering of the Novavax vaccine. Where appropriate, consent may be given by a proxy such as a guardian or person with power of attorney. **Note:** IPC guidance must be observed when dealing with hard-copy consent forms and obtaining consent. For example,

Step	Action
	consumers should use hand-sanitiser before or after handling a pen to sign the form or bring along their own pen.
 **Record consent in CIR**	**Consumer consent record** The vaccinator or an administrative support person must record the consumer's consent to receive the vaccine in CIR. Do not vaccinate if the interval is less than **21 days**. Do not vaccinate if the consumer is under the age of 18 years. If the person does not wish to receive the vaccine, do not vaccinate, and record their decline in CIR.

34 Obtaining written consent for the Novavax Vaccine

The Programme requires written consent to be obtained before administering the Novavax Vaccine as a second primary dose after a non-Novavax vaccination. See section '**Obtaining informed consent**' for more information on written consent.

Table 20.5 – vaccination process: administering the vaccination

Step	Action
 **Check vaccine**	**Check vaccine** Check: • The label and confirm that you have the correct vaccine, and that the vaccine has not expired. • The opened/punctured vial should be used within 6 hours after first puncture whether it is in the fridge or at room temperature up to 25°C. • The unopened vial fridge expiry date (6 months)
 **Administer vaccination**	**Administer the vaccination** Before administering the vaccine verbally check the vaccine type with the consumer. **Note:** Use your clinical judgement to determine if a longer needle is required (38mm). Use of a shorter needle risks delivering the vaccine subcutaneously as opposed to intramuscularly, which has

Step	Action
	the potential to underdose. For more information on needle length, refer to the ***Immunisation Handbook***.
 **Record information**	**Record vaccination information in CIR** 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. This enables accurate data for operational reports (such as number of vaccinations completed and other trend data). This must include: • 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). • Details of the injection site and the date and time of the vaccination event. 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.

Table 26.5 – vaccination process: after vaccination

Step	Action
 **Consumer waits 15 minutes in observation area**	**Observation** 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. If a consumer is required to wait 30 minutes the vaccinator should record this on the CIR so that the staff member observing is aware.

Step	Action
	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.** For further information on post vaccination, see **section 2.3** in the ***Immunisation Handbook***.
Vaccination card	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. **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. Once the vaccine course is complete the consumer can download their vaccine pass, some consumers may need support to complete this.
 **Record exit in CIR**	**Consumer exit time record** The site administrator/vaccinator must record the time of the consumer's exit from the site in CIR. If the consumer insists on leaving early the Site Clinical Lead must be notified and discuss this with the consumer to understand possible implications. A note should be added to the CIR to document the consumer leaving early and the advice given. 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.

Section F: Additional programme guidance, variations and incidents

Section F: Summary of Changes

Version	Date	Section	Summary of Changes
42.0	11/07/22		No changes

Section guidance

This section provides additional guidance to vaccination, including vaccinating affected persons under the COVID-19 Public Health Response (Vaccinations) Order, NIBS, and incidents.

Purpose

It is designed to provide additional programme information and support, to help maintain public safety and ensure consistent and equitable vaccination outcomes across New Zealand/Aotearoa.

Appendices relevant to this section

- **Appendix F: Links to NIBS**

35 Vaccination in high-risk or screened 'positive' consumers

The following is operational guidance for vaccinating consumers who are considered high-risk for being exposed to COVID-19 and are willing to be vaccinated.

While this is not advised as a general delivery model to unknown consumers, in the context of community transmission, it is important to have guidance to support this service.

'Screen positive' means that they have answered yes to any of the standard COVID-19 risk assessment/screening questions asked at vaccination reception (see Operating Guidance Appendix G).

Note: There is an exception to this. Consumers with confirmed or probable COVID-19 infection **are not** recommended to be vaccinated. This reflects the lack of benefit of vaccination in this circumstance, and also risk of transmission. There is advice in the Immunisation Handbook or through IMAC to guide timing for subsequent vaccination in this scenario.

Consumers considered high risk for being exposed to COVID-19 are not suitable to be vaccinated according to the usual service design model (physical set-up of vaccination sites, workforce, and PPE guidance) as these settings are designed to be a low-risk environment. Vaccination of screen positive consumers requires additional considerations (as outlined below) as is currently recommended in only a home visit context, or in a controlled healthcare facility.

Note: Using this type of consumer screening, is to ensure a safe vaccination process of vaccination sites or events. It is different to the High Index of Suspicion (HIS) criteria, and its associated public health actions such as Notification to the local Medical Officer of Health.

It is recommended that this section should be used in conjunction with:

- Ministry of Health COVID-19 Vaccine Operating Guideline.
- Ministry of Health **National Standards for Vaccine Storage and Transportation for Immunisation Providers 2017**.
- 2021 Addendum to **National Standards for Vaccine Storage and Transportation for Immunisation Providers 2017**.
- Ministry of Health's Immunisation Handbook 2020.

Local DHB Standard Operating Procedures. There are three scenarios below that providers could consider for the 'vaccination in high risk/screen positive consumers'.

Additional scenarios could be utilised as long as the appropriate IPC considerations are made. See additional information found "COVID-19: Infection Prevention and Control Recommendations for Health and Disability care workers"

Scenario 1: Home Vaccination

In addition to above it is recommended that providers have Standard Operating Procedures (SOP) specific for home vaccination to support safe delivery processes.

Home visits for vaccination may be required for consumers who are unable to leave their residence because they have been required to isolate (I.e., attendance at a location of interest or contact of a confirmed case). It may also be required for those who have barriers to access due to mobility, disability, comorbidity, or another reason that means they are unable to access vaccination at a site including improving equity.

Outside the scope of this section are additional considerations which would likely be part of a DHB standard operating procedure (SOP). This could include but is not limited to a SOP on vaccine transportation and administration, staff requirements and medical emergency equipment.

Scenario 2: Controlled Healthcare Facility

Vaccination for screen positive consumers and/or accompanying whānau in a controlled healthcare facility may be appropriate. This should only be performed in a controlled healthcare facility, where the flow of consumers and staff is controlled, such as a Hospital Emergency Department or General Practice Clinic.

This excludes dedicated vaccination sites and other settings where there is a risk of uncontrolled flow of people and workforce who are not in appropriate PPE, and so therefore is a transmission risk with other consumers and staff.

Scenario 3: Drive-Through Vaccination

Vaccination for screen positive consumers and/or accompanying whānau in a drive-through vaccination centre may be appropriate. This should only be performed in a planned outdoor site where the flow of cars, consumers and staff is controlled. Post vaccination it is recommended they stay in their car away from others.

This excludes settings where there is a risk of uncontrolled flow of people and workforce who are not in appropriate PPE, and so therefore is a transmission risk with other consumers and staff.

PPE requirements would be the vaccinator, staff, consumer, and others in the car to wear a medical mask.

Requirements for Scenario 1 & 2

In addition to usual vaccination processes, including the Protection Framework Guidance (**Appendix K**), the following table is the requirements for the scenarios above.

	Screen Positive Requirements for Scenario 1 & 2
Location	• Only pre-arranged home vaccination or vaccination in a controlled residence or healthcare facility.
Workforce	• Staff should follow the 'At risk staff' section, in **Appendix K**, for their appropriateness to work. • Staff must be fully immunised. • Home visit must have at least one authorised vaccinator and one staff on site has a CPR certificate and adrenaline administration certified. Limit staff in enclosed environment where practical
PPE	• Consumer: Must wear a medical mask (these could be provided). All staff: P2/N95, eye protection, gown, and gloves. *In 'screen positive' environments, where there may also be 'screen negative' consumers, e.g., during a home vaccination, all consumers in this environment should be treated as 'screen positive'. **In home environments, staff should change PPE if they are moving between different houses. ***Donning and doffing PPE outside in a home environment requires an appropriate space and transporting contaminated PPE back to base for proper disposal, this may be covered in the DHB SOP.
Physical Environment	• Review the physical environment and consider ventilation is adequate. Discuss with local DHB IPC team if unsure. **Home vaccinations** • Vaccination outside the home wherever practically possible and weather permitting. This could include in a carport, open deck area, or in their parked car. Ensure they can be observed appropriately. • If the environment/location does not have mechanical ventilation, improve ventilation through dilution (I.e., opening windows and doors to outside air). • If completing vaccination indoors, use a room with at least one window and keep the window(s) open for as much time as possible (outdoor temperature and safety permitting). **Healthcare Facilities** • Please see section '**Environmental considerations and safety controls at the vaccination site**'. Adequate ventilation (mechanical, natural or hybrid) of all areas, including the screening, waiting, post-vaccination observation, and vaccination areas. Where a mechanical ventilation system is operating in these areas, the ventilation rate should be six air changes per hour or according to national or local requirements for healthcare facilities. • Some older facilities may not meet the ASHRAE Standard. It is then recommended they discuss ways to improve ventilation with their local DHB IPC team.

36 Third primary dose for severely immunocompromised

A third primary dose is recommended for severely immunocompromised consumers. It is evident that some severely immunocompromised people do not mount a sufficient immune response to provide adequate protection against COVID-19.

Advice for clinicians on the guidance is available through the Immunisation Advisory Centre, and this information will be updated periodically through the Immunisation Handbook. Clinical judgement should be applied by the prescriber to determine whether a third primary dose is required for conditions or medicines that are not listed that are associated with severe immunocompromise.

The **Third Primary Dose of the COVID-19 Vaccine Policy Statement and Clinical Guidance** outlines the requirements to be eligible for the third primary dose of the COVID-19 vaccines.

Note: There is information available on the Health Pathways site under COVID-19 Vaccination > Supporting the decision > Medical Conditions >Immunocompromised.

37 Vaccination and Surveillance Testing

The following section is operational guidance for providers who may wish to perform surveillance testing and vaccination at the same site, for the same consumer.

While this is not advised as a general delivery model, it is important to have guidance to support this service in the context of widespread community transmission.

Surveillance testing for COVID-19 has been used to identify cases in a community where there may be a concern around undetected transmission and infection. This would be particularly relevant in the context of a small 'community of risk' where there may be a need to both test and vaccinate consumers within a short timeframe and with an overlapping workforce.

There are differences between the processes of vaccination and testing, even in low-risk groups. Swabbing for COVID-19 is a higher transmission procedure (potentially droplet producing) than vaccinating and thus has additional PPE requirements and recommendations around physical distancing, as well as encompassing the process for swab labelling and sending to a lab.

In addition to any operational guidance, it is recommended that providers have Standard Operating Procedures (SOP) specific for vaccination and surveillance testing to support safe processes.

Due to the complexity of this process, **this model requires approval and support via the Ministry of Health Clinical Quality and Safety team.**

Requesting approval to set up

Contact the CVIP regional account manager to request approval to set up a vaccination and surveillance testing model.

38 Vaccination in Hospital

38.1 Introduction

The following is guidance for vaccinating consumers (including whānau of patients) against COVID-19 in a hospital setting.

Vaccination is hospital offers an opportunity to reach those who may not otherwise have access to vaccination.

Providing this service should be in accordance with local standard operating procedures, and consider local logistic, dispensing, and clinical requirements.

Consumers and/or whānau are not required to stay in hospital for the purpose of vaccination.

38.2 Screening

Screening for COVID-19 follows the same process outlined elsewhere in the Operating Guidelines, however the location and timing would need to be in accordance with local guidance.

Consumers that are 'screen negative' means that they have answered 'no' to all the standard COVID-19 risk assessment/screening questions (see Operating Guidance Appendix G). This means that the consumer is considered low risk for being exposed to COVID-19 and providers can follow the standard vaccination process outlined elsewhere in the Operating Guidelines.

Consumers that are 'screen positive' means that they have answered yes to any of the standard COVID-19 risk assessment/screening questions (see Operating Guidance Appendix G). This means that the consumer is considered high risk for being exposed to COVID-19 and providers should follow the Operational Guidance section "Vaccination in high-risk / screened 'positive' consumers".

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39 Mobile vaccination team

39.1 Setting up mobile vaccination teams

You may choose to deliver vaccinations using a mobile vaccination team who will attend a number of different locations rather than being based at a single site. For example, this may be how you deliver vaccinations in aged residential care settings or workplaces.

As for fixed vaccination sites, you will need to consider how many vaccinators and administrators are needed for each mobile vaccination team.

39.2 Setting up in CIR

Mobile vaccination teams must be correctly set up in CIR, so they are linked to a facility and to track the vaccinations the mobile team have delivered.

Steps to set up mobile vaccination teams in CIR:

Complete the COVID-19 facility and site set-up details form (the regional account manager can provide a copy), with the following information:

- List each mobile team separately using a standard naming convention to identify these as mobile teams and to enable the Ministry to identify the DHB or provider linked to the team. For example, use a naming convention such as:
  CDHB outreach 1, MedPro mobile 2, or ADHB team 3.
- Identify the facility/facilities that will be the parent for the mobile team/s.

Send the completed form to the regional account manager.

The Ministry will load the facilities and sites into CIR so users can select them.
Ensure each mobile team member required to access CIR knows which facility/site they belong to. When users create vaccination events in CIR, they'll need to ensure each event record is correctly linked by checking the related contacts field under site/facility.

40 Home vaccinations

Vaccines can be delivered in or near a consumer's home or place of residence when they are unable to attend a vaccination site.

When administering a vaccine in a consumer's home, providers must meet the minimum requirements to safely administer the vaccine. This includes meeting the **National Standards for Vaccine Storage and Transportation for Immunisation Providers 2017** and the *COVID-19 Vaccine and Immunisation Programme Service Standards* throughout the entire process.

Providers must have a home vaccination delivery plan that includes standard operating procedures (SOPs). Prior to home based vaccinations being implemented, the plan must be approved by the DHB's CVIP clinical leads and the associated lead professional advisors.

40.1 Transportation of vaccine for household vaccinations

Due to regulatory restrictions on compounding and manufacturing of medicines (see section '**Transportation of diluted or drawn-up vaccine**', if a provider is utilising home vaccinations usually only one vial of vaccine can be transported and administered on each trip. This means that for each trip, the vaccinator can only transport the minimum number of doses required to vaccinate the household. This is an important consideration when planning for home vaccinations **Medicines Act 1981**. This restriction on number of vials/doses does not apply to mobile vaccination services as these will have the required resources on board to support dilution and draw up on site see section '**Mobile vaccination team**' above. All transportation of vaccine regardless of whether it is diluted or not should meet the **National Standards for Vaccine Storage and Transportation for Immunisation Providers 2017**.

The home vaccination or mobile delivery plan and SOP must cover the following:

- Maintaining staff and consumer safety, privacy, and well-being
- Respect to the consumers home and whānau
- Processes to mitigate the risk of cold-chain breaches
- Safe vaccine preparation and administration. It is recommended that preparation is carried out back at an approved vaccine preparation site. However, if not possible, preparation in a person's home should follow correct processes (i.e., double checking processes).
- Process to minimise waste
- Documentation and use of CIR
- Management of AEFI in a home environment including the immediate availability of adrenaline and phone access to call emergency services

- Operations at raised alert levels
- Risk register associated with home vaccine delivery

40.2 Consumer Considerations

The preferred method of vaccine delivery is at a fixed COVID-19 vaccination site. Providers should have a process to appropriately identify and approve consumers for vaccine delivery in their home.

Considerations should include:

- Consumer normally has their medical care provided in their home or place of residence.
- Does not normally leave their home or place of residence.
- Not able to be safely transported from their home to a vaccination site.
- Transport to vaccination site requires significant logistical requirement, such as multiple staff and equipment to aid transfer.
- Consumer would benefit from a home vaccination due to a disability barrier to receiving a vaccination at a site.

41 COVID-19 Trial Vaccinations

The Programme recognises the importance of representing the Aotearoa New Zealand population in international clinical trials and values their contribution to new COVID-19 vaccine research. **The COVID-19 Trial Vaccinations and Vaccination Certificates Policy Statement** provides a policy statement on the decisions and implications for consumers considering or participating in Medsafe approved COVID-19 clinical trial in Aotearoa New Zealand.

42 Affected persons under the Vaccinations Order

COVID-19 Public Health Response (Vaccinations) Order 2021

The purpose of the **COVID-19 Public Health Response (Vaccinations) Order 2021** (Vaccinations Order) is to prevent, and limit the risk of, the outbreak or spread of COVID-19 by requiring certain work to be carried out by affected persons who are vaccinated and have received a booster dose, if eligible. Affected persons are eligible for a booster dose with the Pfizer vaccine if they are aged 18 years or over and have completed their primary COVID-19 vaccination course at least 3 months ago. More information is available in the **Booster Vaccination Policy Statement**.

The Vaccinations Order is a legally binding health instruction which requires certain groups of workers to be vaccinated and have received a booster dose in order to undertake 'certain work'.

42.1 Workers subject to the Amended Vaccinations Order

An affected person must not carry out certain work unless they are vaccinated and have received a booster dose or have been granted a COVID-19 vaccination exemption by the Director-General. The affected person who has been granted an exemption may continue working while unvaccinated for the duration of the exemption period. Employers must have a plan for each affected worker, to ensure both the work and those they are in contact with are safe. This includes planning for risk management, health protection, impact on service, and efforts to support the affected worker's to be vaccinated. More information on '**Temporary significant service disruption exemptions**' can be found on the Ministry's website.

The amended Vaccinations Order applies to people working at:

- managed isolation and quarantine facilities (MIQFs) and managed isolation facilities (MIFs), including workers who transport persons to or from MIQFs or MIFs
- affected airports and aircraft, including aircrew members, all airside workers and landside workers who interact with international arriving or transiting passengers, baggage handlers, and other persons who enter enclosed space on board affected aircraft
- affected ports, including pilots, stevedores and other workers who board, or carry out work on or around, affected ships

- accommodation services where specified aircrew members are self-isolating
- settings within the health and disability sector, including health practitioners, care and support workers, and other workers who carry out work where health services are provided
- at a corrections prison, including staff and other persons employed by a contractor or subcontractor to provide services
- settings within the education sector including staff, volunteers and unpaid persons who work at or for an affected education service as well as providers of a home-based education and care service
- settings where a My Vaccine Pass is required for persons to enter or receive service.

It also includes individuals doing work:

- that involves handling affected items removed from ships, aircraft, MIQFs or MIFs
- where the job is for a company that is routinely engaged to provide services at any of the above settings
- where the person 'has contact with' people who belong to different groups specified in Schedule 2 of the Vaccinations Order.

A full list of the groups of affected persons required to be vaccinated to carry out certain work is outlined in Schedule 2 of the **Vaccinations Order.**

Note: Identification of these workers are managed through their employers and regulatory bodies who must notify each affected person.

42.1.1 Booster doses

On 21 December 2021, it was announced that COVID-19 booster vaccinations would be mandated for workforces covered by the Vaccinations Order and this came into effect on 23 January 2022.

A booster dose means a dose of a COVID-19 vaccine specified in Schedule 4 of the **Vaccinations Order** administered in accordance with the requirements specified for that vaccine.

An affected person who has received their primary COVID-19 vaccination course may carry out certain work without receiving a booster dose if they are:

- under 18 years of age; or
- carry out certain work in settings where a My Vaccine Pass may be required (as specified in Part 10 of Schedule 2 in the **Vaccinations Order**).

42.1.2 Scheduling appointments for affected persons

It is the responsibility of the DHBs to ensure access to timely vaccination appointments, including appointments for booster doses, are available to affected persons under the Vaccinations Order.

The transitional provisions for affected persons to be vaccinated and receive a booster dose are outlined in Schedule 1 of the **Vaccinations Order**.

42.1.3 Alternative vaccines

Schedule 3 of the **Vaccinations Order** details the COVID-19 vaccines, number of doses, and administrative requirements that affected persons can receive to be considered to have completed their primary COVID-19 vaccination course.

The COVID-19 vaccines available for booster doses are specified in Schedule 4 of the **Vaccinations Order**.

42.1.4 Further information

For further detail on the requirements contact **IMAC on 0800 IMMUNE (466 863),** option 1 (health professionals) and then option 2 (COVID-19 vaccinator support) and refer to Schedule 3 of the **Vaccinations Order** and the Ministry's **Immunisation Handbook**.

43 National Immunisation Booking System

43.1 Introduction

The National Immunisation Booking System (NIBS) known as **Book My Vaccine** supports a national-led approach to immunising New Zealand/Aotearoa against COVID-19. **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.

This section provides an operating guide for **Book My Vaccine,** including the key stakeholders, staff roles, systems, processes, and guides related to running the **Book My Vaccine** tool.

This section should be used as the first point of reference for all **Book My Vaccine** related activities by any staff member responsible for running vaccination sites and managing bookings. A detailed guide, including process flows, is available in the Detailed Booking System Guidelines document). Links to this document, training and user guides are provided in **Appendix F**.

43.2 Booking system principles

The **Book My Vaccine** operating model is based on the four guiding principles shown below, regarding responsibility and Governance between the Ministry, Whakarongorau Aotearoa (Whakarongorau) and DHBs and providers. These principles are intended to promote consumer safety, equity, and trust in the system. These are detailed in the four steps below:

1 Setup

- The **Book My Vaccine** tool supports the nationally led and locally delivered vaccination programme.
- The Ministry has overall coordination and monitoring responsibility, including key messaging, and leading nationwide booking campaigns.
- DHBs and providers are responsible for vaccinating their populations, including localising their campaigns to meet vaccination targets.

2 Setup

- The **Book My Vaccine** tool will be implemented by all DHBs.

- The **Book My Vaccine** tool will be the trusted source of available booking slots for the public, the DHBs and for Whakarongorau call centre to see what appointments are available for booking.
- All vaccination site types down to Community Hub level will use the **Book My Vaccine** tool. General Practices who only service their own enrolled populations will have the option of using either their own system for vaccination scheduling or the **Book My Vaccine** tool. General Practices who service customers in addition to their own enrolled populations should use the **Book My Vaccine** tool. Pharmacies may either use their own booking system or the **Book My Vaccine** tool.

3 Pre-event

- The **Book My Vaccine** tool will be provided as a package with Whakarongorau as the National Call Centre
- Whakarongorau will only support the **Book My Vaccine** tool and no other booking systems once the **Book My Vaccine** tool is operational. Legacy booking systems will be phased out or replaced.
- Whakarongorau will provide a consumer supporting role for public queries (inbound) and assisted booking for all DHBs and sites available on the **Book My Vaccine** tool.
- The Ministry is responsible to analysing booking system failures (failsafe) and developing operational process, guidelines including communication with all stakeholders.

4 Post-event

- The management of following up individuals for missed vaccination appointments will be a mixed model.
- Whakarongorau can provide the follow-up service for missed appointments (outbound calling) if agreed with the DHB before passing on to the DHB teams for intensive outreach follow-up. This agreement will be defined between the DHB and Whakarongorau in the engagement plan.
- Otherwise DHBs will follow-up on missed appointments (outbound calling), or they can be supported by local models with PHOs or Iwi providers.

43.3 Book my Vaccine system roles

The following key roles have been identified to support the **Book My Vaccine** tool. These roles include staff from the vaccination site, DHB, the Ministry and Whakarongorau. Further information related to the expected support, behaviour and outcomes of these roles is detailed above in the **roles and responsibilities table**.

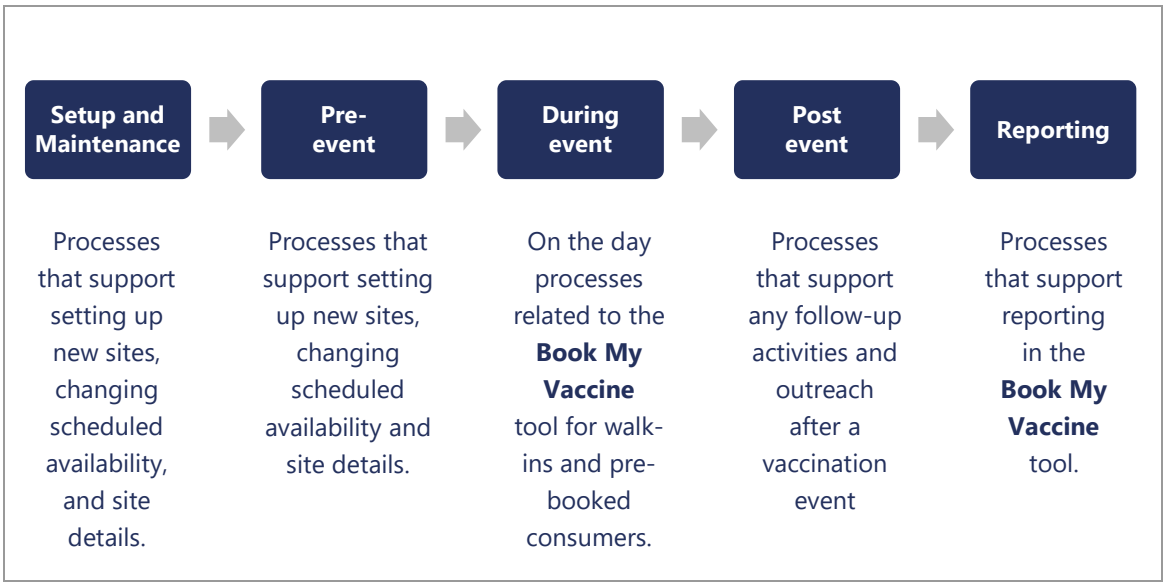
Table 22.1 – Book my vaccine tool key roles

Key roles	Role description
Site receptionist	The site receptionist manages on-site check-in procedures and performs health checks prior to vaccination. The site receptionist is provisioned the role of concierge in the **Book My Vaccine** tool.
Whakarongorau Aotearoa national call centre advisor	The Whakarongorau national call centre advisor is the inbound point of entry for all booking queries. They are responsible for assisting consumers with creating, cancelling, and amending bookings, completing follow-up activities where commissioned to do so, and

Key roles	Role description
	answering general vaccine related queries. They are provisioned the role of special concierge in the **Book My Vaccine** tool. Whakarongorau conduct outbound call campaigns based on direction from the Ministry's Operations Team.
Whakarongorau DHB liaison	The Whakarongorau DHB liaison is the primary point of contact for communications and escalations by DHBs for booking-related processes that require Whakarongorau interactions. They will escalate issues with the Ministry's operations leads and the DHB operations leads, as required. The Whakarongorau DHB liaison and details regarding how to contact them will be agreed as part of the engagement plan.
Site lead	The site lead manages the day-to-day operation of their site and is the primary point of communication for the site. The site lead is responsible for identifying and escalating any scheduling changes to the DHB site admin.
Site admin	The DHB site admin acts as the first point of escalation for managing system technical operations for the sites they oversee (one site lead per ten sites is the recommended ratio). The DHB site admin is responsible for triaging and escalating impactful (minor/major event) site schedule changes. The DHB site admin is provisioned the role of site admin in the **Book My Vaccine** tool.
DHB operations lead	The DHB operations lead is accountable for managing the operational activities for a DHB. Their key functions include generating reports to identify DHB follow-up activities, managing all escalations required for a DHB's attention, and sharing escalations with the Ministry and Whakarongorau as required. They are accountable for the accuracy of all site schedules.
The Ministry's operations lead	The Ministry's operations lead is the primary point of contact for escalations into the Ministry. Their key obligation is managing communications between the Ministry and Whakarongorau/DHBs. They are provisioned the role of super user in the **Book My Vaccine** tool and are responsible for onboarding users and sites in the system. The Ministry's operation team are responsible for failsafe reporting, Tableau dashboards and organising outbound call campaigns to reach consumers.

43.4 Booking system processes and best practice

Figure 22.1 – booking tool processes:



43.5 Setup and maintenance

Creating a new site

Creating a new site relates to setting up a site on the booking system. DHBs are asked to nominate one individual to be responsible for sending information and communicating between parties. If possible, it is preferable that new sites are set up in batches (such as all sites going live in a two-week period are grouped together) to minimise duplication of processes.

The DHB or provider will populate the new site CIR and NIBS setup forms. The nominated DHB staff member is then required to email the forms to the Ministry's central help desk. A seven-day lead time for receiving the completed forms prior to site going live is required by the Ministry. The information within this form is used by teams within the Ministry to setup the new site in CIR and NIBS. It will take up to 72 hours for these sites to be created in the respective systems, after form submission.

New system users required for the site will complete qualifications and training processes as prescribed by their DHB workforce lead. System training includes NIVS and the Covid Immunisation Consumer Support (CICS) tool (if the DHB is using CICS, its use is optional). System users will be trained for the site admin and concierge roles in NIBS and the system user role for CICS. The nominated DHB staff member will inform the Ministry once system user training has been completed (it is mandatory for the training to be completed before users are provisioned). The Ministry will then provision the appropriate users for the site. The nominated DHB staff member will receive a confirmation of this task completion via email.

Amend site schedule

Amending a site schedule involves updating the capacity and availability of appointment slots for a site. The site lead or site administrator is responsible for identifying major schedule changes, escalating these to the DHB operations lead, and making necessary system changes. The thresholds for escalation will be set and be maintained by each DHB.

Note: Changing the schedule in NIBS does not cancel or reschedule any existing bookings. Refer to the **event rebooking** section below for details.

It is crucial the site lead or site administrator performs an impact assessment regarding bookings when amending a site schedule, specifically when the number of appointment slots are reduced.

Event rebooking

In the case of an event causing a disruption to a site, where an existing schedule is set, and appointments are cancelled, consumers must be rebooked in the system. Event severity, minor or major as be determined by the site and DHB staff, will dictate the applicable escalation path to ensure key stakeholders have visibility of the event, and can assist with implementing appropriate resolution measures. When a major event occurs such as a bulk cancellation or a bulk reschedule, this must be approved by the Ministry. Further information is outlined in the Detailed Booking Systems Guidelines document found in **Appendix F**.

Note: Rescheduling is not automatic function. Consumer appointments will not be cancelled or rescheduled when a site schedule change is created.

Amend site details

Amending site details involves updating the site location and other site properties. These changes do not affect scheduling. The site lead, site administrator or DHB operations lead is responsible for identifying such changes are necessary. The site administrator is responsible for making the changes in the system.

Pre-event

Booking an appointment

Where a consumer is eligible to be vaccinated, they are able to book a primary course with the option to include two appointments at the same location, a first dose only and a second dose only (after the required number of days from their second dose). The COVID-19 vaccine is different for those aged 5-11 and so consumers need to select the relevant age band.

When eligible, consumers can select Pfizer, paediatric Pfizer, Novavax or AstraZeneca as the vaccine type. Eligible consumers can also book a booster dose after the required number of days from when their primary course was completed and a second booster dose after the required number of days from when the first booster dose was administered.

Consumers are asked to provide their personal details, allowing the system to send a booking reference and confirmation to the consumer. A contact person's details are required for appointment confirmation and reminders where the booking is for a child aged 5-11. Bookings can also be made by an individual on behalf of a consumer (for instance a family member or friend), or through Whakarongorau.

Consumers can select to book as a small group (2-5 people) for a single dose of a Pfizer vaccine. Consumers are asked to provide their personal details and the contact details for a booking arranger who receives the booking references, confirmation, and reminders for all individuals in the group.

Note: The third primary dose of Pfizer for people who are severely immunocompromised is not booked via the **Book My Vaccine** tool.

Update and/or cancel an appointment

Consumers can update the time and/or location of their vaccine appointment/s or cancel their appointment/s through the **Book My Vaccine** tool. Consumers must enter either an email address or phone number. This will be used to provide the consumer with a confirmation of their booking (such as the booking reference etc.). If a consumer does not have this information, they should contact Whakarongorau for assistance. Consumers have the option to rebook or cancel an appointment any time up to two weeks after the scheduled appointment date. Consumers cannot reschedule as a group, rather each individual should be cancelled or rescheduled using the contact details of the booking arranger and the booking reference of the individual.

During the vaccination event

Consumer arrival

Where a consumer arrives at a site without an appointment (walk-in) or if they show up early for an appointment, providing the DHB or provider has capability to take walk-in consumers and the site has availability, the consumer may be vaccinated. As no appointment was booked, an Immunisation Case will need to be created to record the vaccination activity in CIR. The Concierge must be sure to select the correct Vaccination Plan when creating a new Immunisation Case.

If the walk-in is for a first dose, the consumer should be assisted to book their second appointment on **Book My Vaccine**. This process ensures consumers receive a second vaccine dose. If the site does not have capacity to book a consumer for a vaccination, the consumer can book their appointment/s at or for another site.

With the introduction of the single first booking flow, a consumer can book appointments at different locations, however, they are only able to book the second appointment once they have received their first dose.

Post event: follow-up

Booking Did Not Attend (DNA) follow-up

DHBs remain accountable to ensure that consumers who did not attend (DNA) appointments are contacted. DHBs may utilise Whakarongorau to undertake any follow-up activities to rebook consumers. This process to request follow-up services will be

defined in the engagement plan between Whakarongorau and each DHB. This can be a mixed model, where each party may be responsible for following up with different groups of consumers within the DHB. When a consumer does not attend their appointment, they will be contacted on three separate occasions. The best practice for following-up is to contact a consumer the day after the missed appointment, followed by two more attempts, at the fourth day and seventh day. Where the consumer remains uncontactable, the DHB is responsible for executing the most suitable follow-up response (further outbound calls or ceasing follow-up communications).

44 Incidents

44.1 Incident management

The site team should be trained and prepared to respond to three possible medical emergencies associated with COVID-19 vaccination: fainting, hyperventilation, and anaphylaxis. The appropriate medication and equipment must be on site to manage these incidents.

Refer to **section 2.3 of the *Immunisation Handbook*** for guidance on emergency equipment required to manage post-vaccination medical emergencies.

Adverse events should be managed in accordance with HQSC ***Guide to the National Adverse Events Reporting Policy 2017***.

In the event of a serious adverse event or incident it is important to follow organisational process to report, review, and learn from the incident.

- **Appendix I** outlines the process steps for notifying serious incidents to the programme. This includes the COVID-19 Vaccine related severity assessment codes (SAC) and the form required to notify the programme of incident and serious adverse events.

44.2 Adverse events during observation period

If any consumer has an adverse event during the 15-minute observation period at the vaccination site, appropriate medical attention must be provided. The on-site adverse event must be recorded and submitted in the CIR to support reporting on adverse events following COVID-19 vaccine immunisation.

For more information regarding managing medical emergencies and anaphylaxis, please see **section 2.3 of the *Immunisation Handbook***.

44.3 Recording an anaphylaxis event

Where a suspected anaphylaxis event occurs following a vaccination event, it is important to record and submit consumer details of the event in the CIR. The person who handled the event must complete the anaphylaxis checklist record (found on the **IMAC website**) as soon as practical. The anaphylaxis checklist should be completed and uploaded via the Dropbox to the CARM **link**.

Adverse events should be notified to the site lead clinician, who can undertake a clinical review and determine appropriate actions with the site manager (such as pausing vaccinations for a time, should this be required).

44.4 Adverse events after observation period

Consumers should be advised by the vaccinator, at the time of vaccination, of common **and** rare side effects that can occur after the observation period (after they've left the vaccination site). This should include a discussion about when and how to seek medical attention, and how to submit an adverse reaction report to CARM (as detailed in the 'After your immunisation' flyer). A dedicated COVID-19 Vaccine adverse event report is available on the **CARM website**. This may be completed by the consumer or a health practitioner.

Pfizer and AstraZeneca vaccine

Common side effects include pain, redness or swelling at the injection site, feeling tired or fatigued, headache, muscle or joint aches and pain, chills, fever, and nausea. These effects are usually mild or moderate and improve within a few days after the vaccination.

Pfizer vaccine

Myocarditis is an inflammation of the heart muscle and it can be mild or serious. It is usually caused by viruses, but it is also a **rare side effect** of the vaccine.

Symptoms of myocarditis linked to the vaccine generally appear within a few days, and mostly within the first week after having the vaccine. Consumers should be advised that if they get any of these new symptoms, they should seek medical help, especially if these symptoms don't go away:

- Tightness, heaviness, discomfort or pain in your chest or neck.
- Difficulty breathing or catching your breath
- Feeling faint or dizzy or light-headed
- Fluttering, racing, or pounding heart, or feeling like it is 'skipping beats'.

AstraZeneca vaccine

Thrombosis with thrombocytopaenia syndrome (TTS) (blood clotting combined with low platelets) is a **rare side effect** that can occur after vaccination with the AstraZeneca vaccine. Consumers should be made aware of the symptoms of TTS, which can include severe or persistent headache, shortness of breath, chest pain, leg swelling, unusual bruising, persistent abdominal pain, confusion, or seizures. It's important that anyone who experiences these symptoms after vaccination seeks medical attention promptly.

44.5 COVID-19 treatment injury claims

ACC is sharing advice with providers regarding lodging ACC claims for a physical injury resulting from a COVID-19 Vaccination. Such injuries may be covered by ACC if the injury criteria for treatment are met. Under ACC legislation, the injury must be clearly caused by the vaccination and must not be a necessary part or ordinary consequence of the treatment. For example, inflammation around the site of the injection is common with

COVID-19 Vaccination (an ordinary consequence) and is unlikely to be covered. Infections (such as cellulitis or septic arthritis) due to the vaccination, and anaphylaxis resulting in injury are not ordinary consequences and are more likely to be covered.

Where a consumer has an injury that meets these criteria, they may require further treatment or support. In such cases, providers should lodge an ACC2152 treatment injury claim form with ACC as well as an electronic or manual ACC45 injury claim form. These forms and more information can be found on **ACC's website**.

Providers will need to include the vaccine brand and identifying dose number (for example, whether it the first or second BioNTech/Pfizer COVID-19 Vaccine dose).

Note: Health providers should keep good clinical records of reactions and complications and arrange appropriate clinical management and follow up. Treatment injury claim forms can be completed at the time or any time after the event. However, if longer than 12 months additional information is required. Time should be taken to obtain consumer consent for a claim to be lodged with ACC, as it involves providing their personal and private information to ACC. Consumers should be reassured the health system will manage their treatment regardless of an ACC claim.

44.6 Recording vaccine errors

A vaccine administration error is any preventable event that may cause or lead to, inappropriate use of a vaccine or consumer harm. Administration errors can occur at any stage of the vaccination process (such as storage or handling, site/route of administration, or dosage given).

Some known vaccine errors include unauthorised age group vaccinations, shorter than recommended dosing intervals, injecting errors, dosage errors, vaccine administration errors, or when the consumer has an adverse event due to a vaccine error.

In the event of a vaccine administration error

- Inform the consumer/s involved. This should occur within **seven working days**.
- If guidance/advice is needed, consult **IMAC on 0800 IMMUNE (466 863)**, option 1 (health professionals) and then option 2 (COVID-19 Vaccinator support)
- Record the error in CIR under adverse events error to provide for reporting on vaccine administration errors.
- Determine how the error occurred to provide for strategies to be implemented to prevent a recurrence.

Providers should report all COVID-19 Vaccine administration errors, including those not associated with an adverse event. Upon submitting the adverse event/medical error form to CIR, data will go to the medical assessment team at CARM. Please provide as much detail as possible about the error that occurred, any actions that were taken at the time of the event, and pending actions. The medical assessment team review adverse events and medical errors to help inform any follow up required. Adverse event and medical error reports also inform vaccine safety monitoring.

44.7 Early second doses

If the first and second dose of the BioNTech/Pfizer COVID-19 Vaccine is administered at an interval of **less than 21 days**, or **28 days** for the AstraZeneca Vaccine, this is reported as an early second dose.

In the event of an early second dose, please follow the instructions below with respect to the reported cases:

- Verify the case ID entry - if wrong, then correct the CIR record.
- If correct, complete a CARM medication error report as this is a 'never event' use of the vaccine.
- Inform the affected person of the error and ask them to report any reactions – refer to the handout 'After your vaccination'.
- Clinical advice (e.g., by the medical advisors at 0800IMMUNE) may be required. This will depend on the timing of the second dose and the characteristics of the individual.
- Identify improvements to local practice and process to avoid early second doses and share the learnings as soon as possible.
- On investigation, and if in the event the person reports possible harm, then follow your DHB or provider's adverse event process and or complaints process.
- If an adverse reaction or injury is experienced by the individual following the event, submit an additional CARM AEFI report and arrange ACC treatment injury claim per **ACC2152 form**.

45 Variations

45.1 Missing or incorrect information in the CIR

When it's identified a consumer has missing or incorrect information documented in the CIR relating to the administration of a vaccine in Aotearoa New Zealand, then it must be corrected as it is a legal record.

The CIR can be modified by the provider or health professional within 24 hours after details of a vaccination were entered.

After this time the CIR can only be modified by contacting **help@C-19imms.min.health.nz** or **0800 223 987**.

45.2 Where the consumer has received vaccination overseas

This advice applies when consumer has received a COVID-19 vaccine overseas (which may or may not be of the Pfizer COVID-19 vaccine):

- Specifically, when the consumer has been administered 1 vaccination of a 2-dose primary course (Pfizer or other two-dose vaccine), they are able to receive the Pfizer COVID-19 vaccine if the second dose is at least 4 weeks after their overseas vaccination.
- Please consult IMAC on 0800 IMMUNE for specific clinical advice.

The consumer must provide evidence of their overseas vaccination (e.g., a vaccine receipt card or other documentation). The provider creates a CIR immunisation record for the 2-dose vaccine and uploads the overseas first dose vaccination evidence the consumer has provided.

Note 1: Based on advice from the COVID-19 Vaccine Technical Advisory Group the CIR will only accept the entry of named vaccines. At the time of review of this document those overseas vaccines able to be entered in CIR are contained at: -

www.health.govt.nz/our-work/diseases-and-conditions/covid-19-novel-coronavirus/covid-19-vaccines/my-covid-record-proof-vaccination-status/covid-19-overseas-vaccinations-and-certificates

Note 2: The CIR record of the Aotearoa New Zealand-based dose administered is automatically notified to the consumer's primary care (GP) practice through the existing CIR primary care practice notification functionality. The entry into the CIR of an overseas vaccination contained in the preceding hyperlink is likewise automatically notified to the consumer's primary care practice.

Appendices

Appendices: Summary of Changes

Section guidance

This section provides the appendices for the Vaccine Operating Guidelines.

Version	Date	Section	Summary of Changes
42.0	11/07/22		No changes

Purpose

It is designed to provide additional information and support, to help maintain public safety and ensure consistent and equitable vaccination outcomes across Aotearoa New Zealand.

Appendix A:
Site checklist

As a general principle, the site and staff should be prepared and adhere to standard operating policies and standards, including the clinical governance and health and safety, expected in a clinical environment to ensure staff and consumer safety.

Tables A1 to A5 below, provide an overview of the minimum requirements to deliver COVID-19 vaccinations safely and efficiently.

Table A1 – plan checklist

Plan	Y / N	Comments
Vaccination volume plan Vaccination sites have planned for expected daily volumes of vaccine recipients, considering: • Staffing numbers • Space and distancing • Privacy and confidentiality	 Y ☐ N ☐ Y ☐ N ☐ Y ☐ N ☐	
Workforce plan To maintain the staff roster including managing unavailability, illness, and other absences.	Y ☐ N ☐	
The list of **Key Contacts** is up to date and accessible.	Y ☐ N ☐	
Clinical Quality and Safety oversight is on site.	Y ☐ N ☐	
Local development of: • Infection Prevention • Control guidance • SOPs • Cold Chain Accreditation for this site	 Y ☐ N ☐ Y ☐ N ☐ Y ☐ N ☐ Y ☐ N ☐	
Site locations consideration: • Location/traffic/access/parking/signage • Availability of public transport • Accessibility (including disability access to parking and to vaccination site building) • Traffic management	 Y ☐ N ☐ Y ☐ N ☐ Y ☐ N ☐ Y ☐ N ☐	
The site can maintain temperature requirements of the vaccination preparation space.	Y ☐ N ☐	
A **documented risk assessment** has been conducted for every individual vaccination site including business continuity plan covering changes in COVID response alert levels	Y ☐ N ☐	

Site-specific COVID Tracer App QR codes have been created.	Y ☐ N ☐	
A plan is in place to maintain adequate and appropriate resources including: • PPE supplies • Vaccine and consumables • IPC supplies • Waste management • Signage	Y ☐ N ☐ Y ☐ N ☐ Y ☐ N ☐ Y ☐ N ☐ Y ☐ N ☐	
A plan is in place to **maintain daily supplies** of consumer collateral, including: • Getting your COVID-19 Vaccine: What to Expect • Consent form • After your Immunisation • Vaccination receipt and second appointment card • Privacy Statement • Hard-copy form to collect household contacts.	Y ☐ N ☐ Y ☐ N ☐ Y ☐ N ☐ Y ☐ N ☐ Y ☐ N ☐ Y ☐ N ☐	
A plan is in place for **equitable access**, including: • Access to translation and interpretation services • Written material and signage in easy-to-read formats • Supporting resources/literature is available in a range of languages/formats for those with low health literacy. • Service delivery model provides for whanau/support people accompanying consumers. • Venue access caters for disabled people and support for those with visual or hearing impairments.	Y ☐ N ☐ Y ☐ N ☐ Y ☐ N ☐ Y ☐ N ☐ Y ☐ N ☐	
A plan is in place to manage the transition from locally managed booking systems to the national immunisation booking system or programme accepted booking solution.	Y ☐ N ☐	
A site evacuation plan is in place.	Y ☐ N ☐	
A dry run has been completed for all vaccination sites.	Y ☐ N ☐	

Table A2 – place site checklist

Physical site	Y / N	Comments
Adequate space (including also for whanau/support persons) and associated capacity for: • Screening • Registration • A private space for consultation, family groups, and vulnerable people requiring support	Y ☐ N ☐ Y ☐ N ☐ Y ☐ N ☐	

• Waiting (seated) • Vaccination (including drawing up and administrating) • Post-vaccination observation.	Y ☐ N ☐ Y ☐ N ☐ Y ☐ N ☐	
Access to secure storage for medical records (including consent forms).	Y ☐ N ☐	
Appropriate signage to identify as vaccination site for consumers, including COVID-19 vaccination campaign posters/banners/flags. Signage should also include Code of Consumer Rights.	Y ☐ N ☐	
Site has clearly marked one-way foot traffic flow with clear entry and exit areas.	Y ☐ N ☐	
Adequate number of hand-hygiene stations in strategic areas for public and staff	Y ☐ N ☐	
Appropriate emergency medication, equipment, and space to respond to medical emergencies. All equipment in the site to be well maintained, in good working order, calibrated/monitored as required and with current electrical safety compliance testing/certificates as necessary. **Note:** This should also include equipment suitable for children if the site will be administering paediatric vaccines.	Y ☐ N ☐	
Appropriate cold chain provisions that are applicable for the site are in operating order, including having appropriate refrigerators and opaque containers to store supplies. Cold Chain Accreditation is held and is current if applicable.	Y ☐ N ☐ Y ☐ N/A ☐	
Adequate space for vaccine storage and preparation.	Y ☐ N ☐	
Adequate security (e.g., alarm, overnight security guard) if vaccine is to be stored at vaccination site overnight.	Y ☐ N ☐	
Appropriate waste management facilities, including facilities in place to safely dispose of sharps and unused, damaged, or empty vaccine vials (e.g., Interwaste vial disposal bin ordered).	Y ☐ N ☐	
Vaccination stations at least one metre apart.	Y ☐ N ☐	
Access to CIR-compatible IT hardware including tablets, laptops or desktop computers with screens positioned out of sight of unauthorised persons.	Y ☐ N ☐	
IOS or Android smartphones with Salesforce Authenticator app available to CIR users.	Y ☐ N ☐	
High-speed wireless or 4G coverage.	Y ☐ N ☐	
Access to appropriate internet browser (Note: Internet Explorer is not supported).	Y ☐ N ☐	

Table A3 – process checklist

Process	Y / N	Comments
Scheduling of vaccination appointments avoids over-crowding and allows for physical distancing.	Y ☐ N ☐	
Booking and scheduling system includes arranging for consumers to return for a second dose of the vaccine at least three weeks after receiving the first dose.	Y ☐ N ☐	
All staff have access to the Operational Guidelines.	Y ☐ N ☐	
Procedures are in place for identifying vaccine recipients.	Y ☐ N ☐	
Process in place for screening all staff for signs and symptoms of COVID-19 at the start of each shift.	Y ☐ N ☐	
Standardised screening processes are in place for contraindications, receipt of previous dose of COVID-19 vaccine or other vaccines, and COVID-19 symptoms.	Y ☐ N ☐	
'Where to get help' poster is accessible to all staff.	Y ☐ N ☐	
Consumer information processes in place, including the provision of consumer collateral.	Y ☐ N ☐	
Cold chain process in place, site delivery and receipt.	Y ☐ N ☐	
Processes in place for infection prevention and control including: • Hand hygiene • PPE protocols • Injection safety • Needlestick injury protocol	Y ☐ N ☐ Y ☐ N ☐ Y ☐ N ☐ Y ☐ N ☐	
Processes in place to safely manage waste and for safe disposal of sharps and unused, damaged, or empty vaccine vials.	Y ☐ N ☐	
Process in place for monitoring, managing, and reporting adverse events following immunisation, including anaphylaxis.	Y ☐ N ☐	
Policies in place for blood body and fluid exposures (BBFE) and infection prevention control (IPC).	Y ☐ N ☐	
Appropriate process in place to respond to medical emergencies associated with the vaccination.	Y ☐ N ☐	
Incident management procedures are in place and staff know how to report any clinical incident.	Y ☐ N ☐	
SOP available for accessing and operating CIR and completing inventory reporting requirements.	Y ☐ N ☐	
Business continuity plans in place, including access to hard-copy versions of: • Consent forms with CIR data fields on the reverse and associated secure storage. • COVID-19 Vaccine Adverse Event Report	Y ☐ N ☐ Y ☐ N ☐	

Table A4 – workforce checklist

Workforce	Y / N	Comments
Staffing levels (including trained and accredited as required) are appropriate for delivering the scheduled vaccination volume. At a minimum, the following functions need to be allocated: • Consumer welcome • Preparation and administration of doses • Obtaining informed consent • Events recording in CIR by a CIR-trained person • After-immunisation observation	Y ☐ N ☐ Y ☐ N ☐ Y ☐ N ☐ Y ☐ N ☐ Y ☐ N ☐	
Site workforce encourages equitable access and the workforce demographic, as reasonably practicable, reflects of the likely consumer population or local area.	Y ☐ N ☐	
Staff are educated in disability equity access and know how to apply supported decision-making approach (e.g., the Ministry's **Disability equity course**)	Y ☐ N ☐	
Staff accessing consumer data have completed the appropriate privacy training (e.g., see the **Privacy Commissioner courses link**).	Y ☐ N ☐	
Staff inducted to the site and to have completed all relevant training including cold chain and IMAC/vaccine training, adverse event training, and CIR training.	Y ☐ N ☐	
Appropriate staff training to respond to three possible medical emergencies associated with the vaccination (fainting, hyperventilation, and anaphylaxis).	Y ☐ N ☐	
Staff roles and responsibilities are clearly defined.	Y ☐ N ☐	
Multi-vaccinator sites have a named Lead Clinician.	Y ☐ N ☐	
An appropriate people has been identified to receive vaccine delivery as part of cold chain provisions.	Y ☐ N ☐	
Infection Prevention and Control staff have been identified including: • IPC Lead • IPC trainers	Y ☐ N ☐ Y ☐ N ☐	
Security presence available to control access to the site and be available for support in the event of attempted unauthorised access.	Y ☐ N ☐	
All vaccination site staff have been given the opportunity to receive a COVID-19 vaccination.	Y ☐ N ☐	

Table A5 – other considerations checklist

Other considerations	Y / N
• Staff working in or near MIQ or other locations that may require additional infection prevention controls, must adhere to the standard SOPs and associated protocols for such locations, including physical distancing requirements.	Y ☐ N ☐
• In the event of a change in Alert Levels, adherence to the relevant PPE SOPs and associated protocol is required to operate under the Alert Level, including physical distancing requirements.	Y ☐ N ☐
• Where a mobile vaccination team is being set up, in addition to the above also consider the following: • Staff numbers to match expected demand as well as site health and safety requirements • Site security • Appropriate training • Correct set up in CIR, including completion of the 'COVID-19 Facility and Site Set-up Details'. • Reliability of supply of resources and equipment • Internet connectivity to enable use of CIR • Logistics, including vaccine storage and transport • Business continuity	Y ☐ N ☐ Y ☐ N ☐ Y ☐ N ☐ Y ☐ N ☐ Y ☐ N ☐ Y ☐ N ☐ Y ☐ N ☐ Y ☐ N ☐
• Drive through vaccinations: • Some disabled people use modified vehicles that seat the driver/passengers higher – potentially making it more difficult for vaccinators to reach • A reminder that car doors can also be opened if proper needle positioning can't be achieved through the window	Y ☐ N ☐ Y ☐ N ☐

Version 3

Appendix B:
New facility/site setup

This information must be provided to the Ministry five days in advance of any initial deliveries. Please use the following template to complete the information required to enable us to set up a vaccination facility or vaccination site. Please take care and provide detail when completing the form, as accurate information is required to ensure successful delivery of vaccines and consumables.

Return the completed form to **help@c-19imms.min.health.nz** and CC your Regional Area Manager

Version	Date	Summary of Changes
1.4	05/11/21	New facility/site setup form updated with changes to categorisation of site types and provider types.
1.5	29/03/22	Addition of flu vaccination to vaccination type field Amendment to list of 'site types' Addition of cold chain storage expiry date Addition of field to record location of back up cold-chain storage

Previous revision history can be found at the end of the appendices section.

Has the site been signed off by the DHB CE?		Please attach a copy of signed authorisation	
Y ☐	Please tick if yes	Y ☐	Please tick to confirm

Location details section	New site set up – part one of three

A	Site	*Only complete Section A if a site is being set up.* **Note: Sites are where vaccines are administered**
Site	DHB	Enter the DHB in which the vaccination facility/site is located
	Site name	Please provide the site name
	Site address	Please provide the delivery address. Please include floor number/building number/gate number if relevant.
	Confirm	Suburb and post code of this site
	City	Enter city in which this site is located
	Site type details	
	Please tick	Is this vaccination site also a facility? Y ☐ N ☐
	Vaccine type	☐ Covid-19 ☐ Influenza ☐ Both Covid-19 & Influenza
	Site type Please tick	☐ GP ☐ Hospital ☐ Marae ☐ Off-Site ☐ On-Site ☐ Mobile or Pop-up Site *(short term vaccination site)* ☐ Mass Vaccination Event ☐ Permanent Vaccination Centre *(long term vaccination site)* ☐ Drive-Through ☐ School ☐ Community Pharmacy ☐ Urgent Care Clinic ☐ Residential Facilities (e.g. Aged Care Facility, Residential Care etc.) ☐ Place of Worship ☐ Workplace (Vaccination for staff and whanau) ☐ Bus ☐ Other:
	Equity focus	☐ Not applicable ☐ Māori ☐ Pacific Island ☐ Disability ☐ Mixed
	The following information relates to the Provider(s) responsible for the site.	
	Primary Provider name	Please provide the name of the primary provider
	Provider type	☐ DHB ☐ Occupational Health ☐ Community Pharmacy ☐ GP ☐ PHO ☐ Hauora ☐ Pacific Health Provider ☐ Urgent Care Facility ☐ Other If other, please add details
	Provider equity focus	☐ No Specific Equity Focus (General population) ☐ Māori ☐ Pacific Island ☐ Disability
	Collaborating provider name	Please provide the name of the collaborating provider (if applicable)
	Collaborating provider type	☐ DHB ☐ Occupational Health ☐ Community Pharmacy ☐ GP ☐ PHO ☐ Hauora ☐ Pacific Health Provider ☐ Urgent Care Facility ☐ Other If other, please add details
	Collaborating provider equity focus	☐ No Specific Equity Focus (General population) ☐ Māori ☐ Pacific Island ☐ Disability

Facility details section	New site set up – part two of three

B	Facility	*Please provide Facility or Associated Facility details.* **Note: Facilities are where vaccines are shipped, stored and distributed to sites.**
Facility	DHB	Please provide the DHB where the facility is located
	Facility name	Please provide the facility name if different to site name in Section A
	Facility type	Please provide the facility type, such as hospital, pharmacy, clinic
	Facility address	Please include suburb, city and postcode
	Delivery address (if different from facility address)	Please advise the delivery address - include floor number/building number/gate number if relevant.
	Facility ID (HPI ID)	What is this facility's ID (if unknown, state 'unknown')

Delivery information

Please provide the available delivery times for the facility, such as 7am to 5pm, Monday to Sunday.

Available delivery times	☐ Mon		☐ Tue		☐ Wed		☐ Thu		☐ Fri		☐ Sat		☐ Sun	
	AM	PM	AM	PM	AM	PM	AM	PM	AM	PM	AM	PM	AM	PM
Delivery Notes	Please add any comments which may assist the delivery driver in successfully													

Storage, capacity, and contact details		New site set up – part three of three	
C	**Which of the following storage accreditations does the facility provide?**		
	Ultra-cold (-70C)	Y ☐ N ☐	If yes, please provide details of how many vials can be stored
	Frozen (-20C)	Y ☐ N ☐	If yes, please provide details of how many vials can be stored
	Cold chain (2-8C)	Y ☐ N ☐	If yes, please provide details of how many vials can be stored
	Cold chain (2-8C) accreditation expiry date	Expiry Date: [DD/MM/YYYY]	
	Back-up fridge location	[Please enter name and address of alternative location]	
	Ambient	Y ☐ N ☐	If yes, please provide details of how many vials can be stored
	Consumables	Y ☐ N ☐	If yes, please provide storage details
	Is there a data logger reader at location?	Y ☐ N ☐	If yes, please provide details about brand/type
	Pay per dose contract		
	Pay per dose contract number		If this contract is a Pay per Dose contract – Please provide the contract number.
	Regional Anniversary		In which region will you be observing Regional Anniversary days?
	Pay per dose contract		
	Named role	Please confirm the **named role** at this vaccination facility/site who will be available and is authorised to receive the vaccine/consumables upon delivery, for example lead nurse, clinic manager.	
	Named role name and contact phone number/s	**Name**	Confirm name
		Phone	Confirm phone number/s
	Alternate Name and contact phone number/s of other team members who fit the named role	**Name**	Confirm name alternate 1
		Phone	Confirm phone number/s alternate 1
		Name	Confirm name alternate 2
		Phone	Confirm phone number/s alternate 2
	Completed/signed by		
	Name	Add name	
	Title	Add title	
	Signature	Insert signature	

Appendix C:
Facility/site closure

This information must be provided to the Ministry in the event of a facility or site choosing to no longer administer and distribute certain vaccine types.

Please take care and provide detail when completing the form below. Upon completion, please email this form to the Ministry's service desk at: **help@c-19imms.min.health.nz**

For **user decommissioning**, please liaise with your DHB/Provider workforce lead or alternatively you can request the user decommissioning document from the Ministry's service desk.

The following definitions apply specifically to this form

- **Vaccination facility**
  Where vaccines are shipped, stored, and distributed to sites.
- **Vaccination site**
  Where vaccines are administered.
- **CIR Suite**
  Includes all vaccination recording tools managed by the ministry, the suite covers CIR, CIR Logistics portal, NIBS & Payments

Facility and Site closure form

DHB/Provider name Please state the DHB/Provider the vaccination facility/site is attached to	

A	**Site closure**	
Site	1 Site name	
	2 Site address	
	3 Closure date	
	4 Reason for closure	
B	**Facility closure (if applicable)**	
Facility	5 Facility name	
	6 Facility address	
	7 Facility ID (if known)	
	8 Closure date	
	9 Reason for closure	

C	**Tick to confirm the closure of:**	
Site: ☐	**Facility:** ☐	**Both:** ☐

D	**If your site offers COVID and Flu vaccinations, tick to confirm the vaccine type you will no longer offer:**	
COVID: ☐	**Flu:** ☐	**Both:** ☐

Return of excess stock

1. Please conduct a stocktake of all assets relating to the COVID-19 Vaccination Rollout upon Facility/Site closure. Please send copies of this form to the Ministry's Service Desk and your DHB Lead.
2. The DHB lead should arrange a transfer of any remaining assets from the site which is closing to another site and capture this through raising a transfer order in CIR Inventory.
3. Once there is zero stock on hand visible in CIR Inventory, the DHB logistics Lead should notify the Ministry to change the site status in CIR from Active to Closed.

Note: Once closed the site will not be accessible by CIR inventory users in the system.

Providers must adhere to guidance provided in National Standards for Vaccine Storage and Transportation Providers 2017 and the 2021 Addendum when closing down a vaccine site/facility. Please refer to the links below for a copy.

Please tick to confirm these guidelines have been adhered to	Y ☐	Please tick to confirm

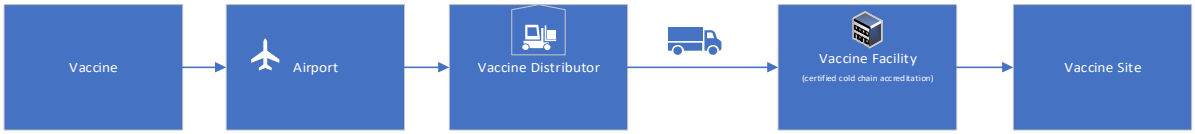
Once submitted, the site will be removed from all vaccination recording tools within the CIR suite. The site will no longer be visible through the logistics portal and if the site operates under a PPD model, they will be paid within the final cycle then removed from the contract.

By completing this document, you agree that the Facility/Site will no longer be administering and/or ordering vaccines.

Appendix D: Logistics and inventory management

The Ministry will maintain the COVID-19 Vaccination Immunisation Register (CIR) logistics module to support ongoing monitoring of inventory and demand. The image below shows the current process for distributing the vaccine to vaccination sites.

Figure D.1 – vaccine distribution process



Various vaccines have different storage conditions at each step of the process, see the Cold Chain Storage and shelf life in Section.

Roles and Responsibilities	**Vaccine Manufacturer** will ship trays to NZ's vaccine distributor, confirm temperature, then transfer ownership.	**The Vaccine Distributor** will store at the optimal temperature for long term storage.	**The Vaccine Distributor** will pick and pack and arrange transport to the vaccine facility for storage at +2°C to +8°C.	**Sites** will forecast their daily volumes on a rolling weekly basis.
	MOH will own the supply from here.	**DHBs** will maintain a demand plan for the upcoming four weeks and keep it up to date weekly.	**Facilities** will receive and store vials at +2°C to +8°C in certified cold chain for later distribution to sites without cold chain.	**DHBs** or **Providers** may transport vials from their facilities to vaccination sites (within transportation time limits on vaccines if applicable).
	The Vaccine Distributor will confirm the vaccine is undamaged and transfer to inventory management.	**MoH** will confirm the order with the distributor to pack and transport to each delivery site.	**Sites** may also receive and store vials at +2°C to +8°C in certified cold chain.	

Appendix E:
CVIP logistics overview/cheat sheets

Regulations

- **COVID-19 Vaccine ownership**
  All COVID-19 vaccine stock is owned by the Ministry of Health.
- **Pharmacy licence**
  This allows DHB hospital pharmacies to pack down full trays of 195 vials and packs of five or 15 of the BioNTech/Pfizer COVID-19 Vaccine into smaller quantities, but only for vaccination sites run by the DHB legal entity; that is, DHB hospital pharmacies can only pack down into smaller pack sizes for vaccination sites run by DHB employees.
- **Wholesale Licence**
  This allows DHB hospital pharmacies to supply the BioNTech/Pfizer COVID-19 Vaccine by wholesale, in full trays of 195 vials and original packs of five and 15 to non-DHB vaccination sites outside their DHB legal entity. For the purposes of this, the definition of DHB means the DHB legal entity, not the geographical DHB boundary.

Cold chain standards

- The **National Standards for Vaccine Storage and Transportation for Immunisation Providers 2017**, describes the standards and requirements for providers.
  The integrity of the cold chain is dependent upon:
  - the people who maintain and monitor the cold chain
  - the systems and processes used
  - and the equipment in which the vaccines are stored.
- **Cold chain accreditation**
  All immunisation providers are required to achieve accreditation (or Cold Chain Compliance, where applicable) if they need to store vaccine overnight. Assessors use this tool to ensure providers' cold chain practices and processes meet the required standards. See the **National Standards** for full details.
- An **Addendum** for ultra-cold vaccine storage of COVID-19 vaccine stock has been developed. Cold Chain Accreditation as per the addendum must be met before vaccines can be received.
- **Cold chain review group**
  Where a DHB hospital pharmacy needs to function outside of the boundaries of the national standards for cold chain storage and transportation, they can request the Ministry's cold chain review group to be convened under urgency for advice. Any advice provided by this group will always be safe and ensure no compromise to the cold chain.

Vaccine ordering

- **Registering new site/facility**
  All sites/facilities need to be registered at least five days prior to the first required vaccine delivery. It is recommended the first delivery is used as a 'wet run' to vaccinate the vaccinators and to validate the delivery processes.
- **Order deadline**
  Vaccine orders must be submitted before 10am the day before their allocated delivery day(s). Orders must be submitted in the CIR portal. The DHB lead needs to submit any urgent orders that are required prior to the next designated delivery day, as an 'out-of-cycle' delivery request to the CST Logistics Desk.

  Note: If DHBs need to check/QA vaccine site orders, ensure there is sufficient time for this process to be completed by 10am.
- **Consumable packs**
  Consumable packs containing needles and syringes can be ordered (100 and 700 kits) in addition to 'order as required' items.

Vaccine handling

- **Receiving/sending at 2°C to 8°C**
  COVID-19 Vaccine arrives in validated cold-chain shipper boxes with a datalogger.
- **Shelf life**
  See summary below, and table 8.1 for full details.
- **Redistribution/transfers**
  Vaccine stock is not to be redistributed between facilities and sites, unless requested by the Ministry or DHB Hospital pharmacy.
  Note: only HCL, DHL, and DHB hospital pharmacies have wholesale licences to support distribution of vaccine stock.

Vaccine handling

- **Cold Chain accreditation and transportation**
  All facilities must have a current cold chain accreditation and the expiry date recorded in the CIR. Providers must use temperature-monitored chilly bins to transport vaccines. A hard walled/robust chilly bin must be used for off-site clinics. For each chilly bin, monitor the temperature using either a digital minimum/maximum thermometer with an audible alarm, or a datalogger with a probe and external display. It must be possible to read the temperature without opening the chilly bin. All chilly bins and temperature monitors must be validated. Full details can be found in **section 7.3 of the national standards**.
- **Dataloggers**
  Use a datalogger with a probe, external display and alarm to monitor the temperature of the vaccines throughout the time they are stored in a chilly bin. Set the datalogger to record the temperature every five minutes, and download, review and save the data after returning to the clinic. Full details can be found in **section 7.3 of the national standards**.

Vaccine	State	At +2°C to+8°C	At ambient temperature
Adult Pfizer (12+yrs)	Undiluted	**Up to 31 days**	**Up to 2 hours** (up to 30°C including excursions)
	Diluted	**Up to 6 hours**	**Up to 6 hours** (up to 30°C)
Paediatric Pfizer	Undiluted	**Up to 10 weeks**	**Up to 2 hours** (up to 30°C)
	Diluted	**Up to 12 hrs**	**Up to 6 hrs when drawn up into syringe** (up to 30°C)

Vaccine		State	At +2°C to+8°C	At ambient temperature
AstraZeneca	DO NOT DILUTE	Unopened	Up to **6 months** DO NOT FREEZE	Up to **12 hours** (up to +30°C)
		Opened/ Punctured	Max. **48 hours** cumulative storage time	Up to **5 hours** (up to +30°C)
Novavax	DO NOT DILUTE	Unopened	Up **to 9 months**. **DO NOT FREEZE**	Up to **6 hours** (up to +25°C)
		Punctured vial or drawn up syringe	Up to **6 hours**	Up to **6 hours** (up to +25°C)

Appendix F: Links to the National Immunisation Booking System

COVID-19 Immunisation Register (CIR)

- All CIR training material can be found at **https://circlassrm-ncts.cs116.force.com/cir/s/recordlist/Knowledge__kav/00B5O000001CNbyUAG**

Individual guides

NIBS

- **https://circlassrm-ncts.cs116.force.com/cir/s/article/CIR-Bookings**
- **https://circlassrm-ncts.cs116.force.com/cir/s/article/CIR-Bookings-Not-NHI-Matched-Quick-Step-Guide**

Accenture Vaccine Management System (AVMS)

- **https://circlassrm-ncts.cs116.force.com/cir/s/article/NIBS-Site-Admin-Managing-Overrides-exceptions-Guide**
- **https://circlassrm-ncts.cs116.force.com/cir/s/article/NIBS-Site-Admin-Managing-Capacity-Guide**

Other information

For any information which is not included in these documents, the DHB is advised to communicate with the Ministry.

This guide will be amended as required and the latest version will be made available via:

- **https://circlassrm-ncts.cs116.force.com/cir/s/recordlist/Knowledge__kav/00B5O000001CNbyUAG**

Appendix G:
Vaccination site screening questions

We encourage you to screen both staff and consumers for risk of exposure to COVID-19 and COVID-19 symptoms. Screening is critical to breaking the chain of transmission of COVID-19 and maintaining staff and consumer safety.

Figure G.1 below details the recommended screening questions and process to create a lower risk environment for transmission of COVID-19 and to ensure PPE advice in Appendix K is appropriate.

Please note:

- In the event of COVID-19 Alert Level changes, additional advice will be formulated by local public health units and the Ministry.
- Any consumer with a confirmed COVID-19 infection should not be vaccinated until they have had the appropriate recovery period (see Immunisation Handbook or consult with IMAC).
- Any consumer that has answered 'yes' to the screening questions below, is considered high risk for the transmission of COVID-19 and deferral is recommended.
- If a provider wishes to vaccinate a higher risk consumer (someone who answered yes below), providers should follow the 'vaccination in high-risk or screen 'positive' consumers' section in the Operating Guidelines.

Figure G.1– recommended screening questions

Q1 – Do you have symptoms of COVID-19?	
Follow link to **COVID-19 Case definition**	If a client has any symptoms suggestive of COVID-19, defer vaccination and do not permit entry to the site. Advise them to follow recommendations and guidance from the Ministry/public health services. Recommend they get a test and self-isolate pending the result.

If no symptoms, continue to the next question.

Q2 – Do you live with someone who has COVID-19?
If an individual lives with someone who has COVID-19, they are considered a household contact do not permit entry to the site and advise them to follow recommendations and guidance from the Ministry/public health services.

If no symptoms, continue to the next question.

Q3 – Have you been requested to stay at home, to self-isolate or are under an isolation order?
If yes, defer vaccination and do not permit entry to the site. Recommend continuing to follow the stay at home/self-isolation plan.

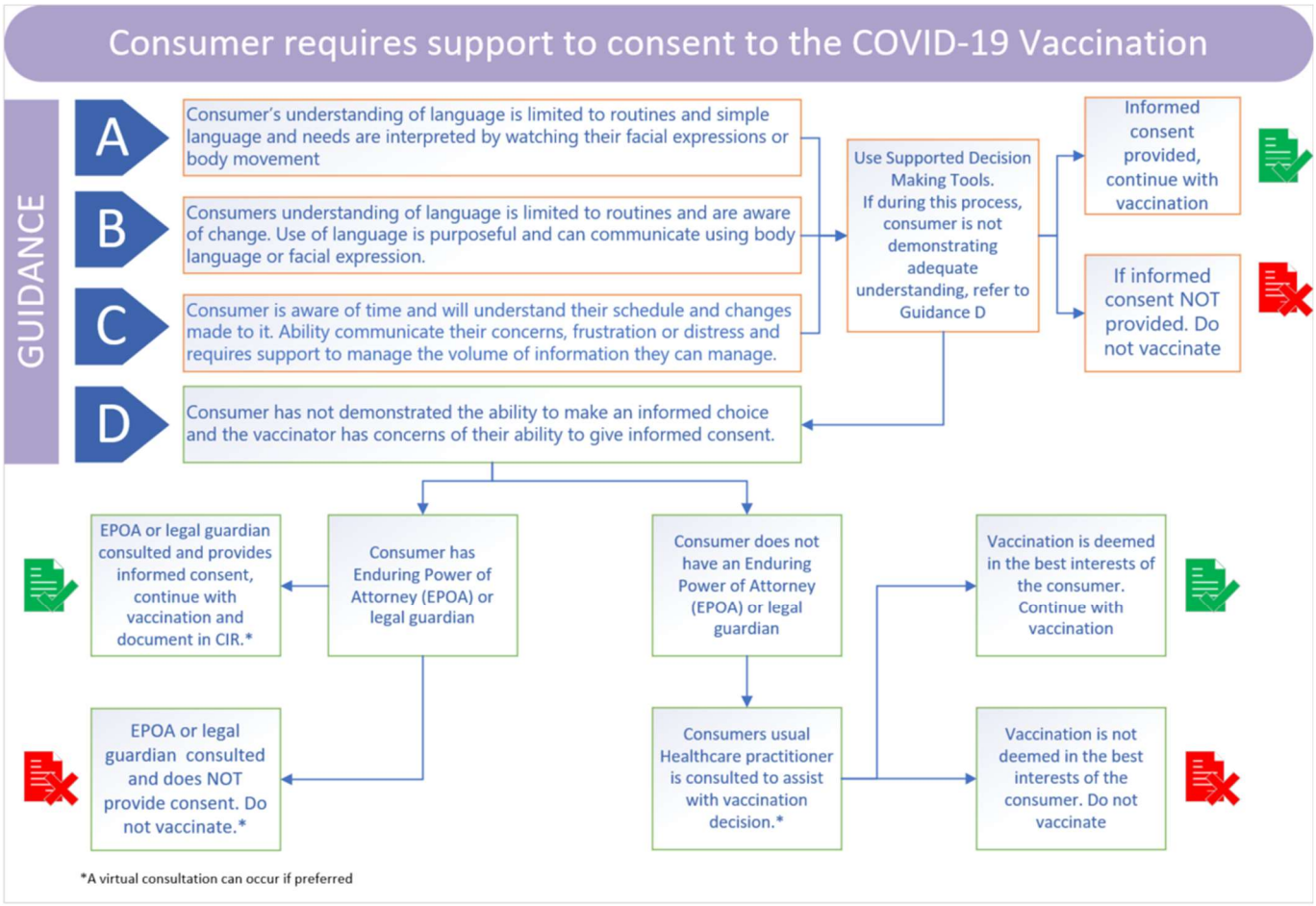
If no symptoms, continue to the next question.

Q4 – Are you currently waiting on a COVID-19 test result?
If yes, defer vaccination and do not permit entry to the site. Recommend rebooking once a negative test result has been received, and they have been told they no longer need to stay at home/self-isolate.

If no, proceed to vaccinate as per the Operating Guidelines.

Appendix H:
Supported decision-making process

Figure H.1 – support to consent



Appendix I:
NIP Adverse Event Process

This Appendix includes

1. Introduction
2. Process Steps
3. Severity Assessment Code (SAC) examples
4. Provider with the Ministry, initial serious incident/adverse event notification form.

Provider and Programme Lead Clinicians

Purpose

The COVID-19 Vaccine Immunisation Programme (CVIP) implementation phase is based on a devolved service delivery model. The CVIP Clinical Lead is committed to supporting a person-centred, safe and high-quality programme with all programme providers.

To support a provider when a serious adverse event occurs, the following process includes timely notification to the programme and consideration of CVIP support to the provider.

The following detail outlines the notification process and describes roles/responsibilities of CVIP provider lead clinicians in relation to COVID-19 vaccination-related serious adverse event[2] or a serious adverse event following immunisation[3].

Scope

This process outlines the notification of CVIP adverse events and uses severity assessment code (SAC) ratings. Any of the following must follow this notification process:

- SAC 1 (e.g., Anaphylaxis resulting in death or permanent loss of function)
- SAC 2 (e.g., Serious adverse reaction with delayed administration of adrenaline or delayed presence of emergency services)
- SAC 3 (e.g., Medication error, vaccine dilution error, or dose error)
- Several similar or close sequenced SAC 4 events (e.g., Breach of confidentiality).
- Near miss with likely significant consequences

Note: For more examples of the SAC ratings please refer to the table below.

This protocol aligns with existing expectations of health and disability service providers under the Health and Disability Services (Safety) Act 2001, as articulated by the Health Quality & Safety Commission, whereby those who voluntarily comply are expected to:

1. Report serious adverse events (SAC rating 1 and 2) and events on the Always Report and Review list to the Commission, using the adverse event brief – part A reporting form. This report should be made within 15 working days of notification of the event to the provider.
2. Undertake formal investigation of serious adverse events (SAC 1 and 2) and events on the Always Report and Review list and send review findings and recommendations to the Commission, using the adverse event brief – part B reporting form. This report should be made within 70 working days of notification of the event to the provider.

Exclusions

This CVIP serious adverse event process does not apply to other CVIP non-clinical incident types e.g., equipment or vaccine damage/loss.

The notification process is not a substitute for the provider's responsibility concerning an adverse event including their normal processes of reporting, reviewing and open communication with the affected person. The outcome may recommend clinical and quality continuous improvement actions.

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[2] An adverse event is an incident resulting in harm, or with the potential to result in harm to a health consumer.

[3] Adverse event following immunisation (AEFI) - an untoward medical event which follows immunisation and does not necessarily have a causal relationship with the administration of the vaccine. The adverse event may be an unfavourable or unintended sign, abnormal laboratory finding, symptom or disease

Process Steps

Pharmacovigilance	Timeframe
Ensure COVID-19 CARM report is completed for any suspected AEFI. CARM Resource **https://nzphvc.otago.ac.nz/report/**	Day 1 (< 8 hours)
Participate in follow-up activities with CARM if required.	On contact by CARM

Next

Notification to the Ministry and provider leads	Timeframe
Commence reporting process. You should use the attached provider or organisation process steps and ensure you identify a preliminary SAC rating. Programme Resource: **CVIP SAC examples in table below** **HQSC resource A Guide to the National Adverse Events Reporting Policy 2017**	Day 1 (< 8 hours)
Notify CVIP programme via email address: cvip.incidentnotification@health.govt.nz • **Attach the completed:** Provider with MoH initial serious incident & adverse event notification form (sections A and B) ○ Email Subject: CVIP Adverse Event Notification • Please refer to the relevant incident toolkit which can be found on the Connex 'Mahi Tahi' platform or your provider's Clinical/Quality Lead. Programme Resource **Provider with MoH Initial serious incident & adverse event notification form[4]**	Expedited (<48 hours)

Next

Plan and execute open communication with affected consumer/s [5]	Within 7 working days

Next

Investigation and reporting outcomes	Timeframe
• Investigate the incident using the provider or organisation's clinical quality and safety governance process, and in accordance with HQSC expectations. • Inform CVIP on investigation findings and recommendations. • This includes confirming the final SAC rating. HQSC resource https://www.hqsc.govt.nz/our-work/system-safety/adverse-events/	Commenced (<24 hours) Reporting to HQSC according to timeframes above.
If required, please arrange an ACC treatment injury claim. Also see the Treatment injury claim lodgement guide and the Treatment Injury Flowchart.	
Updating of CVIP incident form and send an update to the Ministry of Health	Ongoing/ until closed

[4] This is the notification form for all incident types including serious adverse events & AEFI.
[5] As a guide, the Health Quality and Safety Commission's "Root Cause Analysis for clinical incidents - A Practical Guide" have the expectation for communication with affected consumers during week 1 – 2 of the incident investigations.

Provider please:

As an adverse event, either following immunisation or other cause, please arrange for open communication with the affected person/s.

If required, please arrange ACC treatment injury claim per ACC2152 form: **https://www.acc.co.nz/assets/provider/3e3bd2aded/acc2152-treatment-injury-claim.doc**

SAC 1 Death or permanent severe loss of function	SAC 2 Permanent major or temporary severe loss of function
• Medication or dose error resulting in death or causing renal failure and need for permanent renal replacement therapy • Anaphylaxis resulting in death or permanent loss of function • Wrong site of vaccine resulting in removal of healthy limb or organ • Delayed referral, treatment resulting in treatment options limited to palliation (delay direct contributor) • Delayed recognition of patient deterioration resulting in permanent disability or death	• Fall resulting in fracture • Serious adverse reaction with delayed administration of adrenaline or delayed presence of emergency services • Delayed recognition of patient deterioration resulting in unplanned transfer to intensive care or to another hospital for higher acuity care, cardiopulmonary resuscitation and/or intubation • Medication or vaccine dose error resulting in major harm (e.g., requiring dialysis, intervention to sustain life, anaphylaxis) • Consumer serious assault occurring within vaccination care setting when a known safety plan is not upheld (e.g., protection order) • A vaccination incident affecting > 1 consumer
SAC 3 **Permanent moderate or temporary major loss of function**	**SAC 4 Requiring increased level of care** **OR no injury, no increased level of care; includes near misses**
• Fall resulting in laceration requiring sutures • Failure of essential service with moderate consequence to consumer • Medication error, vaccine dilution error, or dose error • Temporary nerve damage or pain from vaccine administration • Severe injection site infection • Vasovagal event following immunisation resulting in injury • Never events: wrong vaccine, early vaccination doses & underage vaccination	• Additional monitoring, investigations, or interventions due to the event post vaccination • Medication, vaccine dilution or dose error resulting in no increased level of care or monitoring- not reaching the consumer is a near miss • Breach of confidentiality • Near miss events

Version 4: Adapted for the COVID-19 Vaccine Programme (CVIP) from Severity Assessment Code (SAC) examples 2019–20 | Health Quality & Safety Commission 2019. This list is guidance only.

NIP incident/adverse event notification form

Notify and attach this completed form to: nip.incidentnotification@health.govt.nz **Email Subject:** NIP Adverse Event Notification			
Verified from the NIP Detecting Failsafe Report: Y ☐ N ☐			
Section A – Provider notification details			
Provider or DHB to complete information below			
Incident date/ time			
Date/ time reported			
Site		DHB	
Person reporting incident:			
Name			
Contact phone number/s			
Email address			
Section B – Description (Provider to complete)			
Type of incident / adverse event / AEFI (it's possible two of the four options apply)			
Near miss ☐	**Incident** ☐	**Serious adverse event** ☐	**AEFI** ☐
Vaccine type and dose (e.g., Paediatric Pfizer):	**Dose details (circle):**	**Primary Dose 1 / Dose 2 / Dose 3 / Booster** **Other:**	
Age of consumer:		**Ethnicity:**	
Have the DHB's/Provider's Clinical Lead or Quality Lead been notified?			Y ☐ N ☐
If adverse event following immunisation, has this been reported to CARM?			Y ☐ N ☐
Has IMAC been contacted for advice and given to the consumer:			Y ☐ N ☐
Has CIR been entered correctly to reflect actual dose given?			Y ☐ N ☐
Has a preliminary investigation been undertaken? List details below			Y ☐ N ☐
Has the consumer been informed and received and apology?			Y ☐ N ☐
Assign a preliminary SAC rating (circle one):			SAC 1 / 2 / 3 / 4

- **Incident** means any unplanned event resulting in, or having a potential for injury, ill health, damage or other loss, an incident includes an accident.
- **Adverse event** is an incident resulting in harm, or with the potential to result in harm to a health consumer. Please assign an adverse event SAC rating. Report a SAC 1,2 or 3 SAC event, a cluster of SAC 3/ 4 events +/- near misses.

- **Adverse event following immunisation (AEFI)** is an untoward medical event which follows immunisation and does not necessarily have a causal relationship with the administration of the vaccine. The adverse event may be an unfavourable or unintended sign, abnormal laboratory finding, symptom or disease.

Provider please note:

- Include information regarding open communication with an affected consumer, including date completed
- Include your findings in the actions you have taken to prevent reoccurrence
- Update this section of the form over time as incident investigation is progressed and then closed

Please provide as much detail of the incident as possible:
What went wrong? Were there any contributing factors? What were the immediate actions taken? What advice were you given and from whom? What changes will you be making to prevent this happening again? What follow up has been arranged for the consumer?
If the consumer received an early dose, please provide the number of days between doses.

Reviewed by (name and role): Clinical Lead or Quality Lead	

Ministry to complete information below		
Date and time received		
Person receiving notification		

Appendix J:
Risk mitigations for vaccination sites

The table below is applicable to any Alert Level.

Table L1 – risk mitigations

Actions Required at all levels	Supporting Document
• Adapt processes as required for screening of staff, consumers, and support people to capture COVID-19 symptoms, travel history, and/or attendance at locations of interest, if they have been directed to have a test or are awaiting a test result. Redirect symptomatic consumers or those with contact history for testing in line with Ministry of Health guidance.	• **COVID-19 Alert System** • **Operating Guidelines for COVID-19 Vaccination** • Refer to the **Vaccination Site Screening Questions** section above.
• Ensure contact tracing NZ COVID app QR codes and alternate contact tracing system (i.e., paper based) are in place and encourage their use.	• **COVID Tracer QR Codes** • **Tips for displaying NZ COVID tracer poster**
• Robust communication strategy to regularly inform staff and consumers of programme and service delivery changes.	• **COVID-19: Q&A for primary health care workers.**
• Promote staff awareness of resources to maintain up-to-date knowledge of national COVID-19 related information.	• **Āwhina App** • **NZ COVID Tracer App**
• Oversee and manage safe access to the site and queue management with ability to adapt to changes in alert level.	• **Operating Guidelines for COVID-19 Vaccination**
• Orientation and Adherence to Infection Prevention and Control (IPC) guidance, including hand hygiene, and Personal Protective Equipment (PPE) guidelines for various situations and alert levels. These must be available and understood.	• **Five Moments of Hand Hygiene** • **FAQ regarding IPC and PPE** • **PPE use in Health and Disability Care Settings**
• Plans to support adequate and safe staffing to deliver services depending on the COVID-19 alert level. This is not limited to but includes work bubbles, green/red streams, and staff cohorts.	• **Operating Guidelines for COVID-19 Vaccination and Planning considerations for various vaccination settings**
• Regular training in place for current and (any extra staff) around changes in approach for different alert levels.	• **Operating Guidelines for COVID-19 Vaccination and Clinical Guidance** • **IMAC COVID-19 information and training**
• Ensure there is sufficient internet connectivity to enable use of the CIR and other technology in all relevant areas of the site. It may be necessary to use mobile Wi-Fi hotspots.	• **Operating Guidelines for COVID-19 Vaccination and Planning considerations for various vaccination settings**
• Staff wellness: Staff must be discouraged from attending work when unwell and must be encouraged to be up to date with occupationally relevant vaccinations.	
• Ensure that environmental safety considerations, including ventilation, are adequately appraised.	

Appendix K: **Vaccination practice variation according to the COVID-19 Protection Framework changes**

This appendix provides guidance in the event of any Protection Framework (traffic light) changes. All guidance will be regularly reviewed and has been updated in response to the Omicron variant. This should be read in conjunction with COVID-19 Readiness Plans The COVID-19 Protection Framework (PDF, 422 KB) and the **Primary care quick reference guide.**

For the latest Ministry guidelines on IPC please see the following **link**.

For "vaccination in high risk or screened positive consumers", please see the corresponding section above for PPE guidance.

Category	C19 Protection Framework: Green (Sporadic Cases)	C19 Protection Framework: Orange (Increasing Cases)	C19 Protection Framework: Red (Widespread Cases)
Environmental and Operational			
Physical distancing	At least 1 metre physical distancing between bubbles for consumers/public being vaccinated.	At least 1 metre physical distancing.	At least 1 metre physical distancing.
Contract Tracing	Must have a way for consumers to record their visit (e.g., NZ COVID Tracer QR code)		
Physical barriers	Not mandated.	Perspex/physical barriers between staff and consumers, where possible, i.e., at reception and screening.	Perspex/physical barriers between staff and consumers, where possible i.e., at reception and screening.
Gathering restrictions	Site planning must apply the Physical distancing guidance. The hospitality guidance does not apply to vaccination sites (including car park drive through sites).	Restrict number of consumers within the vaccination site to maintain 1m spacing, including use of restricted/monitored entry (i.e., one-in, one-out) paying attention to minimising numbers in physically restricted spaces such as the observation area, and mitigation strategies such as outdoor/carpark waiting and observation areas, and observation of physical distancing requirements for consumers. Restrict staff numbers to those essential for core tasks.	Restrict number of consumers within the vaccination site to maintain 1m spacing, including use of restricted/monitored entry (i.e., one-in, one-out) paying attention to minimising numbers in physically restricted spaces such as the observation area, and mitigation strategies such as outdoor/carpark waiting and observation areas and physical distancing requirements for consumers. Restrict staff numbers to those essential for core tasks.
Support people	As above, to apply Physical distancing guidance.	Not permitted in the vaccination site unless extenuating circumstances (for instance, disability, language, or cultural support). **Note:** when vaccinating a child 5-11 years the site clinical lead can decide on support people to accompany a child.	Not permitted in the vaccination site unless extenuating circumstances (for instance, disability, language, or cultural support). **Note:** when vaccinating a child 5-11 years the site clinical lead can decide on support people to accompany a child.
Flow	1-way flow through vaccination site, if possible.	1-way flow through vaccination site, if possible.	1-way flow through vaccination site, if possible.
Staff cohorting	Staff limited to one work site per day as much as possible. Staff should keep at least 1 metre apart, between staff. Avoid unnecessary congregations, like in break rooms, avoiding being in confined spaces unless necessary.	Staff limited to one role/shift (as much as possible) and one site per day. In the setting of extended site opening hours, should be limited to working with a defined team of staff (i.e., working within a defined group and not mixing across shifts). Avoiding unnecessary congregations, like in break rooms, avoiding being in confined spaces unless necessary.	Staff limited to one role/shift (as much as possible) and one site per day, and in general encourage consistency in site and work bubble. In the setting of extended site opening hours, should be limited to working with a defined team of staff (i.e., working within a defined group and not mixing across shifts). Avoiding unnecessary congregations, like in break rooms, avoiding being in confined spaces unless necessary.
At risk staff	No additional precautions	At risk staff should avoid direct consumer contact.	At risk staff should work from home.
Parking on site	If required, additional parking space between vehicles if possible (i.e., block alternate parks off with cones).	Additional parking space between vehicles if possible (i.e., block alternate parks off with cones).	Additional parking space between vehicles if possible (i.e., block alternate parks off with cones).
Ventilation	See 'site considerations' section in Operating Guidelines.	See 'site considerations' section in Operating Guidelines.	See 'site considerations' section in Operating Guidelines.
Infection Prevention and Control			
Staff PPE	In addition to standard precautions, all staff to wear a medical mask continuously. Medical mask can be worn for duration of session, up to four hours. Optional to wear eye protection when administering vaccine (can be worn for the duration of a session and cleaned if reusable).	In addition to standard precautions, all staff to wear a medical mask continuously. Medical mask can be worn for duration of session, up to four hours. Optional to wear eye protection when administering vaccine (can be worn for the duration of a session and cleaned if reusable).	In addition to standard precautions, all staff to wear a medical mask continuously. Medical mask can be worn for duration of session, up to four hours. Optional to wear eye protection when administering vaccine (can be worn for the duration of a session and cleaned if reusable).
Consumer Masks	Consumers are encouraged to wear a face covering (their own or a medical mask provided)	Consumers must wear a face covering (their own or a medical mask provided) at all times. For current guidelines see **here**.	Consumers must wear a face covering (their own or a medical mask provided) at all times. For current guidelines see **here**.
Surfaces & site cleaning	Clean and disinfect as per local cleaning policy.	Clean and disinfect environmental surfaces in the vaccination and vaccine preparation areas at least twice daily. Special attention to high touch surfaces.	Clean and disinfect environmental surfaces in the vaccination and vaccine preparation areas at least twice daily. Special attention to high touch surfaces.
Vaccination Process			
Screening	Before entering site. If vaccinating in high risk COVID-19 environments, see "Vaccination in high risk or screened 'positive' consumers" section above	Before entering site. If vaccinating in high risk COVID-19 environments, see "Vaccination in high risk or screened 'positive' consumers" section above	Before entering the site. If vaccinating in high risk COVID-19 environments, see "Vaccination in high risk or screened 'positive' consumers" section above
Consenting	At reception	Remote consent (telephone or online) prior to entering site, where possible. May consider consent outside in a separate resourced space.	Remote consent (telephone or online) prior to entering site, where possible. May consider consent outside in a separate resourced space.
Vaccination record card	Must be provided to the consumer as a hard copy record		

**Using COVID 19 Community Protection Framework. This guide will be updated as required according to new advice.*

Document version control

Revision History

Version	Date	Section/ Appendix	Summary of Changes
40.0	23/06/22	**Section A**	
		Table 8.1	Novavax Storage at 2-8°C extended to 9 months
		Section B No changes	
		Section C No changes	
		Section D No changes	
		Section E No changes	
		Section F	
		43.5	Removed information with changes to Google Maps process Information added on second booster
		Appendices	
		Appendix A	Table A1 and Table A2: requirement for Cold Chain Accreditation added to the checklists
		Appendix E	Novavax storage at 2-8°C extended to 9 months
41.0	01/07/22	**Section A No changes**	
		Section B	
		18.3	Updated 'Prescription' section with added information about section 34A Medicines Act 1981. Removed sentence about the Immediate Modification Order.
		Section C No changes	
		Section D No changes	
		Section E No changes	
		Section F No changes	
		Appendices No changes	