

Section C: Additional Programme guidance, variations and incidents

Version	Date	Section	Summary of Changes
52.0	28/03/23	32.1	Site receptionist changed to Concierge; role description updated Removed Whakarongorau health district liaison and site lead roles Updated Site admin and Operations lead role descriptions
		32.5	Removed outdated information Updated Pre-event section for booking an appointment and Post-event: follow up

Section guidance

This section provides additional guidance to vaccination, 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](#)

25 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 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 recommended that this section should be used in conjunction with:

- The Immunisation Advisory Centre's
- 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.**
- National Immunisation Programme Operating Guidelines.
- Ministry of Health's Immunisation Handbook 2020.

Local Health District 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 Health District 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, the following table is the requirements for the scenarios above.

	Screen Positive Requirements for Scenario 1 & 2
Location	<ul style="list-style-type: none"> Only pre-arranged home vaccination or vaccination in a controlled residence or healthcare facility.
Workforce	<ul style="list-style-type: none"> 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	<ul style="list-style-type: none"> Consumer: Must wear a medical mask (these could be provided). All staff: P2/N95, eye protection, gown, and gloves. <p>*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'.</p> <p>**In home environments, staff should change PPE if they are moving between different houses.</p> <p>***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 Health District SOP.</p>
Physical Environment	<ul style="list-style-type: none"> Review the physical environment and consider ventilation is adequate. Discuss with local Health District IPC team if unsure. <p>Home vaccinations</p> <ul style="list-style-type: none"> 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). <p>Healthcare Facilities</p> <ul style="list-style-type: none"> 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 Health District IPC team.

26 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.

For information on the requirements for eligibility and timing, refer to **the COVID-19 immunisation policy statement**.

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

27 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 NPHS Te Whatu Ora's Clinical Quality and Safety team.**

Requesting approval to set up

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

28 Vaccination in Hospital

28.1 Introduction

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

Vaccination in 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.

28.2 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".

29 Mobile vaccination team

29.1 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.

29.2 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 NPHS Te Whatu Ora to identify the Health District or provider linked to the team. For example, use a naming convention such as: Canterbury Health District outreach 1, MedPro mobile 2, or Auckland Health District 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.

NPHS Te Whatu Ora 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.

30 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 Health District's immunisation clinical leads and the associated lead professional advisors.

30.1 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

30.2 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.

31 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.

32 National Immunisation Booking System

32.1 Introduction

The National Immunisation Booking System 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**.

32.2 Booking system principles

The **Book My Vaccine** operating model is based on the four guiding principles shown below, regarding responsibility and Governance between NPHS Te Whatu Ora, Whakarongorau Aotearoa (Whakarongorau), Health Districts 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.
- NPHS Te Whatu Ora has overall coordination and monitoring responsibility, including key messaging, and leading nationwide booking campaigns.
- Health Districts 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 Health Districts.
- The **Book My Vaccine** tool will be the trusted source of available booking slots for the public, the Health Districts 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 Health Districts and sites available on the **Book My Vaccine** tool.
- NPHS Te Whatu Ora 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 Health District before passing on to the Health District teams for intensive outreach follow-up. This agreement will be defined between the Health District and Whakarongorau in the engagement plan.
- Otherwise, Health District will follow-up on missed appointments (outbound calling), or they can be supported by local models with PHOs or Iwi providers.

32.3 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, Health District, NPHS Te Whatu Ora and Whakarongorau. Further information related to the expected support, behaviour and outcomes of these roles is detailed above in the **roles and responsibilities table**.

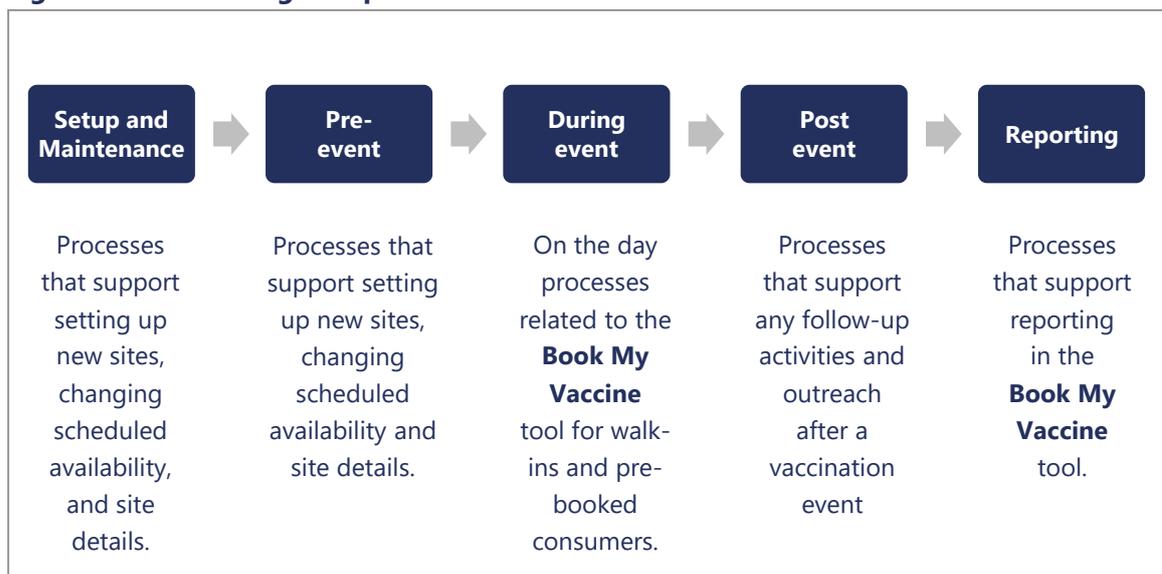
Table 32.1 – Book my vaccine tool key roles

Key roles	Role description
Concierge	The concierge manages on-site check-in procedures and performs health checks prior to vaccination. They are responsible for supporting the site admin to manage consumer bookings and appointment schedules. They are 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 answering general vaccine related queries. They are provisioned the role of special concierge in the Book My Vaccine tool.

Key roles	Role description
	Whakarongorau conduct outbound call campaigns based on direction from NPHS Te Whatu Ora Operations Team.
Site admin	The site admin manages the day-to-day operations of their sites(s) and is the primary point of contact for consumers, Whakarongorau and Te Whatu Ora. They are responsible for managing system technical operations and consumer requirements for their site(s). The site admin is responsible for identifying and managing any schedule changes and escalating impactful (minor/major event) site schedule changes to the Health District operations lead. They are provisioned for the role of site admin in the Book My Vaccine tool.
Health District operations lead	The Health District operations lead is accountable for managing the operational activities for a Health District. Their key functions include approval of sites and users, managing all escalations required for a Health District's attention, and sharing escalations with NPHS Te Whatu Ora as required.
The NPHS Te Whatu Ora operations lead	The NPHS Te Whatu Ora operations lead is the primary point of contact for escalations into NPHS Te Whatu Ora. Their key obligation is managing communications between NPHS Te Whatu Ora and Whakarongorau/Health Districts. 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. NPHS Te Whatu Ora operation team are responsible for failsafe reporting and organising outbound call campaigns to reach consumers.

32.4 Booking system processes and best practice

Figure 32.1 – booking tool processes:



32.5 Setup and maintenance

Creating a new site

Creating a new site relates to setting up a site on the booking system. Health Districts are asked to nominate one individual to be responsible for sending information and communicating between parties.

The Health District or provider will populate the new site CIR and NIBS setup forms. The nominated Health District staff member is then required to email the forms to the NPHS Te Whatu Ora central help desk. A seven-day lead time for receiving the completed forms prior to site going live is required by NPHS Te Whatu Ora. The information within this form is used by teams within NPHS Te Whatu Ora 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 Health District workforce lead. System training includes NIBS and the Covid Immunisation Consumer Support (CICS) tool (if the Health District 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 Health District staff member will inform NPHS Te Whatu Ora once system user training has been completed (it is mandatory for the training to be completed before users are provisioned). NPHS Te Whatu Ora will then provision the appropriate users for the site. The nominated Health District staff member and site admin 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 administrator is responsible for identifying major schedule changes, escalating these to the Health District operations lead, and making necessary system changes. The thresholds for escalation will be set and be maintained by each Health District.

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 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 determined by the site and Health District 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 NPHS

Te Whatu Ora. 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 administrator or Health District 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 single dose appointment. The COVID-19 vaccine is different for certain age groups and the vaccine is determined by their date of birth that the consumer enters.

When eligible, consumers can select Pfizer or Novavax as the vaccine type.

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 6 months to 11 years. 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 group (2-30 people) for a single dose of a Pfizer vaccine. Consumers are asked to provide the first and last name and contact information of the booking arranger.

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. Groups can only be cancelled using the booking arranger's contact details and the booking reference.

During the vaccination event

Consumer arrival

Where a consumer has booked an appointment as an individual and arrives at a site, an Immunisation Case will be in CIR. The Concierge must confirm that the consumer is

eligible for the Vaccination Plan and then check the consumer in. Where a consumer is part of a group, no Immunisation Case will be in CIR and this will need to be created as per a walk-in.

Where a consumer arrives at a site without an appointment (walk-in) or if they show up early for an appointment, providing the Health District 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.

Walk-in consumers should be assisted to book their next appointment on BMV. This process is best practise to ensure that consumers are booked to receive the next dose.

Post event: follow-up

Booking Did Not Attend (DNA) follow-up

Health Districts may choose to contact consumers who did not attend (DNA) appointments. Health Districts may utilise Whakarongorau to undertake any follow-up activities to rebook consumers.

33 Incidents

33.1 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.

33.2 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***.

33.3 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).

33.4 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.

Common side effects of COVID vaccines 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.

Rare side effects of COVID vaccines

Myocarditis and pericarditis are an inflammation of the heart muscle or lining and can range from mild to serious illness. They are usually caused by viruses but are also a **rare side effect** of both the Pfizer and Novavax COVID-19 vaccines.

Symptoms of myocarditis and pericarditis 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'.

33.5 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 Pfizer-BioNTech 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.

33.6 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.

33.7 Early second doses

If the first and second dose of the Pfizer-BioNTech COVID-19 vaccine is administered at an interval of **less than 21 days**, or **28 days** for the Nuvaxovid vaccine following another COVID-19 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 the COVID-19 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 Health District 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**.

34 Variations

34.1 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**.

34.2 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.