MINISTRY OF HEALTH
MANATŪ HAUORA

New Zealand Government

COVID-19 Vaccine Immunisation Programme Service Standards

September 2021

Released 2021 health.govt.nz

Prepared by:	COVID-19 Vaccine Immunisation Programme, Ministry of Health
Date:	September 2021
Version:	1
Status:	TBC

Citation: Ministry of Health. 2021. *COVID-19 Vaccine Immunisation Programme Service Standards*. Wellington: Ministry of Health.

Published in August 2021 by the Ministry of Health
PO Box 5013, Wellington 6140, New Zealand

MINISTRY OF HEALTH
MANATŪ HAUORA

This document is available at **health.govt.nz**

Document Version Control

Revision history

Version	Date	Section/Appendix
0.1	18 May 2021	Draft version sent to DHBs
0.2	30 May 2021	Updates in accordance with the introduction of a new COVID-19 Vaccinator workforce
1	01 September 2021	Reviewed ready for website publication

Abbreviations

ADR	Adverse drug reaction
AEFI	Adverse event following immunisation
CIR	COVID-19 Immunisation Register
CQI	Continuous Quality Improvement
DHB	District Health Board
DOPS	Direct Observation Procedural Skills
DNA	Did not attend
IMAC	Immunisation Advisory Centre
KPI	Key Performance Indicators
Ministry	Ministry of Health
NIBS	National Immunisation Booking System
Programme	COVID-19 Vaccine Immunisation Programme
SRO	Senior Responsible Officer for the COVID-19 vaccine programme within a DHB
Standards	COVID-19 Vaccine Immunisation Service Standards

Contents

Introduction

This document has been prepared by the Ministry of Health's (Ministry) COVID-19 Vaccine Immunisation Programme (Programme) team in partnership with the Programme's clinical leads and key stakeholders.

The Ministry's Immunisation Handbook states 'never in our generation has there been a greater need to have high immunisation coverage than in 2020 when New Zealand Aotearoa and the world are dealing with the COVID-19 pandemic'.

Vaccines will be rolled out through the Programme overseen by the Ministry. This will be New Zealand/Aotearoa's largest immunisation rollout ever. Never has an immunisation programme of this scale, cost or complexity been implemented in New Zealand/Aotearoa.

To quote the World Health Organization, 'Immunisation is one of modern medicine's greatest success stories. Vaccination has greatly reduced the burden of infectious diseases. Only clean water, also considered to be a basic human right, performs better'.

Purpose

The Programme aims to provide free vaccination to protect everyone in New Zealand/Aotearoa. Enough COVID-19 Vaccine has been secured for everyone in New Zealand/Aotearoa aged 12 years and over to receive the two doses they need to protect against COVID-19.

To assure consumer safety and a high-quality service, these COVID-19 Vaccine Immunisation Service Standards (Standards) have been prepared to specify the minimum requirements of the Programme. The Standards are the foundation document of the Programme quality assurance framework, and over time quality assurance audit will evidence conformance to the standard. This is the third release of the Standards; when change is required an updated version will be released

The Standards are supported by the Programme's COVID-19 Vaccine Operating Guidelines and the Ministry's Immunisation Handbook.

At times a standard refers to a DHB or a provider quality or clinical policy, process, and or a procedure. Providers may have a pre-existing suite of core policy documents which inform clinical quality and safety practice, which may be applied in support of the Programme.

This document should be interpreted in a manner that is consistent with 'NZS 8134:2021 Ngā Paerewa Health and Disability Services Standard' and the Health and Disability Commissioner *Code of Health and Disability Services Consumers' Rights* Regulations 1996.

The Standards and New Zealand/Aotearoa legislation, regulations and codes are essential requirements of all Programme providers and form the basis of contractual requirements in the provision of the Programme.

Operating Guidelines for DHBs and providers

The Programme's COVID-19 Vaccine Operating Guidelines are designed to help DHBs, and providers maintain public safety and to ensure consistent and equitable COVID-19 vaccination practices are in place across New Zealand/Aotearoa. It provides guidance on establishing, managing, and operating a COVID-19 vaccination site.

The COVID-19 Vaccine Operating Guidelines will be amended as required and released to DHBs and providers on the Ministry's website. We expect regular iterations based on learnings from the delivery of the Programme. Always ensure the correct version of the COVID-19 Vaccine Operating Guidelines is used.

Programme Planning Guidelines

The Programme's Planning Guidelines (previously known as the Planning Blueprints) are designed to support the initial conversations between DHBs and potential providers who are or will be operating from an existing healthcare facility. The planning guidelines are intended to assist in decision-making around whether a provider is able and willing to participate in the Programme, and what needs to be considered in the early planning stages.

Immunisation Handbook

The Immunisation Handbook 2020 provides clinical guidelines for all health professionals on the safest and most effective use of vaccines in their practice. These guidelines are based on the best scientific evidence available at the time of publication, from both published and unpublished literature.

The Standards must be read in the context of the clinical guidance available in the Immunisation Handbook, available at: **www.health.govt.nz/publication/immunisation-handbook-2020**.

Whakarongorau Aotearoa

Whakarongorau Aotearoa provides a single 0800 call centre service for those who require assistance with registering, booking or information relating to COVID-19 vaccination. The service further provides support for those with barriers to electronically registering or booking for vaccination, whether language, health literacy, or technology access, with pro-active follow-up (electronically, via mail, or via phone) to those not registered or booked to encourage their participation, with a particular focus on priority and vulnerable communities. It also provides data quality and data correction services, including calling participants to obtain accurate data.

National Immunisation Booking System

It is a service agreement requirement the National Immunisation Booking System (NIBS) is used by providers to book consumer vaccination appointments. Where a provider (including General Practice, Hauora Providers, Urgent Care (Primary Care/Hauora Providers) and Community Pharmacy) does not have an operational electronic booking system, that provider must book appointments through the National Immunisation Booking System (NIBS).

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

COVID-19 Immunisation Register

The programme recognises the COVID-19 Immunisation Register (CIR) as a fundamental 'system enabler' to achieve a safe, high quality, person-centred immunisation programme. The CIR is primarily used as the vaccination record for all people receiving the vaccine. All DHBs and programme providers must use the CIR as it is a requirement of the service agreement for the vaccination record and to support the programme objectives.

Document outline

The Standards are formatted so that they can be readily assessed, to specify:

- name of standard
- description of standard
- rationale of standard
- essential criteria
- evaluation process
- evaluation targets

The Standards cover the following areas:

1. Effective leadership
2. Facilities
3. Equipment
4. Vaccine
5. Quality and safety

Standard 1.0: Effective leadership

Standard 1.1: Leadership and organisation

The provider has a structure for leadership, governance, and accountability with clear reporting lines within the organisation.

Rationale	The purpose of this standard is to ensure the provider achieves an integrated person and whānau-centred COVID-19 immunisation service. The provider requires a clear structure for leadership, management, and accountability. This standard ensures the basic components of this structure are in place.
Essential criteria	

	Standard criteria	Guidance
1.1a	There is a designated clinical lead for the COVID-19 Vaccination and Immunisation Programme for each DHB.	Operating Guidelines and Immunisation Handbook
1.1b	There is a designated quality lead for the COVID-19 Vaccination and Immunisation Programme for each DHB	
1.1c	There is a designated equity lead for the COVID-19 Vaccination and Immunisation Programme for each DHB.	
1.1d	There is a provider leadership team comprising: clinical, vaccinator, and managerial lead roles, each with defined responsibilities.	
1.1e	There is a defined service structure with clear lines of reporting and accountability.	
1.1f	The provider has a routine internal audit plan with a named lead and timescales for completion.	
1.1g	The leadership clinical team have dedicated, non-clinical time in their job plans/roles to lead the vaccination service.	
1.1h	There are defined processes and timescales to review and maintain all policies and standard operating procedures.	
1.1i	The leadership team has the managerial and administrative support to organise and deliver the service effectively.	
1.1j	The service has appropriate technical support to enable effective service delivery.	
1.1k	The leadership team has access to timely and appropriate information on capacity, demand and waiting times from which to base operational and planning decisions.	

Essential criteria *(continued)*		Standard criteria	Guidance
	1.1l	The leadership team review and set the service's objectives on a regular basis and develop and implement plans to achieve these objectives.	Operating Guidelines and Immunisation Handbook
	1.1m	There are systems in place to ensure that the leadership team seek and receive feedback about their performance.	
	1.1n	There is a review process in place to consider and plan resources for new service developments.	
Evaluation process	Internal and external audit processes are used to ensure conformance to the criteria. Any identified risks or issues are addressed through a continuous quality improvement (CQI) process and the provider Quality Plan.		
Evaluation targets	No quantitative target. All criteria are met.		

Standard 1.2: Equity

The provider immunisation service is committed to offering a service that facilitates an equitable immunisation outcome for Māori, Pacific and people with disability, including priority access.

Rationale	Māori, Pacific and people with disability are priority populations who face various barriers to accessing vaccines. Adopting people and whānau-centred approaches to the vaccination programme will support uptake for Māori, Pacific and people with disability to ensure both doses of the vaccine are received within recommended timeframes.		
Essential criteria		Standard criteria	Guidance
	1.2a	The provider is delivering a service according to the local DHB policy to prioritise vaccination of Māori, Pacific and people with disability.	Operating Guidelines
	1.2b	The leadership team has a delivery plan, prioritising Māori, Pacific peoples, and people with disability, with equity deliverables and equity performance measures.	
	1.2c	The provider routinely monitors its performance measures and actions to meet equity service standards, service specifications and delivery expectations for Māori, Pacific peoples, and people with disabilities.	
Evaluation process	Internal and external audit processes are used to ensure conformance to the criteria. Any identified risks or issues are addressed through a CQI process and the provider Quality Plan.		
Evaluation targets	No quantitative target other than specified in the provider delivery plan (1.2b above). All criteria are met.		

Standard 1.3:
Policy and procedure management

The provider immunisation service has documented quality assurance and clinical safety policies and procedures that are regularly updated and shared with staff to ensure a person and whānau-centred safe, high quality service.

<table>
<tr><td>Rationale</td><td colspan="3">The quality of the immunisation service will be managed, coordinated, and reviewed within a provider by written protocol and procedure manuals that document quality assurance and clinical procedures.</td></tr>
<tr><td>Essential criteria</td><td colspan="3"><table>
<tr><th></th><th>Standard criteria</th><th>Guidance</th></tr>
<tr><td>1.3a</td><td>Policy and procedure documents are centrally accessible and available to all staff.</td><td rowspan="4">Operating Guidelines and Immunisation Handbook</td></tr>
<tr><td>1.3b</td><td>All policy and procedure manuals will be reviewed and updated two-yearly, or earlier if required.</td></tr>
<tr><td>1.3c</td><td>All relevant staff are notified of all changes to policies and procedures.</td></tr>
<tr><td>1.3d</td><td>There is an emergency management plan including effective liaison and availability of first responders regarding emergency management at temporary sites.</td></tr>
</table></td></tr>
<tr><td>Evaluation process</td><td colspan="3">Internal and external audit processes are used to ensure conformance to the criteria.
Any identified risks or issues are addressed through a CQI process and the provider Quality Plan.</td></tr>
<tr><td>Evaluation targets</td><td colspan="3">No quantitative target. All criteria are met.</td></tr>
</table>

Standard 1.4: Provider-led immunisation plan

The provider prepares a COVID-19 immunisation delivery plan and monitors performance to ensure all eligible consumers can receive both doses of the vaccine within the recommended timeframes.

Rationale	A consumer and whānau-centred immunisation service will ensure all eligible consumers are able to receive both doses of the vaccine within the recommended timeframes.
Essential criteria	

	Standard criteria	Guidance
1.4a	The provider has a local vaccination delivery plan that meets the eligible population vaccination requirements.	Operating Guidelines and Immunisation Handbook
1.4b	The plan meets the ongoing vaccination requirements of prioritised groups, including new border workers for the duration of the programme.	
1.4c	There is a local policy for prioritising vaccination of disabled people, hard to reach and vulnerable populations.	
1.4d	The provider and leadership team has agreed to the delivery plan and routinely assesses performance to the plan deliverables.	
1.4e	The provider routinely monitors its performance and takes actions when it is not conforming to service requirements and delivery expectations.	
1.4f	The provider's immunisation plan is reviewed on an annual basis, or more frequently if required, with amendments disseminated to appropriate stakeholders.	

Evaluation process	Internal and external audit processes are used to ensure conformance to the criteria. Any identified risks or issues are addressed through a CQI process and the provider Quality Plan.
Evaluation targets	No quantitative target other than specified in the provider delivery plan (1.4d and 1.4e above). All criteria are met.

Standard 1.5: Access and booking

There are systems and processes in place to ensure the immunisation service is accessible, timely, person and whānau-centred.

Rationale	A person and whānau-centred immunisation service must ensure that its resources (including scheduling of vaccination clinics) are used appropriately to reach all eligible people.

Essential criteria

	Standard criteria	Guidance
1.5a	The provider has systems and processes to ensure access to timely vaccinations through effective management, booking and scheduling practices.	Operating Guidelines and Immunisation Handbook
1.5b	Roles and responsibilities between vaccination sites, and DHB management, and other providers including the Whakarongorau Aotearoa for the management of booking and scheduling to access the service are clearly defined and documented.	
1.5c	The provider has a system and process in place to ensure persons required to be vaccinated under the COVID-19 Public Health Response (Vaccinations) Order 2021 have priority access to appointments.	
1.5d	There is a process for determining the capacity (workforce, vaccine supply and site size) of each vaccination clinic to enable the setting of the available schedule to be booked in advance of the vaccination event.	
1.5e	There is a system and process for monitoring, reviewing, and adjusting the capacity of the vaccination clinic to enable the setting of the available schedule in advance.	
1.5f	Where a consumer has received a first vaccination other than through a booking system and might therefore be at risk of not receiving their second dose vaccine, there is a plan in place for identifying and to follow up such consumers.	
1.5g	There is a process and communication plan to manage the outbound follow-up for rebooking consumers who miss vaccine appointment(s).	
1.5h	There is a process for pooling of bookings to ensure that consumers are booked in turn or wish to attend as a whānau group.	
1.5i	All appropriate consideration is taken when booking those who require more time, have other heath related needs, or have access requirements.	

<table>
<tr><td>Essential criteria (continued)</td><td>
<table>
<tr><th></th><th>Standard criteria</th><th>Guidance</th></tr>
<tr><td>1.5j</td><td>The provider achieves appropriate interval between vaccination doses.</td><td rowspan="3">Operating Guidelines and Immunisation Handbook</td></tr>
<tr><td>1.5k</td><td>Where required, the National Immunisation Booking System (NIBS) is used to facilitate efficient appointments booking and efficient scheduling of vaccination sites across a district.</td></tr>
<tr><td>1.5l</td><td>When setting or adjusting the vaccination scheduling plan, there is communication and agreement with Whakarongorau Aotearoa and as required, other key partners that will be impacted to facilitate the desired outcomes.</td></tr>
</table>
</td></tr>
<tr><td>Evaluation process</td><td>Internal and external audit processes are used to ensure conformance to the criteria.
Any identified risks or issues are addressed through a CQI process and the provider Quality Plan.</td></tr>
<tr><td>Evaluation targets</td><td>No quantitative target. All criteria are met.</td></tr>
</table>

Standard 1.6: Delivery and planning

There are policies, processes, and schedules in place to ensure that resources and capacity are used effectively.

Rationale	To ensure that provider resources and capacity are utilised effectively and efficiently.
Essential criteria	

	Standard criteria	Guidance
1.6a	There is performance (planning and delivery) metrics documented in the service delivery plan.	Operating Guidelines and Immunisation Handbook
1.6b	The provider must order vaccine and consumables via the CIR Inventory Portal.	
1.6c	There is a weekly review of bookings, demand, capacity, and scheduling.	
1.6d	There is enough flexibility in the plan to accommodate unplanned cancellation or partial loss of capacity for reasons including staff illness or significant weather events.	
1.6e	Booking efficiency is monitored (through DNA and cancellation monitoring, rebooking and delayed appointments) at least weekly and is fed back to the provider leadership group.	
1.6f	There is a communication and delivery pathway for the provider to identify and address any logistic, transport and social issues to minimise late cancellations or did not attend.	
1.6g	Demand, capacity, and utilisation data are used on an on-going basis for service planning to ensure enough capacity to inform scheduling, and the service has a production or delivery plan if shortfalls are identified.	
1.6h	At a minimum, every three months the provider reviews a delivery performance report with an action plan to support service planning.	
1.6i	The provider shall submit a four (4) week forward demand forecast plan each week to the Ministry.	
1.6j	DHBs will plan to have stock of vaccine and consumables for between 5 to 10 normal operating days.	
1.6k	The provider shall submit new site and facility information to the Ministry a minimum of five (5) days in advance of any deliveries.	
1.6l	All urgent orders are approved by the SRO prior to being submitted to the Ministry.	

Evaluation process	Internal and external audit processes are used to ensure conformance to the criteria. Any identified risks or issues are addressed through a CQI process and the provider Quality Plan.
Evaluation targets	No quantitative target. All criteria are met.

Standard 1.7:
Provider workforce capability

The provider has an appropriately trained and resourced workforce.

Rationale	The provider needs a capable well-trained and developed workforce to deliver a high-quality immunisation service.
Essential criteria	

	Standard criteria	Guidance
1.7a	There are policies and systems in place to ensure there are enough competent staff within the service with an appropriate mix of skills to enable delivery of the Programme requirements.	Operating Guidelines and Immunisation Handbook
1.7b	The service rosters staff according to service activity and the competency level. Allocation of the workforce must be based on the expected duration and complexity of the service activity.	
1.7c	There is a process in place to ensure that all new team members receive an immunisation service-specific induction.	
1.7d	There is a training needs analysis for key staff when there is a change or adoption of new practice, when team members leave, during succession planning or at least yearly. This is agreed by the appropriate senior manager responsible for each workforce group.	
1.7e	All staff have undergone Te Tiriti o Waitangi, Kawa and Tikanga Māori training.	
1.7f	There are processes to ensure the recruitment of suitable staff in a timely manner.	
1.7g	Workforce development plans are being provided by each DHB to confirm they understand their resourcing requirements and their plans to address any resourcing gaps.	
1.7h	The service has an active approach to succession planning for critical staff roles.	
1.7i	Where achievable, the ethnic profile of the workforce is reflective of the profile of the local population.	
1.7j	Staff can complete the on-line training on decision-making and informed consent, supporting all consumers including those with disability.	
1.7k	All staff have undergone the Health Information Privacy Code online learning module.	

Essential criteria *(continued)*			
		Standard criteria	Guidance
	1.7l	CIR users must supply an organisational email address to be granted access to the production CIR environment.	Operating Guidelines and Immunisation Handbook
	1.7m	All staff administering the vaccine have completed a CPR course that meets or exceeds the requirements as set out in Appendix 4 of the Immunisation Handbook.	
Evaluation process	Internal and external audit processes are used to ensure conformance to the criteria. Any identified risks or issues are addressed through a CQI process and the provider Quality Plan.		
Evaluation targets	No quantitative target. All criteria are met.		

Standard 1.8: Vaccinator staff

The vaccine is prepared and administered by appropriately trained and authorised staff.

Rationale	Consumers are vaccinated by the right person, at the right time and in the right place, with the right dose and equipment to promote a safe and quality health service delivery.		
Essential criteria			
		Standard criteria	Guidance
	1.8a	All vaccinators are required to complete the relevant COVID-19 Vaccinator training or COVID-19 vaccine training and assessments.	Operating Guidelines and Immunisation Handbook and Medicines Regulations 1984
	1.8b	The number of vaccinators on site will be consistent with the service delivery model being used.	
	1.8c	The vaccine is prepared and administered in accordance with up-to-date instructions provided by the Ministry.	
	1.8d	That vaccinators comply with the Immunisation Standards set out in the Immunisation Handbook 2020.	
	18.e	There is always a suitably qualified healthcare professional on site supervising a COVID-19 vaccinator.	
Evaluation process	Internal and external audit processes are used to ensure conformance to the criteria. Any identified risks or issues are addressed through a CQI process and the provider Quality Plan.		
Evaluation targets	No quantitative target. All criteria are met.		

Standard 1.9: COVID-19 Vaccinators

This standard applies to providers and sites that are utilising the COVID-19 vaccinators. The provider will ensure COVID-19 Vaccinators are delivering a safe, equitable, and quality service.

Rationale	Consumers are vaccinated safely by COVID-19 Vaccinators, under the minimum requirement supervision, at the right time and in the right place, with the right dose and equipment to facilitate a safe and quality health service delivery.
Essential criteria	

	Standard criteria	Guidance
1.9a	All COVID-19 vaccinators have completed the required COVID-19 vaccinator training and assessments through IMAC and must have been authorised under regulation 44AB.	Operating Guidelines and Immunisation Handbook and Medicines Regulations 1984
1.9b	COVID-19 vaccinators have completed a CPR course that meets the requirements as set out in the Immunisation Handbook, Appendix 4.	
1.9c	Providers will meet the minimum supervision requirements of one authorised vaccinator to a maximum of six COVID-19 vaccinators.	
1.9d	COVID-19 vaccinators have the required indemnity cover.	
1.9e	Providers will ensure an escalation process is in place to support, monitor and evaluate the service delivered by COVID-19 vaccinators.	
1.9f	Providers will have enough staff to continuously supervise and support the COVID-19 vaccinator role who require direct supervision for their induction and practical assessment.	
1.9g	Regulation 44AB(3) requires COVID-19 Vaccinators to work under the clinical supervision and direction of a healthcare professional at all time – providers must always have healthcare professionals available to supervise COVID-19 vaccinators.	
19.h	COVID-19 vaccinators maintain ongoing professional development and align practice with any relevant immunisation and programme updates.	

Evaluation process	Internal and external audit processes are used to ensure conformance to the criteria. Any identified risks or issues are addressed through a CQI process and the provider Quality Plan.
Evaluation targets	No quantitative target. All criteria are met.

Standard 2.0: Facilities

Standard 2.1: Vaccination sites and centres

The provider establishes a person and whānau-centred vaccination site that is safe, comfortable, accessible, clean, clinically, and culturally appropriate.

Rationale	Consumers are more likely to feel at ease, and the desired outcome achieved, when their journey through the vaccination site or centre is person and whānau-centred, safe, comfortable, accessible, clean, clinically, and culturally appropriate.
Essential criteria	

	Standard criteria	Guidance
2.1a	Reception area The reception area is of sufficient size to accommodate the expected throughput for the service.	Operating Guidelines and Immunisation Handbook and *Australasian Health Facility Guidelines*
2.1b	Waiting area The waiting area can accommodate (seat) the usual number of consumers and other family/whanau/ support persons who would be waiting at any time.	
2.1c	Office area Of sufficient size to support administrative functions.	
2.1d	Consumer facilities Of sufficient size, with sufficient toilet facilities. There is a suitably discreet location if consumers need to change prior to vaccination. Facility must have appropriate space for supported decision-making and consent.	

Essential criteria *(continued)*		Standard criteria	Guidance
	2.1e	Observation space fittings and features Any service observation space, should it be required, must include: a. Sufficient space for a bed or trolley b. Access to emergency equipment c. Access to hand-washing facilities/hand sanitiser d. Intercom or emergency call system e. Data ports/IT workspace f. Adjustable and appropriate lighting g. Appropriate temperature and ventilation h. Telephone access i. Sharps disposal j. Consumer privacy through appropriate screens/dividers	In accordance with NZS 8134:2021 New Zealand Ngā Paerewa Health and Disability Services Standard
	2.1f	Additional equipment required for immediate resuscitation should it be required: Anaphylaxis management kit containing: a. medications (including adrenaline) b. a laminated card outlining the management of anaphylaxis c. syringes and needles d. Adult and paediatric bag valve mask resuscitator (AmbuBag) e. First aid kit f. Monitoring equipment: g. blood pressure cuff h. pulse oximeter i. observation charts and j. stethoscope	and IMAC anaphylaxis management card or poster
	2.1g	Suitable and sufficient ventilation for closed sites.	
	2.1h	Clinical support areas Dedicated, secure and separate storage should be provided for a range of stock, consumables and equipment, including adequate supplies of needles, cotton balls, skin preparation, plasters, and gloves.	There is wheelchair access to the facility and clinic space which complies with disability regulations in accordance with NZS 8134:2021 New Zealand Ngā Paerewa Health and Disability Services Standard
	2.1i	Consulting or interview room Consulting room is located appropriately close to the observation room and constructed to ensure consumer privacy and confidentiality of discussions and contain enough furniture and fittings for whānau consultation.	
	2.1j	Staff workstation There should be a clinical staff workstation.	
	2.1k	Accessible staffroom.	
	2.1l	Staff toilet and changing rooms.	

		Standard criteria	Guidance
Essential criteria *(continued)*	2.1m	Special considerations a. Consumer and changing area (including disability access facility). b. According to local demand, women only lists should be considered to meet cultural needs.	There is wheelchair access to the facility and clinic space which complies with disability regulations in accordance with NZS 8134:2021 New Zealand Ngā Paerewa Health and Disability Services Standard
	2.1n	Waste disposal area Must contain sharps bin and adequate clinical and non-clinical waste disposal.	
	2.1o	Vaccine vials are safely disposed using the required disposal process.	
	2.1p	Vaccine packaging must be destroyed so packages cannot be replicated.	
	2.1q	The observation area is: Appropriate to the planned throughput of consumers and in accordance with the NZS 8134:2021 *Ngā Paerewa Health and Disability Services Standard*. The observation area has separate stage 1 and 2 zones. Stage 1 requires the ability to provide: • vital sign monitoring • call for assistance facilities Stage 2 must be: • appropriately located, adjacent to the procedure space and freely accessible to an emergency trolley	
	2.1r	There are systems in place to ensure access to the following areas are 'Restricted Access Only': • vaccination storage and preparation area.	
	2.1s	The site or centre must be of an appropriate size to allow safe flow of consumers and staff through the facility in the case of an emergency.	
	2.1t	Site or centre accessibility There should be enough off-street parking and/or on-site access to meet the needs of all consumers including disability car parks, parking for caregivers of young children and, bicycle racks. Site accessibility options are shared in consumer information and on public information sites. There is suitable and sufficient lighting and signage at site egress points.	
	2.1u	Each site or centre must have a Health and Safety Plan to ensure the health and safety of staff, consumers, and other people.	

<table>
<tr><td>Essential criteria (continued)</td><td>
<table>
<tr><th></th><th>Standard criteria</th><th>Guidance</th></tr>
<tr><td>2.1v</td><td>Work health and safety risks relating to the vaccination site are identified and managed, including site evacuation in the case of an emergency and consistent with the building warrant of fitness (where applicable).</td><td></td></tr>
<tr><td>2.1w</td><td>Site checklists must be signed off by the Chief Executive or their delegate to confirm site readiness.</td><td></td></tr>
</table>
</td></tr>
<tr><td>Evaluation process</td><td>Internal and external audit processes are used to ensure conformance to the criteria.
Any identified risks or issues are addressed through a CQI process and the provider Quality Plan.</td></tr>
<tr><td>Evaluation targets</td><td>No quantitative target. All criteria are met.</td></tr>
</table>

Standard 3.0: Equipment

Standard 3.1: Essential equipment

The equipment should be sufficient in quantity and quality to meet vaccination service requirements.

<table>
<tr><td>Rationale</td><td colspan="3">A safe, quality vaccination service requires appropriate, well maintained equipment and in good working order.</td></tr>
<tr><td>Essential criteria</td><td colspan="3"><table>
<tr><th></th><th>Standard criteria</th><th>Guidance</th></tr>
<tr><td>3.1a</td><td>Volume of equipment should be sufficient to maximise efficiency, avoid consumer delays and ensure consumer safety. Processing times and unexpected equipment malfunction should be considered.</td><td rowspan="3">Operating Guidelines and Immunisation Handbook</td></tr>
<tr><td>3.1b</td><td>Access to oxygen is considered for settings where emergency response could be delayed (such as non-traditional vaccination settings and those in rural/remote locations).</td></tr>
<tr><td>3.1c</td><td>Access to an Automatic Electronic Defibrillator (AED) is considered for settings where emergency response could be delayed (such as non-traditional vaccination settings and those in rural/remote locations).</td></tr>
<tr><td>3.1d</td><td>Resuscitation equipment: refer to 2.1f</td><td></td></tr>
</table></td></tr>
<tr><td>Evaluation process</td><td colspan="3">Internal and external audit processes are used to ensure conformance to the criteria.
Any identified risks or issues are addressed through a CQI process and the provider Quality Plan.</td></tr>
<tr><td>Evaluation targets</td><td colspan="3">No quantitative target. All criteria are met.</td></tr>
</table>

Standard 3.2: Maintenance of equipment

All equipment is suitable, functional, accessible, up to date and appropriately maintained for safe optimal performance.

Rationale	Equipment that is regularly maintained as part of regular quality assurance activities and has undergone compliance testing, meeting the manufacturer's specifications for use, will ensure safe quality vaccination service delivery.
Essential criteria	

	Standard criteria	Guidance
3.2a	Guidelines and standard operating procedures for use and maintenance of equipment for vaccination waste is easily accessible at the site.	Operating Guidelines and Immunisation Handbook
3.2b	Testing and validation of equipment is carried out according to standard requirements and guidance; appropriate remedial action is taken as required when results fall outside the acceptable parameters.	
3.2c	There is a designated lead who has overall responsibility for site equipment maintenance and waste management practice	
3.2d	There are systems in place to ensure that access to areas is restricted where appropriate (includes contaminated equipment and site waste management).	
3.2e	There are systems in place to ensure clinical equipment is appropriate and available for consumers and for those with needs including pregnant women, elderly and those significantly under or overweight.	
3.2f	There are systems in place to ensure the management and control of environmental conditions (includes decontamination).	
3.2g	There are systems in place to ensure the maintenance and quality assurance of all equipment with corresponding records (includes decontamination).	
3.2h	There are systems in place to ensure that equipment replacement is planned and implemented as required (includes contaminated equipment).	

Evaluation process	Internal and external audit processes are used to ensure conformance to the criteria. Any identified risks or issues are addressed through a CQI process and the provider Quality Plan.
Evaluation targets	No quantitative target. All criteria are met.

Standard 4.0: Vaccine

Standard 4.1: Storage of the vaccine

All vaccines are safely and appropriately stored, with the correct level of security and access.

Rationale	The vaccine is securely and appropriately stored as per manufacturer's guidelines, legislative and programme requirements.

Essential criteria

	Standard criteria	Guidance
4.1a	The site or centre has a policy and standard operating procedures on the storage of the vaccine.	Providers ensure they have a policy on the storage and transportation of the vaccine which aligns with the *Immunisation Handbook (*and the manufacturer's specific guidelines.
4.1b	The site or centre has a policy and standard operating procedures on the maintenance of the cold chain and maintains records of this.	Providers to ensure they have a policy that aligns with the Ministry of Health *National Standards for Vaccine Storage and Transportation for Immunisation Providers 2017* and all clinical staff have read and understood, and must comply with, their provider's cold chain policy. Providers must also maintain records of the monitoring of the cold chain in accordance with the *Health (Retention of Health Information) Regulations 1996.*
4.1c	The site or centre has a policy and standard operating procedures on the preparation, use and disposal of the vaccine.	Providers must have a policy which reflects best practice and aligns with the manufacturer's specific guidelines and the *Ministry of Health Operating Guidelines for DHBs and Providers, COVID-19 Vaccine Immunisation Programme*.

<table>
<tr><td>Essential criteria (continued)</td><td><table>
<tr><th></th><th>Standard criteria</th><th>Guidance</th></tr>
<tr><td>4.1d</td><td>The site or centre has two (2) authorised leads for cold chain management for each operating day of the service.</td><td>Providers must ensure, in accordance with the National Standards for Vaccine Storage and Transportation for Immunisation Providers 2017. That there is a minimum of two cold chain management leads that are authorised vaccinators, general practitioners or pharmacist vaccinators. Their responsibilities are outlined in section 5.2 of the above document.</td></tr>
</table></td></tr>
<tr><td>Evaluation process</td><td>Internal and external audit processes are used to ensure conformance to the criteria.
Any identified risks or issues are addressed through a CQI process and the provider Quality Plan.</td></tr>
<tr><td>Evaluation targets</td><td>No quantitative target. All criteria are met.</td></tr>
</table>

Standard 4.2: Administration of the vaccine

The vaccine is appropriately and safely administered by trained staff.

Rationale	The preparation and administering of the vaccine must be undertaken by appropriately trained vaccination staff using programme guidelines and local protocols.		
Essential criteria			
		Standard criteria	Guidance
	4.2a	The provider has a policy and standard operating procedures on the preparation and administration of the vaccine.	Refer to local DHB/provider policy on vaccine administration policies and guidelines. Immunisation Handbook
	4.2b	All staff administering the vaccine are lawfully able to administer the vaccine	Vaccinator training is available via: • The Immunisation Advisory Centre Provisional Vaccinator Course, or • The Immunisation Advisory Centre COVID-19 specific vaccinator module, or • Completed the process to become a COVID-19 vaccinator including all online, practical and pre-employment assessments.
	4.2c	Staff preparing the vaccine is lawfully able to prepare the vaccine and adhere to the programme endorsed requirements to safely prepare and administer the vaccine.	IMAC for guidelines on the safe preparation and administration of vaccines. The Operating Guidelines The Immunisation Handbook
	4.2d	Vaccinators are satisfied that informed consent has been given.	
	4.2e	Staff administering the vaccine adhere to infection, prevention and control guidelines during the preparation and administration of the vaccine.	IMAC for guidelines on the safe preparation and administration of vaccines. Refer to local DHB or the provider policy on infection, prevention, and control.
	4.2f	Staff will administer the vaccine in accordance with the requirements as set out in the Immunisation Handbook	
	4.2g	Staff administering the vaccine have been inducted to the vaccine related policies, procedures, emergency equipment including localised training to manage possible adverse reactions.	Providers to ensure local policy and guidelines align with the guidance from the Immunisation Handbook.

Evaluation process	Internal and external audit processes are used to ensure conformance to the criteria. Any identified risks or issues are addressed through a CQI process and the provider Quality Plan.
Evaluation targets	No quantitative target. All criteria are met.

Standard 4.3: Vaccine waste prevention, reporting and monitoring

The vaccine is appropriately managed to ensure waste is kept to a minimum.

Rationale	In accordance with the programme's *Vaccine Use and Waste Policy* there are local measures in place to prevent waste of the vaccine. All vaccine waste is accurately recorded on the day it occurs.
Essential criteria	

	Standard criteria	Guidance
4.3a	The provider will ensure all waste of any vaccine is documented stating the reason for the waste. Monitoring and investigation of waste should be undertaken to mitigate future waste.	The Programme's Vaccine Use and Waste Policy and
4.3b	The provider will ensure local guidance is available to staff on how to minimise waste of the vaccine. Providers should have adequate planning in place to minimise vaccine waste due to unused thawed vaccines or vaccines not administered prior to expiry date or time.	Operating Guidelines and Immunisation Handbook

Evaluation process	Internal and external audit processes are used to ensure conformance to the criteria. Any identified risks or issues are addressed through a CQI process and the provider Quality Plan.
Evaluation targets	No quantitative target. All criteria are met.

Standard 5.0: Quality and safety

Standard 5.1: Quality assurance programme

The provider works collaboratively to implement an active quality assurance programme with an ethos of continuous quality improvement.

<table>
<tr><td>Rationale</td><td colspan="3">A high-quality immunisation service requires a documented, continuous quality improvement programme outlined in a provider quality assurance plan.</td></tr>
<tr><td>Essential criteria</td><td colspan="3"><table>
<tr><th></th><th>Standard criteria</th><th>Guidance</th></tr>
<tr><td>5.1a</td><td>The provider has dedicated resources and time to assure the quality and safety of their service.</td><td rowspan="4">Operating Guidelines and Immunisation Handbook</td></tr>
<tr><td>5.1b</td><td>The provider has a routine internal audit programme incorporating all relevant minimum requirements.</td></tr>
<tr><td>5.1c</td><td>Responsibility for Quality Assurance is assigned to Quality Leads.</td></tr>
<tr><td>5.1d</td><td>The provider routinely assesses clinical quality and safety risks and issues.</td></tr>
</table></td></tr>
<tr><td>Evaluation process</td><td colspan="3">Internal and external audit processes are used to ensure conformance to the criteria.
Any identified risks or issues are addressed through a CQI process and the provider Quality Plan.</td></tr>
<tr><td>Evaluation targets</td><td colspan="3">No quantitative target. All criteria are met.</td></tr>
</table>

Standard 5.2: Consumer quality improvement processes

The provider has processes in place to identify, respond to and learn from incidents and adverse events.

Rationale	Person and whānau-centred continuous quality improvement require appropriate processes to identify and address all the Programme related incidents and adverse events.
Essential criteria	

	Standard criteria	Guidance
5.2a	Systems are in place for monitoring site or centre incidents and adverse events.	Operating Guidelines and Immunisation Handbook
5.2b	There is routine use of a team start-of-day and end-of-day safety checklist or safety huddle.	
5.2c	The provider inducts staff on what, when and how to report an incident or adverse event.	
5.2d	The provider leadership team review incidents/adverse events regularly.	
5.2e	There are local policies, protocols, or standard operating procedures for the management of all types of incidents or adverse events.	
5.2f	Actions required in response to learning from all types of incidents or adverse events are implemented as soon as practicable and in any event within three months of being reported.	
5.2g	The provider has systems in place to monitor and act upon outcomes from a review of a serious adverse event or reaction related to their service.	

Evaluation process	Internal and external audit processes are used to ensure conformance to the criteria. Any identified risks or issues are addressed through a CQI process and the provider Quality Plan.
Evaluation targets	No quantitative target. All criteria are met.

Standard 5.3: Respect and dignity

The provider implements and monitors systems to ensure that the consumers are treated with respect, and dignity. The security of all consumers is protected throughout their immunisation journey.

Rationale	All consumers and whānau have the right to be treated with respect and dignity and vaccinated in a safe environment.
Essential criteria	

	Standard criteria	Guidance
5.3a	The provider has a policy to treat all consumers with respect and dignity, which includes cultural considerations and care of all people accessing the service.	Operating Guidelines and Immunisation Handbook
5.3b	There are standard operating procedures for safeguarding and protecting vulnerable adults and children within the site or centre.	
5.3c	There is a range of communication methods and materials to ensure that people are appropriately informed about what they should expect from the service.	
5.3d	There are facilities available for any clinical conversations to be held in private.	
5.3e	Person-identifiable material is not openly displayed in areas accessible to other consumers, relatives, or carers without their consent.	
5.3f	Consumer experience of privacy, respect and dignity is formally assessed at least annually, using at least two accepted consumer feedback methods.	
5.3g	There is appropriate separation for all consumers between pre- and post-vaccination stages, and at any other stage from the admission stage onwards in the consumer journey to protect privacy, dignity, and respect.	

Evaluation process	Internal and external audit processes are used to ensure conformance to the criteria. Any identified risks or issues are addressed through a CQI process and the provider Quality Plan.
Evaluation targets	No quantitative target. All criteria are met.

Standard 5.4: Informed consent process (including consumer information)

The provider implements and monitors systems to ensure that informed consumer consent is obtained prior to each vaccination.

Rationale	Consumer is given enough information to be able to make informed choices about their vaccination.

Essential criteria

	Standard criteria	Guidance
5.4a	Consumer information is readily available in Māori and other languages about the vaccine and about the vaccination process steps to enable informed consent.	Operating Guidelines and Immunisation Handbook and Health and Disability Commission. (1996) Code of Health and Disability Services – Consumers' Rights Regulation
5.4b	The informed consent process will be verbal or written.	
5.4c	All consumers are given time to ask questions about the vaccination before consent is agreed and before entering the vaccination space or offered the vaccine	
5.4d	The informed consent process is completed by the consumer or their guardian with a health professional before the consumer enters the vaccination space.	
5.4e	Informed consent must be recorded in the CIR to approve or decline the administration of the vaccine.	
5.4f	Written consent can be considered under any of the following points: • If there is significant risk of adverse effects to the consumer, per **clause 7(6c) of the Code** • If it is being prescribed outside of the programme (such as for unapproved use) • If it is the provider's/vaccinator's preferences such as in aged residential care settings	
5.4g	Where written consent is recorded under any of the above criteria, the hard-copy forms do not need to be uploaded to CIR. The provider is responsible for ensuring the forms are archived as a part of that consumer's clinical record.	
5.4h	If written consent forms are unable to be archived in the consumer's clinical record, then this must be uploaded onto CIR. Once this is complete the record can be destroyed	
5.4i	There is a standard operating procedure to upload written informed consent into CIR.	
5.4j	There is a local standard operating procedure for informed consent which includes provision for withdrawal of consent.	
5.4k	There is a standard operating procedure for obtaining informed consent for those who are unable to consent on their own behalf.	

Essential criteria *(continued)*	5.4l	There is a standard operating procedure for obtaining written informed consent for those in Group 1 of the Programme.
	5.4m	Any consumer related issue related to the informed consent process is reported as an adverse event.
	5.4n	The provider will adhere to the Programme 12- to 15-year-old Informed Consent Policy Statement.
Evaluation process	Internal and external audit processes are used to ensure conformance to the criteria. Any identified risks or issues are addressed through a CQI process and the provider Quality Plan.	
Evaluation targets	No quantitative target. All criteria are met.	

Standard 5.5: Vaccination event record

The provider implements and monitors systems to ensure accurate and timely entry of the vaccination event.

Rationale	Accurate and timely completion of vaccination records is essential to ensure safe and high-quality immunisation outcomes.		
Essential criteria		Standard criteria	Guidance
	5.5a	All vaccination records are completed on the day of vaccination. This includes follow-up details and adverse event reports.	Operating Guidelines and Immunisation Handbook
	5.5b	The provider has a standard operating procedure to ensure accurate and timely vaccination record keeping.	
	5.5c	The provider undertakes a routine internal quality assurance audit to assess conformance to the standard.	
	5.5d	The provider has a robust process to manually document vaccination records when the CIR system is unavailable. In case of CIR disruption, all manually documented vaccination records will be entered into the CIR within 24 hours of the system fix.	
Evaluation process	Internal and external audit processes are used to ensure conformance to the criteria. Any identified risks or issues are addressed through a CQI process and the provider Quality Plan.		
Evaluation targets	No quantitative target. All criteria are met.		

Standard 5.6:
Clinical safety and quality assessment

The provider implements and monitors systems to ensure the clinical and technical quality of their vaccination service.

Rationale	Regular assessment and monitoring of clinical safety and quality indicators and performance measures will assure the safety and quality of the immunisation service.		
Essential criteria			
		Standard criteria	Guidance
	5.6a	Provider safety and quality indicators and auditable outcomes are available for performance monitoring and CQI activity.	Operating Guidelines
	5.6b	Systems are in place for regular reporting and monitoring of clinical safety, quality, and performance indicators.	
Evaluation process	Internal and external audit processes are used to ensure conformance to the criteria. Any identified risks or issues are addressed through a CQI process and the provider Quality Plan.		
Evaluation targets	No quantitative target. All criteria are met.		

Standard 5.7:
Post vaccination care and aftercare

The provider implements and monitors systems to ensure that consumers are informed about post vaccination care and understand what to do if there are complications.

Rationale	Consumers require information after their vaccination to ensure safety and early detection of complications.		
Essential criteria			
		Standard criteria	Guidance
	5.7a	Consumers are informed of the phone number to contact the Whakarongorau Aotearoa if they experience problems following their vaccination.	Operating Guidelines and Immunisation Handbook
	5.7b	Consumers are aware of potential side effects of the vaccine and are informed of how to report these to the Centre for Adverse Reactions Monitoring (CARM).	
	5.7c	All consumers are provided with verbal and written information about their care including any follow up arrangements or appointments.	
Evaluation process	Consumer surveys inform the provider's internal and external audit processes to ensure the criteria are complied with. Identified risks or issues are addressed through a CQI process and the provider Quality Plan.		
Evaluation targets	All criteria are met.		

Standard 5.8: Consumer involvement

The provider implements and reviews their systems to ensure consumers can feedback on their experience of the immunisation service and the feedback is acted upon.

Rationale	A consumer-centred immunisation programme demonstrates ongoing quality improvement, which is responsive to the views of the consumers.
Essential criteria	

	Standard criteria	Guidance
5.8a	The provider complaints procedure is documented and is clearly available for consumers, relatives, whānau and carers to access.	NZS 8134:2021 New Zealand Ngā Paerewa Health and Disability Services Standard
5.8b	There are processes in place to ensure that complaints are reported, investigated, recorded, and analysed with findings disseminated to relevant parties and acted upon.	
5.8c	The provider uses more than one method to obtain consumer feedback on a regular basis.	
5.8d	A summary is available for public view of consumer feedback and change made in response where appropriate.	
5.8e	Consumer participation is evident in planning and evaluating the service.	

Evaluation process	Internal and external audit processes are used to ensure conformance to the criteria. Any identified risks or issues are addressed through a CQI process and the provider Quality Plan.
Evaluation targets	No quantitative target. All criteria are met.

Glossary of terms

Adverse event following immunisation (AEFI)	Any untoward medical event which follows immunisation and does not necessarily have a causal relationship with the usage of the vaccine. The adverse event may be an unfavourable or unintended sign, abnormal laboratory finding, symptom or disease.
Adverse drug reaction	A response to a drug which is noxious and unintended, and which occurs at doses normally used in humans for the prophylaxis, diagnosis, or therapy of disease, or for the modifications of physiological function.
Audit (Quality)	The audits referenced in this standard are an essential quality assurance tool to be used for verifying objective evidence of processes to assess conformance to the standards. For the benefit of the organisation, quality auditing should not only report non-conformances and corrective actions, it also highlights areas of good practice. Audit can be classified as internal or external (independent) audits.
Auditor	An auditor performs an audit in accordance with specific laws, standards, or rules required of the entity being audited. An external auditor provides an independent assessment, with findings and corrective actions, based on triangulated evidence of variation between current practice and the required standard.
Legal guardian	A person appointed to make decisions for a child or person who lacks the capacity to understand the nature and consequences of their decisions and/or the ability to communicate their decisions.
Concomitant vaccination	Concomitant vaccination aims to provide optimal protection against disease as quickly as possible by completing a person's recommended vaccination schedule in the shortest but most effective time frame.
Consumer	A health consumer includes any person in respect of whom any health care procedure is carried out and is the standard term used in this document.
COVID-19 vaccinator	A person who has successfully completed the required steps, including the online training and a practical assessment, and meets the requirements set out by the Ministry of Health to become a COVID-19 vaccinator under the direction and supervision of an experienced, registered health professional (typically an authorised or provisional vaccinator).
Credentialling	The process of review and verification of fitness to practise typically performed by an organisation to grant specific clinical privileges such as performing procedures for that organisation.
Criteria	Essential requirement to meet the standard. In audit it will be evaluated to assess conformity to the standard, sometimes described as compliance to the standard.
CQI	Continuous Quality Improvement refers to the iterative process of *plan, do, check, act* to ensure processes are 'fit for purpose' and identifies improvement in the system.
DHB or Provider Immunisation Leadership Committee	The DHB or provider leadership committee consists of (as a minimum): clinical lead, management lead and safety and quality role.

Eligible consumer	A person who is eligible to receive the vaccine in New Zealand/Aotearoa.
Equity	In New Zealand/Aotearoa, people have differences in health that are not only avoidable but unfair and unjust. Equity recognises different people with different levels of advantage require different approaches and resources to progress towards equitable health outcomes.
Essential criteria	The essential criteria are components of service provision that are required to be in place to achieve the indicator.
Evaluation targets	Evaluation targets are specified where quantitative measures are available. If no target has been set, the expectation is that full compliance with all criteria will be met. The evaluation target clearly identifies the level of compliance required to meet the specific standard, indicator, or criteria.
Evaluation process	The evaluation process is the means through which the criteria conformance is assessed.
Group 1	The programme defines Group 1 as border and managed isolation and quarantine (MIQ) workers and the people they live with.
Indemnity Cover	Indemnity insurance covers health professionals for claims related to professional practice, including disciplinary, fitness to practise and competency matters, coroner's inquiries/inquests, Health and Disability Commissioner complaints/investigations, health practitioner disciplinary tribunal proceedings and Human Rights Review tribunal proceedings.
Person and whānau-centred	Providing care and support that is respectful of and responsive to individual consumer preferences, needs and values, and ensuring that consumers have input to all clinical and support decisions.
Policy	A document that states, in writing, principles or a course of required action adopted by a provider.
Quality Indicator	A measurable element of service provision. Quality indicators relate to the desired outcome or performance of services.
Serious adverse event	Any untoward medical occurrence that at any dose: • results in death • is life threatening • requires hospitalisation or prolongation of an existing hospitalisation • causes persistent or significant disability or incapacity • causes a congenital anomaly/birth defect • is a medically important event or reaction.
Skill mix	A combination of different workforce types of who have the required skills and competencies to carry out the work of the vaccination service and safely deliver the Programme across the entire vaccination pathway.

Standard	A standard is mandatory, specifies the minimum requirement for compliance or conformity, and wherever possible, is outcome- and quality-focused. Each standard will always specify the objective that is required. A standard outline the requirements, specifications, guidelines, or characteristics that can be used consistently to ensure that materials, products, processes, and services are fit for their purpose. The standard is achieved when all associated indicators or criteria are met.
Supported decision-making	Supported decision-making (SDM) is a tool that enables a consumer with disability to retain their decision-making capacity. The consumer who needs to decide works with an appropriate support, such as a health professional, who then ensures the consumer gets the right information, at the right time, in the right way, with enough time to consider their self-determined decision. A consumer using SDM can also select a trusted advisor/s, such as a friend, family member/s, or known health professionals, to serve as supporters.
Vaccination centre or site	A Programme registered facility, site or centre.
Vaccination clinic	Open or fixed hours resourced vaccination clinic held at a Programme registered facility, site or centre.
Vaccine administration error	A vaccine administration error is any preventable event that may cause or lead to inappropriate use of vaccine or patient harm.
Vaccination space	A dedicated private area that is resourced for vaccinating a consumer. It allows a vaccinator to safely vaccinate a consumer with at least one support person in attendance.
Whakarongorau Aotearoa	The New Zealand/Aotearoa telehealth service providing the national Healthline support to the COVID-19 vaccine immunisation programme.

References

Medicine Regulations 1984 New Zealand.

Health and Disability Commission. 1996. Code of Health and Disability Services – Consumers' Rights Regulation.

Standards New Zealand. 2021. NZS 8134:2021 New Zealand Ngā Paerewa Health and Disability Services Standard.

Ministry of Health. 2019. National Standards for Vaccine Storage and Transportation for Immunisation Providers (2nd edition). Wellington: Ministry of Health.

Ministry of Health. 2020. *Immunisation Handbook*. Wellington: Ministry of Health (**www.health.govt.nz/publication/immunisation-handbook-2020**).

Ministry of Health. 2021. *The COVID-19 Vaccine Use and Waste Policy Statement*. Wellington: Ministry of Health.

Ministry of Health. 2021. The COVID 19 12- to 15-year-old Informed Consent Policy Statement. Wellington: Ministry of Health.

Ministry of Health. 2021. *The COVID 19 Concomitant Vaccination Policy Statement*. Wellington: Ministry of Health.