MINISTRY OF HEALTH
MANATŪ HAUORA

New Zealand COVID-19 Vaccine Immunisation Service Standards

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Revision History

Version	Date	Section/Appendix	Summary of Changes
0.1	18/05/2021	Draft version sent to DHBs	
0.2	3/05/2021	Updates in accordance with the introduction of a new COVID-19 Vaccinator workforce	

Contents

Introduction

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

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

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'.

Vaccines will be rolled out through the COVID-19 Immunisation Programme run by the Ministry of Health (the Ministry). This will be New Zealand's largest immunisation rollout ever. Never has an immunisation programme of this scale, cost or complexity been attempted in New Zealand.

Purpose

The programme aims to provide a free vaccine to protect everyone in Aotearoa. Enough BioNTech/Pfizer COVID-19 Vaccine has been secured for everyone in New Zealand aged 16 and over to get the two doses they need to protect against COVID-19.

To assure consumer safety and a high-quality service, these New Zealand COVID-19 Vaccine Immunisation Service Standards (the 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 first release of the standards; when minimum requirements change then an update will follow.

As the first step, the standards are recommended to all District Health Board (DHBs) to use as a self-assessment tool with providers as conformance to the standards mitigates the inherent safety and quality risks of the programme. Accordingly, conformance signals the provider's readiness to deliver a safe, high-quality immunisation service.

The standards criteria are supported by the Programme Operating Guidelines and the 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 and can be applied in support of the programme.

This document should be interpreted in a manner that is consistent with 'NZS 8134 Health and Disability Services Standards' and the 'Code of Health and Disability Services Consumers' Rights 1996'. New Zealand legislation and regulations and codes are essential requirements of all programme providers and form the basis of contractual requirements in the provision of the programme.

The standards only apply for the delivery of the BioNTech/Pfizer COVID-19 Vaccine.

Programme Operating Guidelines

This document is designed to help DHBs and providers maintain public safety and ensure consistent and equitable COVID-19 vaccination practices are in place across New Zealand. It provides guidance on establishing and managing a COVID-19 vaccination site.

The operating guideline will be amended as required and re-distributed to DHBs and providers. We expect regular iterations based on learnings from the delivery of the COVID-19 vaccine programme. Please ensure you are always using the correct version of the guidelines.

Programme Planning Guidelines

The Programme Planning Guidelines (or blueprints) are designed to support the initial conversations between DHBs and providers who are or will be operating from an existing healthcare facility. The providers covered within the Planning Guidelines are General Practice, Community Pharmacies, Hauora providers, and Urgent Care Centres.

They are intended to assist in decision making around whether a provider can and is 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 - including the BioNTech/Pfizer COVID-19 Vaccine (the vaccine). These guidelines are based on the best scientific evidence available at the time of publication, from both published and unpublished literature.

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

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 a minimum requirement for the vaccination record 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 target

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 and person and whānau centred COVID-19 immunisation service. The provider requires a clear structure for leadership, management and accountability. This standard ensures that the basic components of this structure are in place.

Essential criteria

	Standard criteria	*Operating Guidance Refer to*
1.1a	There is a designated clinical lead for the COVID-19 vaccination programme for each DHB.	
1.1b	There is a designated equity lead for the COVID-19 vaccination programme for each DHB.	
1.1c	There is a provider leadership team comprising clinical, vaccinator, and managerial lead roles, each with defined responsibilities.	
1.1d	There is a defined service structure with clear lines of reporting and accountability.	
1.1e	The provider has a routine internal audit plan with a named lead and timescales for completion.	Section 5
1.1f	The leadership clinical team have dedicated, non-clinical time in their job plans/roles to lead the vaccination service.	
1.1g	There are defined processes and timescales to review and maintain all policies and standard operating procedures.	Section 5
1.1h	The leadership team has the managerial and administrative support to organise and deliver the service effectively.	
1.1i	The service has appropriate technical support to enable effective service delivery.	
1.1j	The leadership team has access to timely and appropriate information on capacity, demand and waiting times from which to base operational and planning decisions.	Section 8 – Operational reporting
1.1k	The leadership team review and set the service's objectives on a regular basis and develop plans to achieve these objectives.	
1.1l	There are systems in place to ensure that the leadership team seek and receive feedback about their performance.	
1.1m	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 an equitable immunisation outcome for Māori and Pacific people, including priority access.

The provider immunisation service is committed to an equitable immunisation outcome for 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 immunisation service will support vaccination uptake for Māori, Pacific and people with disability to ensure both doses of the vaccinations are received within recommended timeframes.

Essential criteria

	Standard criteria	*Operating Guidance* *Refer to*
1.2a	The provider is delivering a service according to the local DHB policy to prioritise vaccination of Māori, Pacific and people with disability.	
1.2b	The leadership team has agreed to the delivery plan, prioritising Māori, Pacific and people with disability, with equity deliverables and equity performance measures.	
1.2c	The provider routinely monitors its performance and agreed actions to meet equity service standards, service specifications and delivery expectations for Māori, Pacific 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. 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.

Rationale

The quality of the immunisation service will be managed and coordinated within a provider by written protocol and procedure manuals that document quality assurance and clinical procedures.

Essential criteria

	Standard criteria	*Operating Guidance Refer to*
1.3a	Policy and procedure documents are centrally accessible and available to all staff.	
1.3b	All policy and procedure manuals will be reviewed and updated two-yearly, or earlier if required	
1.3c	All relevant staff are notified of all changes to policies and procedures.	
1.3d	Emergency management plan: effective liaison with first responders regarding emergency management at non-traditional sites	

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 1.4: Service lead immunisation plan

The provider prepares an immunisation delivery plan and monitors its performance to ensure all eligible consumers receive both doses of the vaccine within the recommended timeframes.

Rationale

A consumer and whānau-centred immunisation service will ensure all eligible consumers receive both doses of the vaccinations within the recommended timeframes.

Essential criteria

	Standard criteria	*Operating Guidance* *Refer to*
1.4a	The service has a local vaccination delivery plan that meets the eligible population vaccination requirements.	
1.4b	The plan meets the ongoing vaccination requirement of prioritised border workers and new border workers for the duration of the programme	
1.4c	There is a local policy for prioritising vaccination of disabled, hard to reach and vulnerable populations	
1.4d	The service and leadership team has agreed to the delivery plan and routinely assesses performance to the plan deliverables	
1.4e	The service routinely monitors its performance and takes actions when it is not conforming to service requirements and delivery expectations	
1.4f	All local guidelines are 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. 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	*Operating Guidance* *Refer to*
1.5a	The provider has agreed processes to ensure access to timely vaccinations through effective management, booking and scheduling practices.	Section 8
1.5b	Roles and responsibilities (between vaccination sites, and DHB management, and other providers such as Whakarongorau the national call centre) for the management of booking and scheduling to access the service are clearly defined and documented.	
1.5c	The provider has an agreed process in place to ensure persons required to be vaccinated under the COVID-19 Public Health Response (Vaccinations) Order 2021 has priority access to appointments.	
1.5d	There is an agreed 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 an agreed process for monitoring, reviewing and adjusting the capacity of the vaccination clinic to enable the setting of the available schedule in advance.	
1.5f	The service has an agreed plan for identifying and outreaching to consumers who do not have a booking and therefore are at risk of not receiving their vaccine second dose, and any associated issues and risks are appropriately escalated and actioned.	
1.5g	There is an agreed process and communication plan to manage the outbound follow up for rebooking persons 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.	
1.5j	The provider achieves optimum wait time between vaccinations doses.	
1.5k	Where required, the national booking system is used to facilitate efficient appointments booking and efficient scheduling of vaccination site across a district.	
1.5l	When setting and/or adjusting scheduling there is communication and agreement with Whakarongorau and other key partners that will be impacted.	

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 1.6: Delivery and planning

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

Rationale	The purpose of this standard is to ensure that provider resources and capacity are utilised effectively and efficiently.

Essential criteria

	Standard criteria	*Operating Guidance* *Refer to*
1.6a	Agreed performance (planning and delivery) metrics are documented in the service delivery policy.	
1.6b	Providers use the agreed vaccine and consumable ordering and stock management systems	
1.6c	There is a weekly review of bookings, demand, capacity and scheduling of bookings.	
1.6d	There is enough flexibility in the plan to accommodate unplanned cancellation or partial loss of capacity for reasons such as 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 provider leadership group.	
1.6f	There is an agreed communication and delivery pathway for the service to identify and address any logistic, transport and social issues to avoid late cancellations/non-attendance.	
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 an agreed production or delivery plan if shortfalls are identified.	
1.6h	There is a regular planning and delivery performance report for the service with an action plan to support service planning.	
1.6i	The provider submits a four (4) week forward demand plan each week to the Ministry.	
1.6j	The provider must submit new site and facility information to the Ministry five (5) days in advance of any deliveries	
1.6k	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	*Operating Guidance* *Refer to*
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 service.	
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 substantive staff when there is a change or adoption of new practice, when team members leave, during succession planning or at least yearly, which is agreed by the appropriate senior manager responsible for each workforce group.	
1.7e	All staff have undergone Treaty of Waitangi and Tikanga/kawa 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	The ethnicity of the workforce is reflective of the needs of the local population.	
1.7j	All staff have been provided with the opportunity to complete training on how to work with disabled people.	
1.7k	All staff have been provided with the opportunity to complete the Health Information Privacy Code online learning module	
1.7l	CIR users must supply an organisational email address to be granted to the production CIR environment.	
1.7m	All staff administering the vaccine have completed a CPR course that meets the requirements as set out in Appendix 4 of the Immunisation handbook. Note that current authorised vaccinators, provisional vaccinators, pharmacist vaccinators and registered intern pharmacists whose CPR certificate has recently expired are expected to complete an update CPR course as soon as practically possible. An exemption of 12 months from date of expiry will be given,	

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 certified 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 ensure a safe and quality health outcome.		
Essential criteria		*Standard criteria*	*Operating Guidance* *Refer to*
	1.8a	All vaccinators are required to complete the relevant COVID-19 vaccinator training and assessments through IMAC.	
	1.8b	The number of vaccinators on site will be consistent with the service delivery model being used.	
	1.8c	The BioNTech/Pfizer COVID-19 Vaccine is prepared and administered following up to date instructions provided by IMAC.	
	1.8d	All vaccinators are authorised to vaccinate and COVID-19 Vaccinators have an appropriate supervisor onsite.	
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. It ensures that COVID-19 Vaccinators are delivering a safe, equitable, and quality service.

Rationale

Consumers are vaccinated safely and under the correction supervision by COVID-19 Vaccinators, at the right time and in the right place, with the right dose and equipment to ensure a safe and quality health outcome.

Essential criteria

	Standard criteria	*Operating Guidance* *Refer to*
1.9a	All COVID-19 vaccinators have completed the required COVID-19 vaccinator training and assessments through IMAC.	
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 ensure they are meeting 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 care given by COVID-19 vaccinators.	
1.9f	Providers ensure they have sufficient staff to continuously supervise and support COVID-19 Vaccinators who require direct supervision for their induction and practical assessments.	
1.9e	COVID-19 Vaccinators maintain ongoing professional development and align practice with any vaccine 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 service provides a person and whānau-centred vaccination site that is a safe, comfortable, accessible, clean, clinically and culturally appropriate environment.

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, clean, safe, comfortable, culturally appropriate and easily accessible.

Essential criteria

	Standard criteria	*Operating Guidance* Refer to
2.1a	**Reception area** The reception area is of sufficient size to accommodate the expected throughput for the service.	*Australasian Health Facility Guidelines*
2.1b	**Waiting area** The waiting area can accommodate the usual number of consumers and other family/whānau who would be waiting at any time.	
2.1c	**Office area** Enough size to support administrative functions.	
2.1d	**Preparation and holding area** Enough size and facilities to enable consumers to change and toilet prior to undergoing procedures and wait in a suitably discreet location under supervision of staff. Facility must have appropriate space for special need preparation and consent Adequate space for vaccine preparation, out of sight of the consumer.	

	2.1e	**Procedure space fittings and features** Any service procedure room, should it be required, must include: a) Bed space/bed. 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	Procedure rooms are appropriately constructed, fitted out and maintained in accordance with NZS 8134.1.4. *Standards of New Zealand. (2018). Health and Disability Services Standards. NZS 8134.0.2018* *Australasian Health Facility Guidelines (AusHFG)*
	2.1f	Additional equipment required for Immediate resuscitation should it be required: a) Anaphylaxis management kit containing a. Medications (including adrenaline), b. A laminated card outlining the management of anaphylaxis, and c. Syringes and needles. b) Adult and paediatric bag valve mask resuscitator (AmbuBag). c) First Aid kit d) Monitoring equipment: a. Blood pressure cuff, b. Pulse oximeter, c. Observation charts, and d. Stethoscope.	Refer to: Immunisation Handbook IMAC anaphylaxis management card or poster
	2.1g	Suitable and sufficient ventilation and filtration for closed sites.	
	2.1i	**Clinical support areas** Dedicated and separate storage should be provided for a range of stock, consumables and equipment, including adequate supplies of needles, cotton balls, skin preparation, plasters, gloves.	*Australasian Health Facility Guidelines (AusHFG) (2016).*
	2.1j	**Consulting / Interview room** Consulting rooms are located appropriately close to the recovery room, are constructed to ensure consumer privacy	

	and confidentiality of discussions and contain enough furniture and fittings for whānau consultation.	
2.1k	**Staff workstation** There should be a clinical staff workstation	
2.1l	Accessible staff room	
2.1m	Staff toilet & changing rooms	
2.1n	**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 8134.1.4. *Standards of New Zealand. (2018).*
2.1o	**Waste disposal area** Must contain sharps bin and adequate clinical and non-clinical waste disposal	Refer to: IMAC Operating Guidelines Sections 5 and 8
2.1p	Vaccine vials are disposed using the required disposal process	
2.1q	Vaccine packaging must be destroyed so packages cannot be replicated	
2.1r	The observation area is: Appropriate to the planned throughput of consumers and in accordance with NZS 8134.1.4 The observation area has separated 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 is freely accessible to an emergency trolley.	Refer to: Appointed with appropriate equipment and emergency systems per bed space.
2.1s	There are systems in place to ensure that access to the following areas are 'Restricted Access Only': • vaccination storage area	
2.1t	The site or centre be of an appropriate size to allow safe flow of consumers and staff through the facility in the case of an emergency	*Australasian Health Facility Guidelines (AusHFG)*
2.1u	**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 at site egress points.	
2.1v	Each site or centre must have a Health and Safety Plan to ensure the health and safety of staff, consumers and other people.	
2.1w	Work health and safety risks relating to the vaccination site are identified and managed, including site evacuation in emergency.	
2.1x	Site checklists must be signed off by the Chief Executive or their delegate to confirm site readiness.	

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 3.0 Equipment

Standard 3.1: Essential hardware

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

Rationale

Safe, quality vaccination requires appropriate, modern equipment to ensure safe optimal clinical outcomes.

Essential criteria

	Standard criteria	Operating Guidance Refer to
3.1a	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.	
3.1b	Access to oxygen is considered for settings where emergency response could be delayed (e.g. non-traditional vaccination settings and those in rural/remote locations)	
3.1c	Access to an Automatic Electronic Defibrillator (AED) is considered for settings where emergency response could be delayed (e.g. non-traditional vaccination settings and those in rural/remote locations)	
3.1d	Resuscitation equipment: refer to 2.1f	

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 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 QA activities and has undergone compliance testing, meeting the manufacturer's specifications for use, will ensure safe quality vaccination service.

Essential criteria

	Standard criteria	*Operating Guidance Refer to*
3.2a	Guidelines and standard operating procedures for vaccination waste is easily accessible at the site	
3.2b	Testing and validation of equipment is carried out according to standard requirements and guidance; action is taken if necessary, when results which 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 those with particular needs including pregnant women, elderly and those significantly under or over weight.	
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 (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 vaccine

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

Rationale	Vaccine is stored as per manufacturer's guidelines, jurisdictional 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 *Section 2.1 of the Immunisation Handbook (https://www.health.govt.nz/publication/immunisation-handbook-2020)* and the manufacturer's specific guidelines (http://www.medsafe.govt.nz/profs/datasheet/c/comirnatyinj.pdf)
	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 algins 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 *(http://www.medsafe.govt.nz/profs/datasheet/c/comirnatyinj.pdf)* and the *Ministry of Health Operating Guidelines for DHBs and Providers, COVID-19 Vaccine Immunisation Programme*
	4.1d	The site or centre has two (2) authorised leads for cold chain management for each operating day of the service.	Providers must ensure, in accordance with the *National Standards for Vaccine Storage and Transportation for Immunisation Providers 2017,* that a minimum of two (2) authorised vaccinators lead the cold chain management.
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 4.2 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 staff using agreed guidelines and protocols.

Essential criteria

	Standard criteria	*Guidance*
4.2a	The facility has a policy and standard operating procedures on the administration of the vaccine.	Refer to local DHB / provider policy on vaccine administration policies and guidelines. Policies should align with the manufacturer's specific guidelines (*https://www.medsafe.govt.nz/profs/Datasheet/c/comirnatyinj.pdf*) Refer to the Immunisation Handbook
4.2b	All staff administering the COVID-19 vaccine are approved COVID-19 vaccinators. Staff administering the vaccine must also have successfully completed the required training.	Staff can obtain authority to administer via: The Immunisation Advisory Centre Provisional Vaccinator Course or have authority to vaccinate, 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 administering the vaccine adhere to infection, prevention and control guidelines during the preparation and administration of the vaccine.	Refer to local DHB/provider policy on infection, prevention and control. Also refer to IMAC for guidelines on the safe preparation and administration.
4.2d	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 *Section 2.3 of the Immunisation Handbook (https://www.health.govt.nz/publication/immunisation-handbook-2020)*

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 wastage prevention, reporting and monitoring

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

Rationale

Local measures are in place to prevent wastage of the vaccine. All vaccine wastage is accurately documented on the day it occurs.

Essential criteria

	Standard criteria	*Guidance*
4.3a	All vaccine waste is documented with the reason for waste identified.	Providers to ensure all waste of any COVID-19 vaccine is documented stating the reason for the waste. Monitoring and investigation of waste should be undertaken daily to mitigate future waste.
4.3b	Procedures are followed to minimise waste of the vaccine.	Providers must ensure guidance is available and followed on how to minimise waste of the vaccine. Providers should have adequate planning in place to ensure vaccine waste is minimised due to thawed, unused vaccines or vaccines not administered prior to expiry date.

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 (CQI).

Rationale

A high-quality immunisation service requires a documented, continuous quality improvement programme outlined in a provider Quality Plan.

Essential criteria

	Standard criteria	*Operating Guidance Refer to*
5.1a	The provider has dedicated resources and time to assure the safety and quality of their service.	
5.1b	The provider has a routine internal audit programme incorporating all relevant minimum requirements.	
5.1c	Responsibility for clinical safety and quality is assigned to clinical leads	
5.1d	The provider routinely assesses clinical quality and safety risks and issues.	

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 5.2: Consumer quality improvement processes

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

Rationale

Person and whānau-centred continuous quality improvement requires appropriate processes to identify and address all provider incident and adverse events.

Essential criteria

	Standard criteria	*Operating Guidance Refer to*
5.2a	Systems are in place for monitoring site or centre incidents and adverse events.	
5.2b	There is routine use of a start-of-day and end-of-day safety checklist.	
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 adverse events regularly.	
5.2e	There are local policies, protocols or standard operating procedures for the management of all types of incidents or adverse event	
5.2f	Actions required in response to learning from all types of incidents or adverse events are implemented 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 privacy, dignity and security of all consumers are respected throughout their immunisation journey.

Rationale All consumers and whānau have a right to be treated with respect and dignity.

Essential criteria

	Standard criteria	*Operating Guidance Refer to*
5.3a	The provider has a respect, dignity and security policy, which includes the care and culture considerations of all people accessing the service.	
5.3b	There are standard operating procedures for safeguarding 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.	Section 5
5.3f	Consumer experience of privacy 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 security	Section 5

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 for each procedure.

Rationale

Consumers are given sufficient information to be able to make informed choices about their care.

Essential criteria

	Standard criteria	*Operating Guidance Refer to*
5.4a	Consumer information is readily available on the vaccination process steps and about the vaccine to enable informed consent.	Section 8
5.4b	The informed consent process may be verbal or written.	Section 8
5.4c	Informed consent process is completed by the consumer or their authorised guardian before the consumer enters the vaccination space.	Section 8
5.4d	Informed consent must be documented in the CIR	
5.4e	There is a standard operating procedure for informed consent which includes withdrawal of consent.	
5.4f	All consumers are given time to ask questions about the vaccination before consent is agreed and before entering the vaccination space	Section 8
5.4g	There is a standard operating procedure for obtaining informed consent for those who are unable to consent on their own behalf.	Immunisation Handbook Chapter 2
5.4h	There is a standard operating procedure for obtaining written informed consent for those who are in Group 1	
5.4j	Written consent is obtained by consumers in Group 1.	Section 8
5.4k	Any consumer related issue related to the informed consent process is reported as an adverse event.	

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	*Operating Guidance Refer to*
5.5a	All vaccination records are completed on the day of the procedure and includes follow-up details and adverse event reports.	
5.5b	The provider has a local 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*	*Operating Guidance Refer to*
	5.6a	Provider safety and quality indicators and auditable outcomes are available for performance monitoring and CQI activity	
	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 is a complication.

Rationale	Consumers require information after their vaccination to ensure safety and early detection of complications.		
Essential criteria		*Standard criteria*	*Operating Guidance Refer to*
	5.7a	Consumers are informed of the phone number for the Whakarongorau to contact if they experience problems following their vaccination.	Section 8
	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).	Section 8
	5.7c	All consumers are provided with verbal and written information about their care including any follow up arrangements or appointments.	Section 8
Evaluation process	Consumer surveys inform 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	*Operational Guidance* Refer to
5.8a	The provider complaints procedure is documented and is clearly available for consumers, relatives, whānau and carers to access.	
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 of consumer feedback and change made in response is available for public view.	
5.8e	Consumer participation is evident in planning and evaluating the service	

Evaluation process

Internal and external audit processes are used to ensure that the criteria are complied with and 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	An untoward medical event which follows immunisation and does not necessarily have a causal relationship with the administration of the vaccine. The adverse event may be an unfavourable or unintended sign, abnormal laboratory finding, symptom or disease
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.
Authorised guardian	An adult 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.
Consumer	A health consumer includes any person on or 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 professionals (typically an authorised or provisional vaccinator).
Credentialing	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 (CQI) refers to the iterative process of *plan, do, check, act* to ensure processes are 'fit for purpose' and identifies improvement when an error or non-conformance to a standard occurs 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 & quality role.
Eligible consumer	A person who is eligible to receive the vaccine in New Zealand
Equity	In Aotearoa New Zealand, 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 get equitable health outcomes.
Essential Criteria	The essential criteria are components of service provision that are required to be in place in order to achieve the indicator.
Evaluation Target	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	Is defined as border and managed isolation and quarantine (MIQ) workers and the people they live with.
Person and whānau-centred	Providing care and support that is respectful of and responsive to individual consumer preferences, needs and values, and ensuring that consumer guides all clinical and support decisions.
Policy	A document that states, in writing, a course or principles of required action adopted by a provider.
Provider Leadership team	
Quality Indicator	A quality indicator is a measurable element of service provision. Quality indicators relate to the desired outcome or performance of services.
Serious adverse event or reaction	An 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 types of employed staff members who have the required skills and competencies to carry out the work of the vaccination service and safely deliver the vaccination 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 outlines 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.
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 person with at least one support person in attendance.
Whakarongorau	The New Zealand Telehealth service providing the national Healthline support to the COVID-19 vaccination programme

Abbreviations

ADR	Adverse drug reaction
AEFI	Adverse event following immunisation
CIR	COVID-19 Immunisation Register
CQI	Continuous Quality Improvement
DOPS	Direct Observation Procedural Skills
DNA	Did not attend
KPI	Key Performance Indicators

NZNO	New Zealand Nurses Organisation
SRO	Senior Responsible Officer for the COVID-19 vaccine programme within a DHB
The Ministry	Ministry of Health

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