

Appendix 3:

Immunisation standards for vaccinators and guidelines for organisations offering immunisation services

A3.1 Purpose

The 'Immunisation standards for vaccinators' (see section A3.3) are quality levels all vaccinators should achieve to ensure they can competently deliver safe and effective immunisation services.

The 'Immunisation standards for vaccinators' and the 'Guidelines for organisations storing vaccines and/or offering immunisation services' (see section A3.4) apply to all vaccinators, including those delivering National Immunisation Schedule vaccines, vaccines on an authorised programme or privately purchased vaccines including travel vaccines.

The Schedule aims to protect children and adults against 16 serious vaccine-preventable diseases and offers publicly funded immunisation to individuals at risk of COVID-19, hepatitis A, influenza, varicella, TB, meningococcal and/or pneumococcal disease.

Note: The term 'vaccinator' used throughout these standards applies to *any* health professional offering a vaccinator service, including registered nurse vaccinators, authorised vaccinators, pharmacist vaccinators, GPs and midwives. For the purposes of this appendix the term pharmacist vaccinator refers to both registered pharmacist and registered intern pharmacist who have met the educational and clinical requirements: although the scope of vaccines they can administer is different, the process they undergo to gain vaccinator status is the same. These standards apply to fully authorised, pharmacist and provisional vaccinators. For COVID-19 vaccinators (working under supervision), see section A4.3.

A3.2 Health and Disability Commissioner (Code of Health and Disability Services Consumers' Rights) Regulations 1996

It is expected that all organisations and providers offering immunisation services practise in accordance with the Health and Disability Commissioner (Code of Health and Disability Services Consumers' Rights) Regulations 1996. The Regulations establish the rights of consumers and the obligations and duties of providers to comply with the Code of Rights made pursuant to the Health and Disability Commissioner Act 1994.

The obligation under the Regulations is to take 'reasonable actions in the circumstances to give effect to the rights and comply with the duties' in the Code of Rights. The Code of Rights is as follows.

- Right 1: Right to be treated with respect
- Right 2: Right to freedom from discrimination, coercion, harassment and exploitation
- Right 3: Right to dignity and independence
- Right 4: Right to services of an appropriate standard
- Right 5: Right to effective communication
- Right 6: Right to be fully informed
- Right 7: Right to make an informed choice and give informed consent
- Right 8: Right to support
- Right 9: Rights in respect of teaching or research
- Right 10: Right to complain

For more detailed information on the Code of Health and Disability Services Consumers' Rights, refer to the Health and Disability Commissioner's website (hdc.org.nz).

A3.3 Immunisation standards for vaccinators

These standards apply to fully authorised, pharmacist and provisional vaccinators. For COVID-19 vaccinators (working under supervision), see section A4.3.

Standard 1: The vaccinator is competent in all aspects of the immunisation technique and has the appropriate knowledge and skills for the task

Required characteristics of the vaccinator

- 1.1 The vaccinator completes an appropriate training programme approved by the Ministry of Health. If a vaccinator is working as a fully authorised vaccinator, pharmacist or provisional vaccinator, they will also have undertaken a clinical assessment and vaccinate in accordance with their Scope of Practice (see A3.6).

- 1.2 Vaccinators are required to have a summary¹ of their immunisation practice over the past 12 months.
- 1.3 The vaccinator remains current with developments in immunisation theory, practice, cultural competency, and policy. At least every two years the vaccinator is required to retrain having completed a vaccinator update course that meets the current *Vaccinator Update Course Standards* (published by IMAC) and have evidence of completion. See authorisation requirements outlined in A3.6.
- 1.4 The vaccinator maintains linkages with other providers associated with immunisation delivery; for example, immunisation coordinators, outreach immunisation providers, Māori and Pacific health providers, and their local DHB NIR team.
- 1.5 Vaccinators are recommended to carry indemnity insurance for their personal/professional protection.

Standard 2: The vaccinator obtains informed consent to immunise

Required characteristics of the vaccinator

- 2.1 The vaccinator is able to assess the knowledge of the individual/ parent/guardian regarding vaccine-preventable diseases and the process of immunity, and has the knowledge of the relevant diseases and vaccines to be able to provide evidence-based information to enable individuals/parent/guardian to make an informed choice and give informed consent.
- 2.2 The vaccinator communicates in a form, language and culturally appropriate way that enables the individual/parent/guardian to understand the information provided. Communication should be supported by evidence-based health information material (see section 2.1.2).
- 2.3 The vaccinator allows time to answer questions and obtains feedback indicating that the individual/parent/guardian understands which vaccine is being recommended and why.
- 2.4 The vaccinator informs the individual/parent/guardian about the NIR/AIR, including information on the use and disclosure of the information held on the NIR/AIR, how the information is stored, and that all vaccinations given will be recorded on the NIR or AIR (if applicable) unless the individual/parent/guardian chooses to opt off the NIR. If an individual/parent/guardian chooses to opt off the NIR, this process must be explained to them.
- 2.5 Consent does not need to be given in writing (except for school-based immunisation programmes and BCG vaccination), but the vaccinator must document in the clinical notes a summary of the discussion and note that verbal consent was obtained.
- 2.6 The vaccinator obtains consent for each immunisation episode and documents that the individual/parent/guardian has been made aware of the benefits and risks of the disease and the vaccine in order to make an informed choice about

¹ The summary should include type of immunisation practice as a vaccinator (eg, general practice, occupational health, pharmacy, etc); types of vaccinations given (eg, intramuscular, subcutaneous, intradermal); and other responsibilities related to immunisation (eg, cold chain-designated person, etc).

immunisation and the immunisation programme, including the NIR (see section 2.3.5).

- 2.7 If the individual/parent/guardian declines to be immunised/to immunise their child, the vaccinator provides information about keeping themselves and others healthy. The individual/parent/guardian should be advised that they can reconsider their decision at any time, and the declined immunisation will be offered again by their health provider.

Standard 3: The vaccinator provides safe immunisation

Required characteristics of the vaccinator and immunisation setting

- 3.1 The venue provides privacy and is appropriate for the individual/parent/guardian/whānau. Facilities are available for assessment and management of adverse events, including anaphylaxis (see section 2.3.3).
- 3.2 If the venue is a non-clinical setting (eg, in a home, workplace, marae or school) then a minimum of two immunisation team members must be present for vaccination; one of whom must be an authorised vaccinator or pharmacist vaccinator, the other must be a competent adult who is able to call for emergency support and has a current basic life support certificate.
- 3.3 The vaccinator can manage AEFIs, including anaphylaxis, ensures that they have onsite access to the minimum set of emergency equipment (see Table 2.12 in chapter 2), and has a contingency plan for seeking emergency assistance.
- 3.4 Because of the potential for anaphylactic reactions, vaccine recipient (with their parents/guardians if applicable) are required to remain under observation for a minimum of 20 minutes after immunisation.
- 3.5 The vaccinator ensures continuity of the cold chain and adheres to the *National Standards for Vaccine Storage and Transportation for Immunisation Providers 2017 (2nd edition)* and the practice/clinic cold chain management policy. The vaccinator ensures the practice/clinic achieves Cold Chain Accreditation.¹
- 3.6 Before vaccinating, the vaccinator undertakes an appropriate clinical assessment (pre-vaccination screen) (see section 2.1.3).
- 3.7 The vaccinator uses clean techniques in the preparation and administration of all vaccines (see section 2.1 and Appendix 7), visually checks the vaccine, checks expiry date, prepares vaccine as appropriate and uses vaccines within the recommended period after preparation.
- 3.8 The vaccinator provides verbal and written information that is evidence based and follows best practice principles about care after immunisation (see sections 2.1.2 and 2.3.1).

¹ Refer to the National Immunisation Programme cold chain management (available at www.health.govt.nz/our-work/preventative-health-wellness/immunisation/national-immunisation-programme-cold-chain-management).

Standard 4: The vaccinator documents information on the vaccine(s) administered, and maintains patient confidentiality

Required characteristics of the vaccinator

- 4.1 The vaccinator has had training in the correct use of their PMS, the SBVS, the NIR or AIR manual forms to enable them to correctly enter an individual's information on the NIR or AIR (if applicable) and to claim an immunisation benefit (if applicable).
- 4.2 The vaccinator documents the individual's personal details, including NHI number, name, date of birth, ethnicity, address, contact telephone number, next of kin details and primary health care provider (if the vaccinator is not the usual primary health care provider).
- 4.3 Having chosen the appropriate immunisation schedule, the vaccinator documents the following details:
 - consent obtained
 - date vaccine administered
 - vaccine type and number in the series
 - batch number and expiry date
 - injection site (eg, 'right deltoid' not 'upper arm')
 - needle length
 - that the patient was observed for 20 minutes post-vaccination
 - if the vaccine was given by a non-standard route (the reasons must be documented)
 - the immunisation event in the child's *Well Child Tamariki Ora My Health Book* (if applicable)
 - the date for the next immunisation in the child's *Well Child Tamariki Ora My Health Book* (if applicable)
 - advice and resources given.
- 4.4 The vaccinator ensures the immunisation information is sent to the NIR (ie, electronically or manually) where applicable, unless the individual/parent/guardian has opted off the collection of their/their child's immunisation information on the NIR.
- 4.5 The vaccinator ensures the immunisation certificate (see Appendix 5) is accurately completed following the 15-month and 4-year immunisation events.
- 4.6 If the practice/clinic is not the usual primary health care provider, then the individual's primary health care provider is informed by the vaccinator or by NIR notification within five working days of giving the vaccine, unless the individual declines for this to occur.
- 4.7 All clinical documentation is appropriately managed and stored to maintain confidentiality, and is made available to the individual/parent/guardian on request.

Standard 5: The vaccinator administers all vaccine doses for which the vaccine recipient is due at each visit and only follows true contraindications

Required characteristics of the vaccinator

- 5.1 The vaccinator adheres to the National Immunisation Schedule or approved immunisation programme and delivers all the immunisations recommended for that visit, unless the individual/parent/guardian does not consent to this.
- 5.2 When catch-up immunisation is required, this is planned with the minimum number of visits/injections and in conjunction with the individual/parent/guardian.
- 5.3 A dose of vaccine is deferred or avoided only when contraindicated or the individual/parent/guardian has chosen to defer/avoid it. The reason for deferral or avoidance must be documented (see section 2.1.4 and the specific disease chapters).

Standard 6: The vaccinator reports AEFIs promptly, accurately and completely

Required characteristics of the vaccinator

- 6.1 All serious or unexpected AEFIs are reported by the vaccinator to the Medical Assessor, CARM (see section 1.6.3 for the adverse event reporting process) and to the individual's primary health care provider (if the vaccinator is another person). If the individual/parent/guardian does not consent to being identified, the report should be made without personal identification.
- 6.2 The vaccinator informs the individual/parent/guardian that if an adverse event occurs, they can also report it to CARM.
- 6.3 When a CARM report is received, and further doses of the vaccine have been contraindicated, the vaccinator advises the local DHB NIR Administrator so that an appropriate AEFI code is recorded in the individual's NIR record.
- 6.4 The vaccinator seeks specialist (eg, GP, paediatrician, infectious diseases physician or medical officer of health) opinion if uncertain about the safety of further doses, and referral is made to secondary care if required.
- 6.5 The vaccinator ensures the adverse event, and any subsequent decisions relating to the event, are effectively communicated to the individual/parent/guardian and clearly documented in the child's *Well Child Tamariki Ora My Health Book* (if applicable) and in the patient records, and appropriate follow-up is carried out.

A3.4 Guidelines for organisations storing vaccines and/or offering immunisation services

These guidelines apply to all organisations that store vaccines and/or offer immunisation services, including (but not limited to) general practices, public health units, community pharmacies, travel clinics, occupational health clinics, emergency medical services, research units and hospital wards/clinics/departments/pharmacies.

The organisation that employs vaccinators to offer immunisation services has links to primary health care and to Well Child Tamariki Ora providers

Required characteristics

Immunisation is not delivered in isolation, but as an integrated part of primary health care services, including Well Child Tamariki Ora for children.

If possible, at the time of immunisation, the organisation undertakes other health promotion and/or disease prevention activities as applicable, such as the Well Child National Schedule or Care Plus.

Immunisation events, childhood and adult, are well communicated to other health services linked to the individual (eg, primary health care, outreach immunisation services, pharmacies, occupational health).

The organisation achieves high immunisation coverage of its population

Required characteristics

The organisation has an effective, secure, NHI-based system for recording and reporting immunisations and identifying individuals requiring immunisation.

Respecting the individual's/parent's/guardian's rights to make an informed choice, the organisation takes all steps to ensure that an individual's immunisation schedule commences on time and that subsequent events are administered on the due date.

The organisation has electronic linkage to the NIR or AIR for registration and immunisation event notification, and the NIR or AIR is used to assist with follow-up. If electronic linking is not available, manual processes must be used.

The organisation has a robust reminder (pre-call) system which encourages the delivery of on-time immunisation and timely follow-up for overdue immunisation.

The organisation has an effective communication strategy to target high-needs population groups.

Attendance at the practice/organisation is used as an opportunity to remind individuals/parents/guardians of the importance of immunisation and, if appropriate, to check and offer to bring up to date the individual's immunisation status.

Those who do not respond to recall and who have not declined to take part are referred to the outreach immunisation service, as per local protocol.

The organisation supports vaccinators and NIR administrators

Required characteristics

The organisation has comprehensive immunisation-related policies based on best practice, informed consent, the vaccination process and management of adverse events.

The organisation uses a pharmaceutical refrigerator to store vaccines, has a vaccine cold chain policy in place and meets the requirements outlined in the *National Standard for Vaccine Storage and Transportation for Immunisation Providers 2017 (2nd edition)*¹ for all areas within the organisation storing vaccines.

The organisation provides training and support workers (eg, kaiāwhina, community health workers) for vaccinators working in the community.

The organisation supports the need for vaccinators to have access to ongoing education and training on all aspects of immunisation at least every two years and when there are changes to the Schedule.

The organisation provides initial and ongoing training and support specific to the NIR, PMS, and/or the SBVS (if applicable).

The service is readily available, with no barriers to access

Required characteristics

No fee is charged to the individual/guardian for the immunisations that are on the Schedule or high-risk programmes (or for completing the child's immunisation certificate). Regardless of their immigration and citizenship status, all children aged under 18 years are eligible to receive funded Schedule vaccines, and providers may claim the immunisation benefit for these children. Non-residents who were under age 18 years when they commenced HPV vaccination in New Zealand are currently funded to complete the course, even if they are aged 18 years or older when they complete it. Further information on eligibility can be found on the Ministry of Health website (www.health.govt.nz/eligibility).

Immunisations are provided to both enrolled and casual patients, at all times when the organisation or service is open.

¹ Refer to the National Immunisation Programme cold chain management (available at www.health.govt.nz/our-work/preventative-health-wellness/immunisation/national-immunisation-programme-cold-chain-management).

A person's immunisation status is checked at each visit to the service.

The organisation is culturally appropriate (ie, all health workers are assessed as culturally competent, reflect the populations they serve and offer a range of health information resources¹ in different languages).

A3.5 Recommended resources

Ministry of Health (health.govt.nz/our-work/preventative-health-wellness/immunisation)

- The current Immunisation Handbook
- National Immunisation Register Privacy Policy
- The current National Standards for Vaccine Storage and Transportation for Immunisation Providers 2017 2nd Edition (available at www.health.govt.nz/publication/national-standards-vaccine-storage-and-transportation-immunisation-providers-2017)
- Cold Chain Management Policy Template
- Cold Chain Accreditation Provider Self-Assessment Form
- Cold Chain Accreditation Provider Reviewer Form
- Kōrero Mārama: Health Literacy and Māori – Results from the 2006 Adult Literacy and Life Skills Survey, February 2010 (www.health.govt.nz/system/files/documents/publications/korero-marama.pdf)
- Whakamaua: Māori Health Action Plan 2020–2025, July 2020 (www.health.govt.nz/publication/whakamaua-maori-health-action-plan-2020-2025)

A3.6 Relevant legislation and regulations

See www.legislation.govt.nz.

- Health (Immunisation) Regulations 1995
- Medicines Act 1981
- Medicines Regulations 1984
- Health (Infectious and Notifiable Diseases) Regulations 1966, Amendment No. 2, regulation 44A
- Health Act 1956, section 22F
- Health Information Privacy Code 1994

¹ Ministry of Health immunisation resources are available in English and a variety of languages from the HealthEd website (healthed.govt.nz) or from the local health education authorised provider.

- Health and Disability Commissioner Act 1994: Code of Health and Disability Services Consumers' Rights 1996 (see hdc.org.nz)
- Health Practitioners Competence Assurance Act 2003
- Privacy Act 1993
- Care of Children Act 2004
- Accident Compensation Act 2001
- Health and Safety at Work Act 2015
- Resource Management Act 1991
- Primary Maternity Services Notice 2007 (see www.health.govt.nz) pursuant to section 88 of the New Zealand Public Health and Disability Act 2000

Immunisation Advisory Centre (immune.org.nz)

- Vaccinator Foundation Course Standards
- Vaccinator Update Course Standards