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GP Vaccination Guidance 2024/2025				
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1. Executive Summary

This support document, first developed by a multidisciplinary committee in 2012-2013, covers the key issues and best practice for General Practice Nurses (GPNs) and General Practitioners (GPs) providing immunisation in primary care as part of the HSE funded Primary Childhood Immunisation Programme (PCIP) and other HSE funded programmes.

The guidelines should be read in conjunction with the guidance issued by the <u>National Immunisation Advisory</u> <u>Committee</u> (NIAC) of the Royal College of Physicians of Ireland (RCPI) and contained in the <u>Immunisation Guidelines</u> for Ireland.

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.

This support document has been updated in September 2024 to include the <u>NIAC</u> recommended changes to the primary childhood immunisation programme (PCIP), for children born on or after the 1st of October 2024.

Summary of the key changes to the PCIP:

- The MenC vaccine will no longer be given at the 6-month visit.
- NIAC advise that it is now known that giving one dose of MenC vaccine in the 2nd year of life (at 13 months), with a booster dose of MenC vaccine (in the MenACWY vaccine) in adolescence, provides protection against severe meningococcal C disease and establishes herd immunity which helps to protect younger children.
- Varicella vaccine will be offered at 12 months of age with MMR and MenB vaccines. This will reduce the significant burden of Varicella (Chickenpox) zoster virus morbidity and its complications1.
- A fourth dose of 6 in 1 vaccine will be offered at 13 months of age. Hib/MenC vaccine will no longer be available from 2026. The 6in1 vaccine will provide Hib vaccine and offer enhanced protection in young children from diphtheria, pertussis and paralytic polio.

Note: Children born on or prior to the 30th of September 2024 will continue on the previous Primary Child Immunisation Programme schedule.

The maintenance of cold chain and vaccine ordering section has been updated in accordance with the latest HSE guidance.

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¹ The second dose of Varicella (Chickenpox) vaccine will be given as a combined MMR and Varicella vaccine (MMRV) when children are aged 4-5 years, in junior infants in primary school.

2. Introduction

2.1. Purpose

This purpose of this support document, first developed by a multidisciplinary committee in 2012-2013, is to cover the key issues and best practice for General Practice Nurses (GPNs) and General Practitioners (GPs) providing immunisation in general practice as part of the HSE funded Primary Childhood Immunisation Programme (PCIP), and other HSE-funded programmes.

The guidelines should be read in conjunction with the guidance issued by the <u>National Immunisation Advisory</u> <u>Committee</u> (NIAC) of the Royal College of Physicians of Ireland (RCPI) and contained in the <u>Immunisation Guidelines</u> for Ireland.

2.2. 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) and other HSE funded programmes.

2.3. Objective

The objective of this document is to support GPs and GPNs in the administration of vaccinations in primary care on behalf of the HSE, as part of the Health Service Executive, Health Protection Strategy 2022-2027.

The following vaccination programmes are included:

- Primary Childhood Immunisation Programme
- Schools Immunisation Programme²
- Seasonal influenza and Pneumococcal Polysaccharide Vaccination (PPV) campaigns
- COVID-19 vaccination programme
- Vaccinations in Pregnancy
- Vaccination of persons coming to Ireland from other countries, as per the Irish schedule
- Vaccination of late entrants/missed the standard vaccination schedule
- · Vaccinations carried out as Public Health response to an outbreak

²In Donegal, Sligo and Leitrim the primary school vaccinations are administered in general practice.

This document provides information on the relevant training for vaccinators, vaccine schedules in conjunction with the guidance issued by NIAC and the storage and administration of vaccines included in HSE funded immunisation programmes.

Having reviewed this supporting document the vaccinator will be able to:

- Ensure they are aware of the education and training requirements required to administer vaccines
- Ensure safe & effective delivery of vaccinations in the primary care setting in accordance with NIAC guidance.
- Optimise vaccine uptake and address vaccine hesitancy.
- Reduce and prevent the occurrence of vaccine preventable diseases in Ireland.

2.4. Communication and Dissemination

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

- 1. This online supporting document available on www.immunisation.ie.
- 2. National Immunisation Office (NIO) emails, Ezine bulletin and social media accounts.
- 3. Irish College of GP's Website/Ezine/ Forum Magazine.
- 4. Update to programme letters sent from NIO and Irish Medical Organisation (IMO)
- 5. Practice Development Coordinators for General Practice Nursing (PDCGPN) mailing lists and webinars

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.immunisation.ie/
www.medicines.ie
www.medicines.ie

3. Immunisation Schedules

3.1. Introduction

In Ireland, the National Immunisation Advisory Committee (NIAC) provides evidence-based advice to the Chief Medical Officer (CMO) and Department of Health (DoH) on, immunisation and related health matters to inform health policies in Ireland. NIAC prepares this advice through extensive review of the latest clinical and scientific information. NIAC develop and publish the Immunisation Guidelines for Ireland online at https://www.rcpi.ie/Healthcare-Leadership/.

NIAC provides comprehensive and reliable information on immunisation for healthcare professionals, while advocating for best immunisation practices.

Additional information on NIAC's membership, purpose, governance and responsibilities is outlined in their <u>Terms of</u>
Reference

The <u>Immunisation Guidelines for Ireland</u> is available online as chapters are regularly updated, it is essential that all healthcare professionals involved in immunisation, ensure that they are referring to the most up-to-date guidance. Printing chapters is not recommended as they may become quickly out of date.

NIAC make recommendations to the DoH on immunisation policy in Ireland and, if endorsed by the DoH, the Health Service Executive (HSE) is responsible for the implementation of such policy. The National Immunisation Office is responsible for managing vaccine procurement and distribution, developing training and communication materials along with the relevant HSE teams for the public and health professionals of all National Immunisation Programmes in line with Department of Health Immunisation Policy. The NIO also provides support to healthcare professionals about HSE funded immunisation programmes, via email to immunisation@hse.ie.

All healthcare professionals are encouraged to promote and support the recommended child and adult immunisation schedules for Ireland.

3.2. Primary Childhood Immunisation Programme (PCIP)

The average birth rate in Ireland (2013-2023) is 61,308, births per year (CSO, Vital Statistics Yearly Summary 2023). The World Health Organization (WHO) has set a target uptake of 95% for primary childhood immunisation to prevent outbreaks of vaccine preventable diseases.

The PCIP vaccinations are routinely delivered in primary care by GPs in the first two years of life with catch up vaccination administration funded to age of 10 years.

Figure: 2 New PCIP schedule

The PCIP schedule is designed to protect each child from vaccine preventable diseases specific to Ireland. Two schedules will run concurrently for the PCIP.

Children born on or prior to the 30th of September 2024 will continue on the old PCIP schedule while children born on or after the 1st of October 2024 will follow the new NIAC recommended PCIP.





Figure 2 summarises the changes to the PCIP for all children born on or after the 1st October 2024.

- Visit 1 (2 months of age) remains unchanged.
- · Visit 2 (4 months of age) remains unchanged.
- Visit 3 (6 months of age) has changed. These children will receive the 6-in-1 and PCV vaccines, but the MenC vaccine will no longer be given at this visit. Children born on or after 1st October 2024 will now receive only 2 injections at this visit.
- Visit 4 (12 months of age) has also changed. Due to the incorporation of varicella vaccination into the schedule, these children will now receive an MMR, varicella and MenB vaccine. Children will now receive a total of 3 injections at the 12-month visit.
- Visit 5 (13 months of age) has also changed. Children will now receive the PCV, MenC and 6-in-1 vaccines. They
 will no longer receive the combined Hib/MenC vaccine. This means that children will now receive a total of 3
 injections at the 13-month visit.

There is no catch up for chicken pox vaccine for those on the old schedule (born before 1st October 2024).

The quarterly and annual statistics on vaccine uptake rates for Ireland are produced by the Health Protection Surveillance Centre (HPSC). The latest HPSC statistics are available here. Quarterly uptake is reported on children 12 months and 24 months of age. Annual uptake figures are calculated from the quarterly data and are published separately and can be found here Annual Reports - Health Protection Surveillance Centre

The completeness of the data submitted for uptake reporting is subject to timely vaccine record returns from GPs, and timely database input at HSE Local Immunisation Offices (LIO). Vaccine record returns should be sent to each HSE LIO no later than the seventh working day of each month to facilitate routine monitoring of uptake and in particular, to identify children who have not been immunised.

HSE LIOs will generate a list of children between 16-32 months who are missing vaccinations, and issue same to GPs on a monthly basis. GP practices should review and update this list with those children whose parents or guardians have refused vaccination, moved to a different area, changed GP, have contraindications for vaccination, or any other reasons for delay in vaccination. This updated list should be returned to the HSE LIO.

Every effort should be made to ensure that all children are age appropriately immunised. Practices should make contact with parents or guardians of children who have missed a vaccination to arrange catch up vaccinations as early as possible. All catch up vaccinations should be administered in line with the catch-up schedule (see Appendix B) available at: https://www.hse.ie/eng/health/immunisation/hcpinfo/frequentlyaskedquestions/catchupvacc/

Where GPs have been unable to make contact with a parent or guardian, they should inform the HSE LIO, to allow for PHN and HSE Live follow up.

3.3. School Immunisation Programme

The Schools Immunisation Programme is part of a national strategy to protect children from infectious diseases through vaccination. Specifically the Schools Immunisation Programme protects against the following diseases with the named vaccines in primary and secondary school (outlined in Appendix A)

Junior infants' class

- · Measles, mumps rubella with MMR vaccine
- Tetanus, diphtheria, polio, pertussis with DTaP/IPV vaccine

First year students in secondary school or age equivalent in special schools or home educated

- Tetanus, diphtheria, pertussis with Tdap vaccine
- Human papillomavirus (HPV) with HPV9 vaccine
- Meningococcal A, C, W and Y infection with MenACWY vaccine

School going children receive vaccinations as outlined in "Supporting Information for Staff – Schools Vaccination Programme" available here.

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

3.4. Seasonal Influenza Vaccination, COVID-19 Vaccination and Pneumococcal Polysaccharide Vaccination (PPV) campaigns

Each influenza season, the HSE offers influenza vaccine for all those at higher risk of influenza and its complications, either because of age (older people), or in <u>medically at risk groups</u>, pregnant women, health care workers and carers. Since the 2020/21 influenza season, children are offered LAIV vaccine licensed from the age of 2 to 17 years inclusive.

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 the choice to attend either their GP or pharmacist. For healthcare workers the flu vaccine may be provided onsite at work or is available from their local pharmacy or GP.

Live Attenuated Influenza Vaccine (LAIV)

NIAC recommends LAIV for all children aged 2 to 17 years. Each year the HSE provides those eligible in this age group with a free LAIV vaccine.

Please check eligibility age groups for free vaccine each flu season before administering influenza vaccine. Recipients can receive this vaccine either from their GP or pharmacist. LAIV may also be administered in schools by HSE teams, GP's or pharmacists. Each influenza season, plans for influenza vaccination are communicated to GPs.

Pneumococcal Polysaccharide Vaccine Programme

Pneumococcal polysaccharide vaccine (PPV23) is delivered in general practice settings for all those aged 65 and older and all those aged 2 to 64 years at increased risk of invasive pneumococcal disease as per the recommendations in the Pneumococcal chapter of the Immunisation Guidelines.

For routine adult pneumococcal vaccine administration in those aged 65 and older, 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 <u>Pneumococcal chapter</u> 16 of the <u>Immunisation Guidelines</u>.

This vaccine can be obtained from the National Cold Chain Service (NCCS) free of charge, for all those who are eligible. Reimbursement for administration of PPV23 is available for GMS or DVC eligible patients. The PPV23 vaccine can be co-administered with both the Influenza and COVID-19 vaccine

COVID-19 vaccination programme

NIAC recommends antigenically updated COVID-19 mRNA vaccines to protect against COVID-19.

Recommendations on primary vaccination, and seasonal booster vaccination, including eligible groups for whom booster vaccination is recommended, can be found in the NIAC guidelines.

When autumn COVID-19 booster vaccines are being administered, COVID-19 and adult seasonal influenza vaccines should be co-administered where practicable, to maximise uptake. COVID-19 vaccines and other adult vaccines (except mpox vaccine) may be administered at the same time or at any interval. Co-administered vaccines should be given in different arms.

No interaction studies in young children have been performed on co- administration of COVID-19 vaccines with childhood vaccines. Priority should be given to other routine childhood immunisations. Until there is more evidence it is prudent to separate COVID-19 vaccination in children aged 6 months-4 years from other vaccines for a period of 14 days.

For more details, please refer to the NIAC Chapter 5a of the Immunisation Guidance.

3.5. Vaccination in Pregnancy

Tdap vaccine (Boostrix) is recommended for all pregnant women, ideally between 16-36 weeks' gestation, in every pregnancy to reduce the morbidity and mortality in infants too young to be vaccinated and to reduce the risk of pertussis infection in the mother. Pertussis vaccine should be offered to women in the week after birth if they have not had a pertussis vaccine during pregnancy to protect themselves and their baby. For more details about Tdap vaccine in pregnancy 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. If women are pregnant over two flu vaccination seasons they should receive the appropriate vaccine for each season.

Pregnant women are recommended to be up to date with COVID-19 vaccination and are recommended a booster dose once in pregnancy ideally between 20- 34 weeks' gestation. Please refer to <u>Immunisation Guidelines</u> for details chapter 5a of the Immunisation Guidance.

Flu vaccine, COVID-19 and Tdap vaccines can be co-administered or given at any interval.

MMR should <u>NOT</u> be given in pregnancy as it is a live vaccine. MMR vaccine can be safely administered at least one month prior to pregnancy in female patients who have not been fully immunised. Women who give no history of having received at least one dose of MMR vaccine or have no history of rubella infection, should receive one dose of MMR. To protect against measles for those who have never had the MMR vaccine or measles disease, two MMR doses 28 days apart are needed after the birth if not given prior to pregnancy.

MMR vaccination of women who are non-immune to rubella and have no history of vaccination with the MMR vaccine is recommended as outlined by NIAC Guidance on Rubella vaccination.

"If a woman has documented evidence of having received one dose of a rubella-containing vaccine, irrespective of rubella serology, no further rubella (MMR) vaccine is necessary.

Two doses may be needed for protection against measles and mumps".

Pregnancy should be avoided for one month after MMR.

Serological testing after routine MMR vaccination is not recommended.

3.6. Vaccination of persons coming to Ireland

The HSE is offering catch up vaccination to people who are Refugees and Applicants Seeking International Protection. The NIO have developed information for healthcare professionals and for the public.

Children and adults coming to Ireland who do not have a documented or reliable verbal history of past immunisation, should be assumed to be unimmunised. Individuals living in Ireland who are identified as having had no previous immunisations or an incomplete primary course, should have arrangements made to ensure they are age-appropriately vaccinated in line with the Irish catch-up schedule (see Appendix B) available at https://www.hse.ie/eng/health/immunisation/hcpinfo/frequentlyaskedquestions/catchupvacc/ and chapter 2 of the immunisation guidance table.

Vaccination of late entrants to the primary childhood immunisation programme

- 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.
- Refer to the NIAC Chapter 2 for the latest NIAC catch-up schedule. https://www.rcpi.ie/Healthcare-Leadership/NIAC/Immunisation-Guidelines-for-Ireland

Key principles for catch-up vaccination

If a dose of MMR vaccine is given before the first birthday, either because of travel to an endemic country or because of a local outbreak, two further doses should be given at 12 months of age or older (at least four weeks after the first dose) and at 4 to 5 years of age

Pneumococcal Conjugate Vaccines (PCV) 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 PCV only, regardless of the number of doses of PCV vaccine they received in their first year of life.

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

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

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

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

A child over the age of 1 year, needs a single dose of Men C 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) containing vaccine 1 dose from 1 ≤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 counties is available from WHO portal at

https://immunizationdata.who.int/global?topic=Vaccination-schedule&location= at https://bit.ly/WHOVacc

Other vaccines

GPs and GPNs may also provide vaccinations as part of a Public Health response in the event of an outbreak e.g., measles, pertussis, Hepatitis A, Hepatitis B, or meningococcal disease. GPs/GPNs, in collaboration with the Departments of Public Health, may 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 <u>National Immunisation</u> <u>Guidelines</u>.

4. Carrying out Vaccination in General Practice

4.1. Introduction

This section outlines the roles and responsibilities of general practice staff to ensure the safe and effective delivery of immunisation programmes.

Roles and responsibilities are assigned on a local basis according to the professional qualifications, training and experience of practice staff. Vaccinations must be administered by healthcare professionals who have completed the appropriate training and competencies (i.e. General Practice Nurses or General Practitioners).

For a registered nurse or registered midwife to administer vaccines: They must be prescribed by a Doctor or a Registered Nurse Prescriber OR A Medicines Protocol (MP) should be in place.

Medicine Protocols are 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 or 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. The underlying guidance for same comes from the NMBI Guidance for Medicines Management at https://www.nmbi.ie/nmbi/media/NMBI/Publications/Guidance-Medicines-Management.pdf?ext=.pdf Section 4 of this

You are advised to review the NMBI guidance document on Medicines Management (2020): https://www.nmbi.ie/Standards-Guidance/Medicines-Management

And

centres on MPs.

The HSeLanD PPPG programme is a very useful foundation for the development and review of any practice guidance: https://www.hseland.ie/ekp/servlet/ekp?PX=N&TEACHREVIEW=N&PTX=&CID=EKP0000000658&TX=FORMAT1&LANGUAGE_TAG=0&DECORATEPAGE=N

If you have any queries in relation to Medicine Protocols, please contact your nearest Professional Development Coordinator for GP nursing (PDCGPN)

Training, HSE guidance and supports for vaccination in general practice have been developed for GPs and registered nurses or registered midwives. There is no nationally developed, agreed or recognised training programme for any other healthcare profession to give vaccines in general practice. There is no nationally developed, agreed or recognised training programme for healthcare assistants, GP assistants or any other non-registered healthcare professional to administer vaccines in general practice and there is no statutory instrument that covers the administration of vaccines by non-registered healthcare professionals.

Delegation of tasks

Delegation of key tasks is important for the efficient running of an immunisation programme. It should be clearly stated which staff member is responsible for key tasks and staff should receive appropriate information and training to allow tasks to be carried out efficiently and safely

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 immunisation schedule Healthcare worker information, NIO available at https://bit.ly/HCPPCIP
- d. Medicine protocol for each individual vaccine if individual prescription is not in use

4.2. Setting up and training

To provide childhood vaccinations a GP must hold a current contract under the Primary Childhood Immunisation Programme. Staff should ensure that they have completed the recommended training as detailed below.

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 and Training for General Practice Nurses

- Basic Life Support for Health Care Workers within the last two years (For e.g. Irish Heart Foundation (IHF), American Heart Association (AHA))
- Initial anaphylaxis programme (National Anaphylaxis Education Programme for Health Care Professionals) available via HSeLanD followed by a two-hour classroom-based skills workshop.
- Subsequent updates of anaphylaxis every two years via HSELand Anaphylaxis e-learning programme.

Recommended HSeLand Online programmes (www.HSElanD.ie)

- Primary Childhood Immunisation Programme
- Vaccinations in pregnancy
- Seasonal influenza –Injectable Influenza Vaccine and Live Attenuated Influenza Vaccine (LAIV) modules
- Talking About Immunisation Programme
- Storing and Managing Vaccines
- Catch up vaccines for refugees and applicants seeking protection
- Pneumococcal Polysaccharide vaccine (PPV23)
- COVID-19 Vaccination training programme

Complete Competency assessment for General Practice Nurses

- Self-assessment of competency form should be completed (see <u>Appendix F</u>)
- Medicine Protocol

Recommended Clinical Experience for Practice Nurses

Currently employed as a practice nurse and have had the opportunity to shadow an experienced vaccinator in gaining experience. Utilisation 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 Nursing See <u>Appendix C</u> Professional Development Coordinators for Practice Nurses in your 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.

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

4.3. General Practitioner Role

The role of the GP is to:

- Avail of every opportunity (including the post-natal check/6-week visit) to promote vaccination and ensure that
 parents/guardians have received the correct vaccination passport and booklet. Ensure a system is in place to
 remind parents when babies are due and overdue vaccines.
- Prior to administration of vaccines by nursing staff, ensure individual prescription or up-to-date medicine protocols
 are in place for the administration of each individual vaccine.
- Carry out an individual medical assessment for patients if requested by GPN working under a medicine protocol.
- Answer pre- and post-vaccination queries from parents/legal guardians/patients or colleagues within the general practice team.
- Be present in the building while vaccines are being given by GPN 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.
- Ensure that adverse events are notified to the Health Products Regulatory Authority (HPRA) (see Section 6.0). http://bit.ly/HPRAar
- See Appendix D for GP practice clinical administration issues.
- Facilitate training and continuing professional development for vaccinators including links with PDCGPN, online and in –person learning as available.

4.4. Vaccinator role and responsibilities (GP and GPN)

- 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.
- Should utilize the self-assessment of competency tool to identify and address any gaps in knowledge and practice
 prior to accepting delegation as vaccinator.
- Should link with PDCGPN who have a devised a suite of Medicine protocol templates for GPN's- (for contact details see Appendix C)
- The vaccinator should remain up to date with the <u>NIAC guidelines</u>, ensure subscribed to NIO updates and avail of CPD opportunities including online training, webinars and study days where available.
- The vaccinator must adhere to and comply with the guiding principles as set out in their professional regulatory frameworks e.g., relevant NMBI guidelines.
- The vaccinator should be available to answer queries from parents/legal guardians/ patients being immunised and other members of the general practice team.
- The vaccinator should be able to assist the parents/legal guardians/patient to make an informed decision about the vaccine.
- They should also check that:
 - All the equipment necessary for the administration of the vaccines follows best practice.
 - Appropriate medication and equipment as outlined in the NIAC guideline <u>Anaphylaxis</u> are available for management of anaphylaxis and are included in regular safety checks, to ensure all equipment and medications are available and in date.
 - All documentation is available which include patient information leaflets and patient held vaccination record cards.
 - Prior to vaccination, the vaccinator should complete a checklist to ensure the patient meets the eligibility/inclusion criteria for the vaccination.
- The roles and responsibilities of HSE staff are outlined in <u>Appendix G</u> and see <u>Appendix H</u> for the HSE Area Immunisation Unit Directory.
- Ensure vaccine records/returns are correct and update including parents contact details and address.
- Ensure vaccine records/returns are sent to HSE Local Immunisation Offices in a timely manner (no later than the
 seventh working day of each month). Triplicate forms may be used but software generated records are preferable
 (Further information and advice on optimising use of software to manage vaccine records and returns available
 from PDCGPN).

4.5. 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, page 35).

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 and the patient meets the inclusion criteria.

The underlying guidance for same comes from the NMBI Guidance for Medicines Management at https://www.nmbi.ie/nmbi/media/NMBI/Publications/Guidance-Medicines-Management.pdf?ext=.pdf Section 4 of this centres on medicine protocols.

Note: Indemnifier should be informed if medicine protocols are used in practice

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

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

The risks of not giving specific vaccines should be carefully considered when precautions exist (see individual <u>NIAC</u> <u>chapters</u>). When there are doubts whether or not to administer a vaccine, contact the relevant specialist.

Medicine protocols for vaccines administered under national programmes are available in template form from the PDCGPN which can be authorised and adopted within the practice under direction of the lead GP (for contact details see Appendix C).

Arrangements should be in place in each practice for the audit of medicine protocol usage.

4.6. Maximising 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 to ensure the child is vaccinated at the correct time. Flexible appointments for vaccination including evenings and weekend (if possible) are effective and improve attendance.
- Perform opportunistic checking of a child's immunisation status 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 for 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 <u>English</u> and <u>as Gaeilge</u> and other languages
- E-Learning module: *Talking About Immunisation* complete on <u>HSeLanD</u>. This uses the WHO recommended approach on communicating with people who are hesitant about vaccines, which has been shown to increase vaccine acceptance.
- Ensure vaccine records/returns are sent to the HSE Local Health Office on time as this facilitates routine monitoring of uptake, and allows for the prompt identification of children who have not been immunised.

5. Procedures

5.1. Before vaccine administration

Prior to vaccination the vaccinator should:

- 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. Confirm 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 informed consent (see the consent section).
- f. Assesses the person's suitability for immunisation on the day. Vaccines should be given to patients for whom no contraindication is identified as per the <u>Immunisation Guidelines of Ireland</u>.
- g. Routine physical examinations and procedures (e.g., measuring temperatures) are NOT recommended for vaccinating people who are healthy.
- h. Acute moderate or severe febrile illness, defer until recovery. Minor illness with fever <38°C is NOT a contraindication to immunisation.
- 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 on recommended and minimum intervals at Table 2.2 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.
- I. Checks that the appropriate vaccine(s) are in the vaccine fridge, are in date and stored in accordance with cold chain directions.
- m. Removes vaccine from the vaccine fridge only when the patient is ready for vaccination. Find information about vaccine storage, usage and stock rotation.
- verifies with the parent/legal guardian/patient or other health professional that the correct vaccine is being given,
 the expiry date has not passed and documents this on the form.
- o. Washes their hands or uses disinfectant gel before vaccine administration.
- p. Reconstitutes vaccines in accordance with manufacturer's instruction.
- 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 patient 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.
- Ensures that all vaccines are administered within the recommended time frame.

Vaccine Reconstitution

Applies to some of the commonly used childhood vaccines

- 6 in1
- MMR

Vaccines should be prepared according to the SmPC.

SmPC for each of the vaccines available at www.hpra.ie or www.medicines.ie

Unless the SmPC requires mixing of vaccines in one syringe (e.g. DTaP/IPV/ HepB with Hib), multiple vaccines given at the same visit must be given at least 2.5cm apart, and if necessary in different limbs. Some vaccines (e.g. 6 in 1, MMR, Hib/MenC, MenACWY) require reconstitution. It is not necessary to change needles after a vaccine dose has been drawn into a syringe.

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

NMBI(2020)

5.2. 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. Section 13 of the Irish Medical Council's <u>Guide to Professional Conduct & Ethics for Registered Medical Practitioners</u>, <u>9th Edition</u>, <u>2024</u> relates to consent, and states: "In order to come to a decision about whether to proceed with any proposed treatment, patients must be sufficiently informed about the treatment options and the nature, risks and benefits of such treatment options. (Section 13.3.)"
- c. The <u>Code of Professional Conduct and Ethics for Nurses and Midwives, 2021</u> 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 in Section 3 of the HSE National Consent Policy Consent and refusal: children under the age of 16 years.
- e. Those age16 years of age and older 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. See <u>HSE National Consent Policy</u>
- 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 patient's capacity to give consent
 - There has been a change to the proposed vaccine schedule to which the patient/ parent/ legal guardian
 has not given consent
- h. A PCIP Declination Form is being developed for parents/ legal guardians who do not want their child to be vaccinated and will be available from www.immunisation.ie.
- i. Where a person's capacity to make a decision about an intervention is in question, the relevant Guiding Principles of the Assisted Decision-Making (Capacity) Act 2015 apply. Any action, where a person's capacity to decide about an intervention is in question, must:
 - In so far as is possible give effect to the past and present will and preference of the person if these are reasonably ascertainable;
 - At all times be done in good faith and for the benefit of the person;
 - Be made in a manner that minimizes the restriction of the person's rights and freedom of action;
 - Have due regard to the rights of the person to dignity, bodily integrity, privacy, autonomy, and control over his or her financial affairs and property;
 - Be proportionate to the significance and urgency of the situation; and
 - Be as limited in duration as is possible in the circumstances.

5.3. Vaccine administration

This supporting guidance is intended for use in maintaining standards in vaccine administration practices, and does not replace the need to undertake all relevant education and training to be deemed competent as a vaccinator.

The vaccinator:

Prepares vaccines according to the SmPC

Administers vaccine in accordance with <u>NIAC guidelines</u> with respect to the patient'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	Vastus lateralis muscle (figure 5 below)	25 mm1
		23-25 gauge
12 to <36 months	Vastus lateralis or deltoid muscle (depending	25 mm
	on muscle mass)	23-25 gauge
3 years and older	Deltoid muscle2 (Figure 6 below)	25 mm3
		23-25 gauge

¹ Use a 16 mm needle in infants under 2.5-3 kg.

Immunisation Guidelines of the NIAC Chapter 2

Administer intramuscular (IM) injections

- There are only two routinely recommended IM sites for administration of vaccines, the vastus lateralis
 muscle (anterolateral thigh) and the deltoid muscle (upper arm), (Figures 4 and 5 below). Using these
 sites reduces the chance of involving significantly sized nerves or blood vessels. The site depends on
 the age and muscle mass of the recipient.
- 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 routinely required when administering intramuscular injections. However, if the patient's or vaccinator's skin is not intact, gloves should be worn.

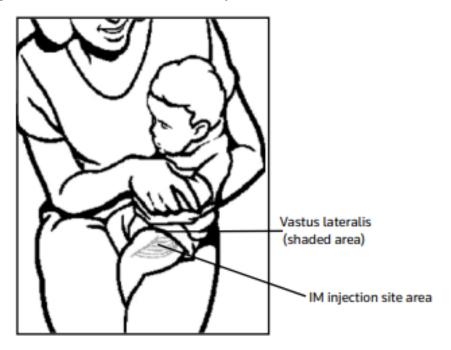
Vastus lateralis

The Vastus lateralis muscle is located on the antero-lateral aspect of the thigh. 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.

² The anterolateral thigh may also be used.

³ Use 40 mm needle in females >90 kg, males >120kgs.

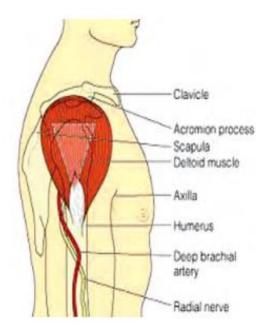
Figure 4: Vastus lateralis site for IM injection, birth to 36 months



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

Figure 5: 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 4 and 5 taken from Immunisation Guidelines of the NIAC chapter 2.

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

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.

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.

5.4. After vaccine administration (including liquid infant paracetamol)

After administering the vaccine(s) the vaccinator:

- a. Directly places the used needle into the appropriate sharps container. Needles should NOT be recapped as it increased the risk of needle stick injury. 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 on the electronic patient record AND on the consent/record form if using, immediately after the vaccine is given. Use peel-off labels where possible.
 - For reconstituted vaccines, the batch number recorded is the number on the box and/ or peel off labels.
- d. Scans completed paper forms into the patient's individual electronic record.
- e. Ensures the patient's vaccination record (immunisation/vaccination passport for children) is completed and given to the parent/legal guardian/patient before they leave the practice with a reminder to bring it along when attending for all future vaccines
- 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 to order 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.

Liquid infant paracetamol 2.5mls (60mgs) should be administered 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 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 administered 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), or 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.
- Reports adverse events to the HPRA

- k. Completes vaccine record/return to be sent to HSE LIO in the case of PCI vaccinations.
- Complete vaccine record in Covax in the case of Influenza, COVID19 and PPV23 vaccines (automatically linked to practice software or via GPvax).

5.5. 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 <u>online reporting form on the HPRA website</u>. All reporting should contain as much detail as possible regarding the adverse event, and include the batch number of the vaccine(s) administered. The HPRA has when appropriate withdrawn products from the Irish market where there have been public safety concerns.

6. Common clinical vaccine administration issues

When there are clinical 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 <u>local Department of Public Health</u> (See <u>Appendix H</u>).

You may also email clinical queries to the NIO at immunsation@hse.ie.

Issues in relation to training or scope of practice may be directed to the PDCGPN (see details in Appendix C).

6.1. Administration of two or more vaccines to the patient at the same visit

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

- a. Each vaccine should be prepared appropriately (either presented in a prefilled 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

- 1. 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.
- 2. Men B vaccine should be given first into the LEFT anterolateral thigh. Then 6 in1 vaccine should be given into the RIGHT anterolateral thigh.

At 6 months

1. As PCV is more reactogenic it is recommended that this vaccine is given in one limb and that 6 in 1 is given in a separate limb, separated by 2.5cm.

At 12 months

- 1. Give Men B vaccine first in the LEFT anterolateral thigh.
- 2. Then give Varicella (Chickenpox) vaccine in the RIGHT anterolateral thigh.
- 3. Then give MMR vaccine in the RIGHT anterolateral thigh this allows the most painful vaccine, MMR to be given last.

At 13 months

- 1. Give MenC vaccine first in the LEFT anterolateral thigh.
- 2. Then 6 in 1 vaccine in the RIGHT anterolateral thigh,

3. Then give PCV vaccine in the RIGHT anterolateral thigh. This allows the most painful vaccine (PCV) to be given last.

An at-risk adult receiving Influenza and PPV23 vaccines – these vaccines should be given in separate limbs, if a COVID-19 vaccine is required this should be separated by 2.5cm

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.

6.2. Contraindications and precautions

Routine physical examination and temperature measurement of persons who appear to be well are not necessary prior to vaccination. Ask if the proposed recipient is well; postpone vaccination if an acute febrile illness is present (temperature >38°C). The risks of not giving specific vaccines should be carefully considered when precautions exist (see individual chapters). When there are doubts whether or not to give a vaccine, contact a relevant specialist.

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 neutropoenia (absolute neutrophil count <0.5x 109/L) should not receive any vaccines. This does not apply to children with primary autoimmune neutropoenia.

Patients receiving chemotherapy, immunotherapy (including a single checkpoint inhibitor) or radiation therapy can receive non-live vaccines if not contraindicated (see NIAC Chapter 3).

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 <u>NIAC guidelines</u> should not receive live vaccines).

Please refer to NIAC guidelines for details of individual vaccines.

Precautions for vaccination

Acute febrile illness: defer until recovery (temperature >38°C).

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 ONLY 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. It is therefore, 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 (QIV) vaccine is recommended in any stage of pregnancy.

Pertussis vaccine Tdap (Boostrix) is recommended between 16- and 36-weeks' gestation for each pregnancy. COVID-19 vaccine is also recommended in each pregnancy.

Other non-live vaccines may be administered in pregnancy based on an individual assessment (refer to the detailed guidance in the <u>Immunisation Guidelines for Ireland</u>).

Live vaccines (MMR, Varicella and LAIV) should NOT be administer in pregnancy.

6.3. 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.

- 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.
- 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:
 - 1. Are there any diseases in the family that affect the immune system?
 - 2. Did anyone in either parents' family need a bone marrow transplant aged < 12 months?
 - 3. When your baby had their newborn bloodspot screening (heel prick test) was there any follow up needed because of the results of the test?

If the parent / caregiver answers "Yes" to any of these questions:

- Check if a full blood count (FBC) was taken at birth and confirm the results.
- If a FBC was not taken, a full blood count with differential white cell, including lymphocyte count should be ordered. If the lymphocyte count is below <2.0/109 litre referral to a consultant paediatrician should be made urgently.
- If follow-up was needed after newborn bloodspot screening, check if any of the concerns raised from the newborn bloodspot screening are to do with ADA-SCID?

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.
- MMR vaccine must not be administered during pregnancy.
- Vaccination should be deferred for between three and eleven months following the administration of blood or blood products (see <u>Immunisation Guidelines for Ireland</u> Chapter 2 for full details).

Precautions to MMR

• 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.

Varicella

- Varicella vaccine may be given at the same time or at any interval before or after non live vaccines
- Varicella and the MMR may be administered on the same day or else there must an interval of 4 weeks apart.
- Varicella must not be given in pregnancy or in those with immunosuppression.

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 PCV. This is because of a slightly increased risk of febrile convulsions if the vaccines are
 given at the same time in this age group

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 <a href="https://high-risk.org/high-ris

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).

There is no recommendation for any patients to receive PPV23 every five years.

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.

- Every ten years for health care workers who are in contact with infants, pregnant women and the immunocompromised.
- Carers or parents of premature infants born before 32 weeks' gestation

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).
- See vaccine ingredient guide for Healthcare worker

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 the <u>Chapter 2 of the Immunisation Guidelines– General</u> Immunisation Procedures.

Vaccines given after the expiry date

If a vaccine is given after the expiry date (usually 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).

Contact NIOpharmacy@hse.ie with vaccine expiry or cold chain queries e.g. fridge failures.

Refusal of vaccination

In those instances, where a parent/legal guardian/patient refuses vaccination and all avenues of communication have been explored, it is best practice that the parent/legal guardian/patient sign a vaccine declination form (a form is currently in development and will be available from www.immunisation.ie soon). 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 declination form. In the event that the parent or guardian is refusing vaccines, but is unwilling to sign the declination form, GP/GPN should inform the LIO.

The GP/GPN should make the parent/ legal guardian aware that vaccinations will be accommodated should they change their mind

7. Maintenance of the Cold Chain and Vaccine Ordering

7.1. Introduction

The Cold Chain is a temperature-controlled supply chain for products that require a specific temperature range for distribution and storage. For vaccines supplied to General Practice, 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 https://www.hse.ie/eng/health/immunisation/hcpinfo/vaccineordering/sopnio01.pdf for more details.

7.2. 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. This 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 (<u>Appendix I</u>). 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 ambient temperature of the room in which the fridge is located should also be monitored twice daily and recorded. In the event of fridge failure, this information may be required by the NIO in order to assess the viability of the vaccines.
- f. 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 +8oC 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.

After such a period of high activity the maximum temperature should be recorded, and the memory erased. A note on the Temperature Log (<u>Appendix I</u> – '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.

- g. 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.
- h. 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.
- i. While undertaking the inside of the fridge clean, the vaccines should be stored in another fridge. The inside of the fridge should be cleaned regularly, using a 1:10 solution of sodium hypochlorite (Milton) solution. 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.
- j. 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.

- k. The fridge and thermometers should be serviced and calibrated annually.
- I. 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

7.3. Ordering vaccines

- a. Vaccine stocks should be kept to a minimum by twice 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 one weeks but no more than three 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 7-Digit account number starting with 300XXXX
 - Online at ordervaccines.ie
 - E-mail <u>vaccines@udd.ie</u>

- d. NCCS will send a confirmatory email 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 as per the calendar available on the NCCS online ordering system.

7.4. 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 8oC.
- 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.

7.5. 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.
- 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 <u>Appendix J</u> 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.

7.6. Breakdown in the Cold Chain

- a. In accordance with the vaccine license, 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 quarantine the vaccines in a fridge maintaining the correct temperature and contact the NIO by email

<u>pharmacynio@hse.ie</u> for further advice. If the vaccines are privately supplied, contact the relevant supplier or manufacturer for advice.

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).
- 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 J). 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 J for vaccine returns form.

Transporting Vaccines to a vaccination clinic

 a. <u>Domestic cool boxes should not be used to store, distribute or transport vaccines.</u> 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 vaccination clinic,
 - throughout the vaccination 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.
- I. 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
- n. Vaccines should not be routinely transported between practices or sites unless required for vaccination off site specifically

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 ice block will retain its cold and thaw slowly. The ice block 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 NIO at pharmacynio@hse.ieif it exceeds + 8°C.

e. Use a data logger

A data logger 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.

8. References

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- 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 available at www.immunisation.ie
- HSE Guidelines for maintenance of cold-chain in vaccine fridges and management of vaccine stock https://www.hse.ie/eng/health/immunisation/hcpinfo/vaccineordering/sopnio01fridge.pdf
- HSE Guidelines for maintaining the vaccine cold-chain in vaccine cool boxes
 https://www.hse.ie/eng/health/immunisation/hcpinfo/vaccineordering/sopnio02box.pdf
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 Dublin: Nursing and Midwifery Board of Ireland available at: https://www.nmbi.ie/Standards-Guidance/More-Standards-Guidance/Recording-Clinical-Practice

9. 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
	1 500 500 500 500 500 500 500 500 500 50
MenC	Meningococcal C conjugate vaccine
HPV	Human Papillomavirus Vaccine
MenB	Meningococcal B Conjugate vaccine
MenC	Meningococcal C Conjugate vaccine
MMR	Measles, Mumps, Rubella vaccine
Chickenpox	Varicella vaccine
vaccine	
MMRV	Measles, Mumps, Rubella and Varicella 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

For babies born after 1st of October 2024

Age	Vaccines			
2 months	6 in 1 + MenB + PCV + Rotavirus			
4 months	6 in 1 + MenB + Rotavirus			
6 months	6 in 1 + PCV			
12 months	MMR + Varicella + MenB			
13 months	6 in 1 + MenC + PCV			
4-5 years (Junior Infants)	DTaP/IPV (4 in 1) + MMRV			
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 60 years and older, HCWs, those in specific medically at-risk groups aged 6 months to 64 years	Seasonal influenza vaccine Seasonal COVID-19 Boosters (check updated guidance on eligible groups and seasons)			
People 65 years and older, People with high risk (Group A) for Invasive Pneumococcal Disease (IPD) as per the NIAC guidelines	PPV23			
Pregnancy	Pertussis, Seasonal Influenza and COVID-19			

Valid at time of publication October 2024

Appendix B: Catch Up Immunisation Schedule

See NIAC chapter 2, Table for Catch-up schedule

https://www.rcpi.ie/Healthcare-Leadership/NIAC/Immunisation-Guidelines-for-Ireland

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

Professional Development Coordinators for General Practice Nurses by area

As of April 2024, all other areas are currently vacant

Name	Address	Email	Phone	Mobile	RHA Areas
Elizabeth	South East Community	Elizabeth.Carroll	087 4912159		Carlow, Kilkenny,
Carroll	Health Care	2@hse.ie			Wexford,
	Primary Care, Lacken,				Waterford, South
	Dublin Road,				Tipperary).
	Kilkenny R95NV08				
Kathy Taaffe	CHO 1, Office 12, Butt	Kathy.taffee@	071	087	Sligo, Leitrim,
	Building, Lower Main	<u>hse.ie</u>	9189014	1321424	Cavan,
	Street, Ballybofey. Co.				Monaghan,
	Donegal				Donegal (CHO1)
Marie	HSE Primary Care Unit,	Marie.Courtney	021	086	Kerry, Cork, North
Courtney	Block 15 (3rd Floor), St	<u>@hse.ie</u>	4923832	7872408	Lee, South Lee
	Finbar's Hospital, Douglas				and West Cork
	Road, Cork				(CHO 4)
Marie	HSE Community	marie.cantwell@	01 8467141	087	Dublin North City
Cantwell	Healthcare Organisation,	<u>hse.ie</u>		6078925	& County
	Dublin North City and				
	County				
	HSE Unit 1,2,3, Nexus				
	Building, Block 6A,				
	Blanchardstown Corporate				
	Park, Ballycoolin, Dublin				
	15, Eircode D15 CF9K				
Mairead	Community Health Care	Mairead.Murphy		087	Community
Murphy	West (Galway, Mayo and	11@hse.ie		1206184	Health Care West
	Roscommon).				(Galway, Mayo
	St. Mary's Campus,				and Roscommon)
	Primary Care Services,				
	Castlebar, Co. Mayo.				
	F23XE39				

Appendix D: GP Practice administration issues

Ideally optimise use of GP software to manage and record vaccinations and to provide returns to HSE LIO. Customer support for GP software on Clanwilliam website and YouTube provides up to date information and helpful video tutorials to ensure practices are getting the best from their software in this regard.

Website: Clanwilliam IRL (clanwilliamhealth.com)

YouTube Channel: http://www.youtube.com/@HelixHealthGroup

It is good practice to:

- a. Retain a register (preferably electronic using a GPIT accredited system) with patient details which will allow for the easy identification and communication with people requiring vaccination. (See <u>Appendix K</u> for data entry standards used in HSE school immunisation programme).
- b. Ideally record the patient's phone number and provide this to the HSE to enable SMS alerts and follow up either by the GP or the HSE. The patient 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 patients 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 patient 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 child moves out of the area
 - a child dies
 - · the vaccine is refused
 - the vaccine is contraindicated

Appendix E: 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

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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 and template medicine protocols and their use in general practice setting 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/patient 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							
minute post vaccination observation period to assist wit							
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 t	he HPRA						
Procedure for the reporting and documentation of er	rors 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

This must be completed and appended to medicine protocols in practice

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 "Supporting Information for Vaccinations in General Practice"

Medicine Protocols Yes No

Date of planned training:

Domain	Performance Criteria: Critical Element	Needs Theory	Needs	Competent
of		Date/ Initial	Practice	Date/Initial
Practice			Date/	
			Initial	
1, 2, 4, 5	I understand the role and function of medicine			
	protocols in the context of Nursing and Midwifery			
	Board guidelines:			
	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 "Supporting			
	Information for Vaccinations 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.			

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.
within the scope of the medicine protocols. 2, 4
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
vaccine. 1, 4 I am aware of the correct preparation/reconstitution of vaccines. 2, 4 I can prepare all vaccines using aseptic
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preparation/reconstitution of vaccines. 2, 4 I can prepare all vaccines using aseptic
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

General Practice Nurse's Signature:	Date:
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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: HSE Area Immunisation Unit Directory

HSE Area Immunisation Unit Directory

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

Appendix H: Departments of Public Health

Department of Public Health Contact details

Visit https://bit.ly/DPHContact

Appendix I: Temperature Log Template

Fridge ID: Month:													
	AM						PM						
	Temp	erature	°C	Min/			Temperature °C			Min/			
Day				Max	Time	Initials				Max	Time	Initials	Comments
	Min	Max	Current	Reset			Min	Max	Current	Reset			
1													
2													
3													
4													
5													
6													
7													
8													
9													
10													
11													
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29													
30													
31													
			viewed by:				Date						

Note: When a temperature reading is missed, retain the log entry as a blank.

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

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

Appendix K: 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 patient 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 patient 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 patient.

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 patient'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 patient 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).

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

Care of. Some patients 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 L: 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.

Where a child or young person is in foster care and consent is required for vaccination, the GP/GPN may be required to link with Tusla (the Child and Family Agency) to gain consent from a representative that has legal authority to give consent on behalf of the child. Where the child has been in foster care for 5 or more years, a foster carer may apply to the district court for an order, giving them control over the child as if they were their parent. The GP/GPN should satisfy themselves that the foster carer has the necessary legal authority to give consent, which can be done by requesting a copy of the court order.

For complex issues regarding consent for childhood immunisations, please contact your indemnifier for further medic-legal advice please refer to HSE National Consent Policy (2022) Part 1- General Principles and Part 2- Children and Young People for more detailed information around consent. The following information is taken directly from the HSE National Consent Policy.

Consent to vaccinations

On the basis that appropriate information is provided in the information leaflet, parental consent can be presumed to be valid for each of the repeated booster doses or vaccinations specified in the information leaflet, unless this consent has been revoked by the parent(s) or legal guardian(s).

In general, the consent of one parent or legal guardian to vaccination will suffice unless both parents or all legal guardians have expressly indicated a wish to be involved in the process. If the vaccinator has been expressly notified that one parent agrees to vaccination but the other disagrees, the vaccination should not be carried out until both parents reach agreement or, rarely, there is a specific Court approval that vaccination is in the best interests of the child.

In such situations, the parent(s) or legal guardian(s) should be advised to discuss matters between themselves to seek to resolve their dispute. Discussion with the child's general practitioner may be helpful to address any concerns.

The parent(s) or legal guardian(s) should also be encouraged to discuss vaccination with their child, whose own views are also important.

Every reasonable effort should be made to avoid vaccination of a child where there is parental disagreement about the vaccination. In some situation, this may include contacting a local vaccination centre or the child's general practitioner. It is, however, not possible to guarantee success in this regard.

Where one parent or legal guardian has given consent and the healthcare worker is informed that this parent or legal guardian has died, this consent is no longer legally valid and a new consent should be obtained from the other parent or legal guardian.