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1. Executive Summary

A multidisciplinary committee was established in 2012 by the Health Service Executive (HSE) to develop guidelines for best practice for immunisations carried out in general practice on behalf of the HSE.

These guidelines have been updated to include the [National Immunisation Advisory Committee](#) (NIAC) latest catch-up advice for MenB vaccine (March 2020) immunisation schedule, principles of catch-up vaccination, Live Attenuated Influenza Vaccine (LAIV) programme for children, intramuscular injection technique. The maintenance of cold chain and vaccine ordering section has been updated in accordance with the latest HSE guideline.

The vaccinations administered in general practice on behalf of the HSE are part of a national strategy to protect children and adults from vaccine preventable diseases through vaccination and include:

- [Primary Childhood Immunisation Programme](#)
- [Schools Immunisation Programme](#)
- [Seasonal influenza](#) and pneumococcal polysaccharide vaccination campaigns
- Pertussis vaccination in pregnancy
- [Persons coming to Ireland from other countries](#)
- Vaccination of late entrants/defaulters from vaccination programmes
- Vaccinations carried out for public health and occupational health purposes

To provide childhood vaccinations a General Practitioner (GP) must hold a current contract under the Primary Childhood Immunisation Programme.

Staff should ensure that they have training in Basic Life Support (BLS) and the management of anaphylaxis, and that retraining is provided in accordance with best practice. They should be familiar with the following documents/ learning resources:

- [Immunisation Guidelines for Ireland](#)
- Summary of Product Characteristics (SmPC) for each of the vaccines available at www.hpra.ie or www.medicines.ie
- [Managing Anaphylaxis](#) – Refresher Programme available at www.hseland.ie
- HSE Immunisation Foundation Programme is available at www.hseland.ie
- Primary Childhood Immunisation Programme (for Nurses only)
- Vaccinations and pregnancy
- Influenza vaccination
- Talking About Immunisation
- Medication Management (for Nurses only)
- Live Attenuated Influenza Vaccine Programme
- Storing and Managing Vaccines

Immunisation should be promoted at every opportunity with the provision of appropriate information regarding the vaccines to be administered including the benefits of vaccinating and risk of not vaccinating.

Standard procedures should be followed for all immunisations. This includes having:

- for nursing staff, a medicine protocol for the administration of vaccines. In the absence of a medicine protocol an individual prescription for vaccination should exist
- availability of appropriate drugs and equipment for [Anaphylaxis: Management by First Medical Responders \(in GP surgery or hospital\)](#)
- vaccine administration at the correct time, and in the correct site, interval and dose
- timely ordering, storage and recorded maintenance of the cold chain for all vaccines.

The only contraindication to all vaccines is a confirmed anaphylactic reaction to the vaccine or excipient, or a constituent of the syringe, syringe cap or vial (e.g., Latex anaphylaxis). Specific vaccines may have other contraindications.

For example, live vaccines (e.g., MMR and varicella) are contraindicated in pregnancy, for patients who are immunosuppressed or those on high dose steroids or immunomodulatory therapy. Rotavirus oral vaccine is contraindicated in infants who are 8 months and 0 days or older; have a history of intussusception, have an uncorrected gastrointestinal tract malformation, have a diagnosis of Severe Combined Immunodeficiency Disorder (SCID) or have a fructose intolerance, sucrose-isomaltase deficiency or glucose-galactose malabsorption. Rotavirus oral vaccine is also contraindicated if the infant's mother was administered Infliximab during pregnancy

Please refer to the [Immunisation Guidelines](#) for Ireland for further details.

When there are queries about giving a vaccine, the Assistant Director of Public Health Nursing with responsibility for immunisation or a Consultant in Public Health Medicine in the [local Department of Public Health](#) should be contacted for guidance. For further advice, vaccinators can send the immunisation related queries to the HSE National Immunisation Office (NIO) via email at immunisation@hse.ie.

1.1 Purpose

The purpose of this document is to provide guidance for best practice for vaccinations carried out in general practice on behalf of the HSE.

These guidelines were first developed by a multidisciplinary committee in 2013 with the aim to inform relevant staff in general practice and the HSE about procedures to be followed for vaccinations carried out in general practice.

The guidelines should be read in conjunction with the guidance issued by the NIAC of the Royal College of Physicians of Ireland (RCPI) and contained in the [Immunisation Guidelines for Ireland](#).

1.2 Scope

These clinical and administrative guidelines apply to HSE staff supporting vaccine administration in general practice as well as all staff involved with the administration of vaccinations in GP surgeries contracted to provide services under the Primary Childhood Immunisation Programme (PCIP).

GPs providing vaccinations on behalf of the HSE must hold a current contract under the (PCIP).

Clinical staff should maintain up to date certification in Basic Life Support (BLS) and [Anaphylaxis: Management by First Medical Responders \(in GP surgery or hospital\)](#). There is an online learning module for the management of anaphylaxis available at www.hseland.ie.

They should be familiar with the following documents:

- [Immunisation Guidelines for Ireland](#)
- Immunisation-related courses on HSeLanD www.hseland.ie
- SmPCs for each of the vaccines available at www.hpra.ie or www.medicines.ie
- Managing Anaphylaxis – Refresher Programme available at www.hseland.ie

1.3 Objective

The vaccinations administered in general practice on behalf of the HSE are part of a national strategy to protect children and adults from infectious diseases through vaccination and include:

- Primary Childhood Immunisation programme
- Seasonal influenza programme
- Pneumococcal Polysaccharide Vaccination programme
- Pertussis vaccination in pregnancy programme
- Vaccination of late entrants/defaulters from vaccination
- Vaccination of persons coming to Ireland from other countries
- Vaccinations carried out for public health and occupational health purposes (e.g., COVID-19 vaccination)

1.4 Outcomes

- To ensure the safe & effective delivery of vaccination in GP practices and optimise vaccine uptake
- To reduce and prevent the occurrence of vaccine preventable diseases
- To ensure best practice in the delivery of vaccination in accordance with [the guidelines of the NIAC](#).

1.5 Supporting Evidence

- [The Vaccine regulations, 1942](#).
- [National Immunisation Advisory Committee Immunisation Guidelines for Ireland](#). Dublin: Royal College of Physicians of Ireland, NIAC
- NIAC guidelines on Anaphylaxis (2022): [Immediate Management in the Community](#)
- [Nursing and Midwifery Board of Ireland \(2021\) Code of Professional Conduct and Ethics for Registered Nurses and Registered Midwives](#). Dublin: Nursing and Midwifery Board of Ireland
- [Nursing and Midwifery Board of Ireland \(2020\) Guidance for Registered Nurses and Registered Midwives on Medication Administration](#). Dublin: Nursing and Midwifery Board of Ireland
- [Nursing and Midwifery Board of Ireland \(2022\) Practice Standards for Midwives](#) Dublin: Nursing and Midwifery Board of Ireland
- [Nursing and Midwifery Board of Ireland \(2015\) Scope of Nursing and Midwifery Practice Framework](#). Dublin: Nursing and Midwifery Board of Ireland
- [Nursing and Midwifery Board of Ireland \(2015\) Recording Clinical Practice. Guidance to Nurses and Midwives](#). Dublin: Nursing and Midwifery Board of Ireland
- [NIO Guidelines for maintenance of cold-chain in vaccine fridges and management of vaccine stock](#).

1.6 Communication and Dissemination

The following methods will be used for communication and dissemination across General Practices:

1. An online version made available on www.immunisation.ie.
2. Hard copies sent to all general practices that receive HSE vaccine deliveries.
3. NIO emails, bulletins and social media accounts.
4. Irish College of General Practitioners Website/ Ezine/ Forum Magazine.

2. Immunisation Schedules

2.1 Introduction

NIAC is an independent committee of the RCPI comprising of experts in infectious diseases, paediatrics, public health, microbiology, occupational health, general practice and nursing.

NIAC recommendations are based on the epidemiology of the relevant vaccine preventable disease in Ireland, as determined by the [Health Protection Surveillance Centre \(HPSC\)](#), and international best practice in relation to immunisation. NIAC makes recommendations to the Department of Health (DoH) on immunisation policy in Ireland and, if endorsed by the DoH, the HSE is responsible for the implementation of such policy.

[NIAC guidance](#) is regularly updated and it is essential that all staff involved in vaccination check the updated chapters.

All staff should promote and support the recommended child and adult immunisation schedules for Ireland.

2.2 Primary Childhood Immunisation Programme

The PCIP comprises vaccinations routinely delivered in general practice in the first two years of life. See [Appendix A](#).

The birth cohort in Ireland is approximately 60,000 births per year. The World Health Organization (WHO) has set a target uptake of 95% for primary immunisations to prevent outbreaks of vaccine preventable diseases. The quarterly statistics on vaccine uptake rates for Ireland are produced by the Health Protection Surveillance Centre (HPSC). [The latest HPSC statistics are available here.](#)

2.3 Supporting Information for Staff: School Immunisation Programme

The school immunisation programme comprises vaccinations administered in primary and secondary school. The current school immunisation programme is outlined in [Appendix A](#).

School going children receive vaccinations as outlined in “Supporting Information for Staff – Schools Vaccination Programme” available at [Supporting Information for Staff - Schools Immunisation Programme 2022/2023 academic year](#)

These vaccinations are administered by HSE staff (Medical Officers and Nurses) except in Donegal and Sligo/Leitrim where the primary school vaccinations are administered in general practice.

2.4 Seasonal influenza and pneumococcal polysaccharide vaccination programmes

The HSE provides seasonal influenza vaccine for those aged 65 and over, those in [medically at risk groups](#), pregnant women, health care workers and carers.

The WHO has set a target uptake of 75% for influenza vaccination for those aged 65 and older. Most seasonal influenza vaccine is given in general practice – since 2011/2012 flu season those eligible have had a choice to attend either their GP or pharmacist.

Pneumococcal polysaccharide vaccine (PPV23) is delivered in general practice settings for all those aged 65 and older and all those aged <65 years at increased risk of invasive pneumococcal disease as per the recommendations in the [Pneumococcal chapter](#) of the [Immunisation Guidelines](#).

Routine adult pneumococcal administration for those aged 65 and older where a single dose of PPV23 vaccine only is required. No further PPV23 vaccine is recommended for this age group.

For persons at increased risk of pneumococcal disease, risk groups can be seen in the [Pneumococcal chapter](#) of the [Immunisation Guidelines](#).

Live Attenuated Influenza Vaccine (LAIV)

NIAC recommends LAIV for all children aged 2 to <18years.

Since 2020/21 the children's nasal flu vaccine has been introduced for all children aged 2-17. Please check eligibility age groups for flu season before administering vaccine. Recipients can receive this vaccine either from their GP or pharmacist.

2.5 Vaccination of late entrants/defaulters from vaccination programme

Children and adults coming to Ireland who do not have a documented or reliable verbal history of immunisation or disease, should be assumed to be unimmunized. Individuals living in Ireland are identified as having had no previous immunisations or an incomplete primary course, arrangements should be made to ensure age-appropriate vaccination in line with the catch-up schedule (see [Appendix B](#)) available at

<https://www.hse.ie/eng/health/immunisation/hcpinfo/frequentlyaskedquestions/catchupvacc/>

The [NIAC Catch up schedule](#) was updated in August 2022:

- Those more than one month or dose behind schedule should be on a catch-up schedule, with minimum intervals between doses.
- If a person is incompletely vaccinated, provide those vaccines which were not already received. There is no need to restart a course. Once catch-up has been completed, continue with the routine schedule.
- If a fourth dose of diphtheria, pertussis, polio and tetanus containing vaccine has been given at age ≥ 3 years and 4 months, a fifth dose is not required until age 12-13 years.

Seven principles for catch-up vaccination

1. Men C vaccine given before 12 months, provides protection for a child's first year of life only.

When a child reaches the age of 12 months, they need 1 dose of MenC (given in the Hib/MenC vaccine) only, regardless of whether they received Men C vaccine in their first year of life.

2. Pneumococcal Conjugate Vaccines (PCV13) given before 12 months, gives protection for a child's first year of life only.

When a child reaches the age of 12 months, they need 1 dose of PCV13 only, regardless of the number of doses of PCV13 vaccine they received in their first year of life.

3. If the 6-month vaccines are late e.g., given at 9 months, there is no need to delay the 12-month vaccines

4. If a child needs to catch up with both 12- and 13-month vaccines, they can be given at one visit

5. Once a child reaches the age of 2, NIAC advises they no longer need PCV13 vaccine or MenB vaccine, even if they have never had these vaccines.

The exception is children with at-risk conditions who should be vaccinated.

6. Once a child reached the age of 10, they no longer need Hib vaccine

7. A child over the age of 1 year, needs a single dose of MenC up until MenACWY is given in school

Those who move to Ireland to live, work or study should be checked to make sure they have had the following vaccines:

- MMR vaccine – 2 doses
- Meningococcal C (MenC) vaccine – 1 dose from 10 - <23 years of age
- Haemophilus influenzae type b (Hib) vaccine – 1 dose from 1 - <10 years of age

Information on the vaccine schedules from EU countries is available at <https://bit.ly/VaccScheduler>. Vaccines schedules from other countries is available at <https://bit.ly/WHOVacc>

2.6 Vaccinations in pregnancy

Pertussis vaccine Tdap (Boostrix) is recommended for all pregnant women between 16-36 weeks' gestation in every pregnancy. After pregnancy whooping cough vaccine should be offered to women in the week after birth who have not had a whooping cough vaccine in the past ten years to protect themselves and their baby. For more details see <https://bit.ly/PregWC>.

Influenza vaccine is recommended for all pregnant women at any stage of pregnancy. For more details see <https://bit.ly/PregInfluenza>.

Pregnant women are recommended to be up to date with COVID-19 vaccines and recommended booster doses. Please refer to [Immunisation Guidelines](#)

Vaccination of women who are non-immune to rubella is recommended as outlined in the [Rubella chapter](#) of the [Immunisation Guidelines](#).

MMR should **NOT** be given in pregnancy as it is a live vaccine. MMR vaccine can be safely administered at least one (1) month prior to pregnancy in female patients who have not been fully immunised. If the patient has not had at least one MMR vaccine previously – offer the MMR vaccine **after pregnancy** to protect against rubella infection in any future pregnancies. The MMR vaccine is safe to give while breastfeeding.

2.7 Other vaccinations

GP clinical staff also provide vaccinations for public health purposes. In the event of an outbreak e.g., measles or meningococcal B disease, general practice staff in collaboration with Departments of Public Health provide vaccinations for contacts of cases. Vaccine for this purpose can be requested from the National Cold Chain Service (NCCS) online using the following website www.ordervaccines.ie If you have any questions about your order please contact the HSE NCCS by Phone 01 463 7770 or Email vaccines@udd.ie. Please include the relevant outbreak code available from your [local Department of Public Health](#). Vaccination may also be given in general practice in the event of a Public Health Emergency or pandemic.

[Immunocompromised persons](#), [healthcare workers and other at-risk occupations people](#) and [international travelers](#) may require additional doses of vaccines to protect them from diseases to which they might be susceptible e.g., people with asplenia require additional vaccines to protect them from haemophilus influenzae type b, pneumococcal and meningococcal disease.

For more details click on the relevant links above or refer to the relevant chapter in the [National Immunisation Guidelines](#).

3. Carrying out Vaccination in General Practice

3.1 Introduction

This section outlines the roles and responsibilities that need to be carried out by general practice staff to ensure the safe and effective delivery of the immunisation programme.

Roles and responsibilities may be assigned on a local basis according to the professional qualifications, training and experience of staff. Vaccinations must be administered by clinical staff who have completed the appropriate training and competencies (i.e., General Practice Nurses (GPNs) and physicians).

Delegation of key tasks is important to the efficient running of an immunisation programme, which is assigned to a “designated person” to ensure that all members of staff know who is responsible for that key task.

The person designated to a particular task may change or rotate depending on local arrangements.

All clinical staff administering vaccines should be familiar with the following documents:

- A. [Immunisation Guidelines for Ireland](#)
- B. SmPC for each of the vaccines available at www.hpra.ie or www.medicines.ie
- C. Primary childhood schedule - Healthcare worker information, NIO available at <https://bit.ly/HCPPCIP>
- D. Medicine protocol for each individual vaccines or the system for authorization of vaccine administration using prescription for vaccines administered by nurses documented in the patient’s health record.

3.2 Setting up and training

To provide childhood vaccination, all GPs need to have a HSE Primary Childhood Immunisation (PCI) contract.

Once the contract is in place the GP should contact the [HSE National Cold Chain Service](#), complete a set up form and will then receive a vaccine delivery schedule.

Changes in practice addresses, additional practices or movement between practices must be notified in writing to the HSE.

Recommended Education & Training for General Practice Nurses

- Basic Life Support for Health Care Workers within the last two years
- Initial anaphylaxis programme (National Anaphylaxis Education Programme for Health Care Professionals) available via HSeLand followed by a one-and-a-half-hour classroom-based skills workshop
- Subsequent updates every two years via [HSeLand](#) Anaphylaxis e-learning programme.

Recommended HSeLand Online programmes (www.HSeLand.ie)

- HSE Immunisation Foundation Programme
- Primary Childhood Immunisation Programme, Vaccinations in pregnancy, Flu
- Talking About Immunisation
- Medicines Management
- Live Attenuated Influenza Vaccine Programme
- 'Storing and Managing Vaccines'

Complete Competency assessment for General Practice Nurses

- Self-assessment of competency form should be completed (see Appendix F)
- Medicine Protocol self-assessment of competency
- PCIP self-assessment of competency

Recommended Clinical Experience

Currently employed as a practice nurse and have had the opportunity to shadow an experienced vaccinator in gaining experience. Utilization of the PCIP self-assessment for competency form to identify and address any gaps in knowledge and practice prior to accepting delegation as vaccinator.

Contact the local Professional Development Coordinators for General Practice Nurses or the Centre of Nurse and Midwifery Education (CNME) for more information. See [Appendix C Professional Development Coordinators for Practice Nurses by CHO \(Community Healthcare Organisation\) area.](#)

Practice nurses should develop their personal understanding of the enabling Scope of Practice Framework produced by the Nursing and Midwifery Board of Ireland in 2015 available at <https://bit.ly/NMBISOP>

The GP should ensure that all general practice clinical staff involved in the provision of vaccination in general practice are aware of all relevant guidelines and should facilitate any training required.

3.3 General Practitioner Role

The role of the GP is to:

- A. Avail of every opportunity (including the post-natal check/ 6-week visit) to promote vaccination and to provide parents with the [Before Immunisation](#) tear pad, when they attend their baby's 6-week check. Ensure a system is in place to remind parents when babies are overdue vaccines.
- B. Have a medicine protocol within the practice for the administration of each individual vaccine by nursing staff. In the absence of a medicine protocol (see Section 3.4) an individual prescription for vaccination should exist. Practice software systems should support authorized prescribers to prescribe individual vaccines in patient's file prior to GPN's administration of any vaccine.
- C. Carry out an individual medical assessment for patients if requested by practice nurse working under a medicine protocol (see Section 3.4).
- D. Answer pre- and post-vaccination queries from parents/legal guardians/patients or colleagues within the general practice team.
- E. Be present in the building while vaccines are being given by nurse vaccinators and for 15 minutes after the last vaccine is administered to deal with anaphylaxis or any other adverse events that might occur, including syncope.
- F. Ensure that adverse events are notified to the Health Products Regulatory Authority (HPRA) (see Section 6.0). <http://bit.ly/HPRAar>
- G. See **Appendix D** for GP practice administration issues.

3.4 Administration of vaccines under individual prescription or Medicine Protocol

The Nursing and Midwifery Board of Ireland defines medicine protocols as “*written directions that allow for the supply and administration of a named medicinal product by a registered nurse or midwife in identified clinical situations*”. A medicine protocol involves the authorisation of the nurse/midwife to supply and administer a medicine to groups of patients in a defined situation meeting specific criteria and who may not be individually identified before presentation for treatment” (An Bord Altranais, 2007).

The e-learning programme “Medicines Management” provides guidance for medicine protocol use for nurses and midwives. Available at www.hseland.ie

Vaccines given in primary care are prescribed individually by a GP or administered under medicine protocols agreed at practice level. An individually named prescription is not required for the supply and administration of medicine when a medicine protocol is in effect.

Practice nurses working under medicine protocols will be accountable for their own clinical practice and should be familiar with and adherent to the practices as set out in these guidelines.

All clients meeting the exclusion criteria of a medicine protocol must be referred to the GP for an individual medical assessment.

Arrangements should be in place in each practice for the audit of Medicine Protocol usage.

See **Appendix E** for a sample medicine protocol which can be adapted by an individual general practice.

3.5 Vaccinator role and responsibilities (GPs and GPNs)

- Each vaccinator should take accountability and responsibility when administering vaccines to patients within their scope of practice and be aware of changes in legislation that may direct or guide their practice.
- The vaccinator should remain up to date with the [NIAC guidelines](#).
- The vaccinator must adhere to and comply with the guiding principles as set out in their professional regulatory frameworks e.g., relevant NMBI guidelines. (See Self-Assessment of Competency Tool in **Appendix F**).
- The vaccinator should be available to answer queries from parents/legal guardians/ clients being immunised and other members of the general practice team.
- They should also check that:
 - All the equipment necessary for the administration of the vaccines follows best practice.
 - Appropriate drugs and equipment are available for management of anaphylaxis.
 - All documentation is available which include patient information leaflets and patient held vaccination record cards.
- The roles and responsibilities of HSE staff are outlined in **Appendix G** and see **Appendix H** for the HSE Area Immunisation Unit Directory.

3.6 To maximise vaccine uptake in GP practices

The NIO has developed a [Toolkit for GP practices to increase primary vaccine uptake](#).

This tool kit includes evidence-based interventions which have been proven to improve vaccine uptake.

- Adopt a practice-wide team approach to increasing uptake - involve everyone, from the person who answers the phone, to the GP principal/ clinical lead.
- Invite the parents of infants requiring vaccination for their appointments well in advance so parents can plan their visit accordingly.
- Send reminders - they work! Text, write or phone parents to remind them that vaccines are due or overdue.
- Facilitate appointments for vaccination - encourage reception staff to facilitate appointments. Flexible appointments for vaccination including evenings and weekend (if possible) are effective and improve attendance.
- Perform opportunistic checking of a child's immunisation when attending for other reasons – ensure that your practice management team or software flags children with outstanding vaccinations.
- Recommend vaccination if children are overdue vaccines; book appointments of any missing vaccines.
- Advice from a trusted healthcare professional is known to be very influential in vaccine acceptance - communicating effectively with parents who have concerns about vaccines has been shown to increase vaccine uptake.
- Keep up to date with the current information about vaccines - please visit www.immunisation.ie

- Promote vaccination on your website and in your practice, display leaflets and posters.
- Guide parents where to find reliable information in [English](#) and [as Gaeilge](#).
- E-Learning module: *Talking About Immunisation* - complete on www.hseland.ie. This uses the WHO recommended approach on communicating with people who are hesitant about vaccines, which has been shown to increase vaccine acceptance.

4. Procedures

4.1 Before vaccine administration

Prior to vaccination the vaccinator

- A. If the vaccinator is not a GP, ensures that a GP is present in the building while vaccinations are being given and for 15 minutes after the last vaccine is administered to deal with anaphylaxis or any other adverse events that might occur, including syncope.
- B. Check and record patient's information accurately including permission to use mobile numbers for text alerts and reminders (see **Appendix D**).
- C. Confirms person's identity (Name, address, date of birth and mother or father's name as appropriate. For younger children it will be necessary to confirm identity with parent/legal guardian).
- D. Provides appropriate information regarding the vaccines to be administered including the benefits of vaccination and the risks of not vaccinating
Addresses vaccination concerns and queries. Find the information at <https://bit.ly/GPPNToolkit>
- E. Obtains written informed consent (see **Section 4.2**).
- F. Assesses the person's suitability for immunisation on the day. Vaccines should be given to clients for whom no contraindication is identified as per the [Immunisation Guidelines of Ireland](#).
- G. Routine physical examinations and procedures (e.g., measuring temperatures) are NOT recommended for vaccinating people who are healthy. The person or parent should be asked if the person being vaccinated is ill.
- H. Defers any persons with an acute febrile illness on the day and reschedules vaccination.
- I. Ensures that when vaccines are being given according to a particular schedule e.g., PCIP that the interval from last vaccines given is appropriate. If not, vaccination should be deferred, and the appointment rescheduled. Find the information at <http://bit.ly/NIACCh2>
- J. Checks that the intervals between different vaccines are appropriate.
- K. If vaccination is being carried out by a nurse, checks that the vaccine has been prescribed by the GP or that the vaccine can be administered under medicine protocol (see **Section 3.4**).
- L. Checks that the appropriate vaccine(s) are in the vaccine fridge, are in date and stored in accordance with cold chain directions (see **Section 8**).
- M. Removes vaccine from the vaccine fridge when the client is ready for vaccination. Find the information about Vaccine storage, usage, stock rotation at <https://bit.ly/CCSOP1>.
- N. Verifies with the parent/legal guardian/client or other health professional that the correct vaccine is being given, the expiry date has not passed and records this on the form.
- O. Washes their hands or uses disinfectant gel before vaccine administration.
- P. Reconstitutes vaccines in accordance with manufacturer's instruction.

Vaccine Reconstitution

Applies to some of the commonly used childhood vaccines

- 6 in1
- MMR
- Haemophilus influenzae type b/Meningococcal C

Involves

- attaching the 21-gauge needle provided to the prefilled syringe containing diluent
- inserting the syringe into the vial
- mixing and then drawing the reconstituted vaccine back into the syringe
- changing the needle on the syringe ready for administration using an appropriate gauge needle as per [Section 4.3](#)

- Q. Ensures that the vaccine colour and composition is in accordance with the SmPC for that vaccine. Discard vaccines that do not meet SmPC characteristics.
- R. Ensures the client is correctly positioned for the safe administration of the vaccine(s) with help from a parent/legal guardian or other member of the general practice team for children.
- S. Ensures that all vaccines are administered within the recommended time frame.

MMR vaccines must be used within one hour of reconstitution or be discarded.

Any vaccine which is removed from their packaging and not used should be discarded.

The Rights of Vaccine Administration

1. Right patient
2. Right reason
3. Right vaccine
4. Right route
5. Right time
6. Right dose
7. Right form
8. Right action
9. Right documentation
10. Right response

4.2 Consent issues

Vaccination is not compulsory.

- A. Informed consent must be obtained prior to vaccination. The person providing consent to a vaccination should be offered as much information as they need to make their decision as per the latest [HSE National Consent Policy](#).
- B. The [Guide to Professional Conduct & Ethics for Registered Medical Practitioners, 8th Edition, 2016 \(Medical Council\)](#) states in Section 11 'Information for patients' section 11.1 that '*You must give patients enough information, in a way that they can understand, to enable them to exercise their right to make informed decisions about their care. Consent is not valid if the patient has not been given enough information to make a decision*'.
- C. The [Code of Professional Conduct and Ethics for Nurses and Midwives, 2021](#) Principle 1, Standard 11, states that '*You are responsible for seeking the patient's consent to nursing and midwifery treatment and care. Never presume a patient's consent. The consent is valid if: information is communicated in a clear manner about the nature, purpose, benefits and risks of treatment and care in a way the patient can understand; the patient has the capacity to make a decision about a particular procedure; the patient gives their agreement freely.*'
- D. Information on who can give consent for a young person under the age of 16 years in Ireland is available at <https://www.hse.ie/eng/about/who/national-office-human-rights-equality-policy/consent/documents/hse-national-consent-policy.pdf>
- E. Those over the age of 16 years of age may consent on their own behalf.
- F. Special consideration needs to be given to children who are in the care of the HSE either on a voluntary or statutory basis and contact should be made with the appropriate social worker.
- G. There is no maximum duration for consent. Consent remains valid for an indefinite period unless
 - It is withdrawn
 - There has been a change in the client's capacity to give consent
 - There has been a change to the proposed vaccine schedule to which the client has not given consent
- H. A PCIP Declination Form is attached in **Appendix J** for parents/ guardians who do not want their child to be vaccinated. GPs can send a copy of this signed form to the local immunisation office and keep a copy for the practice file.

4.3 Vaccine administration

The vaccinator:

- A. Administers vaccine in accordance with [NIAC guidelines](#) with respect to the client's age, site of vaccination and needle size outlined in the table below.**

NIAC recommendations regarding patients age, site of vaccination and needle size

Patients Age	Site	Needle Size
Birth to 12 months*	Anterolateral aspect of middle or upper thigh	25 mm needle 23-25 gauge
12 to 36 months	Anterolateral aspect of middle or upper thigh until deltoid has developed adequate muscle mass	25 mm needle 23-25 gauge
From 3 years onwards**	Most dense portion of the deltoid muscle – between acromion and muscle insertion	25 mm needle 23-25 gauge

* Use a 16mm length needle in infants under 2.5-3kgs.

** Use 40mm length needle on women >90kgs, men >118kgs.

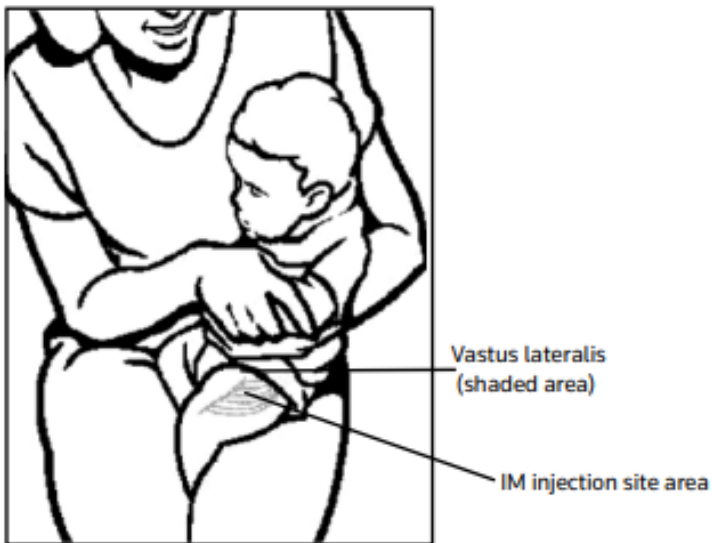
B. Administer intramuscular (IM) injections

- Where it is necessary to administer two vaccines in the same limb the vaccination sites should be separated by 2.5cms (about 1 inch) and the sites and vaccines administered recorded accurately.
- The skin does not require cleaning before the vaccine is administered unless visibly dirty.
- If the skin is visibly dirty, clean it with soap and water. If an alcohol wipe is used the skin should be allowed to dry before the vaccine is injected.
- Gloves are not normally required when administering intramuscular injections. However, if the client's or vaccinator's skin is not intact, gloves should be worn.

Vastus lateralis

The Vastus lateralis muscle is located on the antero-lateral aspect of the thigh, from one of the patient's hand breadths below the greater trochanter to one hand's breath above the knee. The middle third of the muscle is the site for injections. The width of the injection site extends from the mid-line of the thigh anteriorly to the mid-line of the outer thigh.

Figure 1: Vastus lateralis site for IM injection, birth to 36 months



The injection site is the middle third of the vastus lateralis, in the anterolateral thigh (shaded area above).

Figure 2: Deltoid site for IM injection, older toddlers, children and adults

The light triangle in Figure 2 indicates the site for IM injection into the deltoid muscle for older toddlers, children and adults.



Figures 1 and 2 taken from Immunisation Guidelines of the NIAC.

1. Landmark the injection site in the deltoid muscle:

- Two finger widths down from the acromion process; the bottom edge is at an imaginary line drawn from the axilla
- Injection site: 5cms (about 1.97 in) below acromion process
- The recommended site is in the middle of the triangle. To avoid causing an injury, do not inject too high or too low. Vaccinators should landmark the injection site and use correct injection techniques to prevent shoulder injuries.

2. **At the injection site spread the skin taut between the thumb and forefinger with the non-dominant hand.**
 - Do NOT bunch up the skin as this leads to administering the vaccine into subcutaneous tissue inadvertently.
3. **Use the dominant hand to inject the medication.**
 - This ensures control of the needle and syringe during the procedure.
4. **Hold the syringe firmly between thumb and forefinger, with heel of hand resting on the thumb of the non-dominant hand.**
 - This ensures a 90-degree angle is achieved and the correct site is targeted
5. **Insert the needle smoothly and swiftly.**
6. **Inject at a 90-degree angle, to ensure the medication reaches the muscle. Inject medication over 1-2 seconds.**
7. **After removing the needle, use gentle pressure with a cotton ball or gauze. Do not massage the injection site.**
8. **If there is a leakage at the injection site after withdrawal of needle: apply light pressure with gauze.**

Swift needle entry, slow injection of medication, swift needle withdrawal = less pain

The practical demonstration of Intramuscular injection into the deltoid muscle is available at

<https://bit.ly/IMinjTechnique>

C. Administers rotavirus oral vaccine as follows:

Ensure the baby is sitting in a reclining position. Remove protective tip cap from the oral applicator. Insert applicator tip into the baby's mouth, towards the inner cheek. Administer vaccine into the baby's mouth. The applicator containing the vaccine should be aimed down one side and towards the back of the baby's mouth. The applicator should not be inserted so far back that the baby gags. All the applicator contents should be given to the baby.

D. Administers Live Attenuated Influenza Vaccine (LAIV) via intra nasal route as follows:

- This vaccine is given as a divided dose in both nostrils with 0.1ml per nostril.
- The child should breathe normally. There is no need to actively inhale or sniff.
- The vaccine is rapidly adsorbed so there is also no need to repeat either half of dose if child sneezes or blows their nose, or their nose drips following administration.

The vaccinator must complete the HSeLanD module for LAIV to learn about how to administer LAIV via intranasal route. <https://www.hseland.ie>.

4.4 After vaccine administration (including liquid infant paracetamol)

After administering the vaccine(s) the vaccinator:

- A. Disposes of sharps immediately, without recapping the needle, into the sharp's containers provided. Discard the empty oral applicator and tip cap into approved biological waste containers.
- B. Performs hand hygiene with either soap and water or an alcohol-based hand gel.
- C. Completes the administration details including the vaccine name, manufacturer, batch number and expiry date, using peel off labels provided where appropriate, at the end of the consent form immediately after the vaccine is given. For reconstituted vaccines, the batch number recorded is the number on the box and/ or peel off labels. (See [Section 4.1.P](#)).
- D. Scans completed electronic forms into the client record.
- E. Ensures the client's vaccination record (immunisation passport for children) is completed and given to the parent/legal guardian/patient before they leave the practice.
- F. Vaccine recipients should be observed for at least 15 minutes after vaccination. If this is not practicable, vaccine recipients should wait in the vicinity for 15 minutes.
- G. Gives parents/legal guardians of children attending for vaccination under the PCIP a copy of the HSE "After immunisation information" tear pad (provides post vaccination advice, available from www.healthpromotion.ie).

This includes advising parents/legal guardians that babies are recommended to have 3 doses of **liquid infant paracetamol after the 2- and 4-month MenB vaccines due to** the increased risk of fever when the MenB vaccine is administered with the other PCIP vaccines.

The liquid infant paracetamol 2.5mls (60mgs) should be given at or just after the MenB vaccine, with a second dose 4-6 hours later and a third dose 4-6 hours thereafter.

If the baby remains well but has a fever still at this stage, parent/legal guardians may give one further dose of liquid infant paracetamol.

If the baby is unwell at any stage or has a fever (>39°C) after the four doses of liquid infant paracetamol, then they should be advised to contact their GP surgery or Out of Hours Service.

This recommendation for liquid infant paracetamol follows recent studies undertaken to demonstrate there is no reduction in vaccine immunogenicity.

Babies weighing less than 3.5kg (7lb 7 oz) at their 6-week check should be reweighed on the day of vaccination. If they weigh less than 4kg (8lb 8oz) 3 doses of liquid infant paracetamol should be given at a dosage of 15mg/kg.

Babies do not need to routinely have liquid infant paracetamol after the 6-, 12- or 13-month immunisations. If a baby develops a fever (greater than 39°C), is sore at the injection site or is distressed

following immunisation, they may receive paracetamol or ibuprofen.

- H. Addresses queries from parents/legal guardians/patients about possible adverse reactions that occur post vaccination.
- I. Provides parents/legal guardians/patients with the appropriate contact details so that they can inform the general practice team about any concerns following vaccination.
- J. [Reports adverse events to the HPRA](#) (see **Section 4.5**).
- K. If a patient requires referral to hospital for vaccination under supervision, the vaccinator makes a referral through their [local Department of Public Health](#).

4.5 Reporting adverse events following immunisation

Vaccines used in Ireland have been licensed by the EMA in conjunction with the HPRA. Following licensing of vaccines or other medicines the HPRA is responsible for post marketing surveillance. Reporting of adverse events can be completed by clicking on the [online reporting form on the HPRA website](#). The HPRA has when appropriate withdrawn products from the Irish market where there have been public safety concerns.

5. Common vaccine administration issues

When there are queries related to vaccine administration, you may choose to contact the Assistant Director of Public Health Nursing (ADPHN) with responsibility for immunisation or a Consultant in Public Health Medicine in the [local Department of Public Health](#) (See **Appendix I**). You may also email clinical queries to the NIO at immunsation@hse.ie.

5.1 Administration of two or more vaccines to the client at the same visit

Where two or more vaccines are to be administered to clients at the same visit:

- A. Each vaccine should be prepared appropriately (either presented in a pre-filled syringe or requiring reconstitution) as per manufacturer's instructions.
- B. An agreed convention should be followed about the site of each vaccine as this will make it easier to attribute local reactions to the correct vaccine in the event of a report of an adverse reaction.

Examples include:

for the primary childhood immunisation schedule

- At 2 months Rotavirus oral vaccine should be given at the beginning of the visit before MenB, 6 in 1 and PCV vaccines. Men B vaccine should be given first into the **LEFT** anterolateral thigh. Then 6 in 1 vaccine followed by PCV should be given into the **RIGHT** anterolateral thigh. This is so that adverse events related to immunisation can be more easily identified.
- At 4 months Rotavirus oral vaccine should be given at the beginning of the visit before MenB and 6 in 1 vaccines. Men B vaccine should be given first into the **LEFT** anterolateral thigh. Then 6 in 1 vaccine should be given into the **RIGHT** anterolateral thigh.
- At 6 months as PCV is more reactogenic it is recommended that this vaccine is given in one limb and that 6 in 1 and MenC vaccines are given in a separate limb, separated by 2.5cms.
- An at-risk adult receiving Influenza and PPV23 vaccines – these vaccines should be given in separate limbs

The administration site of all vaccinations given should be recorded accurately. This helps to identify if an individual vaccine causes a local adverse reaction post-vaccination.

5.2 Contraindications and precautions

Refer to Immunisation Guidelines for Ireland for details of contraindications and precautions to individual vaccines

Contraindications to vaccination. Please refer to [NIAC guidelines](#) for details of individual guidelines.

All vaccines

Confirmed anaphylactic reaction to the vaccine or to a constituent or a constituent of the syringe, syringe cap or vial (e.g., Latex anaphylaxis).

To avoid an acute vaccine-related febrile episode, patients with cancer and severe neutropenia (absolute neutrophil count $<0.5 \times 10^9/L$) should not receive any vaccines. This does not apply to children with primary autoimmune neutropenia.

Patients taking combination checkpoint inhibitors (e.g., ipilimumab plus nivolumab) should not receive any vaccines because of a significant increased incidence of immune-related adverse reactions.

Live vaccines (e.g., MMR and varicella and LAIV)

- Patients who are pregnant should not receive MMR, Varicella or LAIV immunisations.
- Patient who are immunosuppressed, taking high-dose systemic steroid or immunomodulator therapy (refer to the detailed guidance in the [NIAC guidelines](#)).

Rotavirus oral vaccine

- Babies aged 8 months and 0 days or older
- Uncorrected congenital GIT malformation (e.g., Meckel's diverticulum) which would predispose an infant to intussusception
- Previous intussusception.
- Severe combined immunodeficiency (SCID)
- Hereditary fructose intolerance, sucrose-isomaltase deficiency or glucose-galactose malabsorption
- Infants born to patients who were treated with infliximab during pregnancy and/or during breastfeeding should not receive rotavirus vaccine. Consideration may be given to administration of rotavirus vaccine if maternal infliximab did not extend beyond the first trimester in a non-breastfed infant.

Please refer to [NIAC guidelines](#) for details of individual vaccines.

Precautions for vaccination

Acute severe febrile illness: defer until recovery.

Bleeding disorders: Vaccines should be administered with caution to individuals with coagulation defects.

In those with a severe bleeding tendency vaccination can be scheduled shortly after administration of clotting factor replacement or similar therapy.

Vaccines recommended for intramuscular injection may be administered subcutaneously to persons with a bleeding

disorder if the immune response and clinical reaction to these vaccines are expected to be comparable by either route of injection. This only applies to MMR, influenza and yellow fever vaccines because these vaccines only are known to be effective if given subcutaneously. So, it is not recommended to give e.g. 6 in1, MenB or MenC vaccines subcutaneously.

Technique for IM injections in persons with bleeding disorders or on anticoagulants

Only one injection per muscle mass should be given at each visit.

Using a 23- or 25-gauge needle will reduce the pressure gradient and cause less trauma to the muscle tissue.

The vaccine should be injected slowly (≥ 5 seconds) to reduce the risk of tissue damage.

- Firm pressure should be applied to the site for 5 to 10 minutes after injection.
- Stabilisation of the limb will reduce the risk of a haematoma.
- The site should not be rubbed or massaged.
- Instruct the patient/parent to monitor the injected limb and to report any concerns to their GP or out of hours GP service / supervising consultant.

Immunosuppression: The immune response of immunocompromised individuals to non-live vaccines may be inadequate. Babies immunosuppressed with conditions other than SCID should be considered for oral rotavirus vaccination. This may require discussion with their clinical team if the diagnosis is unclear.

Pregnancy: Influenza vaccine is recommended in any stage of pregnancy. Pertussis vaccine Tdap (Boostrix) is recommended between 16- and 36-weeks' gestation for each pregnancy. Other non-live vaccines may be administered in pregnancy (refer to the detailed guidance in the [Immunisation Guidelines for Ireland](#)). Live vaccines (e.g., MMR) should NOT be administered in pregnancy.

5.3 Specific vaccine issues

Rotavirus

- Rotavirus oral vaccine is recommended for all babies at their 2- and 4-month visits.
- Rotavirus oral vaccine can be administered with all other PCIP vaccines.
- With increasing age there is an increased risk of intussusception. Rotavirus oral vaccine must NOT be given on or after 8 months and 0 days of age.
- Rotavirus oral vaccine must NOT be given to infants with a previous history of intussusception, Severe Combined Immunodeficiency Disorder (SCID), a malformation of the gastrointestinal tract which might predispose them to intussusception, or a hereditary fructose intolerance, sucrose-isomaltase deficiency or glucose-galactose malabsorption.
- SCID is a rare inherited primary immune deficiency that can result in the onset of one or more serious and even life-threatening infections within the first few months of life. Children with SCID can also become ill from live vaccines, including rotavirus oral vaccine. The risk from rotavirus vaccine needs to be balanced against the risk of a baby with undiagnosed SCID contracting rotavirus disease.
- To determine the risk of SCID, ask the person accompanying the baby;
- Are there any diseases in the baby's biological parents which have affected the immune system?

- Did anyone in the baby's biological family need a bone marrow transplant as a baby?

If the parent/caregiver answers “No” to these questions rotavirus oral vaccine should be given.

If the parent/caregiver answers “Yes” to either of these questions

- Check if a Full Blood Count (FBC) was taken at birth and confirm the results.
- If an FBC was not taken, a full blood count with differential white cell, including lymphocyte count should be ordered.
- If the lymphocyte count is below $<2.0 \times 10^9/L$, refer the baby to a paediatrician urgently.

Any baby at risk of SCID should NOT be given rotavirus oral vaccine.

MMR

- MMR vaccine may be given at the same time or at any interval before or after any non-live vaccines.
- MMR and yellow fever should NOT be administered on the same day. They should be given ≥ 4 weeks apart.
- MMR, varicella and zoster vaccine can be given on the same day or ≥ 4 weeks apart.
- Pregnancy should be avoided for 1 month after MMR vaccination.
- Vaccination should be deferred for between three and eleven months following the administration of blood or blood products (see [Immunisation Guidelines for Ireland](#) for full details).
- Those who developed thrombocytopenia within 6 weeks of their first dose of MMR vaccine should undergo serological testing to decide whether a second dose is necessary. The second dose is recommended if the patient is not fully immune to the 3 component viruses.

Influenza

The HSE provides free seasonal influenza vaccine to people who are eligible for influenza vaccine as per the DoH policy. Please check the HSE webpage [Getting the Flu Vaccine](#) for the latest recommendations.

- Egg allergy: People with confirmed egg anaphylaxis or egg allergy may be given influenza vaccine in a primary care or school setting with the exception of those who have required admission to ICU for a previous severe anaphylaxis to egg.
- Those requiring non-live influenza vaccine who have had a previous ICU admission for a severe anaphylaxis to egg should be referred for specialist assessment with regard to vaccine administration in hospital.
- LAIV is the preferred vaccine for children who have required admission to ICU for a previous severe anaphylaxis to egg as the intranasal route is less likely to cause systemic reactions; it should be given in hospital.
- In children aged 12-23 months of age, an interval of one week is recommended between the administration of influenza vaccine and PCV13.

PPV23

Booster doses of PPV23 vaccine are NOT routinely recommended in immunocompetent persons as there is a lack of evidence of improved immunity and an increased incidence of local side effects from repeated doses.

People aged 65 years and older, and individuals aged 2 years and older at [high-risk of invasive pneumococcal disease](#) (as classified by the [Immunisation Guidelines for Ireland](#)) are recommended the following:

Aged 65 years and older:

One dose is required irrespective of immune status.

Aged <65 years:

- **One dose is required for those at risk**
- **A booster** vaccination is recommended 5 years after the first vaccination for some individuals: those whose antibody levels are likely to decline rapidly e.g., those who have asplenia, hyposplenism, immunosuppression including HIV infection, chronic renal disease, nephrotic syndrome or renal transplant.

Patients with these conditions who received their dose of PPV23 at less than 65 years of age require one further PPV23 booster at or after 65 years of age (five years after the previous dose)

Pertussis

Low dose pertussis vaccine (Tdap) is recommended for:

- Pregnant patients between 16-36 weeks' gestation in each pregnancy, to protect themselves and their infant. Administration of the vaccine within this timeframe allows for the greatest transfer of maternal antibodies (which occurs from 34 weeks' gestation) thus providing protection for infants too young to be vaccinated.
- Health care workers who are in contact with infants, pregnant women and the immunocompromised.

Latex allergy:

Vaccines supplied in vials or syringes containing rubber

- Should not be used in those who have had an anaphylactic reaction to latex.
- May be given to those with a latex allergy other than an anaphylactic reaction (e.g., those with a history of a contact allergy to latex gloves).

Check the SmPCs or contact the NIO at immunisation@hse.ie for advice.

Vaccine given too early

If a vaccine has been given before the minimum recommended date or interval (e.g., as part of the PCIP) this vaccination should not be considered as part of the primary series as there may be a suboptimal response. The one exception is where the vaccine has been administered within 4 days of the correct immunisation date.

Early dose(s) should be disregarded and repeated at least one month after the disregarded dose.

See Table on Minimum Intervals between vaccine doses in [general immunisation procedures](#) chapter of [Immunisation Guidelines](#).

Vaccines given after the expiry date

If a vaccine is given after the expiry date (the last day of expiry month) there may be a suboptimal response.

If the vaccine is a live vaccine a further dose should be given one month after the expired dose.

If the vaccine is non-live, the vaccine can be given on the same day or at any interval after this is discovered.

This should be reported as a medication error to the HPRA (See [Section 4.5](#)).

Refusal of vaccination

In those instances where a parent/legal guardian/client refuses vaccination and all avenues of communication have been explored, it is best practice that the parent/legal guardian/client sign a refusal form (see [Appendix J](#)). In the instance where combination vaccines or multiple vaccines are recommended the name of each vaccine and the disease/diseases that they protect against should be clearly outlined on the refusal form.

6. Maintenance of the Cold Chain and Vaccine Ordering

6.1 Introduction

The Cold Chain is a temperature-controlled supply chain for products that require a specific temperature range for distribution and storage. For vaccines, the recommended temperature-controlled range is between +2°Celsius and +8°Celsius (+2°C to +8°C).

At each practice, a designated staff member (named the person responsible and his/her deputy) should be nominated to ensure that all procedures are followed. The assigned deputy covers in absence of the designated staff member. It is the responsibility of the named responsible person (and his/her deputy) of the practice to ensure that all the procedures are followed and all staff who handle or administer vaccines are trained in proper vaccine storage and handling practices.

Domestic fridges are not suitable for the storage of vaccines. Vaccines must only be stored in a pharmaceutical fridge. Please refer to [HSE Guidelines for maintenance of cold-chain in vaccine fridges and management of vaccine stock](#) for more details.

6.2 Vaccine fridge monitoring and maintenance

- A. The fridge should be placed in an appropriately ventilated room away from any heat source and direct sunlight.
- B. Fridge temperatures (current, maximum and minimum) should be recorded **twice** daily, at the start and end of each day during the working week. Record the maximum and minimum temperature every morning especially after the weekend or any other time when the vaccine storage site has been closed for a day or more must be done before any vaccine is administered.

The maximum/minimum reading should be cleared from fridge memory and **reset after each reading**. To ensure the reset has been carried out correctly, the maximum, minimum and current temperatures should all display the same temperature (i.e., current temperature).

Reset the fridge thermometer:

- at the end of a clinic,
- after the fridge door has been opened on several occasions,
- after the fridge has been re-stocked or cleaned,
- at the start and end of every day.

Resetting should be carried out once the current temperature reading has returned to within the recommended range.

- C. A **data logger** (a battery powered continuous temperature recording device) should be used in fridges where vaccines are stored. This should be placed in the middle of the fridge adjacent to the vaccines. This device is independent of the fridge and continues to record the temperatures even when there is no power supply and therefore gives an accurate account of the temperatures reached and the duration of any temperature breach. Data loggers should be set to record temperatures at 5 to 10 minute intervals.

The data logger should be downloaded and reviewed regularly (at least once every two weeks), and the electronic or printed record should be retained as per the HSE Standards and Recommended Practices for Healthcare Records Management. The stored data will suffice as a permanent temperature record for the fridge.

Once a temperature breach is registered by fridge thermometer (current, maximum or minimum) or the fridge has alarmed, the data logger should be downloaded to confirm the temperatures reached and the duration of the breach.

The data logger does not replace reading the fridge temperatures (current, maximum and minimum) twice daily, unless the data logger is downloaded or reviewed twice daily, morning and evening.

- D. A temperature monitoring chart should be on each vaccine fridge door (**Appendix K**). This chart should record maximum, minimum and current temperature twice daily. When a temperature record has been completed, replace it with a new record and keep completed records close to the fridge. These records should be stored securely indefinitely unless data logger records are being retained.
- E. The door should remain closed when it is not required to remove or place vaccines within the fridge. Reducing door opening helps to keep internal temperatures stable. Check that the doors are properly sealed by giving a gentle tug on the door handle. The doors should be routinely locked.

Note: A door that is not fully sealed or unnecessarily left open can result in a temperature recording above +8°C and therefore a temperature breach.

When restocking the fridge, removing vaccine, cleaning the fridge or during stock rotation, door openings may cause the air temperature in the fridge to increase for a brief time. If the vaccines are exposed to temperatures of up to +12°C for 15 minutes or less no action is required.

After such a period of high activity the maximum temperature should be recorded, and the memory erased. A note on the Temperature Log (**Appendix K– ‘Comments’ section**) should indicate the cause of the increase in temperature e.g., vaccine removal. Record fridge temperature breaches and actions on the flipside of this log.

- F. Containers of water may be placed in spaces at the sides of/ or on empty shelves in the fridge to help maintain the temperature. This may arise if there is a planned power outage and/ or when the fridge is not full.
- G. Prevent interruptions to the electricity supply to the vaccine fridge. This can be achieved by directly wiring the

fridge to the electricity supply without using a plug and using a dedicated circuit for the fridge and by labeling the fuse. Avoid using plugs that can be activated by a wall switch. Where this is not possible, arrangements should be put in place to ensure the plug is never removed, and the switch is never turned off (these arrangements could include difficult access to the socket e.g., behind the fridge or physical cover) or by placing cautionary notices on plugs and sockets e.g. “Don’t unplug me” stickers can be requested from the NIO by emailing immunisation@hse.ie.

- H. The inside of the fridge should be regularly cleaned using warm soapy water. Dry thoroughly and only restock once the temperature is within the recommended range. Dust on the external/ rear of the fridge should be removed with a vacuum cleaner to keep it dust free.
- I. The fridge seals should be regularly inspected. The seal should not be torn or brittle and there should be no gaps between the seal and the body of the unit when the door is closed. Check the seal by placing a thin strip of paper against the door seal, close the door and pull the paper strip. If the paper falls or comes away easily, then the seal needs to be replaced or serviced. Check all around the door and particularly the corners.
- J. The fridge and thermometers should be serviced and calibrated annually.
- K. Fridge should be cleaned regularly (as per the HSE Infection Prevention and Control Guidance and Framework). Fridge should be serviced regularly as recommended by the manufacturer.
- L. Vaccine storage procedures should be audited at least annually or more frequently if experiencing cold chain problems.
- M. Ensure that your practice has an insurance policy in place to remunerate losses in case of fridge breakdown or power outages.

REMEMBER THE 7Rs
Read: temperature twice daily at clinic/surgery opening and closing times
Record: maximum, minimum and current temperatures stating date and time of reading and sign/initial) and download data logger regularly
Reset: after recording temperatures and all 3 readings (max/ min /current) should concur
React: if the temperature falls outside +2°C to +8°C and document this action
Review: temperature records regularly (at least once a month)
Rotate: vaccines after each delivery placing shorter dated vaccines to the front
Remove: expired stock from fridge immediately and return to NCCS for destruction

6.3 Ordering vaccines

- A. Vaccine stocks should be kept to a minimum by monthly ordering only the quantity of vaccine required until the next delivery.
- B. A “vaccine stock sheet” should be maintained to record the date, stock on hand and quantity ordered to facilitate monthly ordering. A minimum vaccine stock of two weeks but no more than six weeks should be retained. Overstocking vaccines can lead to wastage because of cold chain failure the expiry date being exceeded. There is an increased risk of administering an expired vaccine when excess volumes of vaccines are stored.
- C. Vaccines should be ordered from the NCCS using your 5- or 7-Digit account number starting with 300...
- Online at ordervaccines.ie
 - E-mail vaccines@udd.ie
 - Fax number (01) 463 7788
- D. NCCS will send a confirmatory email or fax outlining that they have received the order and confirming the vaccine delivery date. If confirmation is not received NCCS should be contacted directly. If more than one confirmation email is received and the emails have different delivery details, contact the NCCS directly for clarification.
- E. Vaccines must be ordered by a specific date each month as per the calendar available on the NCCS online ordering system.

6.4 Accepting delivery

- A. Vaccine deliveries must be acknowledged by signature and checked for discrepancies. Any discrepancies or damage must be reported to the NCCS immediately.
- B. Vaccines must be refrigerated immediately. They must never be allowed to reach temperatures above 8°C.
- C. On delivery, the temperature of vaccines should be inspected and recorded to demonstrate that they were maintained within an appropriate temperature range.
- D. Vaccines must be removed from the delivery box, checked against delivery docket, allocated to appropriate area in fridge and recorded. The delivery docket should be retained as it contains details of the delivery, batch number and expiry dates of products.

6.5 Storage, stock rotation and disposal

- A. Vaccines should always be stored in their original packaging. Light exposure to light sensitive vaccines causes a deleterious and cumulative effect. The packaging protects the vaccines from light and heat. The supplied packaging displays the appropriate batch number and expiry date. Vaccines should not be removed from their packaging until required for use.
- B. Vaccine boxes must not touch the sides, back or bottom of the fridge as air needs to circulate throughout the

fridge. Fridges should not be filled greater than 2/3s of their capacity as this will prevent proper airflow.

- C. Vaccine expiry dates should be regularly checked, and vaccine stock rotated to ensure that vaccines with the shortest expiry date are administered first.
- D. Opened vaccine vials should be safely disposed of into a sharps bin. They should not be returned to the NCCS.
- E. Unopened expired or damaged vaccines must not be used. If the damage is apparent on delivery, they should be returned to the NCCS delivery person with a completed vaccine return form. If the damage becomes apparent after delivery, these returns should not be stored in the fridge but safely stored for return in future.
- F. A copy of the vaccine return form should be retained locally. Please see **Appendix M** for vaccine returns form. An electronic version is available to download at <https://bit.ly/ReturnVacc>
Expired or damaged unopened vaccines must not be put into a sharps bin but must be returned to NCCS for destruction.

6.6 Breakdown in the Cold Chain

- A. In accordance with the vaccine licence, all vaccines must be stored in a fridge between +2°C and +8°C and must not be frozen.
- B. A breakdown in the Cold Chain occurs when vaccines are NOT stored between +2°C and +8°C. This can be due to delay in refrigerating vaccines once delivered, faulty fridge, electrical power cut, fridge unplugged /switched off, or fridge door left open. For vaccines supplied by the NCCS, if the temperature recorded is less than +2°C or greater than +8°C, contact the NIO by email immunisation@hse.ie for further advice. If the vaccines are privately supplied, contact the relevant supplier or manufacturer for advice. This does not include temperature deviations or excursions when the temperature reaches a maximum of +12°C for 15 minutes or less.

If there is a breakdown in the Cold Chain:

- A. Check the temperature on the fridge thermometer (current, maximum and minimum). Record the time and remove the continuous temperature recording device (data logger) to download the readings and return to fridge. Note the room temperature if the fridge temperature is not available.
- B. Ensure that the fridge door is closed and working normally. If the fridge is not working within the manufacturers specifications or maintaining the temperature between +2°C and +8°C, remove the vaccines to an operational fridge immediately (if available).
- C. Download the continuous temperature recording device to determine the duration and extent of any temperature deviation(s). If there is no temperature logging device, refer to your manual temperature recording data.
- D. Record the type, quantity and batch number including the extent of the temperature deviation(s) - duration and min/max temperatures.

- E. If temperatures outside the permitted range are recorded the NIO should be contacted for further advice ([Appendix L](#)). The NIO will carry out a risk assessment and will advise on a case-by-case basis whether it is appropriate to use the vaccines or whether they should be discarded. This does not include temperature deviations or excursions to 12°C for 15 minutes or less. Any deviation below +2°C must be reported.
- F. Do not **use** or **dispose** of any vaccine and keep vaccines **between +2°C and +8°C in quarantine** until advised by the NIO.
- G. Once advised by NIO, any vaccines that cannot be used must be removed from the fridge, details on the returns form completed and returned to the NCCS on the next delivery day. A copy of this should be retained locally. Please see [Appendix M](#) for [vaccine returns form](#).

Transporting Vaccines

- A. **Domestic cool boxes should not be used to store, distribute or transport vaccines.** Cool boxes should be purchased from medical equipment suppliers.

Note: The box does not cool. It relies on ice/gel packs to maintain the correct temperature of +2°C to +8°C. In the cool box, air does not circulate to create an even temperature zone therefore the temperature needs to be monitored at regular intervals by the user via the external display.

- B. It is important to test and validate the method of packing vaccines by simulating the process and recording the cold chain for a similar period required for a typical transportation and clinic duration.
- C. Ice packs/Gel packs must not come in direct contact with the vaccines. The packs must be sufficiently wrapped or separated by insulating material to prevent direct contact with the vaccines and to avoid the risk of freezing or the temperature to drop to less than 2°C.
- D. Position the ice packs/gel packs appropriately above, below and at the sides of the vaccines as space in the cool box allows (as recommended by the manufacturer and local SOP (Standard Operating Procedures)).
- E. Thermometer probe (or data logger) should be placed in the middle of vaccines and should not touch ice packs/gel packs. To prevent probe from moving during transport, it can be placed in an empty vaccine box, placed in the middle of the vaccines.
- F. The vaccines must be transported in their original packaging.
- G. Only the number of vaccines estimated for administration on any day should be brought to the site.
- H. Record the temperature in the cool box:
- when vaccines are packed,
 - upon arrival at the immunisation clinic,

- throughout the immunisation clinic,
 - when returning vaccines to the fridge.
- I. The cool box should be placed in,
- An appropriately ventilated room,
 - Away from any heat source,
 - Away from direct sunlight.
- J. If there are any unused vaccines remaining at the end of a vaccination session, providing that the cold chain has been maintained, the vaccines can be returned to the vaccine fridge. They must be marked and should be used first on their next vaccination session.
- K. If temperatures outside the permitted range are recorded, first check the position of the temperature probe. The temperature probe should be in a vaccine box in the middle of the vaccines – if it is not correctly positioned reset the probe and ensure it is positioned correctly away from ice packs or at the lid of cool box then close the box firmly and recheck the temperature in 15 minutes.
- L. If the temperature is still outside the permitted range, place the vaccine under quarantine in the fridge, and contact the NIO for further advice. The NIO will carry out a risk assessment and will advise on a case-by-case basis whether it is appropriate to use or discard the vaccines.
- M. **Do not use or dispose of any vaccine which has been exposed to temperatures outside the permitted range. Quarantine and maintain these vaccines between +2°C and +8°C until advised by the NIO.**

For more information on Vaccine Ordering and Storage, and accessing HSeLanD online module please refer to link below: <https://bit.ly/VaccOrder>

Procedure for fridge maintenance during a planned power-cut

A. Keep the room as cold as possible

Without power the fridge will come to room temperature, therefore if the room temperature remains at +8°C or below then the fridge cannot exceed +8°C. The lower the temperature of the room, the slower the rate the fridge increases in temperature. Reduce room temperature by leaving the window wide open, if that is not a possibility keep internal doors open and turn off any heating well in advance of the planned outage. If the fridge is in a room with a south facing window, close the blinds to prevent the sunshine from heating the room.

B. Fill the fridge

A full fridge will not fluctuate in temperature as quickly as a half full fridge. Place vaccines on higher shelves without touching the sides of the fridge. If the bottom is empty, fill this space with containers of very cold salty water (use empty milk cartons/plastic bottles filled with salty water) and place in fridge the day before to allow the containers to come to fridge temperature before the power outage.

Also, where possible just before the power cut place one or two ice blocks under the water containers. The ice block will only freeze the water. If you do not have sufficient space for the water containers place wrapped ice blocks in the fridge. It is vital that the vaccines do not freeze, therefore double wrap the ice block with bubble wrap or else with newspaper. Use a lot of paper so that the iceblock will retain its cold and thaw slowly. The iceblock should never touch the vaccines.

If there is space between the shelves (between top of vaccines and shelf above) place newspapers in this area. This can be done the day before so that the newspaper will be at the fridge temperature before an outage.

C. Lock the fridge

Do not open the fridge once the power is lost. The only exception to this is if there is a room thermometer and the ambient temperature is less than + 8°C.

D. Record the temperature

Record the temperature and erase the maximum and minimum recording before the outage. Therefore, when the power returns, the maximum recording will be a true value for the temperature during the outage. Record the temperature immediately once it returns. Please note the maximum temperature and contact the Chief Pharmacist or Medical Officer at the NIO (Phone 087 9915452 or 01 8676108) if it exceeds + 8°C.

E. Use a datalogger

A datalogger is a USB temperature data logger for use in vaccine fridges independent of fridge power supply. This device will give the temperature recording and time so that the duration of the temperature breach is exact.

F. Ensure vaccines are insured

Contingency plan for an alternate storage site

Contingency plans should be prepared (where possible) for an alternate storage site(s) of the vaccines in the event of a refrigerator malfunction or prolonged electricity disruptions. Prepared plans should consider vaccine storage capacity of existing and potential site(s), and availability of an emergency backup power supply.

7. References

- [A Guide to Data Protection Legislation for Irish General Practice Data Protection Working Group](#) (April 2011)
Irish College of General Practitioners
- [Children First – National Guidance for the Protection and Welfare of Children \(2017\)](#).
- Centers for Disease Control and Prevention – Immunisation information available at <http://www.cdc.gov/vaccines/>
- [NIO Supporting Information for Staff School Immunisation Programme](#)
- [Primary Childhood Immunisation Schedule Frequently Asked Questions for Health Professionals \(Nov 2018\)](#)
- [HSE Guidelines for maintenance of cold-chain in vaccine fridges and management of vaccine stock \(2020\)](#)
- [HSE Guidelines for maintaining the vaccine cold-chain in vaccine cool boxes \(2020\)](#).
- [Immunisation Guidelines for Ireland](#)
- Immunisation training at HSeLanD www.hseland.ie
- Medicines Management e-learning programme July 2016 HSeLanD www.hseland.ie
- New Zealand, Ministry of Health immunisation website available at <https://www.health.govt.nz/your-health/healthy-living/immunisation>
- [Recommendations for maintenance of Vaccine Fridge within Temperature during a Planned Power-cut.](#)
- [HSE Waste Management Awareness Handbook. 2011 Health Service Executive](#)

8. Glossary of Terms and Definitions

- **Immunisation** denotes the process of artificially inducing or providing immunity. This may be either active or passive.
- Active immunisation is the administration of a vaccine or toxoid to stimulate production of an immune response.
- Passive immunisation is the administration of preformed antibodies (such as human normal immunoglobulin, specific antibody preparation and antitoxins) to provide temporary immunity.
- **Toxoid** is a modified bacterial toxin that has been rendered non-toxic but stimulates the formation of antitoxin.
- **Vaccine** is a suspension of live attenuated or inactivated micro-organisms or fractions thereof, administered to induce immunity and thereby prevent infectious disease. Non-live vaccine is a vaccine that contains killed bacteria or viruses. The response may be weaker than for a live vaccine and so repeated doses are often needed. Live attenuated vaccine is a vaccine that contains a weakened strain of live bacteria or viruses that replicate in the body and induce a longer-lasting immunity than non-live vaccine vaccines.
- **Vaccination** is the term used to refer to the administration of any vaccine or toxoid.
- **Adverse Event Following Immunisation (AEFI)**: is an unwanted or unexpected event occurring after the administration of vaccine(s). Such an event may be caused by the vaccine(s) or may occur by chance after vaccination (i.e., it would have occurred regardless of vaccination).

Vaccine abbreviations:

4 in 1	Tetanus, low dose diphtheria toxoid, low dose pertussis and inactivated Polio
6 in 1	Diphtheria, Haemophilus influenzae type b (Hib), Hepatitis B, acellular Pertussis, inactivated Polio and Tetanus vaccine
Hib/MenC	Haemophilus influenzae type b/Meningococcal C conjugate vaccine
HPV	Human Papillomavirus Vaccine
MenB	Meningococcal B Conjugate vaccine
MenC	Meningococcal C Conjugate vaccine
MMR	Measles, Mumps, Rubella vaccine
PCV	Pneumococcal Conjugate Vaccine
MenB	Meningococcal B conjugate vaccine
PPV23	Pneumococcal Polysaccharide Vaccine
Rotavirus	Rotavirus oral vaccine
Tdap	Tetanus, low dose diphtheria, low dose pertussis vaccine

Appendix A: National Immunisation Schedule

Age	Vaccines
2 months	6 in 1 + MenB+ PCV+ Rotavirus
4 months	6 in 1 + MenB+ Rotavirus
6 months	6 in 1 + PCV + MenC
12 months	MMR + MenB
13 months	Hib/MenC + PCV
4-5 years (Junior Infants)	DTaP/IPV (4 in 1) + MMR
12-13 years (1st year second level schools)	MenACWY
12-13 years (1st year second level schools)	Tdap
12-13 years (1st year second level schools)	HPV9
2-17yrs	LAIV
All aged 65 years and older, HCWs, those in specific medically at-risk groups	Seasonal influenza vaccine
People 65yrs and older, People with high risk (Group A) for Invasive Pneumococcal Disease (IPD) as per the NIAC guidelines	PPV23

Valid at time of publication December 2022

Appendix B: Catch Up Immunisation Schedule

March 2022 – [Catch Up Immunisation Schedule](#)

In the absence of reliable information /documentation to the contrary, children should be assumed to be unimmunised and started on an age-appropriate catch-up programme.

If the child or adult has already received some doses of these vaccines these doses do not need to be repeated.

4 months to <12 months of age

DTaP/IPV/Hib/Hep B (6 in 1)	3 doses ≥8 weeks apart
Men B	2 doses ≥8 weeks apart (1 dose if ≥ 10 months), and all children require a booster at ≥12 months, ≥8 weeks after previous dose
MenC	1 dose at >6 months
PCV	2 doses 2 months apart
Rotavirus	2 doses if <8 months 0 days (1 dose if 7-<8 months)

Continue with routine childhood immunisations from 12 months of age

1 to <4 years of age

DTaP/IPV/Hib*/Hep B (6 in 1)	3 doses ≥8 weeks apart (*1 dose of Hib may be given if this is the only vaccine required)
MenB	2 doses ≥8 weeks apart if aged <2 years
MenC	1 dose (as Hib/MenC if both vaccines required)
MMR	1 dose
PCV	1 dose (only for at risk ≥2 years of age)

Continue with routine school immunisations from 4 years of age

- Booster DTaP/IPV at least 6 months and preferably 3 years after the primary course
- Second MMR at least one month after the first dose

4 – <10 years of age

DTaP/IPV/Hib*/HepB (6 in 1)	3 doses ≥8 weeks apart (*1 dose of Hib may be given if this is the only vaccine required) Booster of DTaP/IPV at least 6 months and preferably 3 years after the primary course
MenC	1 dose (as Hib/MenC if both vaccines required)
MMR	2 doses ≥28 days apart

Continue with the routine school immunisations.

10 - <18 years of age

MenC	1 dose <23 years of age if MenC containing vaccine not given at ≥10 years
MMR	2 doses ≥28 days apart
*Tdap/ IPV	3 doses at ≥28 days apart

Booster doses of Tdap/IPV after 5 years and Tdap 10 years later

18 years and older

MenC	1 dose <23 years of age if MenC containing vaccine not given at ≥10 years
MMR	2 doses ≥28 days apart (for health care workers born in Ireland since 1978 or born outside Ireland and for adults from low resource countries).
*Tdap/ IPV	1 dose, then Td/IPV, 2 doses ≥28 days apart

*Tdap/IPV vaccine is not available in Ireland since 1 August 2022, see Table 2.4a for advice

See NIAC Chapter 2, Table 2.4a NIAC Catch-up schedule for unvaccinated or incompletely vaccinated aged 10 years and older if Tdap/IPV is unavailable.

August 2022 – NIAC Catch up Immunisation Schedule

Those more than one month or dose behind schedule should be on a catch-up schedule, with minimum intervals between doses. Choose the age-appropriate column:

- If a person is completely unimmunised, vaccinate using the intervals stated below.
- If a person is incompletely vaccinated, provide vaccines not already received. There is no need to restart a course. Once catch-up has been completed, continue with the routine schedule.

NIAC Catch-up schedule for unvaccinated or incompletely vaccinated aged 4 months to < 4 years¹

Table 2.3 Catch-up schedule for unvaccinated or incompletely vaccinated aged 4 months to < 4 years

Vaccine	4 months to <12 months	1 to < 2 years	2-<4 years
DTaP/IPV/ HepB¹/Hib² 6 in 1	3 doses ≥8 weeks apart	3 doses ≥8 weeks apart ²	3 doses ≥8 weeks apart ^{1,2}
MenB	2 doses ≥8 weeks apart (if aged ≥ 10 months give 1 dose and a booster at ≥ 12 months 8 weeks after the first dose)	2 doses ≥8 weeks apart	
PCV	2 doses ≥8 weeks apart	1 dose	
Rotavirus³	2 doses 8 weeks apart (No dose after 8 months 0 days)		
MenC⁴	1 dose	1 dose	1 dose
MMR		1 dose	1 dose
NOTE	Continue with routine childhood immunisation schedule from 12 months	Routine school immunisations DTaP/IPV at least 6 months and preferably 3 years after primary course MMR2 ≥1 month after MMR1	

Details of superscripts are below Table 2.4

¹ The above table is taken from NIAC guidelines

NIAC Catch-up schedule for unvaccinated or incompletely vaccinated aged 4 years and Older

Table 2.4 Catch-up schedule for unvaccinated or incompletely vaccinated persons aged 4 years and older

Vaccine	4 -9 years	10 -17 years	18 years and older
DTaP/IPV/HepB¹/Hib² 6 in 1	3 doses ≥8 weeks apart ^{1,2}		
MenC³	1 dose	1 dose up to 23 years of age, if Men C containing vaccine not given at age ≥10years	1 dose up to 23 years of age, if Men C containing vaccine not given at age ≥10years
MMR	2 doses ≥28 days apart ⁴	2 doses ≥28 days apart	2 doses ≥28 days apart ⁵
Tdap/IPV⁶		3 doses ≥28 days apart	1 dose ⁷
Td/IPV			2 doses ≥28 days apart – leave ≥28 day gap after Tdap/IPV
NOTE	DTaP/IPV at least 6 months and preferably 3 years after primary course and MMR2 ≥ 1 month after MMR1	Booster of Tdap/IPV 5 years after primary course; Tdap 10 years later	

General Immunisation Procedures • August 2022

¹ Hep B vaccine is not needed if this is the only vaccine required unless in a risk group (Chapter 9)

² A dose of monocomponent Hib vaccine may be given to those aged 12 months to <10 years of age if this is the only vaccine required

³ Combined Hib/MenC can be given up to 10 years of age if these are the only two vaccines required

⁴ One dose if not yet in primary school; second dose will be given in junior infants

⁵ For HCWs or contacts in outbreaks born in Ireland since 1978 or born outside Ireland, and for adults from low resource countries without evidence of two doses of MMR vaccine

⁶ If Tdap/IPV is unavailable, see Table 2.4a

⁷ Only one dose of Tdap/IPV is required due to likely previous exposure to pertussis infection

Table 2.4a Catch-up schedule for unvaccinated or incompletely vaccinated aged 10 years and older if Tdap/IPV is unavailable

Vaccine	10-13 years	14 – 17 years	18 years and older
DTaP/IPV	3 doses ≥28 days apart		
Tdap		1 dose ¹	1 dose ¹
Td/IPV		3 doses ≥28 days apart – leave ≥28 day gap after Tdap ²	3 doses ≥28 days apart – leave ≥28 day gap after Tdap ²
MenC	1 dose up to 23 years of age, if Men C containing vaccine not given at age ≥10 years		
MMR	2 doses ≥28 days apart ³		
NOTE	Booster of Td/IPV 5 years after primary course; Tdap 10 years later		

¹ Only one dose of Tdap is required due to likely previous exposure to pertussis infection

² There may be increased reactogenicity due to four tetanus containing vaccines in a short time

³ For HCWs or contacts in outbreaks born in Ireland since 1978 or born outside Ireland; and for adults from low resource countries, without evidence of two doses of MMR vaccine

Appendix C: Professional Development Coordinators for General Practice Nurses (PDCGPN)

Professional Development Coordinators for General Practice Nurses by [CHO area](#)

Name	Address	Email	Phone	Fax	Mobile	CHO Areas
Kathy Taaffe	CHO 1, Office 12, Butt Building, Lower Main Street, Ballybofey. Co. Donegal	Kathy.taffee@hse.ie	071 9189014		087 1321424	Sligo, Leitrim, Cavan, Monaghan, Donegal (CHO1)
Marie Courtney	HSE Primary Care Unit, Block 15 (3rd Floor), St Finbar's Hospital, Douglas Road, Cork	Marie.Courtney@hse.ie	021 4923832	021 4923820	086 7872408	Kerry, Cork, North Lee, South Lee and West Cork (CHO 4)
Mary Cantwell	HSE Community Healthcare Organisation, Dublin North City and County 2nd Floor, Ballymun Healthcare Facility, Ballymun, Dublin 9	mary.cantwell@hse.ie	01 8467141		087 6078925	Dublin North City & County
Mairead Murphy	Community Health Care West (Galway, Mayo and Roscommon). St. Mary's Campus, Primary Care Services, Castlebar, Co. Mayo. F23XE39	Mairead.Murphy11@hse.ie			087 1206184	Community Health Care West (Galway, Mayo and Roscommon)

As of December 2022, all other areas are currently vacant

Appendix D: GP Practice administration issues

GP Practice administration issues

It is good practice to:

- A. Retain a register (preferably electronic using a GPIT accredited system) with client details which will allow for the easy identification and communication with people requiring vaccination. (See [Appendix M](#) for data entry standards used in HSE school immunisation programme).
- B. Ideally record the client's phone number and provide this to the HSE to enable SMS alerts and follow up either by the GP or the HSE. The client must be informed at the time of data capture that in providing the mobile phone number they consent to its use for these limited purposes.
- C. Confirm contact details with parents at every visit and notify HSE of any changes.
- D. Ensure that there is a system of alerts and that clients are vaccinated opportunistically. Where a child is overdue a vaccination, make all efforts to contact the parent and advise them that the child requires the next vaccinations.
- E. Ensure that Data Protection and client privacy and confidentiality is maintained as part of the service provided.
- F. Provide accurate immunisation details within one month to the HSE for uptake and payment purposes as appropriate using an approved methodology. This includes details of all immunisations carried out in General Practice with HSE supplied vaccine.
- G. Ensure that batch numbers and details are kept updated for cross validation purposes on the practice management system.
- H. Immunisation Outbreaks – a code will be given to all GPs from their local Department of Public Health when an outbreak occurs. This code is used to order required vaccine through the National Cold Chain, and payment is made through the PCRS browser with the code, batch number and expiry date.
- I. Notify the HSE of any reason to terminate the sending of communication and to allow accurate vaccine uptake statistics where;
 - a. a child moves out of the area
 - b. a child dies
 - c. the vaccine is refused
 - d. the vaccine is contraindicated

Appendix E: Sample medicine protocol

Sample medicine protocol

Medicine Protocol for the administration of (insert name of vaccine) vaccination by registered general nurses employed as Practice Nurses in General Practice services contracted by the HSE.

This medicine protocol is a specific written instruction for the administration of (insert name of vaccine) vaccine to groups of patients who may not be individually identified before presentation for treatment.

This medicine protocol enables registered nurses and midwives in the primary care services of a General Practitioner holding an HSE Immunisation Contract to administer (insert name of vaccine) with reference to and guidance from The Nursing and Midwifery Board of Ireland.

An Bord Altranais (2007) Guidance to Nurses and Midwives on Medication Management. Dublin: An Bord Altranais Nursing and Midwifery Board of Ireland (2021) Code of Professional Conduct and Ethics for Registered Nurses and Registered Midwives. Dublin: Nursing and Midwifery Board of Ireland available online <https://www.nmbi.ie/Standards-Guidance/Code>

Nursing and Midwifery Board of Ireland (2020) Guidance for Registered Nurses and Registered Midwives on Medication Administration. Dublin: Nursing and Midwifery Board of Ireland available at: <https://www.nmbi.ie/Standards-Guidance/Medicines-Management>

Nursing and Midwifery Board of Ireland (2022) Practice Standards for Midwives Dublin: Nursing and Midwifery Board of Ireland available at: <https://www.nmbi.ie/Standards-Guidance/Midwives-Standards>

Nursing and Midwifery Board of Ireland (2015) Scope of Nursing and Midwifery Practice Framework. Dublin: Nursing and Midwifery Board of Ireland available at: <https://www.nmbi.ie/Standards-Guidance/Scope-of-Practice>

Nursing and Midwifery Board of Ireland (2015) Recording Clinical Practice. Guidance to Nurses and Midwives. Dublin: Nursing and Midwifery Board of Ireland available at: <https://www.nmbi.ie/Standards-Guidance/More-Standards-Guidance/Recording-Clinical-Practice>

National Immunisation Advisory Committee Immunisation Guidelines for Ireland. Dublin: Royal College of Physicians of Ireland National Immunisation Advisory Committee (Online Update available at: <https://www.hse.ie/eng/health/immunisation/hcpinfo/guidelines/>)

Summary of Product Characteristics and Patient Information Leaflet as detailed by the Health Products Regulatory Authority are available at www.hpra.ie.

The Nursing and Midwifery Board defines medicine protocols as “written directions that allow for the supply and administration of a named medicinal product by a nurse or midwife in identified clinical situations. A medicine protocol involves the authorisation of the nurse/midwife to supply and administer a medication to groups of patients in a defined situation meeting specific criteria and who may not be individually identified before presentation for treatment. An individually named prescription is not required for the supply and administration of medication when a medicine protocol is in effect” (The Nursing and Midwifery Board, 2007, p35).

For further information on Medicine Protocols and their use in general practice please contact your local Professional Development Coordinator for General Practice Nurses.

1.0 Critical Elements
Name of Organisation where protocol applies
Date the protocol comes into effect
Date for review of protocol* (* 2 years from date of production or when required if new information becomes available)
Names and signatures of protocol authors and reviewers
Name(s) and Signature(s) of the employing authority who is authorising the implementation of the protocol

2.0 Clinical Criteria
Clinical Condition for use of the protocol
Circumstances in which the medicine protocol applies
Inclusion criteria for patient/service user treatment using the protocol
Exclusion criteria for patient/client treatment using the medicine protocol
Actions to be taken for those who are excluded from the Protocol
Precautions
Documentation required to support implementation of the medicine protocol

3.0 Details of Medication to be supplied	
Name of Medication	
Instructions for administration of the vaccine	N.B. A General Practitioner or other suitably qualified medical practitioner must be on the practice premises during the administration of vaccines and during the 15-minute post vaccination observation period to assist with any adverse events which may result from vaccination administration.
Warnings and precautions for use	
Possible Side Effects	
Potential adverse reactions and procedures for treatment of same	

Procedure for reporting Adverse Drug Reactions to the HPRA

Procedure for the reporting and documentation of errors and near misses involving the medication

Mechanisms for storage of medications and for obtaining supply

Resources and equipment required

Audit process to identify appropriate use of the protocol or unexpected outcomes

4.0 Patient/service-user care information

Advice to be given to the patient/ service user and/or carer before and/ or after treatment

Provision of Patient Information Leaflet/Fact Sheet

Details of any necessary follow-up, action and referral arrangements

5.0 Staff authorised to use protocol

Staff authorised to use protocol

Professional qualifications, training, experience and competence relevant to this medicine protocol

Requirements for staff for continuing training and education for supplying medication using protocol

Appendix F: Self-assessment of competency to supply and administer vaccinations under medicine protocol

Self-assessment of competency to supply and administer vaccinations under medicine protocol

I have attended an Immunisation Study Day/Update in the past 2 years? Yes No

I have attained/have plans to attain competencies noted in 'Guidelines for Immunisations carried out in General Practice' and in practice Medicine Protocols Yes No

Date of planned training:

Domain of Practice	Performance Criteria: Critical Element	Needs Theory Date/ Initial	Needs Practice Date/ Initial	Competent Date/Initial
1, 2, 4, 5	I understand the role and function of medicine protocols in the context of Nursing and Midwifery Board guidelines: <ul style="list-style-type: none"> • The Code of Professional Conduct • Guidance to Nurses and Midwives on Medicine Management • Scope of Nursing and Midwifery Practice 			
1, 2, 4, 5	I carry out vaccination according to 'Guidelines for Immunisations carried out in General Practice'.			
1, 2, 4, 5	I can utilise the guidance document produced by NIAC "Immunisation Guidelines for Ireland" in application of practice.			
1, 2, 4	I am aware of and comply with the guidance on ordering, storage and stock rotation of vaccines.			
1, 2, 3, 4	I can obtain informed consent from parent/guardian including the information regarding the indications.			
1, 2, 3	I can explain the expected side effects post vaccination and management of same.			
1, 2, 4	I am aware of all vaccines given in general practice and their role in the management of vaccine preventable illness.			
1, 2, 4	I can outline the inclusion/exclusion criteria for use of the medicine protocols.			

1, 2, 3, 4	I can refer those who are excluded from the protocol to GP for individual assessment.			
1, 2, 3, 4	I can undertake a clinical assessment of a patient within the scope of the medicine protocols.			
2, 4	I am aware of the correct dosage of each vaccine.			
1, 4	I am aware of the correct preparation/reconstitution of vaccines.			
2, 4	I can prepare all vaccines using aseptic technique.			
1, 2, 4	I can follow the correct procedure for the intramuscular administration of vaccine(s).			
1, 2, 3	I am aware of potential adverse reactions in relation to vaccination.			
1, 2, 4	I am aware of the procedures for treatment of adverse reactions			
1, 2, 3	I understand the procedure for reporting and documentation of medication errors/near misses.			
1, 2, 3	I understand the procedure for the reporting and documentation of adverse drug reactions.			
1, 2, 3, 4	I am aware of relevant written/oral instructions to be given to patients, parents/guardians regarding completion of their vaccination programme.			
1, 4	I dispose of all equipment and sharps in accordance with standard precautions and local policies.			
1, 2, 4	I record the administration of vaccines as required by practice and HSE documents and update patients record as appropriate.			

I have sufficient theoretical knowledge and practice to undertake this role, and

I acknowledge my responsibility to maintain my own competence in line with the Scope of Nursing Practice

Practice Nurse's Signature:

Date:

If any deficits in theory and/or practice identified, the nurse must discuss with the authorising General Practitioner and implement an appropriate action plan to achieve competency within an agreed time frame.

Action necessary to achieve competency:

Date to be achieved:

Supporting evidence of measures taken to achieve/enhance competency:

General Practice Nurse's Signature:

Date:

Appendix G: Roles and Responsibilities of HSE Staff

Roles and Responsibilities of HSE Staff

1. Introduction

This section outlines the roles and responsibilities of HSE staff to ensure the safe and effective delivery of the immunisation programme. Roles and responsibilities may be assigned on a local basis according to the professional qualifications and expertise of staff.

2. Managerial role and responsibilities

- A. Area Managers should ensure that all administrative staff involved in the immunisation programme carried out in general practice are aware of these guidelines and should facilitate any training required.
- B. Directors of Public Health Nursing should ensure that all Assistant Directors of Public Health Nursing with responsibility for immunisation are aware of these guidelines and should facilitate any training required.
- C. Professional Development Coordinators for Practice Nurses should be familiar with these guidelines and should facilitate any training required in collaboration with the local Department of Public Health and the local immunisation coordinators.

3. Role of HSE clerical/administrative staff

HSE clerical/administrative staff should:

- A. Create and maintain a database of children born in the state.
- B. Add clients to the database (new entrants to Ireland, EU originating, Immigrants, Asylum Seekers, etc.) as they become aware of same.
- C. Provide immunisation information (either via the public health nurse, publications or by mail) to parents/legal guardians.
- D. Send out invitations/alerts for vaccination events to parents/legal guardians.
- E. Liaise with general practice in relation to changes, developments, events etc.
- F. Provide a means of making vaccination returns for uptake and payment purposes. Distribute return forms.
- G. Provide a relevant Privacy Statement for general practice.
- H. Ensure that GPs are set up with appropriate immunisation contracts, including ensuring that all necessary checks are done at appropriate intervals e.g., indemnity, registered with the Medical Council etc.
- I. Ensure that GPs with immunisation contracts are appropriately set up with the NCCS.
- J. Provide vaccine and vaccination related information to GPs.
- K. Retain a register of all Immunisation Service Providers and their related details including; Practice(s) name(s) and address(es), registration details, cold chain and immunisation account numbers and details, payment account and details, messaging ID for both GP and practice.
- L. Provide payment for vaccinations given as appropriate.
- M. Provide detailed payment information both online and manually to all GPs and GP Practices and answer queries relating to same.

- N. Where possible, advise general practice of any deaths relevant to them.
- O. Follow up on non-starters, late-starters, defaulters in conjunction with general practice via Assistant Director of Public Health Nursing with responsibility for immunisation.
- P. Provide information in relation to defaulters, uptake blackspots, outbreaks as appropriate.
- Q. Ensure that when a client has moved out of area and address of new location is known that client details are sent to the immunisation section for the new location.
- R. Ensure that when a client has died that this is flagged on the patient file and other relevant HSE sections are notified.

4. Role of the HSE Assistant Director of Public Health Nursing with responsibility for immunisation

The Assistant Director of Public Health Nursing with responsibility for immunisation should:

- A. Ensure that all public health nurses receive any relevant guidance regarding the childhood and adult immunisation programmes.
- B. Ensure that all public health nurses obtain details of the child's general practitioner at the first public health nurse visit and that this is relayed to the immunisation section.
- C. Ensure that all public health nurses distribute the booklet '*Your Child's Immunisation – A Guide for Parents*' at the first public health nurse visit.
- D. Ensure that all public health nurses provide advice at the first PHN visit on the importance of vaccination and at each subsequent encounter with parents/legal guardians and adults.
- E. Develop good working relationships with the general practice team in the area and provide support in relation to clinical queries, best practice etc.
- F. Obtain the monthly listing of those children who have defaulted from the immunisation programme.
- G. Follow up defaulters with local public health nurse and general practice team.
- H. Liaise with Practice Nurse Development Coordinator for the area. See **Appendix D** Professional Development Coordinators for GPNs for CHO 1-9 area

Appendix H: HSE Area Immunisation Unit Directory

HSE Area Immunisation Unit Directory

Visit <https://www.hse.ie/eng/health/immunisation/whoweare/lhos.html>

Appendix I: Departments of Public Health

Department of Public Health Contact details

Visit <https://bit.ly/DPHContact>

Appendix J: PCI Vaccination Refusal Form

Primary Childhood Immunisation (PCI) Schedule Vaccination Refusal Form

Privacy Statement: HSE staff are aware of their obligation under the Data Protection Acts, 1988-2018 (including GDPR). The information provided will be included in an Immunisation Database. The HSE will use this information to validate clients, monitor vaccination programmes and provide health care.

Child's Forename		Middle name	
Surname		Child's Date of Birth	/ /
Child's Gender	(Please tick): Male <input type="checkbox"/> Female <input type="checkbox"/>		
Address			
GP's Name & Address			

I acknowledge that I am aware of the following facts:

- I understand that the Primary Childhood Immunisation schedule will protect my child from Diphtheria, Tetanus, Pertussis (whooping cough), Polio, Haemophilus influenzae type b, Hepatitis B, Meningococcal B, Pneumococcal, Rotavirus, Meningococcal C, Measles, Mumps, and Rubella diseases.
- I understand that by not having the Primary Childhood Immunisation schedule my child will be at risk of contracting vaccine preventable diseases.
- I understand that by not having the Primary Childhood Immunisation schedule my child can spread these vaccine preventable diseases to other vulnerable children and adults.

I refuse the following vaccines (please circle as appropriate):

6in1 Men B PCV Rotavirus Men C MMR Hib/MenC

6 in 1 Diphtheria, Tetanus, Pertussis (whooping cough), Polio, Haemophilus influenzae type b, Hepatitis B vaccine

MenB Meningococcal B vaccine PCV Pneumococcal conjugate vaccine MenC Meningococcal C vaccine

MMR Measles, Mumps, Rubella vaccine Hib/MenC Haemophilus influenzae type b/ Meningococcal C vaccine

I am choosing to refuse vaccination for the following reasons:

I understand I can arrange for my child to be vaccinated through my GP if I change my mind at a later date.

I have read and fully understand the information on this refusal form and am authorised to refuse vaccination on behalf of the above-named child.

Signature:

Date:

DD/MM/YYYY

Name (please print)

(Please circle) Parent

Legal Guardian

Appendix K: Temperature Log template

Fridge ID:	Month:
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AM							PM						Comments
Day	Temperature °C			Min/ Max Reset	Time	Initials	Temperature °C			Min/ Max Reset	Time	Initials	
	Min	Max	Current				Min	Max	Current				
1													
2													
3													
4													
5													
6													
7													
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31													

Monthly readings reviewed by:		Date:	
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Note: When a temperature reading is missed, retain the log entry as a blank.

Appendix L: HSE Cold Chain/Fridge Breakdown/Power Failure Form

An editable version of the form is accessible at: <https://bit.ly/3xP2SG1>

Appendix M: Data Entry Standards

Data Entry Standards used in HSE School Immunisation Programme

Data accuracy is especially important. Care should be given to the correct spelling of client demographic details and GP details. All Mandatory Fields must be completed correctly with meaningful and accurate data. In addition to the mandatory fields, users should make every effort to input as much client information as possible. If additional information is entered on forms in notes fields or on the back of the form where there is no data entry field available this information should be entered into the notes field

Data entry of names:

Ensure that the name entered in the Surname field is the family name and that the name entered in the First Name field is the first or given name of the client.

Surname Data Entry Convention to be followed

Surnames should be input without any spelling abbreviations, commas, apostrophes, dashes etc. No characters other than alpha characters (letters) are acceptable in the surname field.

- Names prefixed with 'Al' should be entered as 'Al' [space] Hussain i.e., 'Al Hussain'
- Names prefixed with 'Mc' should be entered as 'Mc' [space] i.e., 'Mc Carthy'
- Names prefixed with 'Mac' should be entered as 'Mac' [space] i.e., 'Mac Amhlaigh'
- Names prefixed with 'O' [apostrophe] should be entered as 'O' [space] i.e., 'O Connor'
- Names prefixed with 'D' should be entered as 'D' [space] i.e., 'D Eathe'
- Names prefixed with 'Ni' should be entered as 'Ni' [space] i.e., 'Ni Bhroin'
- Names prefixed with 'Nic' should be entered as 'Nic' [space] i.e., 'Nic Ailin'
- Names prefixed with 'De' should be entered as De [space] i.e., 'De Burca'
- Double barrel names should also be entered without commas, apostrophes, dashes etc.
- Enter with a space between names i.e., 'Tierney Monahan' not 'Tierney-Monahan'

First Name Data Entry Convention to be followed

Forenames must be entered in full. Initials or spelling abbreviations are not acceptable e.g., type Michael not MI, Margaret not Mags, Patrick Joseph and not Patk J. etc. Junior/Senior: Where the suffix is used in a client's name, it must be typed in full with brackets directly after the forename e.g., Michael (Junior) or Patrick (Senior). Ensure that the proper first name is given and recorded not the "known as" name i.e., Margaret rather than Mags. When the client uses an alias which differs from their official forename, this may need to be recorded for correspondence and identification purposes. In such cases, the alias name should be typed in brackets directly after the official forename e.g., Margaret (Peggy). Please note that aliases are not to be confused with name abbreviations such as Robert (Bobby).

Supporting Information for Vaccinations in General Practice

Date of Birth should be entered in the European format i.e., DD/MM/YYYY

Mobile Numbers may be used to send short SMS messages therefore it is important that they are collected and recorded accurately. Enter number as 0861234567 leaving no space between numbers (do not enter anything else into this field).

Address Abbreviations for addresses are not acceptable. All mandatory address fields must be completed correctly, and information typed in the appropriate fields. All elements of the address must be typed in full without any dashes, hyphens etc. e.g., Saint Mary's Street.

The following common address must be entered in full: Avenue, Apartments, Circular, Cottages, Court, Crescent, Drive, East, Estate, Garden, Glade, Grove, Heights, House, Lawn, Lower, Middle, North, Parade, Park, Place, Road, Saint, Square, Terrace, Upper, Walk, West.

Apartment Number. If the client address contains an apartment number, type the word Apartment and the appropriate number in the Apartment field e.g., Apartment 7.

Care of. Some clients may be residing 'care of' someone or somewhere. This should be entered as c/o. When entering a c/o location, type this information in the first line of the address i.e., c/o Mary Burke.

Appendix N: Consent Issues

Under normal circumstances the parent(s) of a child can give consent for vaccination on their child's behalf. For children aged under 16, consent must be obtained from a parent or legal guardian. Under current Irish law, the mother is given automatic parental responsibility for the child.

The father is also given parental responsibility if he is married to the mother at the time of the child's birth or if they marry after the birth of the child or if both adults adopt the child together.

However, if a child is born outside marriage the mother is given automatic responsibility for all decisions relating to the child. The child's father is an automatic legal guardian if he has lived with the child's mother for 12 consecutive months including at least 3 months with the mother and child following the child's birth.

This provision is not retrospective, so guardianship will only be acquired automatically where the parents live together for at least 12 months after 18 January 2016.

Under certain circumstances legal guardianship of the child may be changed e.g., an unmarried father can become a joint guardian if both parents sign a statutory declaration, if one parent dies the remaining parent will automatically assume sole legal guardianship of the child or another legal guardian can also be appointed by the court

Supporting Information for Vaccinations in General Practice

The information materials produced by NIO have been approved by the National Adult Literacy Agency (NALA). HIQA and NALA Guidance for providers of health and social care services. Communicating in plain English states that “One in six people find reading and understanding everyday texts difficult: for example, reading a health leaflet, bus timetable or medicine instructions. One in four has difficulties in real world math from simple addition and subtraction to the calculation of averages”. Many adults therefore would have difficulty understanding the technical details in the Patient Information Leaflet. Additional information can be accessed through websites including, www.immunisation.ie/ www.hpra.ie and www.medicines.ie