Operating Guidelines for DHBs & Providers

COVID-19 Vaccine Immunisation Programme

Version 4.0 – Tier 1

Last Updated 11 March 2021

MINISTRY OF HEALTH
MANATŪ HAUORA

Document Version Control

Revision History

Version	Date	Section/ Appendix	Summary of Changes
0.1	14/2/2021		Draft version for input issued to DHBs to support Tier 1 planning & operations
0.2	14/2/2021		Minor grammatical updates
1.0	18/2/2021		Significant changes including: • Addition of abbreviations table • Additional equity guidance • Additional clinical leadership guidance • Removal of 'Social distancing and consumer flow' section with detailed IPC section and guidance • Additional vaccine and on-site security guidance • Clarification of collateral available and purpose of each • Modified CIR access request process • Clarification of written consent process for Tier 1 cohort • Guidance for situations when consumers are not in CIR or do not have a NHI number • Addition of waste disposal process, vaccine quality control process and clarification of Credo Cube return process • Additional detail on operational reporting that DHBs can request • Guidance on recording vaccine errors • Guidance on administering leftover vaccine
2.0	25/2/2021		Minor updates throughout to include providers as well as DHBs. Minor formatting changes throughout.
		1	Addition of link to Immunisation Handbook as resource for clinical guidance on immunisations.
		5.4	Addition of new process for ordering Interwaste vial disposal bin; Interwaste contact details added to Key Contacts table.
		5.15.1	Updated section on running a site dry run
		5.13.3	Addition of CIR support process image
		7.2	Reformatting information on channels to collect household contacts in a table; additional channel added for collection during current DHB interactions with Border/MIQ staff.
		8.3 & 8.4	Existing content reformatted as tables with graphics; conducting clinical assessment and obtaining consent moved to vaccination process (from pre-vaccination process).
		8.4.1	Additional guidance on responding to adverse events on site.
		8.5	Updated text on recording vaccine errors
		8.7 & 8.8	Removal of requirement to monitor and report numbers of vials discarded to MoH.

		8.7.2 & 9.4	Added photo of Interwaste container and Credo Cube
3.0	4/3/2021	3 & 8.5	Updated phone number for IMAC clinical support
		5.1	Additional bullet points to encourage planning for consumers with visual or hearing impairments and support people who attend vaccination sites with consumers.
		5.7	Updated to include timeframe for entering hard-copy forms in CIR.
		8.1.1	Updated to clarify distinction between bulk-loading immunisation event records vs consumers for those on the BWTR; removed what was 8.3.1 as it duplicated information 8.1.1.
		8.3.1	Added note that collecting consumer residency information is not mandatory when setting up new NHI numbers.
		8.4.3	New content regarding COVID-19 treatment injury claims with ACC
		9.6.2	New guidance on managing refrigerator temperature excursions
4.0	11/3/2021	5.13	Note about consumers notifying their doctors that they've received the vaccine removed as completed vaccination records will now be passed to the Practice Management System (PMS).
		8.4	Post-vaccination observation period updated to 20 minutes from 30 minutes
		8.5	Updated guidance on reporting medical errors in CIR instead of on manual forms
		8.7.4	Updated guidance to note that vaccine vial boxes can be securely destroyed in document destruction bins or biohazard bags.
		9.6.4	Additional information on vaccine shelf-life timeframes.

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Signature	
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Contents

1. Purpose

This document provides guidance on establishing and managing a COVID-19 vaccination site, including guidelines for the vaccination workforce. This document is designed to help District Health Boards and providers maintain public safety and ensure consistent and equitable COVID-19 vaccination practices are in place across New Zealand.

This version of the guidelines is specifically designed for Tier 1 vaccinations. This guide will be amended as needed and re-distributed to DHBs and providers. We expect regular iterations based on learnings from the delivery of the COVID-19 vaccine programme. Please ensure you are always using the correct version of the guidelines.

Please note that this document provides 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)'.

1.1 Focus of current version

The guidance in this version focuses on delivery of the vaccine to Tier 1 of the Vaccination Programme, that is, the vaccination of Border and Managed Isolation and Quarantine Facilities (MIQF) workforces and their household contacts and the vaccination of high-risk healthcare workers.

The guidance in this document is designed for administering the Pfizer COVID-19 vaccine. This document will be updated as other vaccine types become available.

2 Abbreviations

Abbreviation	Full Name
BWTR	Border Worker Testing Register
CARM	Centre for Adverse Reaction Monitoring
CIR	COVID Immunisation Register
DHB	District Health Board
HCL	Healthcare Logistics
IMAC	Immunisation Advisory Centre
IPC	Infection Prevention and Control
MIQF	Managed Isolation and Quarantine Facility
MoH	Ministry of Health
NHI number	National Health Index number
ULT	Ultra Low Temperature (-90°C to -60°C)

3 Key Contacts

See also Appendix A for more information on the support organisation, noting that each region will have a dedicated MoH regional liaison.

Issue Type	When to Contact	Contact Details	Hours of Operation
IT hardware or non-COVID Immunisation Register (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 business hours
COVID Immunisation Register Issues	For help on using CIR	For system help, contact your super user or help@c-19imms.min.health.nz	8am-6pm, weekdays & weekend (TBC)
	Logging-in issues, password resets, or after hours help,	0800 223 987 or help@c-19imms.min.health.nz	
Vaccine or Consumables Supply Issues	To raise an issue with supplies	Covid-19.logistics@health.govt.nz or 0800 335 778	Email: 9am-5pm, weekdays Phone: 8am-8pm, weekdays & weekends
Clinical Vaccine Queries	To receive clinical advice on the vaccine or vaccination process	0800 223 987, option 3	Available during site operating hours
Order Vaccination Collateral	To request additional pamphlets or other collateral	Your DHB Comms Manager	
Privacy Incident or Concern	If you identify a known or suspected privacy breach	COVIDPrivacy@health.govt.nz	9am-5pm weekdays
Adverse Event Following Immunisation	If an individual has an adverse reaction to the vaccine	https://nzphvc.otago.ac.nz/report/ (03) 479 7247 carmnz@otago.ac.nz	
Interwaste Vial Disposal Bin Requests/Collection	To arrange first delivery of vial disposal bin and collection of full bins	0800 102 131	8am-5pm, weekdays

4 Roles and Responsibilities

Activity	Ministry of Health	DHBs & Providers	Tier 1 Employers	IMAC	CARM	HCL
Purchasing	• Purchase vaccine from Pfizer • Purchase consumables	• Purchase PPE through existing channels	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 Tier 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 Tier 1 employers • Engage with household contacts • Provide collateral files to DHBs/providers & distribute site banners/cards • Manage adverse event comms	• Engage with Tier 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

5 Preparing a Vaccination Site

5.1 Equitable Access

You should ensure that your vaccination sites are accessible to all members of your community and ensure equitable opportunity for Māori and Pacific people, other ethnic communities, and disabled people. You should take reasonable steps to improve access and reduce potential inequalities. This 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/
- Actively incorporating Te Tiriti O Waitangi considerations, including:
    - making sure 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, hapu and whanau
    - seeking Māori specific advice from the outset
    - resourcing and investing where it is required the most
- Ensuring your site workforce reflects the demographic make-up of the likely consumer group or local area.
- Considering which site locations can best meet the community's needs in terms of both ease of access and comfort or familiarity with the location (e.g. marae, churches).
- Where drive-in sites are planned, ensuring consumers can either attend this site if they do not have a car or have access to a non-drive-in site.
- 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:** MoH has prepared translations of COVID-19 vaccine information (see section 'Ordering Site Collateral' below).
- Encouraging site staff to greet consumers in Te Reo or the language the consumer uses where possible
- Starting and ending the day with a karakia
- Ensuring key written material and any signage is in easy to read formats.
- Ensuring access for disabled people, including venue accessibility and accessible information. For more information on venue accessibility, see the Ministry of Health website.
- Designing site support processes to support individual with visual or hearing impairments, e.g. providing a card to ask individuals to advise site staff if they have a hearing impairment to ensure their needs can be met during the vaccination or any follow up interactions.
- Considering how your service delivery model caters for support people that consumers may bring to the vaccination event (e.g. friends, whanau or carers).
- Building early and regular engagement with Māori and Pacific partners into your service delivery model to design for the community's needs.

5.2 Clinical Leadership

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

5.3 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 Organisation (WHO) guidance.[1]

This guidance is intended for policy makers, immunisation programmes and IPC leads 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.

5.3.1 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 that the population to be vaccinated consists of individuals **not** presenting signs and symptoms of infection.

However, additional IPC precautions are necessary in the context of the COVID-19 pandemic to reduce the risk of SARS-CoV-2 transmission (e.g. mask use).

It is critical to provide health workers with specific training and the public with targeted information regarding IPC measures for safe COVID-19 vaccine delivery.

A clean, hygienic and well-ventilated environment, appropriate waste management and adequate spaces that facilitate best IPC practices (e.g. physical distancing) are necessary for COVID-19 vaccination activities.

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

5.3.2 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 there is sufficient staff and time to support correct implementation of the IPC practices required to safely administer the vaccine.

Identify trained staff to deliver IPC training to those involved in vaccination activities (including managers, logistical support vaccinators, cleaners and health workers dedicated to screening) and to provide information for people 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.

MoH recommends you create a vaccination site specific COVID Tracer App QR code posters. You can create QR code posters using the current self-service webform. More information about QR code posters is available on the Ministry of Health website.

5.3.2.1 Local IPC Guidance

Develop local IPC guidance and standard operating procedures for COVID-19 vaccination, outlining the following:

- screening policies for COVID-19 signs and symptoms of staff and individuals arriving for vaccination 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;

[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*

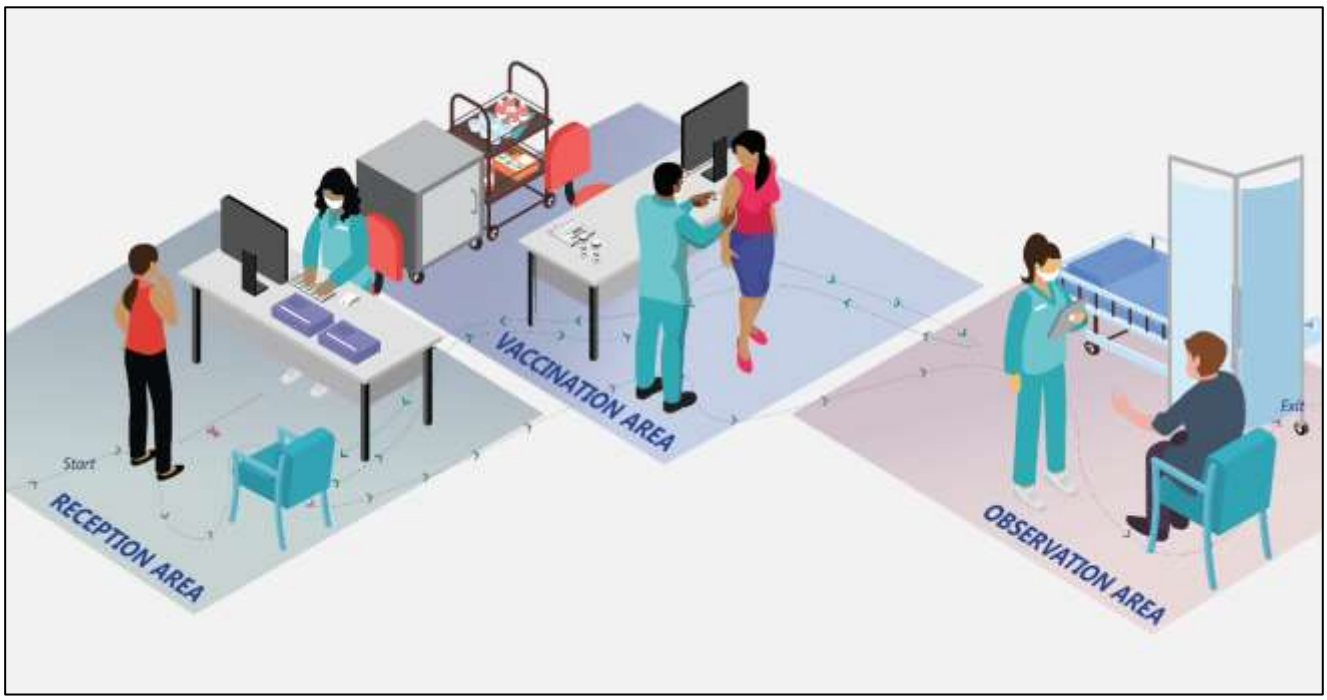
- appropriate waste management taking in consideration the increase of waste associated with COVID-19 vaccination activities, and where possible include environmentally-friendly approaches to manage both general and medical waste at point of use, segregation, disposal and collection;
- visual reminders emphasizing hand hygiene, safe injection practices, safe use of medical masks, respiratory hygiene, and other IPC measures;
- training materials for relevant staff and educational and informational materials for the public.

5.3.2.2 Environmental considerations and engineering controls at the vaccination venue

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

- clearly marked one-way foot traffic flow with clear entry and exit areas through the vaccination clinic; these should be separated when the vaccination area or clinic is located in a health care facility;
- adequate screening area (ideally, private spaces) at the entry where people are assessed, including questioning for signs and symptoms of COVID-19 and other criteria for inclusion;
- sufficient space to allow at least 1 metre physical distance between all individuals including between health workers at all stations (at the entrance, at the screening stages, while waiting to be vaccinated and during the observation period post-vaccination) and between staff;
- adequate ventilation (mechanical, natural or hybrid) of all areas, including the screening, waiting, post-vaccination observation, and vaccination areas; if a mechanical ventilation system is operating in these areas, the ventilation rate should be 6 air changes per hour or according to national or local requirements for healthcare facilities;
- medically equipped post-vaccination observation area for dealing with possible vaccine adverse reactions;
- adequate number of hand hygiene stations in strategic areas to support appropriate hand hygiene for the public and staff (i.e., at the entrance and exit areas, in the waiting areas, and in each vaccination station);
- laminated signage/posters to include reminders about:
    - reporting COVID-19 signs and symptoms;
    - medical mask wearing;
    - hand and respiratory hygiene;
    - physical distancing (e.g. floor markings, seating arrangements, tapes, ropes, and cones);
- adequate space for vaccine storage and preparation (e.g. clean and hygienic environment, adequate ventilation and equipment to adhere to specific COVID-19 vaccine cold chain requirements);
- vaccination stations a least 1 metre apart (ideally with installation of physical barriers between vaccination stations);
- adequate 'cleanability' of screening areas, vaccination stations, waiting areas (e.g. removal of items that cannot be readily decontaminated and minimizing clutter to aid effective cleaning);
- appropriate waste management system including safe disposal of waste (such as vials and masks) and sharps at each vaccination station (see also 'Disposable of consumables, vaccine and vaccine packaging' section below).

Figure 1: Example consumer flow between site areas



5.3.2.3 IPC supplies

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

- Medical masks
- Other personal protective equipment (PPE) including eye protection, long-sleeve fluid resistant gowns and gloves, in case it is required for vaccination team's protection when dealing with a vaccine adverse event, to prevent exposure to non-intact skin to blood and body fluids or if a suspected case of COVID-19 is identified during the screening process.
- Other supplies include; alcohol-based hand sanitisers, thermo-scans for temperature screening, tissues; waste bins and bin liners, sharp disposal bins, cleaning and disinfection products, visual reminders and signage and physical barriers to aid spatial separation.

Identify a suitable area for storage of supplies.

5.3.3 Operational phase

Use a daily checklist to monitor and ensure that the 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 Government 'higher index of suspicion' (HIS) criteria.

Ensure that 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.

5.3.3.1 Key IPC measures to be implemented

Hand hygiene:

- Vaccination team members to wash their hands with soap and water and dry thoroughly or use hand sanitiser at the start of the shift.
- Facilitate hand hygiene by people attending for vaccination

- 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:

- Select PPE based on risk assessment as part of Standard Precautions
- In the context of COVID-19 pandemic, vaccinators should wear a medical mask and the individual should wear a medical or non-medical/cloth mask
- For pre-vaccination screening and vaccine administration PPE other than a mask is not indicated. Gloves are not indicated.

Injection safety:

- Sterile, single use syringes and needles should be used.
- 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
- 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

5.3.3.2 Environmental cleaning and disinfection, waste management

Prepare each injection in a clean, designated area.

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.

Seal and remove sharp containers 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.

5.3.3.3 MIQF requirements

If the vaccination site is located within a Managed Isolation and Quarantine Facility (MIQF). In that instance, staff must abide by the IPC guidance set out for workers in MIQF in the MIQF Operations Framework.

5.4 Ordering Interwaste Vial Disposal Bin

As part of your site preparations, please contact Interwaste to arrange the delivery of an Interwaste vial disposal bin (see 'Disposal of Consumables, Vaccine, and Vaccine Packaging' section below).

Contact Interwaste on 0800 102 131 as soon as your site is confirmed. You should provide at least 48 hours' notice before you need the container 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.

5.5 Incident Management & First Aid

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.

5.6 Occupational Health Requirements

Ensure you have appropriate occupational health requirements in place for your site team, including an accessible needlestick injury protocol. Staff must understand what to do and who to contact if they experience a needlestick injury.

5.7 Business Continuity

Ensure you have a business continuity plan in place for your sites, e.g. to manage power failures.

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

- Consent form (required consumer data fields that will need to be added to CIR are included on the back of this form)
- COVID-19 Vaccine Adverse Event Report. This is the form used to submit adverse event information to the Centre for Adverse Event Monitoring (CARM). If CIR is unavailable, you may use this form 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 'Ordering Site Collateral' section below for information on obtaining these forms.

Any hard copy forms must be entered into CIR by close of business on the following day. Make sure any printed copies of information are locked away when not in use.

5.8 Protecting Security and Privacy

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

Health information can be sensitive so it is important that it is protected and treated with respect.

- All medical records (e.g. written consent forms) at vaccination sites will need to be securely stored out of the sight of patients (e.g. a drawer) and it is preferable that this drawer is in the constant presence of an authorised person (e.g. administrator, security guard or vaccinator) or alternatively it can be locked.
- At the conclusion of the vaccination event the personal information documentation needs to be taken directly (no transit points) by an authorised person (e.g. administrator, security guard or vaccinator) to the site where the record will be held.

In addition to ensuring the security of health records as per above, you should also consider the following security and privacy factors:

- Tell people why you're collecting their information and what it will be used for (e.g. that it will not be used for immigration or law-enforcement purposes)
- Think about who can see your computer screen if you're looking at personal information
- Keep your password and log-in details confidential
- If you spot something going wrong, let your DHB or provider privacy officer or COVIDPrivacy@Health.govt.nz know as soon as possible
- Dispose of unnecessary duplicate information securely
- Be mindful about people overhearing confidential conversations in public places
- Use secure methods when transferring information outside of the core vaccine systems, e.g. when emailing or using USBs or online cloud storage password protect the data

5.9 Vaccine Security

To ensure the security of the vaccine, please ensure the following minimum standards are met:

- The vaccines must be stored in a work area that has the constant presence of an authorised person (e.g. administrator, security guard or vaccinator) during hours of operation.
- If the vaccine is to be stored overnight at the vaccination site, then the building should be in a controlled-access environment (e.g. Maritime Port or Managed Isolation and Quarantine Facility (MIQF)).
- If the building is not in a controlled-access environment (e.g. Community Hall), then the building should be able to be secured and have a monitored alarm.
- In the event the vaccines are stored at a vaccination site that does not have controlled access and is not a building (e.g. a tent) then an overnight onsite security guard should be present.

5.10 Site Physical Security

To ensure the safety of patients and staff all vaccination sites should have a security presence to control access to the site and be available to support in the event of attempted unauthorised access (e.g. public attempting 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 (e.g. separate access from the general public).

5.11 Site Security Assessment

All vaccination sites will need to be able to ensure the following:

- Staff safety
- Patient safety
- Security of the vaccine (storage facilities, in-transit, at vaccination sites)
- Security of information – particularly paper-based information i.e. spreadsheets
- Confidence that contingency plans exist to deal with a 'disturbance'/potential protest event at a vaccination site.

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 access to the site controlled?
- How is the vaccine transported to and from the location?
- How is the vaccine securely stored at the vaccination location?
- How are consumables including needles securely stored at the vaccination location?
- How is hard copy information (if any) securely stored at the vaccination site?
- How will staff act if there is any disruption e.g. protest activity or if persons other than border workers or their household contacts turn up for vaccination?

5.12 IT Equipment

You'll need to cater for the following IT requirements at vaccination sites to ensure staff can access the COVID-19 Immunisation Register (CIR):

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. Wi-Fi specifications: • Coverage ranging to reception, vaccination and waiting areas within the site • Highly available network (e.g. Fibre & 4G backup)
Internet Browser	**Chrome** is the recommended internet browser; however, other browsers will support CIR. 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 5 years should be compatible with CIR so long as it has 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.

Prior to starting vaccination, make sure you have tested all IT equipment and that all staff have received the necessary training to use the devices and CIR.

Make sure you advise each site team where they can access additional IT support (i.e. for non-CIR issues such as hardware issues), including after-hours support if your vaccination site is operation outside standard business hours.

5.13 COVID-19 Immunisation Register (CIR)

The COVID-19 Immunisation Register (CIR) is a browser-based system where you'll record all vaccination details. CIR using email address, phone number and 6 identifiers to match consumer records with NHI records.

You will need to request access to CIR for your vaccinators and administrators following the process outlined below. This will also enable MoH to liaise with IMAC to ensure your vaccinators have access to IMAC training modules.

5.13.1 Requesting Access to Training, CIR Classroom, and CIR

The DHB or provider workforce lead needs to send a list of all staff requiring CIR access to MoH at covid-19vaccine@health.govt.nz. **Note:** MoH is developing a process to share these details via Microsoft Teams.

MoH will then liaise with the Immunisation Advisory Centre (IMAC), who will provide staff with CIR and/or Pfizer vaccine eLearning modules. CIR users will also be advised to attend a drop-in session, where the CIR drop-in

team will set them up in CIR Classroom. This will allow the user to log into the classroom version of CIR and practice using the system.

Once staff have completed required training, the DHB or provider workforce lead must confirm to MoH that the staff member is now 'approved' and MoH will then give them access to the live CIR environment.

5.13.2 New User Onboarding Support

For any questions or support on new user onboarding, please contact covid-19vaccine@health.govt.nz with the subject line: Vaccinator List Support.

5.13.3 CIR Support

If the site team requires CIR support, they should contact their super user in the first instance. CIR ServiceDesk queries can be raised at 0800 223 987 or help@c-19imms.min.health.nz.

CIR eLearning modules and Quick Step Guides will be made available to all staff (see 'Staff Training and Reference Materials' section below).

5.14 Ordering Site Collateral

MoH has prepared the following collateral to support the vaccination programme. Files will be shared with DHB Comms Managers via an existing All of Government (AoG) Dropbox or via a MoH weblink and these can then be printed and supplied to sites.

MoH is arranging for consumer collateral to be translated into multiple languages. These versions will be made available as soon as possible. Translations are now available in the following languages on the MoH website, with additional languages to 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 on sites in site reception areas if designed. MoH will provide a link to the final version of the video when it is available.

Purpose	Collateral	How to Order
To share with consumers on site or before attending the vaccination site	COVID-19 Vaccine Information & Consent Pack, which includes: • Getting your COVID-19 Vaccine: What to Expect • Consent form • After your immunisation • Privacy statement	Contact your DHB Comms Manager
	COVID-19 Vaccine FAQs	Available on MoH website
To provide after the consumer has been vaccinated	Vaccine record and appointment card	MoH will arrange distribution of physical cards to sites.
To collect household contact information on site *(only to be used if consumers cannot access the online form or 0800 number)*	Household contacts of Border Workers form	Contact your DHB Comms Manager
For use if CIR is unavailable	Consent form (which includes fields to capture required consumer data)	Contact your DHB Comms Manager
	COVID-19 Vaccine Adverse Event Report	Available on the Centre for Adverse Event Monitoring (CARM) website: https://nzphvc.otago.ac.nz/reporting/
	Vaccine Error Reporting Form	Contact your DHB Comms Manager
To be displayed on site	Pull-up banners for site (2 designs: 'Vaccinations here' and 'Protecting our people')	MoH will arrange distribution of banners to sites.
	Teardrop flag for outside site	MoH will arrange distribution of flags to sites.
	COVID-19 vaccine posters (A3/A4 size)	Contact your DHB Comms Manager

Purpose	Collateral	How to Order
	Large vaccination site poster (A0 size)	MoH will arrange distribution of these large posters to sites.
For vaccinators on site	Instructions for the Pfizer Vaccine - Preparation and Administration	This will be included in vaccine shipments and are available on the IMAC website.

5.15 Site Readiness Checklist

Complete the site readiness checklist included in Appendix B to assess whether the vaccination site is ready to commence vaccinations.

5.15.1 Completing a dry run

MoH recommends you complete 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. You can also request the delivery of an empty Credo Cube to test the delivery process. MoH has prepared a pack to help you run your dry run; contact your MoH regional liaison to get a copy of the latest pack.

6 Preparing the Vaccination Site Workforce

6.1 On-Site Functions

MoH has identified the following functions for the site team. Note that someone with a clinical role (e.g. a vaccinator) may perform non-clinical functions, particularly in smaller sites.

This table is not intended to be a prescriptive list of all functions on site and expectations for different roles; rather, it outlines what likely functions will be required to aid in your workforce planning.

Non-Clinical Functions	Clinical Functions
• Greeting consumers and answering questions • 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 recovery room • Providing the vaccination receipt card • Capturing household contact information from Border and MIQF workers where this information has not already been provided • Completing or arranging daily cleaning of the site • Arranging collecting of medical waste • Decommissioning the site when it is no longer needed • Providing reporting back to MoH or DHB or provider leads as needed	• Preparing the vaccination dose • Obtaining consent to receive the vaccination • Asking health questions prior to administering the vaccine • Vaccinating the consumer • Monitoring consumers in recovery room for any adverse events • Attending to adverse events and recording them Staff performing clinical functions must be appropriately trained to administer the Pfizer vaccine by the Immunisation Advisory Centre (IMAC).

6.2 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 you to consider as you plan your vaccination workforce.

Note that the modelling below is only recommended and you should tailor your resourcing based on your expected site volumes, your service delivery model and your understanding of the needs of the consumers (for example, if the cohort being vaccinated is expected to have low health literacy or low English skills, they may need more support throughout the process which may affect timing and resourcing).

Please 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.

Waiting Room		Immunisation Event	After the Event
Activity	Consumer will be checked in then watch a consent video in the waiting room (~10mins).	Consumer and vaccinator will have 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 20 mins after the event for monitoring. Monitoring staff will ask consumers for their Household Contact information if this hasn't been provided before they arrived on site.
Staffing	1 x Administrator	1 x Administrator 1 x Vaccinator	1 x Registered/Practice Nurse 1 x support person with bystander CPR/first aid training as per minimum specifications in Appendix 4.2 of the *Immunisation Handbook*.

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

If 20 vaccinations per day	If 120 vaccinations per day	If 360 vaccinations per day
• 2 vaccinators working at the site who will undertake all roles	• 1 Admin in waiting room • 3 Vaccinators and 3 Admin support in Imms event • 1 Vaccinator drawing up the dose in Imms event • 1 Nurse and 1 support person monitoring after	• 1 Admin in waiting room • 9 Vaccinators and 9 Admin support in Imms event • 3 Vaccinators drawing up the dose in Imms event • 2 Nurses and 1 Support person monitoring after

Note: Given this is a new vaccine, DHBs and providers will need to be prepared to adjust site staffing requirements as the reality of administering the Pfizer vaccine will likely vary from these assumptions as delivery progresses.

6.3 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.

eLearning modules and Quick Step Guides include:

- Working with the COVID Immunisation Register (eLearning)
- COVID-19 Vaccinator Education Course (eLearning)
- CIR Quick Step Guides – Reception, Vaccination, Recovery, Quick Adverse Event, Adverse Event

- Inventory management (eLearning)

In addition to these training materials, staff will have access to a range of reference materials. These include:

- COVID-19 Vaccinator Guidelines: Paper-based (maybe laminated) reference information for vaccinators to use. Includes more detailed advice on health screening responses, informed consent. And vaccine preparation. (TBC if this will be available in Week 1)
- IMAC FAQs: These are available on the IMAC website: https://www.immune.org.nz/covid-19-vaccines
- Immunisation Handbook- COVID chapter: IMAC is preparing a COVID-specific chapter for this existing Ministry resource that will be available soon. https://www.health.govt.nz/publication/immunisation-handbook-2020

See 'Ordering Site Collateral' section above for detail on collateral available to be given to consumers.

7 Vaccinating Household Contacts

Household contacts of staff working in border or MIQF are eligible to receive vaccination in Tier 1.

7.1 Definition of a Household Contact

A household contact is defined as someone who usually resides in a household or household-like setting with a border or MIQ worker. Household contacts are eligible regardless of whether they are related or unrelated people and it includes people who may reside part-time in the household. Partners and dependents of eligible workers should be included (for dependents 16 years or older as per MedSafe approvals).

7.2 Collecting Household Contact Information

Channel	Description	Timing
 **Digital**	In the first instance, MoH will directly contact staff with eligible household contacts using information in the Border Worker Testing Register. Contact will be made with eligible staff to invite them to provide details of their household contacts (this will include an approximate geographic location field to support delivery planning).	Prior to event and ongoing
 **Phone 0800 2VAXCOVID**	An 0800 phone line – 0800 2VAXCOVID – will also be available for workers with an eligible household contact to call. This will be operated from 8am to 8pm. Multiple language options will be available. Callers will be verified and asked to provide details for themselves and their household contacts. These details will be passed on to DHBs for scheduling per the following section. Please provide the 0800 2VAXCOVID number in your engagements with Border or MIQF workers so they can proactively supply household contact information.	Prior to event and ongoing
 **During current interactions**	DHBs currently have a presence in the border and MIQ facilities and may choose to collect contact information during their current interactions with border and MIQ workers. For example, this may include collecting household contact information at the next mandatory test.	During regular testing
 **At the time of vaccination**	At the time of vaccination, the vaccination team should remind border and MIQ workers to submit the details of their household contacts. The first preference is for consumers to use the digital link to complete the online form. The hard copy form should only be provided as a back-up for completion if the consumer cannot access the online form or is unable to contact 0800 2VAXCOVID. Where hard copy forms are completed, administration staff must transfer these details into an online form for MoH to collate. This will reduce the privacy risk associated with holding hard copy information and enables sharing of information about household contacts if they are living in different regions. Any hard copy forms must then be destroyed.	At event

7.3 Scheduling appointments

Responses will be compiled by MoH and subsequently shared with the appropriate DHB via a report. DHBs can then liaise with the household contact to schedule an appointment and complete the vaccination event.

MoH intends to move to a self-service reporting model to enable DHBs to generate the report with household contact details rather than MoH sending it out.

7.4 Vaccinating Household Contacts Without Appointment

There may be instances where household contacts accompany workers to their vaccination. If this happens, individuals should be provided with a digital or hardcopy form to complete in order to enable the scheduling of their vaccination. Note that household contacts will need to provide information that provides a link to an eligible worker (i.e. name and phone number) and be loaded into CIR manually.

In some cases, it may be possible to provide a vaccine in a 'walk-in' scenario. This will be at the discretion of the site manager based on their scheduled vaccine supply.

8 Running a Vaccination Site

8.1 Booking and Scheduling

Arrangements for the booking and scheduling of Tier 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 the second dose of the Pfizer vaccine. This should also include re-scheduling second dose visits if needed and providing a mechanism for people to reconfirm their appointment time (e.g. if they lose their appointment card).

At present, a national booking system is not available. MoH will provide more details about the national booking system as soon as possible. It will not be mandatory for DHBs or providers to utilise this system.

8.1.1 Pre-loading immunisation event records in CIR

CIR is linked to consumers' NHI numbers, meaning anyone with a NHI will be automatically available in CIR, i.e. they will have a CIR profile. Where consumers are in the Border Worker Testing Register (BWTR), MoH 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.

8.2 Preparation of Doses

The Pfizer vaccine comes as a concentrate and **must be diluted on site** following the instructions provided by the Immunisation Advisory Centre (IMAC). These instructions will be included in vaccine shipments and are also available on the IMAC website.

Please note the Pfizer vaccine is fragile and **must not be shaken** during preparation.

Once the vaccine has been diluted, it **must be administered within 6 hours**. Any prepared doses not used within this time period must be discarded. Prepared doses cannot be transported to other sites.

You **must avoid exposing the vaccine to direct sunlight or UV light at all times** (when both a concentrate and prepared).

8.3 Pre-Vaccination Steps

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 the consumer whether they have any COVID-19 symptoms as per standard site practices. Please note: • People who have symptoms of COVID-19 should be advised to stay at home and get a test. They are able to be vaccinated once they have a negative test result and symptoms are mild only. • 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.

Step	Action
 **Verify consumer's identity**	The vaccinator/site administrator will also verify the consumer's identity using name, DOB and address and locate their record in CIR. **Note:** Photo ID is not required to confirm the consumer's identity.
 **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 MoH website. You may also display the privacy statement in the reception area as well as supplying the information in hard-copy.

8.3.1 Where the consumer does not have an NHI number

You will need to confirm that the consumer is in the eligible cohort and manually collect all required vaccination information to ensure the vaccination can take place that day. If you have the ability to create an NHI number, please do so. Alternatively, you can contact the MoH contact centre on 0800 855 066 to request an NHI number be set up.

Once the NHI is created, you'll need to wait for an overnight CIR process to run for the NHI to become available in CIR. You must then enter the vaccination data into CIR to ensure we can provide accurate reports of vaccination numbers.

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

8.4 Vaccination and Observation

Step	Action
 **Complete a pre-vaccination clinical assessment**	The vaccinator must undertake a pre-vaccination clinical assessment to identify if the consumer has medical reasons why they should not receive the vaccine. The outcome of this clinical assessment must be recorded in CIR.

Step	Action
 **Obtain informed consent**	The vaccinator (or vaccinator support person) must obtain the consumer's informed consent to receive the vaccine prior to the administering of the vaccine. Use the COVID-19 Vaccination form to obtain the consumer's written consent. Where appropriate, consent may be given by a proxy such as a guardian or person with power of attorney. See below for instructions on managing the written consent forms. **Written consent must be obtained for Tier 1 consumers.** **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**	The vaccinator or an administrative support person must record the consumer's consent to receive the vaccine in CIR. If the person does not wish to receive the vaccine, record their decline in CIR.
 **Administer vaccination**	Administer the vaccination.
 **Record vaccination information in CIR**	Once the vaccination is complete the vaccinator or administrative support person must update the consumer's record in CIR to include: • The vaccine batch and sub-batch number, e.g. EP2163-012 (the first part is the batch number, the second part is the sub-batch number. These are recorded on the vaccine box) • Details of the injection site and the date and time of the vaccination event.
 **Consumer waits 20 minutes in observation area**	The consumer must remain on site under observation for at least 20 minutes. If the vaccinator determines it necessary, they **may** ask the consumer to wait for longer than 20 minutes, for example, if the individual is in a rural or remote area or has a history of anaphylaxis. The vaccinator or site administrator will provide the consumer with a card recording the date/time of their vaccination and the date when they will be expected to receive the second dose of the Pfizer vaccine.

Step	Action
 **Record exit in CIR**	The site administrator/vaccinator must record the time of the consumer's exit from the site in CIR.

8.4.1 Adverse Events During Observation Period

If the consumer has an adverse event during the 30-minute observation period at the vaccination site, appropriate medical attention must be provided. The on-site adverse event must be recorded in CIR to enable reporting on adverse reactions to the vaccine.

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

Adverse events should be notified to the site clinical lead, who can then undertake a clinical review and determine appropriate actions with the site manager (e.g. pausing vaccinations for a time if needed).

The adverse event must be recorded in CIR. The Centre for Adverse Reaction Monitoring (CARM) will then undertake further investigation and provide any additional guidance to the consumer and site as appropriate.

8.4.2 Adverse Events After Observation Period

If the consumer has an adverse event after the observation period/when they've left the vaccination site, they will be advised (in the 'After your immunisation' flyer) to contact Healthline and submit an adverse reaction report to the Centre for Adverse Reaction Monitoring (CARM). 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.

Note: Implementation of a national active monitoring process is being developed but is unlikely to be in place for Tier 1. Future active monitoring will likely consist of a text follow up with consumers a few days after receiving their vaccination asking if they have an adverse event and to report any symptoms to CARM. This will enable ongoing monitoring of adverse events and aid MedSafe's ongoing assessment of the vaccine. We will provide more information on this process in due course.

8.4.3 COVID-19 treatment injury claims

ACC are sharing advice with providers about lodging ACC claims for a physical injury resulting from a COVID-19 vaccination. Such injuries may be covered by ACC if the criteria for treatment injury 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 likely to be covered.

If a patient has an injury that meets these criteria, they may require further treatment or support. If so, providers would submit an ACC2152 treatment injury claim form should be lodged with ACC as well as an electronic or manual ACC45 injury claim form.

Providers will need to include the vaccine brand and dose number (i.e. for the Pfizer vaccine, whether it is the first or second 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 at a later date (e.g. within months). 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 that the health system will manage their treatment regardless of an ACC claim.

8.4.4 Uploading written consent forms

Written consent forms signed by Tier 1 consumers must be uploaded into CIR. This may be managed on-site or by a centralised administration team. Given the information on the written form contains personal information, **forms must be held and transported securely at all times** (e.g. in a locked cabinet or drawer or in a tracked courier bag or other secure container if transported between locations).

To upload the forms, the administrator must scan each form to their computer, locate the consumer's CIR record, and then upload the form to the consumer's CIR record. The administrator must then delete the local copy of the form on their computer and securely destroy the written form. If needed, the written form may be kept for a few days or weeks to check for inaccuracies in transcribing before they are destroyed.

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

8.5 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 (e.g. storage or handling, site/route of administration or dosage given).

If a vaccine administration error occurs:

- Inform the consumer(s) involved
- If guidance/advice is needed, consult IMAC on 0800 223 987, option 3
- Record the error in CIR under Adverse Events 'error' to enable reporting on vaccine administration errors.
- Determine how the error occurred to allow strategies to be implemented to prevent it from happening again.

Providers should report all COVID-19 vaccine administration errors – even those not associated with an adverse event. On submission of the Adverse Event/Medical Error form in CIR, the data will go to the medical assessment team at the Centre for Adverse Reaction Monitoring (CARM). 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.

8.6 Administering Leftover Vaccines

To minimise wastage, MoH recommends you plan a back-up or stand-by list of consumers that aligns with the sequencing framework. This may include the Tier 2 cohort, but preferably not the Tier 3 cohort. If you have vaccine left at the end of the day/week (i.e. vaccine that will expire before the next clinic), we encourage you to administer these individuals on your stand-by list.

MoH does not require visibility of your stand-by list; you can manage this list as needed to align with the sequencing framework as best you can.

Individuals on your stand-by list will need to be manually loaded into CIR rather than being pre-loaded by MoH.

Please note that any unused vaccine cannot be returned to HCL for redistribution. It must be either used on site or disposed of following the disposal process below. Any vaccine that has already been drawn into a syringe must also be disposed of and cannot be stored or transported to another site.

8.7 Disposal of Consumables, Vaccine and Vaccine Packaging

eLearning modules will be available on vaccine disposal alongside other inventory management topics outlined below.

8.7.1 Disposal of consumables

Consumables should be disposed of according to existing procedures (e.g. disposal into sharps bin and/or biohazard bags). Follow your local procedures to arrange collection of the sharps bin.

8.7.2 Disposal of damaged, empty and expired vaccine vials

As part of your site preparations, make sure you contact Interwaste to request a vial disposal bin to be delivered to the site. You can contact them on 0800 102 131 (their call centre is available from 8am-5pm weekdays).

Interwaste will then provide you a 20 litre-sized container in which to dispose empty, broken or damaged vials. When the container is almost full, you can contact Interwaste on 0800 102 131 to arrange for pick-up. Interwaste will deliver a new disposal container at the same time and remove the existing container so they can destroy the vials in an appropriate manner.

Make sure you keep the lid of the Interwaste disposal container closer when not in use.

Figure 2: Interwaste disposal bin

8.7.3 Disposal of vaccines drawn up but not administered & 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 can be disposed of in the sharps bin.

8.7.4 Disposal of vaccine packaging

You must ensure all packaging the vaccine is sent in is destroyed so 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. You can dispose of it 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 you need additional biohazard bags, please advise MoH Logistics for your next consumables order.

8.8 Operational Reporting

Sites must ensure vaccination events are recorded in CIR at the time of administration to enable accurate data for operational reports (such as number of vaccinations completed and other trend data).

Sites will need to report to MoH:

- Significant events on sites (e.g. significant adverse reaction, protest etc) (daily)
- Stock on hand (weekly)
- Stock movements (weekly)
- Demand allocation (weekly)

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

Feedback on the immunisation process or recommendations for operational improvements can be provided to help@c-19imms.min.health.nz.

8.8.1 Reports available to DHBs

COVID-19 vaccine reporting is linked to the NHI database, meaning you can request existing NHI data fields (e.g. ethnicity) to track vaccination rates and meet other reporting needs.

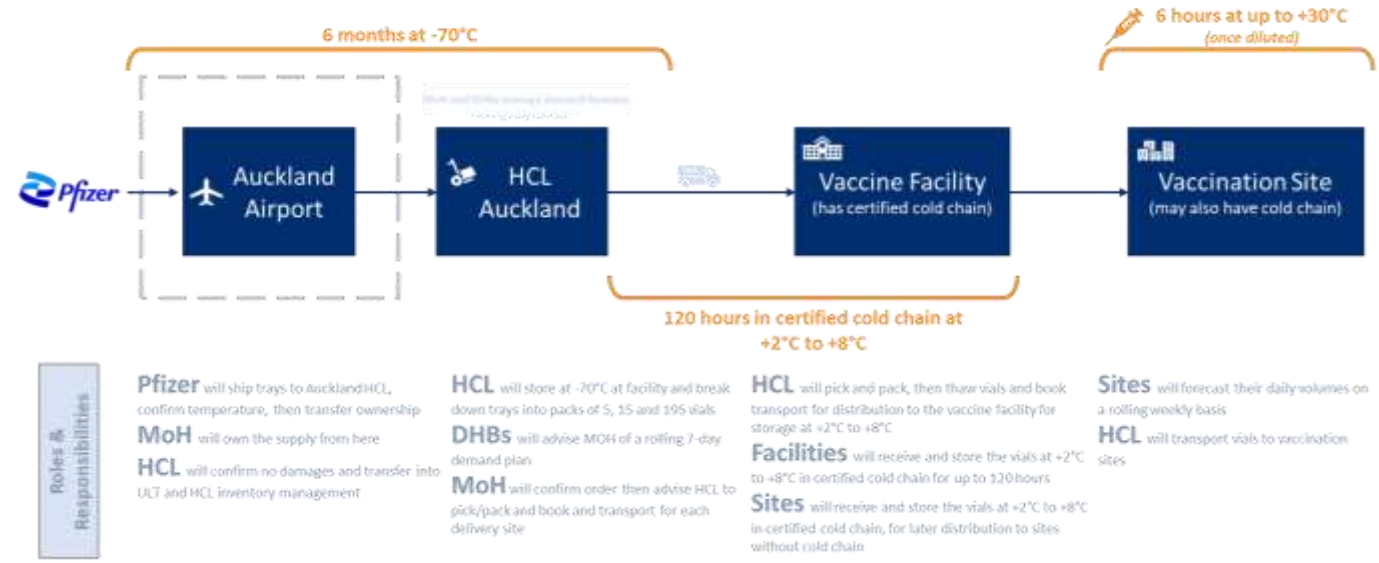
To request vaccine reporting, contact your DHB or provider reporting team, who will then submit your request to the MoH reporting team. Once the report is prepared, it will be available in CIR as both a dashboard and downloadable report that will be updated in real-time. Note that if you need data for multiple DHBs, you must specify this in your request.

9 Inventory Management

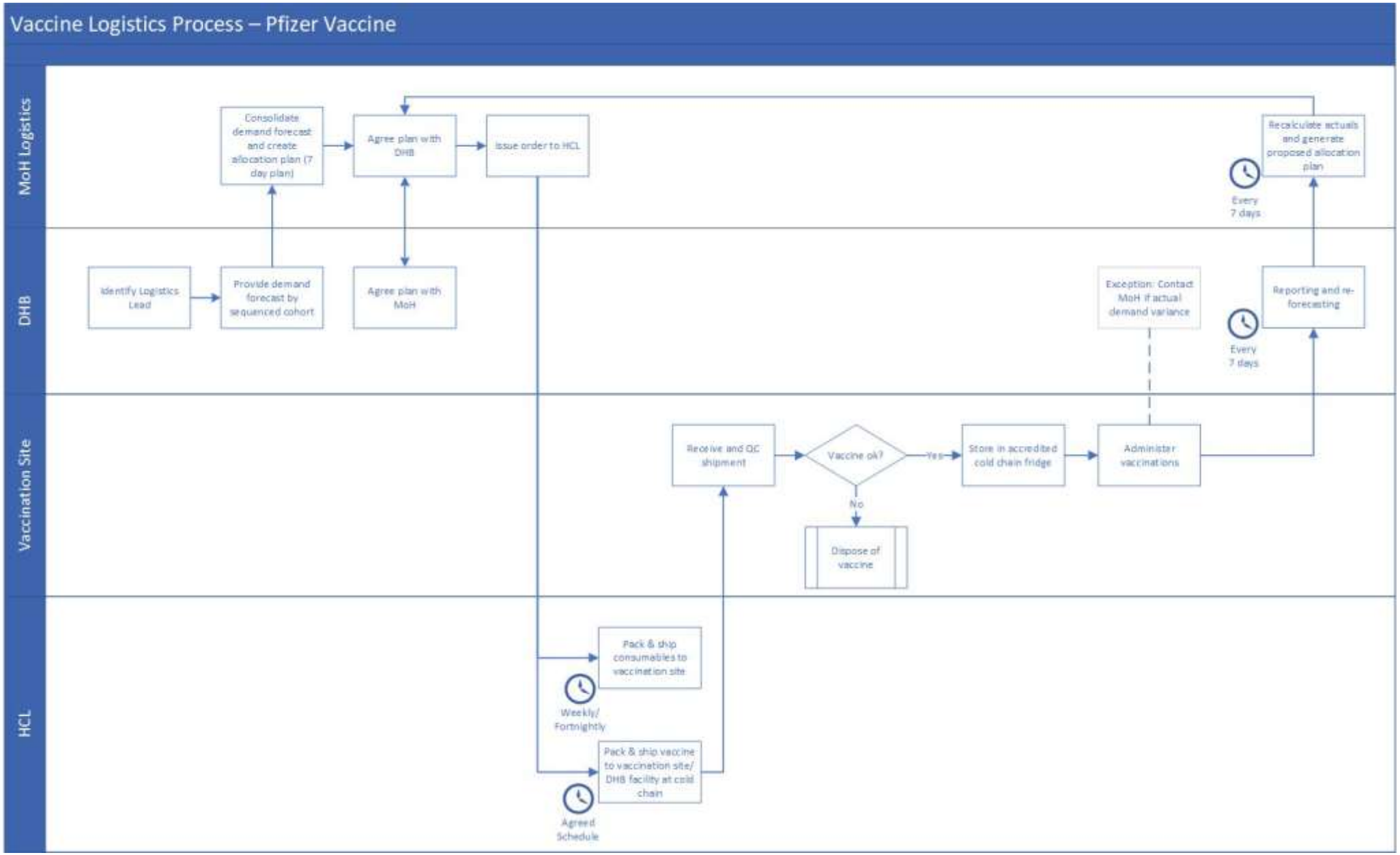
MoH will maintain a demand planning system to enable a centralised Logistics team to support ongoing monitoring of inventory and demand. The image below shows the current process for distributing the vaccine to vaccination sites.

Note that MoH will engage individually with DHBs or providers in Tier 1 with respect to their specific requirements. Guidance in this section relates only to the initial 4-week period from the first receipt of vaccine in New Zealand and distribution to vaccinate Tier 1.

Distribution Map and Timeline



9.1 Vaccine Logistics Process Overview



9.2 Demand Planning and Vaccine Allocation

MoH will work with DHBs or providers to create an agreed demand plan. This plan will provide detail for the upcoming 7-day period with forecast, higher-level detail up to 4 weeks out. A 3 days plan will remain fixed to enable deliveries to be packed and shipped efficiently.

The Logistics team will generate a national allocation plan that will cover both consumables and vaccine allocation. The national allocation plan will be re-planned on Day 6 of the weekly cycle. Vaccines are expected to be delivered to sites or DHB facilities twice a week.

MoH Logistics will liaise directly with DHB or provider Logistic Leads to collect required demand plan and site delivery information.

9.2.1 Managing demand variances

If your actual demand changes by more than 20%, please contact MoH to directly to re-plan your upcoming shipment as needed. You can contact the MoH Logistics team directly at Covid-19.logistics@health.govt.nz or 0800 335 778.

9.3 Provision of Consumables

MoH will provide consumables required to administer the Pfizer vaccine. As they do not require the same care in handling during transport and storage as the vaccine, consumables will be shipped separately to the vaccine itself.

Consumables will be shipped in quantities to supply approximately 2 weeks of stock, depending on the capacity to store consumables at DHBs or provider sites.

MoH will calculate the volume of consumables shipped, including any safety margins, based on the amount of vaccine expected to be consumed. If additional consumables are required, you can order these by contacting Covid-19.logistics@health.govt.nz or 0800 335 778.

To administer 6 doses per vial under an Alert Level 1 setting, the Ministry will provide the following consumables:

Category	Description
Saline	Sodium chloride solution - saline 5ml (same quantity as the number of vaccines)
Disinfectant Wipe	Antiseptic swab box of 200
Syringe & Needle	21-gauge needle (drawing needle) box of 100
Syringe & Needle	Prep 3ml syringe x 100
Syringe & Needle	Syringe 1ml Tuberculin box of 100
Syringe & Needle	Needle 25g 1in box of 100
Syringe & Needle	Low dead space (LDS) needle 1 box
Swab	Gauze swabs 5cm x 5 cm box 100
Container	Sharps container – various sizes
Waste Disposal	Bio bags box of 50

Category	Description
Plasters	Box of 250

9.3.1 Personal Protective Equipment (PPE)

PPE will not be supplied by MoH. DHBs or providers will continue to order PPE through existing channels.

9.4 Delivery to Sites

9.4.1 Delivery security

MoH will organise secure transportation of the large quantities of vaccine from HCL to the cold chain storage facility (e.g. DHB facility or vaccination site) using a MoH-contracted courier and security firm.

If the vaccine is transported to a DHB cold chain storage facility, the secure transportation of the vaccines from that facility to the vaccination sites is the responsibility of the relevant DHB or provider.

If you are transporting vaccine from a local facility to the vaccination site, the unique circumstances of these transportations should be considered in the site risk assessment. MoH recommends that if couriers or authorised persons (vaccinators, administrators or security personnel) are conducting the transport there should be direct travel (no transit points) to the vaccination site.

Figure 3: External Packaging

9.4.2 Delivery schedule

Vaccine will be shipped to agreed locations on a schedule agreed with DHBs or providers. This means that 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 shipments per week.

Each site receiving shipments from MoH will receive a notification containing details of the amount of vaccine and/or consumables due to be delivered the following day. Delivery tracking will be managed centrally by MoH.

Figure 4: Credo Cube

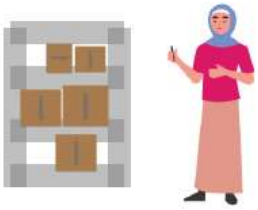
9.4.3 Delivery temperature

Vaccine will be shipped at under cold chain at +2°C to+8°C from HCL in Credo Cubes.

Vaccines will be labelled with a use-by date once they are removed from ULT -90°C to -60°C and begin thawing. This date will be 5 days/120 hours after removal from ULT. The use-by date/time will be on the vaccine carton.

9.5 Site Delivery and Receipt Process

Step	Action
 **DHB/Provider Logistics Lead provides site contact & delivery details**	The DHB or Provider Logistics Lead must provide MoH with a site contact (a named role and a phone/mobile number) and detailed delivery instructions, including address and any special instructions (such as separate entrances etc). The contact must be regularly available on site to accept deliveries to minimise the admin involved in changing the site contact person (Notify urgent site contact changes to MoH Logistics). MoH recommends that individuals handling vaccines are cold chain accredited; however, this is not a requirement.
 **HCL packs and ships vaccine**	HCL will pack and ship the vaccine under cold chain conditions in Credo Cubes 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 Credo Cube 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)
 **Site contact checks the temperature logger**	The site contact must check the temperature logger included in the Credo Cube to confirm whether a temperature excursion has occurred in transit. The temperature logger will have a green light if the temperature has remained within limits or a red light if an excursion has occurred. Where an excursion has occurred the site contact must quarantine the shipment in cold chain conditions while the logger is returned to HCL for reading. The site contact must call the MoH Logistics team on 0800 335 778. The 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. In this situation, the site contact will **not** sign for the package with the transport provider and it will be returned to HCL.
 **Site contact conducts visual check**	The site contact will open the Credo Cube and the internal vaccine packaging and conduct a visual check of the vials in each package to ensure vials are intact. Where over 20% of the vials are broken or spoiled, the site contact must contact the MoH Logistics team on 0800 335 778. The Logistics team will talk the site contact through the actions to be taken (e.g. disposing of the vaccine and sending out an urgent replacement shipment).

Step	Action
 **Site contact signs for vaccine package**	Where over 80% of 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**	The site contact will then store the vaccine at cold chain conditions in the internal packaging carton it arrived in (not the Credo Cube, but the white vaccine box) until the use-by date and time marked on the vaccine box is reached. Any vials that are not viable must be disposed of following the disposal process detailed above.

9.6 Vaccine Storage & Handling

9.6.1 Cold chain storage

Vaccine must be stored and transported in cold chain accredited conditions. MoH recommends that any individuals responsible for handling the vaccine have cold chain accreditation; however, this is not a requirement.

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.

9.6.2 Handling refrigerator temperature excursions

The following advice applies to handling the Comirnaty™ vaccine (mRNA vaccine by Pfizer/BioNTech). In its thawed and undiluted state can be stored at room temperature (+8°C to +30°C) for up to 2 hours (120 minutes). This includes any breaches above +8°C that occur during storage in the vaccine refrigerator.

If your refrigeration fails and your data logger readings confirm your vaccine has been exposed temperature of +8°C to +30°C for more than 2 hours (120 minutes) you need to:

- Label the vaccines 'not for use'.
    - If the refrigerator is currently running within the +2°C to +8°C range, leave the labelled vaccines in your refrigerator.
    - If the refrigerator is not within the +2°C to +8°C range, look for obvious reversible causes (door open, power interruption). If no cause found, pack your labelled vaccines into a chilly bin, with a temperature monitoring device and consider transporting to your back-up provider (details for this are in your cold chain policy).
- Contact your local immunisation coordinator for advice and further actions.
- Document the steps and actions you have taken.

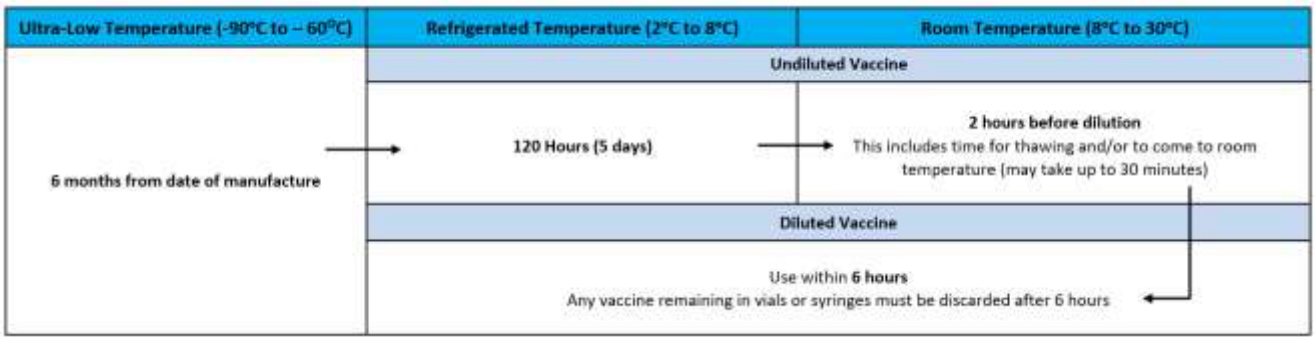
9.6.3 Vaccine quantities and package sizes

Unit	Size
Full tray	290 x 290 x 40 mm
15 vial pack	130 x 130 x 45mm
5 vial pack	130 x 65 x 45mm

9.6.4 Shelf-life of vaccine

Size	-90°C to -60°C	At +2°C to+8°C	At ambient temperature (up to +30°C)
Frozen Tray or Vial	**6 months** from date of manufacture	N/A	**Closed lid trays:** Up to **5 minutes** for transfer between ULT environments. **Open lid trays:** Up to **3 minutes** for transfer between ULT environments. **Note:** Following room temperature exposure, trays must be returned to the ULT -70°C freezer for 2 hours before they can be removed again.
Thawed Tray or Vial (undiluted)	N/A	**120 hours (5 days)** from time of removal from ULT. **Note:** Transportation time at +2°C to +8°C is included in the 5-day limit.	**2 hours**
Prepared Dose	N/A	**6 hours**	**6 hours**

Vaccine shelf-life is also visualised in the table below.



Please note that each of these "stages" are separate, so for undiluted vaccine, there is a 2-hour window where you can keep the vaccine at room temperature once removed from refrigerated temperature. Should you dilute the vaccine in 30 minutes, it does not provide an additional 1.5 hours of expiry to diluted vaccine in room temperature; once the vaccine is diluted, it only has a 6-hour expiry.

Vaccine in an ULT environment has an expiry of 6 months from the date of manufacture (this will be reflected as the expiry date on the vial and tray). Total time, if you were to only progress from each stage after the **maximum allotted time**, it will be as follows:

- Post-ULT → 120 hours in refrigerated temperature (not diluted) → 2 hours in room temperature (not diluted) → 6 hours in refrigerated or room temperature (diluted); that is 120 hours + 2 hours + 6 hours.

9.7 Repacking Vaccine at DHB Facilities

If vaccine packages are delivered to a DHB or provider facility (as distinct from a vaccination site), that facility **cannot** further break down the package size to redistribute it to vaccination sites in smaller quantities. Packages must remain whole to ensure traceability of the vaccine batches and sub-batches.

9.8 Transportation of Vaccine to Second Location

The DHB or provider facility can transport the vaccine to a second location where the vaccine will be administered provided the vaccine is transported in cold chain and the pack remains whole. In this case, a pharmacist must oversee the process (i.e. it must be completed under a wholesale pharmacy license).

Similarly, DHBs or providers may use vaccinators to go to discrete locations to deliver vaccines. In this case, the vaccine must be transported and stored in cold chain conditions as required by the manufacturer's specifications.

9.9 Returning Credo Cubes and Temperature Monitoring Equipment

Vaccination sites or DHB/provider facilities must return the Credo Cube and temperature monitoring equipment 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. Please call the number on the instructions to arrange collection.

You may need to remove/cross out the original courier label and original address details.

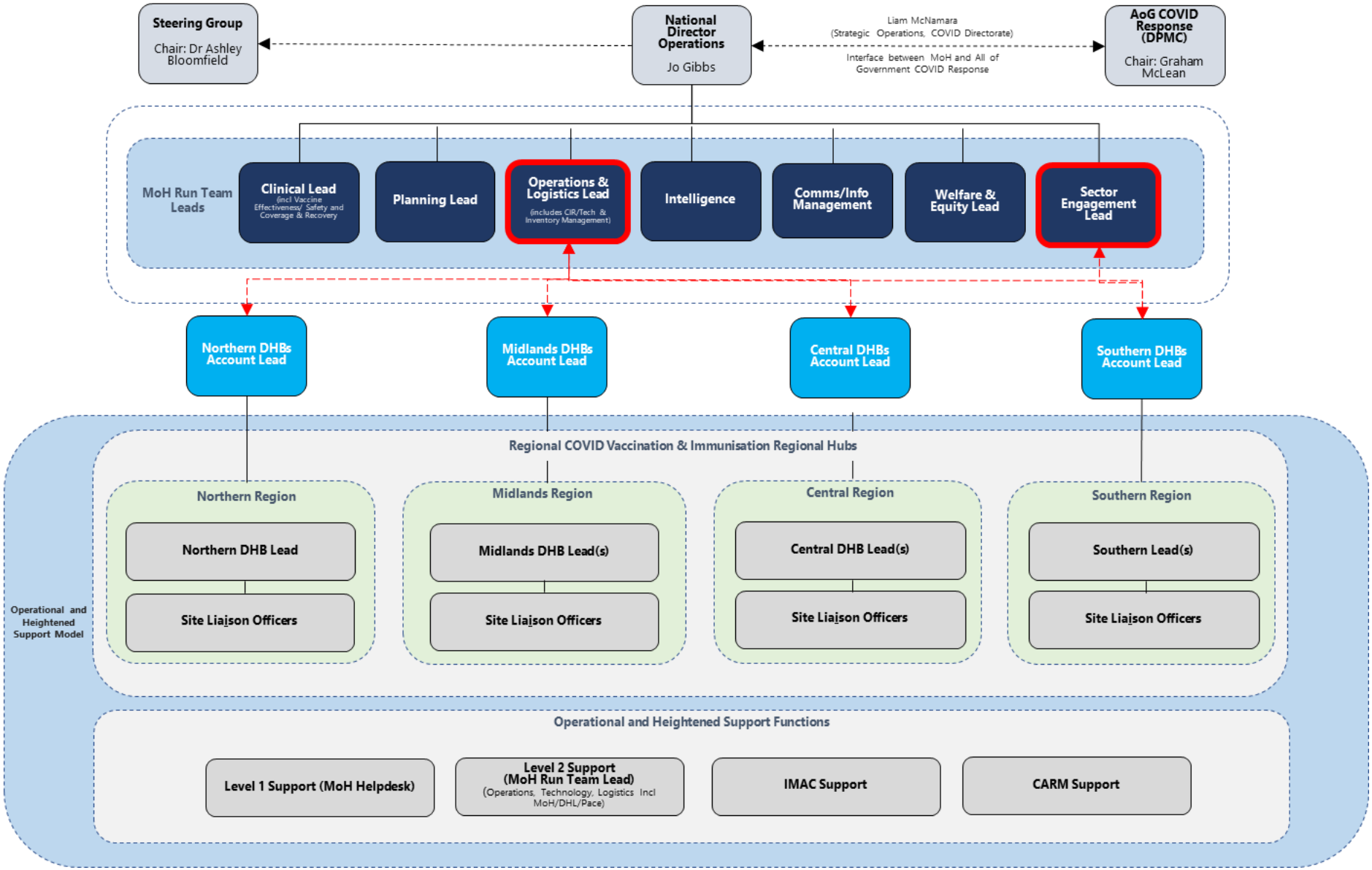
9.10 Inventory Reporting

The MoH Logistics team will continue to monitor demand and allocation using data from CIR and information from liaison with DHBs or providers. DHB and provider Logistics Leads must supply weekly reporting on:

- Stock on hand
- Stock movements

The MoH Logistics team will liaise with Logistics Leads to collect this information through an agreed mechanism.

Appendix A: Support Organisation



Appendix B: Site Checklist

The following list provides an overview of the minimum requirements that you need to consider and have in place to safely and efficiently deliver COVID-19 vaccinations.

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

Physical site	**Yes / No**	**Comments**
Adequate space and associated capacity for registration, vaccination (including drawing up and administering) and post vaccination observation area		
Appropriate cold chain provisions that are applicable for the site, including having: • An appropriate individual to receive the vaccine • Appropriate refrigerators and opaque containers to store material		
Equipment that is not provided in the consumable pack, including: • kidney dish • PPE		
Appropriate signage to identify as vaccination site for consumers and associated consumer collateral including: • Getting your COVID-19 Vaccine: What to Expect • Consent form • After Your Immunisation • Vaccination receipt and second appointment card • Privacy statement • COVID-19 vaccination campaign posters/banners/flags • Hard-copy form to collect household contacts		
Facilities and processes in place to safely dispose of unused, damaged or empty vaccine vials (e.g. Interwaste vial disposal bin ordered)		
Appropriate protocols in place to safely manage waste		
Ability to maintain the room temperatures between 19-30°C		
Appropriate security provision to ensure vaccinator and consumer safety that is applicable and appropriate to the site context.		
Completed site risk assessment		
Appropriate emergency medication and equipment and protocol to respond to three possible medical emergencies associated with the vaccination (fainting, hyperventilation and anaphylaxis), as per IMAC guidelines and standard vaccination site protocol		
Information Technology	**Yes / No**	**Comments**
Sufficient tablets, laptops or desktop to access and operate CIR and complete inventory reporting requirements		
High speed wireless or 4G coverage		
Hard-copy consent forms with CIR data fields on the reverse and associated secure storage in case of system disruption		
Booking mechanism to support scheduling (A national solution is being developed)		

Screen to display IMAC video (if applicable)		
Workforce	**Yes / No**	**Comments**
Staffing levels 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, including obtaining informed consent (these could be separate roles) • Event recording in CIR by a CIR-trained person • After-immunisation observation		
Staff have completed relevant training and accreditations, including cold chain and vaccine accreditation and training, adverse event accreditation and training, and CIR training.		
All staff on site are appropriately briefed on the site protocol including the Operational Guidelines and are clear on their respective roles and responsibilities for the shift		
Vaccination event	**Yes / No**	**Comments**
Procedures for identifying vaccine recipients		
Standardised screening process for contraindications, receipt of previous dose of COVID-19 vaccine or other vaccines, and COVID-19 symptoms		
Ability to monitor, manage and report adverse events following immunisation, including anaphylaxis		
Incident management procedures are in place and staff know how to report any clinical incident		
Other considerations		
If you are working in MIQ or other location that may require additional infection prevention controls, please adhere to the standard SOPs and associated protocols, including physical distancing requirements		
If there is change in Alert Level, please adhere to the relevant PPE SOPs and associated protocol required to operate under the Alert Level, including physical distancing requirements		
If you are operating a drive-in facility, please have an appropriate Traffic Management plan in place		