

Guidelines for **VACCINATIONS** in General Practice

September 2016



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Executive Summary

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

These guidelines have been updated because of the new primary childhood immunisation schedule for all children born on or after 1st October 2016.

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

- ▶ Primary Childhood Immunisation Programme
- ▶ Schools Immunisation Programme
- ▶ Seasonal influenza and pneumococcal polysaccharide vaccination campaigns
- ▶ Vaccination of late entrants/defaulters from vaccination programmes
- ▶ Vaccinations carried out for public health and occupational health purposes

In order to provide childhood vaccination a General Practitioner (GP) must hold a current contract under the Primary Childhood Immunisation Programme.

Staff should ensure that they have training in Basic Life Support and Anaphylaxis and that retraining is provided in accordance with best practice i.e. every 2 years. They should be familiar with the following documents:

- ▶ Immunisation Guidelines for Ireland <http://www.hse.ie/eng/health/immunisation/hcpinfo/guidelines/>
- ▶ A Practical Guide to Immunisation, National Immunisation Office, 2008 <http://www.hse.ie/eng/health/immunisation/hcpinfo/trainingmanual/>
- ▶ Immunisation training slides for Health Professionals, National Immunisation Office 2016 <http://www.hse.ie/eng/health/immunisation/hcpinfo/conference>
- ▶ Summary of Product Characteristics (SmPCs) for each of the vaccines available at www.hpra.ie or www.medicines.ie
- ▶ Managing Anaphylaxis – Refresher Programme available at <https://www.hseland.ie>

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

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

- ▶ a medicine protocol for the administration of vaccines. In the absence of a medicine protocol an individual prescription for vaccination should exist
- ▶ availability of appropriate drugs and equipment for resuscitation
- ▶ vaccine administration at the correct time, and in the correct site, interval and dose
- ▶ timely ordering, storage and recorded maintenance of the cold chain for all vaccines.

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

In addition, live vaccines (e.g. MMR and varicella) are contraindicated in pregnancy, for those with immunosuppression, and on steroid or immunomodulator therapy. Rotavirus oral vaccine is contraindicated in babies who are 8 months and 0 days or older; have a past history of intussusception, have an uncorrected gastrointestinal tract malformation, have a diagnosis of Severe Combined Immunodeficiency Disorder (SCID) or have a sugar intolerance.

When there are queries about giving a vaccine, the Assistant Director of Public Health Nursing with responsibility for immunisation or a Consultant in Public Health Medicine in the local Department of Public Health should be contacted for further advice.

1. Purpose

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

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

These guidelines have been updated because of the new primary childhood immunisation schedule for all children born on or after 1st October 2016.

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

<http://www.hse.ie/eng/health/immunisation/hcpinfo/guidelines/>

2. Scope of the Guidelines

These clinical and administrative guidelines apply to all general practice staff (general practitioners GPs, practice nurses and administrators) involved in vaccinations on behalf of the HSE and HSE staff (medical officers, nurses and administrators) supporting the vaccinations administered in general practice.

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

- ▶ Primary Childhood Immunisation Programme
- ▶ Schools Immunisation Programme
- ▶ Seasonal influenza and pneumococcal polysaccharide vaccination campaigns
- ▶ Vaccination of late entrants/defaulters from vaccination programmes
- ▶ Vaccinations carried out for public health and occupational health purposes

In order to provide childhood vaccination a GP must hold a current contract under the Primary Childhood Immunisation Programme.

Staff should ensure that they have training in Basic Life Support and Anaphylaxis and that retraining is provided in accordance with best practice i.e. every 2 years.

They should be familiar with the following documents:

- ▶ Immunisation Guidelines for Ireland
<http://www.hse.ie/eng/health/immunisation/hcpinfo/guidelines/>
- ▶ A Practical Guide to Immunisation, National Immunisation Office, 2008
<http://www.hse.ie/eng/health/immunisation/hcpinfo/trainingmanual/>
- ▶ Immunisation training slides for Health Professionals, National Immunisation Office 2016
<http://www.hse.ie/eng/health/immunisation/hcpinfo/conference>
- ▶ Summary of Product Characteristics (SmPCs) for each of the vaccines available at www.hpra.ie or www.medicines.ie
- ▶ Managing Anaphylaxis – Refresher Programme available at <https://www.hseland.ie>

3. Immunisation Schedules

3.1 Introduction

The National Immunisation Advisory Committee (NIAC) is an independent committee of the Royal College of Physicians of Ireland comprising of experts in a number of specialties including infectious diseases, paediatrics, public health, microbiology, occupational health, general practice and nursing.

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

NIAC guidance is regularly updated and it is essential that all staff involved in vaccination check the updated chapters at <http://www.hse.ie/eng/health/immunisation/hcpinfo/guidelines/>

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

3.2 Primary Childhood Immunisation Programme

The primary childhood immunisation programme (PCIP) comprises vaccinations delivered in general practice in the first years of life. The schedule of vaccines a child is given is dependent on their date of birth. The PCI schedule is changing for those children born on or after 1st October 2016 to allow for the inclusion of Meningococcal B vaccine (MenB) and rotavirus oral vaccine. The PCI schedule for children born before 1st October 2016 will not change. See **Appendix A**.

The birth cohort in Ireland is approximately 66,000 births per year. The World Health Organization (WHO) has set a target uptake of 95% for primary immunisations to prevent outbreaks of vaccine preventable diseases.

As outlined in quarterly statistics produced by the Health Protection Surveillance Centre (HPSC), uptake rates for Ireland have reached or are approaching the WHO target.

- ▶ Diphtheria, tetanus and pertussis (DTP) vaccine uptake at 24 months has increased from 90% in 2005 to 96% in 2015
- ▶ Measles, mumps and rubella (MMR) vaccine uptake at 24 months has increased from 84% in 2005 to 93% in 2015. The latest HPSC statistics are available at <http://www.hpsc.ie/hpsc/A-Z/VaccinePreventable/Vaccination/ImmunisationUptakeStatistics/>

3.3 Schools Immunisation Programme

The school immunisation programme comprises vaccinations given in the first year of primary school and the first year of second level school. The current (2016/17) school immunisation programme is outlined in **Appendix A**.

School going children receive vaccinations as outlined in "Guidelines for Staff – Schools Vaccination Programme" available at <http://www.hse.ie/eng/health/immunisation/pubinfo/schoolprog/4in1mmr/schoolguidelines.pdf>

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

Vaccine uptake of 4 in 1 was 91% and MMR was 91% in 2014/2015

<http://www.hpsc.ie/A-Z/VaccinePreventable/Vaccination/ImmunisationUptakeStatistics/ImmunisationuptakestatisticsforJuniorInfants/>

Vaccine uptake of HPV was 86.9%, Tdap was 88.4% and MenC was 87.9% in 2014/15.

<http://www.hpsc.ie/A-Z/VaccinePreventable/Vaccination/ImmunisationUptakeStatistics/HPVImmunisationUptakeStatistics/>

<http://www.hpsc.ie/A-Z/VaccinePreventable/Vaccination/ImmunisationUptakeStatistics/TdapImmunisationUptakeStatistics/>

3.4 Seasonal influenza and pneumococcal polysaccharide vaccination programmes

The HSE provides seasonal influenza vaccine for those aged 65 and over (~606,000), those in medically at risk groups, pregnant women, health care workers and carers.

The World Health Organization has set a target uptake of 75% for influenza vaccination for those aged 65 and older.

Analysis of returns from GPs for those aged 65 years and older over (who have a medical or doctor only card) shows that the WHO target has not yet been achieved

Vaccine uptake was 60.2 % in 2014/2015 a slight increase on recent years but a decrease from 70.1% in 2008/2009. <http://ndsc.newsweaver.ie/epiinsight/6xiy5gxfmnk?a=1&p=49675795&t=17517774>

The majority of seasonal influenza vaccine is given in general practice – since 2011/2012 those aged 65 and older and since 2012/2013 those 18 and older in an at risk group have had a choice to attend either their GP or pharmacist.

Pneumococcal polysaccharide vaccine (PPV23) is delivered in general practice settings for those at increased risk of pneumococcal disease as per the recommendations in the Pneumococcal chapter of the Immunisation Guidelines <http://www.hse.ie/eng/health/immunisation/hcpinfo/guidelines/chapter16.pdf>

Most people only require one dose of PPV23 vaccine.

3.5 Vaccination of late entrants/defaulters from vaccination programme

Where individuals are identified as having had no previous immunisations or an incomplete primary course, arrangements should be made to ensure appropriate vaccination in line with the catch up schedule (see **Appendix B**) in the Immunisation Guidelines for Ireland available at <http://www.hse.ie/eng/health/immunisation/hcinfo/frequentlyaskedquestions/catchupvacc/Guidelateentry.pdf>

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

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

Information on the vaccine schedules in different countries is available at http://apps.who.int/immunization_monitoring/globalsummary/schedules and <http://vaccine-schedule.ecdc.europa.eu/Pages/Scheduler.aspx>

3.6 Vaccinations in pregnancy

Pertussis vaccine Tdap (Boostrix) is recommended for all pregnant women between 16-36 weeks gestation in every pregnancy. For more details see <http://www.hse.ie/eng/health/immunisation/pubinfo/pregvaccs/pertussis/>

Influenza vaccine is recommended for all pregnant women at any stage of pregnancy. For more details see <http://www.hse.ie/eng/health/immunisation/pubinfo/pregvaccs/Flu/>

Vaccination of women who are non-immune to rubella is recommended as outlined in the Rubella chapter of the Immunisation Guidelines at <http://www.hse.ie/eng/health/immunisation/hcinfo/guidelines/chapter20.pdf>

3.7 Other vaccinations

General practice personnel also provide vaccinations for public health purposes. In the event of an outbreak e.g. measles or meningococcal B disease, general practice staff in collaboration with Departments of Public Health provide vaccinations for contacts of cases.

Some people 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 see the Immunisation of the Immunocompromised chapter of the Immunisation Guidelines at <http://www.hse.ie/eng/health/immunisation/hcinfo/guidelines/immunisationguidelines.html>

General practice also provides vaccinations for occupational health e.g. provision of hepatitis B vaccine for healthcare workers.

4. Carrying out Vaccination in General Practice

4.1 Introduction

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

Roles and responsibilities may be assigned on a local basis according to the professional qualifications and expertise of staff.

There are key tasks important to the efficient running of an immunisation programme, which are assigned to a “designated person” to ensure that all members of staff know who is responsible for that key task. The person designated to a particular task may change or rotate depending on local arrangements.

All staff should be familiar with the following documents:

- A. Immunisation Guidelines for Ireland <http://www.hse.ie/eng/health/immunisation/hcpinfo/guidelines/>
- B. A Practical Guide to Immunisation, National Immunisation Office, 2008 <http://www.hse.ie/eng/health/immunisation/hcpinfo/trainingmanual>
- C. Immunisation training slides for Health Professionals, National Immunisation Office 2016 <http://www.hse.ie/eng/health/immunisation/hcpinfo/conference>
- D. Summary of Product Characteristics (SmPCs) for each of the vaccines available at www.hpra.ie or www.medicines.ie

4.2 Setting up and training

In order to provide childhood vaccination a GP must hold a current contract under the Primary Childhood Immunisation Programme. New applications should be made to the Local Health Office.

Once the contract is in place the GP should make contact with 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.

National training in immunisation is offered by the Professional Development Coordinators for Practice Nurses and facilitated by the National Immunisation Office in cooperation with the local Departments of Public Health. Training materials are available at www.immunisation.ie

Staff should ensure that they have training in Basic Life Support and Anaphylaxis and that retraining is provided in accordance with best practice i.e. every 2 years.

Contact the local Professional Development Coordinators for Practice Nurses or the Centre of Nurse and Midwifery Education (CNME) for more information. See Appendix C Professional Development Coordinators for Practice Nurses by CHO area.

Practice nurses should develop their personal understanding of the enabling Scope of Practice Framework produced by The Nursing and Midwifery Board of Ireland in 2015 available at <http://www.nmbi.ie/Standards-Guidance/Scope-of-Practice>

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

4.3 General Practitioner role

The role of the GP is to

- A.** Avail of every opportunity (including the post natal check/6 week visit) to promote vaccination and to provide parents with the Before Immunisation tear pad, when they attend for their baby's 6 week check.
- B.** Have a medicine protocol within the practice for the administration of each individual vaccine.
In the absence of a medicine protocol (see Section 4.4) an individual prescription for vaccination should exist.
- C.** Carry out an individual medical assessment for clients if requested by practice nurse working under a medicine protocol (see Section 4.4).
- D.** Answer queries from parents/legal guardians/clients being vaccinated and other members of the general practice team.
- E.** Be present in the building while vaccines are being given by nurse vaccinators and for 15 minutes after the last vaccine is administered to deal with anaphylaxis or any other adverse events that might occur, including syncope.
- F.** Take queries from parents/legal guardians/clients being vaccinated about possible adverse reactions that occur after the client has left the general practice venue.
- G.** Ensure that adverse events are notified to the Health Products Regulatory Authority (HPRA) (see Section 6.0).

See **Appendix D** for GP practice administration issues.

4.4 Administration of vaccines under individual prescription or Medicine Protocol

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 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 an defined situation meeting specific criteria and who may not be individually identified before presentation for treatment”.

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

- A.** 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.
- B.** Practice nurses working under medicine protocols will be accountable for their own clinical practice and should be familiar with and adherent to the practices as set out in these guidelines.
- C.** All clients meeting the exclusion criteria of a medicine protocol must be referred to the GP for an individual medical assessment.
- D.** Arrangements should be in place in each practice for the audit of Medicine Protocol usage.

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

4.5 Vaccinator role and responsibilities (GPs and Practice nurses)

Each vaccinator is accountable for his/her own clinical practice and ensures that they are familiar with and adhere to the practices as set out in these guidelines (see Self Assessment of Competency Tool in **Appendix F**). They should also be available to answer queries from parents/legal guardians/clients being immunised and other members of the general practice team.

They should also check that

- A.** All the equipment necessary for the administration of the vaccines is in compliance with best practice.
- B.** Appropriate drugs and equipment are available for resuscitation.
- C.** All documentation is available.

The roles and responsibilities of HSE staff are outlined in **Appendix G** and see **Appendix H** for the HSE Area Immunisation Unit Directory.

5. Procedures

5.1 Before vaccine administration

Prior to vaccination the vaccinator

- A.** 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.** Checks and records client information accurately including permission to use mobile numbers for text alerts (see **Appendix D**).
- C.** Confirms client'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 risk of vaccinating and not vaccinating.
- E.** Obtains written informed consent (see Section 5.2).
- F.** Assesses the client's suitability for immunisation on the day. Vaccines should be given to clients for whom no contraindication is identified as per the Immunisation Guidelines of Ireland.
- G.** Routine physical examinations and procedures (e.g. measuring temperatures) are NOT recommended for vaccinating persons who appear to be healthy. The client or parent should be asked if the person being vaccinated is ill.
- H.** Defers any clients with an acute febrile illness on the day and reschedules vaccination.
- I.** Ensures that when vaccines are being given according to a particular schedule e.g. PCIP that the interval from last vaccines given is appropriate. If not, vaccination should be deferred and the client rescheduled.
- J.** Checks that the intervals between different vaccines are appropriate.
- K.** Checks that the vaccine has been prescribed by the GP or that the vaccine can be administered under medicine protocol (see Section 4.4).

- L. Checks that the appropriate vaccine(s) are in the vaccine fridge, are in date and stored in accordance with cold chain directions (see Section 8).
- M. Removes vaccine from the vaccine fridge when the client is ready for vaccination.
- N. Verifies with the parent/legal guardian/client or other health professional that the correct vaccine is being given, the expiry date has not passed and records this on the form.
- O. Washes their hands or uses disinfectant gel before vaccine administration.
- P. Reconstitutes vaccines in accordance with manufacturer's instruction.

Vaccine Reconstitution

Applies to some of the commonly used childhood vaccines

- ▶ 6 in1
- ▶ Haemophilus influenzae type b
- ▶ MMR
- ▶ Haemophilus influenzae type b/Meningococcal C (available from October 2017)

Involves

- ▶ attaching the 21 gauge needle provided to the prefilled syringe containing diluent
- ▶ inserting the syringe into the vial
- ▶ mixing and then drawing the reconstituted vaccine back into the syringe
- ▶ changing the needle on the syringe ready for administration using an appropriate gauge needle as per Section 5.3

- Q. Ensures that the vaccine colour and composition is in accordance with the Summary of Product Characteristics for that vaccine – if not discard the vaccine.
- R. Ensures the client is correctly positioned for the safe administration of the vaccine(s) with help from a parent/legal guardian or other member of the general practice team.
- S. Ensures that all vaccines are used within the recommended time frame.

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

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

The Five Rights Of Vaccine Administration

1. The right patient
2. The right vaccine
3. The right dosage
4. The right route
5. The right time

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 reasonably need to make their decision.

The Guide to Professional Conduct & Ethics for Registered Medical Practitioners, 8th Edition, 2016 (Medical Council) states in Section 11 'Information for patients' section 11.1 that 'You must give patients enough information, in a way that they can understand, to enable them to exercise their right to make informed decisions about their care. Consent is not valid if the patient has not been given enough information to make a decision'. <http://www.medicalcouncil.ie/News-and-Publications/Reports/Guide-to-Professional-Conduct-and-Ethics-8th-Edition-2016-.pdf>

The Code of Professional Conduct and Ethics for Nurses and Midwives, December 2014, Principle 1, Standard 9, 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.'
<http://www.nmbi.ie/Standards-Guidance/Code/Respect-Dignity>

- B.** The information materials produced by the National Immunisation Office (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 maths 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, <http://www.immunisation.ie/> <http://www.hpra.ie> and <http://www.medicines.ie>
- C.** Under normal circumstances the parent(s) of a child can give consent for vaccination on their child's behalf. For students aged under 16, consent must be obtained from a parent or legal guardian.

Under The Legal Guardianship of Infants Act, 1964, 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. 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.

- D.** Those aged 16 years of age and over can consent on their own behalf.
- E.** Special consideration needs to be given to children who are in care of the HSE either on a voluntary or statutory basis and contact should be made with the appropriate social worker.

- F.** There is no maximum duration for consent. Consent remains valid for an indefinite period unless
- ▶ It is withdrawn
 - ▶ There has been a change in the client's capacity to give consent
 - ▶ There has been a change to the proposed vaccine schedule to which the client has not given consent

Further guidance on consent, if required, is contained in "A Practical Guide to Immunisation" (Chapter 6) which is available at <http://www.hse.ie/eng/health/immunisation/hcpinfo/trainingmanual/>

5.3 Vaccine administration

The vaccinator

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

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

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

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

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

- B.** Administers single dose of 0.5ml of the appropriate vaccine by intramuscular (IM) injection at a 90° angle to the skin at the appropriate site.

Where it is necessary to administer two vaccines in the same limb the vaccination sites should be separated by 2.5cms and the site and vaccine administered recorded accurately (see Section 7.1.B).

- ▶ The skin does not require cleaning before the vaccine is administered unless visibly dirty. In this instance the skin can be cleaned with soap and water. If an alcohol wipe is used the skin should be allowed to dry before the vaccine is injected.
- ▶ Gloves are not normally required when administering intramuscular injections. However, if the client's skin or the vaccinator's skin is not intact gloves should be worn.

- C.** Administers rotavirus oral vaccine as follows:

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

5.4 After vaccine administration (including liquid infant paracetamol)

After administering the vaccine(s) the vaccinator

- A.** Disposes of sharps immediately, without recapping the needle, into the sharps containers provided. Discard the empty oral applicator and tip cap into approved biological waste containers.
- B.** Washes their hands or uses disinfectant gel.
- C.** Completes the administration details including the vaccine name, manufacturer, batch number and expiry date, using peel off labels provided where appropriate, at the end of the consent form immediately after the vaccine is given. For reconstituted vaccines the batch number recorded is the one on the box and on the peel off labels. (See Section 5.1.P).
- D.** Scans completed electronic forms into the client record.
- E.** Ensures the client's vaccination record (immunisation passport for children) is completed and given to the parent/legal guardian/client before they leave the practice.
- F.** Ensures that each client remains in the practice under observation for 15 minutes, as most anaphylaxis episodes begin within 15 minutes of vaccination.
- G.** Gives parents/legal guardians of children attending for vaccination under the PCIP a copy of the HSE After immunisation information "tear pad" (provides post vaccination advice, available from www.healthpromotion.ie).

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

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

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 contact their GP surgery.

This recommendation for liquid infant paracetamol is a change to previous recommendations and follows recent studies undertaken to demonstrate there is no reduction in immunogenicity of babies to the vaccines with liquid infant paracetamol.

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

Babies should not need to routinely have liquid infant paracetamol after the 6, 12 or 13 month injections. However, if a baby develops a fever (over 39°C) or is sore where the injection was given, or is distressed they can be given paracetamol or ibuprofen.

- H.** Takes queries from parents/legal guardians/clients about possible adverse reactions that occur post vaccination.
- I.** Provides parents/legal guardians/clients with the appropriate contact details so that they can inform the general practice team about any concerns following vaccination.
- J.** Reports adverse events to the HPRA (see Section 6.0).
- K.** In the event that a client requires referral to hospital for vaccination under supervision arranges same (if necessary contact the local Department of Public Health for details).

6. Reporting adverse events following immunisation

Vaccines used in Ireland have been licensed by the European Medicines Agency (EMA) in conjunction with the Health Products Regulatory Agency (HPRA). Following licensing of vaccines or other medicines the HPRA is responsible for post marketing surveillance. Reports of adverse events are available on www.hpra.ie The HPRA has when appropriate withdrawn products from the Irish market where there have been public safety concerns.

Details of adverse events following immunisation (AEFI) should be recorded on the adverse event report form and sent to the HPRA.

Adverse events can be reported online at:

<https://www.hpra.ie/homepage/about-us/report-an-issue/human-adverse-reaction-form>

or an adverse event form can be downloaded, and returned by FREEPOST, from:

<http://www.hpra.ie/homepage/medicines/safety-information/reporting-suspected-side-effects>

7. Common vaccine administration issues

When there are queries about giving a vaccine, contact the Assistant Director of Public Health Nursing with responsibility for immunisation or a Consultant in Public Health Medicine in the local Department of Public Health for further advice (see **Appendix I**).

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

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

- A.** Each vaccine should be prepared appropriately (either presented in a 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 new schedule for babies born on or after 1st October 2016,
 - ▼ At 2 months
Rotavirus oral vaccine should be given at the beginning of the visit before MenB, 6 in 1 and PCV vaccines. Men B vaccine should be given first into the **LEFT** anterolateral thigh. Then 6 in 1 vaccine followed by PCV should be given into the **RIGHT** anterolateral thigh.
 - ▼ At 4 months
Rotavirus oral vaccine should be given at the beginning of the visit before MenB and 6 in 1 vaccines. Men B vaccine should be given first into the **LEFT** anterolateral thigh. Then 6 in 1 vaccine should be given into the **RIGHT** anterolateral thigh.
 - ▼ At the 6 month visit, infants will receive three vaccines (6 in 1, MenC and PCV) –as PCV is more reactogenic it is recommended that this vaccine is given in one limb and that 6 in 1 and MenC are given in a separate limb, separated by a distance of 2.5cms.
- ▶ An at risk adult receiving Influenza and PPV23 – these vaccines should be given in separate limbs

The site of all vaccinations given should be recorded accurately.

7.2 Contraindications and precautions

Contraindications to vaccination

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).

Live vaccines (e.g. MMR and varicella)

- ▶ Pregnancy
- ▶ Immunosuppression, steroid and immunomodulator therapy (refer to the detailed guidance in the Immunisation Guidelines for Ireland).

Rotavirus oral vaccine

- ▶ babies aged 8 months and 0 days or older
- ▶ babies with a past history of intussusception
- ▶ babies with uncorrected gastrointestinal tract malformations
- ▶ babies with a diagnosis of Severe Combined Immunodeficiency Disorder (SCID)
- ▶ babies with a sugar intolerance.

Precautions for vaccination

Acute severe febrile illness: defer until recovery.

Bleeding disorders: Vaccines should be administered with caution to individuals with coagulation defects. When vaccines are given intramuscularly to persons with bleeding disorders or on anticoagulants, NIAC has recommended it is prudent to use a 23 gauge or wider needle to reduce the pressure gradient and cause less trauma to the tissues and to apply gentle pressure to the vaccine site for 1-2 minutes after the injections. If using a 25 gauge needle, the vaccine should be injected into the muscle over 5 seconds to reduce the risk of tissue damage.

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

Vaccines recommended for intramuscular injection may be administered subcutaneously to persons with a bleeding disorder if the immune response and clinical reaction to these vaccines are expected to be comparable by either route of injection. This only applies to MMR, influenza and yellow fever vaccines.

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.

Use of Tacrolimus (Protopic™) and other topical immunomodulators: It is advised that these preparations should be discontinued four weeks before the administration of live vaccines. They should not be restarted until four weeks after vaccination.

Pregnancy: Influenza vaccine is recommended for all pregnant women at any stage of pregnancy. Pertussis vaccine Tdap (Boostrix) is recommended for pregnant women between 16 and 36 weeks gestation of each pregnancy. Other non-live vaccines may be administered in pregnancy (refer to the detailed guidance in the Immunisation Guidelines for Ireland). Live vaccines (e.g. MMR) are contraindicated in pregnancy.

7.3 Specific vaccine issues

Rotavirus

- ▶ Rotavirus oral vaccine is recommended for all babies born on or after October 1st 2016 at their 2 and 4 month visits.
- ▶ Rotavirus oral vaccine can be given with all other PCI vaccines.
- ▶ Due to an increased risk of intussusception with increasing age, rotavirus oral vaccine CANNOT be given on or after 8 months and 0 days of age.
- ▶ Rotavirus oral vaccine cannot be given to infants with a previous history of intussusception, Severe Combined Immunodeficiency Disorder (SCID), a malformation of the gastrointestinal tract which might predispose them to intussusception, or a hereditary fructose intolerance, sucrose-isomaltase deficiency or glucose-galactose malabsorption.
- ▶ SCID is a rare inherited primary immune deficiency that can result in the onset of one or more serious and even life-threatening infections within the first few months of life. Children affected by SCID can also become ill from live vaccines, including rotavirus oral vaccine. However the risk from rotavirus vaccine needs to be balanced against the risk of a baby with undiagnosed SCID contracting rotavirus disease.

Prior to giving rotavirus oral vaccine, the following questions should be asked of all parents to see if their baby may be at risk of SCID

- ▼ Are there any diseases in the baby's family that affect the immune system?
- ▼ Did anyone in either family need a bone marrow transplant as a baby?

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

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

- ▼ check if a Full Blood Count (FBC) was taken at birth and confirm the results.
- ▼ if 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 $<2.0/10^9$ litre referral to a consultant paediatrician should be made urgently.

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

MMR

- ▶ MMR may be given at the same time or at any interval before or after any non-live vaccines.
- ▶ MMR is a live vaccine and must not be administered within four weeks of varicella, zoster and yellow fever live vaccines.
- ▶ Pregnancy should be avoided for 1 month after MMR vaccination.
- ▶ Vaccination should be deferred for between three and eleven months following the administration of blood or blood product (see Immunisation Guidelines for Ireland for full details).
- ▶ Patients who developed thrombocytopenia within six weeks of their first dose of MMR should undergo serological testing to determine if a second dose is necessary.

Influenza

- ▶ Influenza vaccine is recommended during influenza season (September to April) for ALL pregnant women irrespective of the stage of pregnancy.
- ▶ People with a known anaphylactic hypersensitivity reaction to eggs can be given an influenza vaccine with a low ovalbumin content (<0.1 micrograms ovalbumin per dose)
- ▶ In children aged 12-23 months of age a 1 week interval is recommended between the administration of influenza vaccine and PCV.

PPV23

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

A ONCE ONLY booster vaccination is recommended 5 years after the first vaccination for those

- ▶ Aged 65 years and older if they received PPV23 vaccine more than 5 years before and were less than 65 years of age at the time of the first dose,
- ▶ Whose antibody levels are likely to decline rapidly e.g. asplenia, splenic dysfunction, immunosuppression, chronic renal disease or renal transplant.

A second dose of PPV23 vaccine is recommended 3 months after treatment if the first dose was given during chemotherapy or radiotherapy.

An algorithm outlining the requirement for booster doses of PPV23 is available at <http://www.hse.ie/eng/health/immunisation/hcpinfo/OtherVaccines/pneumo/ppv.pdf>

Pertussis

Low dose pertussis vaccine (Tdap) is recommended for

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

7.4 Latex allergy

Vaccines supplied in vials or syringes containing rubber

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

Check the SmPCs or contact the National Immunisation Office at 01 8676108 for advice.

7.5 Thiomersal

Thiomersal is a mercury-containing compound that has been used since the 1930s to prevent bacterial and fungal contamination in some vaccines. Thiomersal is not the same as methyl mercury, which can accumulate in the body and become toxic. Thiomersal contains a different form of mercury (ethyl mercury) which is metabolised and removed from the body much faster than methyl mercury. A European review of the available evidence concluded that there is no evidence of harm from thiomersal in vaccines other than hypersensitivity reactions. The World Health Organization has concluded that there is no evidence of mercury toxicity in infants, children or adults exposed to thiomersal in vaccines.

None of the vaccines provided by the HSE National Cold Chain Service contain thiomersal.

7.6 Vaccine given too early

In the event that a vaccine has been given too early 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.

This early dose should be discarded and another dose given at least one month after the disregarded dose.

However inadvertently giving a dose less than 4 days before the minimum recommended interval is unlikely to have a significantly adverse effect on the immune response to that dose and so can be considered valid.

See Table on Minimum intervals between vaccine doses in General Immunisation procedures chapter of Immunisation Guidelines at <http://www.hse.ie/eng/health/immunisation/hcinfo/guidelines/chapter2.pdf>

7.7 Vaccine given after the expiry date

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

A further dose should be given one month after the expired dose.

This should be reported as a medication error to the HPRA (See Section 6.0).

7.8 Refusal of vaccination

In those instances where a parent/legal guardian/client refuse vaccination and all avenues of communication have been explored it is best practice that the parent/legal guardian/client sign a refusal form (if available from the local immunisation office). 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 in the refusal form.

If a refusal form is unavailable these details should be recorded in the patient notes.

8. Maintenance of the Cold Chain and Vaccine Ordering

8.1 Introduction

The “Cold Chain” is the system of correct storage, transport and maintenance of vaccines to ensure that they are protected from inappropriate temperatures and light from the time of manufacture to the time of administration.

The correct temperature range for storage, transport and maintenance of vaccine is between +2°C to +8°C. This range is important to maintain the potency and efficacy of vaccine and comply with the vaccine licence.

A designated person at each practice should be nominated to ensure that all procedures are adhered to. In their absence an alternative trained member of staff must be available.

It is the responsibility of the designated member of the general practice team to ensure that all the procedures are adhered to.

KNOW WHAT'S RIGHT FOR VACCINES

Vaccines should be stored in a pharmaceutical fridge. Domestic fridges are not suitable and should not be used for vaccine storage. Do monthly stock takes and check expiry dates.

Always use your account number when ordering vaccines.

When your vaccines arrive:

- ▶ check your order before signing for it
- ▶ place your vaccines in the fridge immediately
- ▶ put new stock at the back of the fridge and shorter dated stock at the front.

Never use out of date vaccines.

Always keep the temperature between +2°C to +8°C.

Store vaccines in their original packaging.

Store vaccines on shelves not touching the sides of the fridge.

It is recommended that the fridge temperature is checked and recorded twice daily.

Wire the fridge directly to power supply without using a plug or if this is not possible highlight the fridge must not be unplugged.

Return all expired or damaged vaccines in their original packaging – DO NOT put into sharps bin.

In the event of a power failure or breakdown in the “Cold Chain”

- ▶ **keep the fridge door closed**
- ▶ **contact the Chief Pharmacist or Medical Officer at the National Immunisation Office (Phone 087 9915452 or 01 8676108).**

8.2 Procedure for fridge maintenance

- A.** The vaccine fridge should not be overfilled and the vaccine boxes should not touch the sides or back of the fridge. Air needs to circulate around the packages.
- B.** Vaccine should always be stored in their original packaging. This packaging protects them from light and heat and this box carries the appropriate batch number and expiry date which is required for recording. Vaccines should not be removed from their packaging until required for use. The deleterious effects of light exposure on light sensitive vaccines are cumulative.
- C.** The vaccine fridge should be placed
 - ▶ in an appropriately ventilated room
 - ▶ away from any heat source
 - ▶ away from direct sunlight
 - ▶ Food and other goods should not be stored in the fridge.
- D.** A temperature monitoring chart should be on each vaccine fridge door. When a temperature chart has been completed, replace it with a new chart and keep completed chart indefinitely.
- E.** 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.

The data logger should be downloaded regularly (at least once every two weeks) and the electronic or printed record should be retained indefinitely. The stored data will suffice as a permanent temperature record for the fridge.

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

The data logger does not replace reading the fridge thermometer twice daily.

- F.** It is recommended that the fridge temperature is checked twice daily i.e. current, minimum and maximum temperature records at the start of the morning and again at end of the clinic day with time of reading and sign/initial. (This is in line with recommendations from the USA Centers for Disease Control and Prevention).

The maximum/minimum reading should be cleared from the fridge memory and reset after each reading. The reset has been correctly carried out when the maximum, minimum and current temperature all display the same reading.

- G.** The door should remain closed as much as possible and staff should keep opening to a minimum. (Reducing door openings 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 also be checked at the end of each day to make sure that they are properly closed and sealed.

When loading the fridge, vaccine removal, fridge cleaning or stock rotation, door openings may cause the air temperature in the fridge to increase up to room temperature for a short time.

Once the fridge door is closed the temperature should drop to between +2°C and +8°C within 15 minutes. After such a period of high activity maximum temperature should be recorded and memory erased. A note on the temperature recording record (**Appendix K**) should indicate the cause of the increase in temperature e.g. vaccine removal. temperature e.g. vaccine removal.

- H.** Containers of water can be placed in the fridge to help stabilise the temperature in the unit. This may arise if there is a planned power outage and the fridge is not full.
- I.** The electricity supply to the vaccine storage fridge should not be accidentally interrupted. 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, also label 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 pulled out, 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 are available from the NIO.
- J.** The fridge should be kept clean and dust free at all times. 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 strip. If the paper falls or comes away easily, then the seal needs to be replaced or adjusted. Check all around the door and particularly the corners.
- K.** The fridge should be serviced and thermometers calibrated annually. The inside of the fridge should be regularly cleaned with warm slightly soapy water. During cleaning of the fridge, vaccines may be stored in an appropriate alternative pharmaceutical fridge or a validated cool box. Further details including cool box specifications can be found at <http://www.hse.ie/eng/health/immunisation/hcpinfo/vaccineordering/SOP2016.pdf> and <http://www.hse.ie/eng/health/immunisation/hcpinfo/vaccineordering/sopcoolboxes2016.pdf>.
Dry thoroughly and only restock once the temperature is within the recommended range.
- L.** Records of servicing and cleaning should be maintained.
- M.** Vaccine storage procedures should be audited at least 12 monthly or more frequently if experiencing cold chain problems.
- N.** Ensure that adequate insurance for vaccine damage is in place in case of fridge breakdown to allow for vaccine replacement.

REMEMBER THE 4Rs

Read: Twice daily readings of the fridge thermometer's maximum, minimum and current temperatures at the same time every day (at opening and closing time) during the working week.

Record: record fridge temperatures in a standard fashion and on a standard form stating date and time of reading and sign/initial (**Appendix K**) or down load data logger regularly.

Reset: reset the max/min thermometer (i.e erase thermometer memory) after each reading and when temperatures have stabilised after a period of high activity also at the end of every day.

React: the person making the recordings should take action if the temperature falls outside +2°C to +8°C and document this action.

8.3 Procedure for ordering vaccines

- A.** Vaccine stocks should be kept to a minimum by monthly ordering only the quantity of vaccine required until the next delivery.
- B.** A “vaccine stock sheet” should be kept to record the date and stock on hand and quantity ordered to facilitate monthly ordering. A minimum vaccine stock of two weeks supply but no more than six weeks should be kept. Overstocking can lead to wastage in the event of cold chain failure or due to expiry date being reached or increase the risk of administering an expired vaccine.
- C.** Vaccines should be ordered from the HSE National Cold Chain Service (NCCS) (current contract holders are United Drug Distributors UDD).
 - ▶ online at <http://ordervaccines.ie/login.aspx>
 - ▶ E-mail vaccines@udd.ie
 - ▶ Fax number (01) 463 7788
- D.** NCCS should send a confirmatory email or fax outlining that they have received the order and confirming the vaccine delivery date. If confirmation is not received NCCS should be contacted directly.
- E.** Vaccines should be ordered by a specific date each month as per a prescribed schedule from the NCCS.

8.4 Procedure for accepting delivery

- A.** Vaccine deliveries must be signed for and must be checked against the order for discrepancies. Any discrepancies or any damage must be reported to the NCCS immediately.
- B.** Vaccines must be placed immediately in the vaccine fridge and must never be left at room temperature.
- C.** The temperature on delivery should be checked and recorded to show that vaccines were in temperature on delivery.
- D.** Vaccines must be removed from delivery box, checked against delivery docket, allocated to appropriate area in fridge and recorded. The delivery docket should be filed as it contains details of the delivery, batch number and expiry dates of products.

8.5 Procedure for stock rotation and disposal

- A.** Expiry dates of vaccines should be regularly checked and vaccine stock should be rotated so that vaccines with the shortest expiry date are closest to hand.
- B.** Vaccine with the shortest expiry date should be used first.
- C.** Expired and damaged unopened vaccines must not be used and should be removed from the fridge and returned to the NCCS driver with a completed vaccine return form. A copy of this should be retained locally. Vaccine return forms are available to download from <http://www.hse.ie/eng/health/immunisation/hcpinfo/vaccineordering/gpvaccreturn.pdf>. Never use the sharps bin to dispose of expired or damaged stock
- D.** These returns should not be kept in the fridge but should be ready to hand to the driver.

8.6 Procedure following breakdown in the “Cold Chain”

In accordance with product licence, all vaccines must be stored in a fridge between +2°C to +8° C and must not be frozen.

A break down in the “Cold Chain” occurs when vaccines are NOT stored between +2°C to +8°C.

This can be due to

- ▶ Delay in refrigerating vaccines once delivered
- ▶ Faulty fridge
- ▶ Electrical power cut
- ▶ Unplugged fridge switch
- ▶ Open fridge door

Any use of the vaccine outside of the licensed storage conditions is at the doctor’s own responsibility unless the NIO, on a case by case basis has advised whether it is appropriate to use the vaccines or whether they should be discarded.

If a breakdown in the cold chain occurs

- A.** Check the temperature on the fridge thermometer (current, maximum and minimum), note the time and remove the continuous temperature recording device (data logger) to download the readings and return to fridge.
- B.** Ensure that the fridge door is closed and fridge is working. If the fridge is not working or holding temperature between +2°C to +8°C then move vaccines to a working fridge immediately.
- C.** Determine (if possible) how long the fridge has been outside temperatures between +2°C to +8°C.
- D.** Record date, time and nature of breakdown.
- E.** Record the type, quantity and batch numbers of vaccines in each fridge affected by the incident.
- F.** If temperatures outside the permitted range are recorded, complete the Report following a breakdown in the Cold Chain (**Appendix L**) and the Details of Vaccines in a Cold Chain breakdown (**Appendix M**). and Contact the Chief Pharmacist or Medical Officer at the National Immunisation Office (Phone 087 9915452 or 01 8676108) for further advice. Advice will be given on a case by case basis whether it is appropriate to use the vaccines or whether they should be discarded.
- G.** Do not **use or dispose** of any vaccine and keep vaccines between +2°C to +8°C in quarantine until advised by the NIO.
- H.** Vaccines should be marked as recommended by NIO or those 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 form should be retained locally.
- I.** Any returns should be ready to hand to the driver.

If the fridge has electrical problems or a new fridge is required, record the temperature for 48 hours before using the fridge to store a new supply of vaccines. When a new fridge is placed in its permanent position, it should be allowed to stand for minimum of 24 hours before it is switched on. This allows gases to reach equilibrium before power is switched on. Then record the temperature for 48 hours to ensure it is maintaining the correct temperature.

The fridge should be leveled in a way that allows the door to close automatically if left ajar.

In the event of a fridge breakdown ensure that an insurance claim is submitted for damaged vaccines and the National Immunisation Office is reimbursed.

8.7 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 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 come in contact with 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 day before so that the newspaper will be at the fridge temperature before outage.

C. Lock the fridge

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

D. Record the temperature

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

E. Use a datalogger

A datalogger is a USB temperature data logger for use in vaccine fridges independent of fridge power supply. This can store up to a year's worth of data (16,382 readings). This device will give the temperature recording and time so that the duration of the temperature breach is exact.

F. Ensure vaccines are insured

9. References

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Guidelines for Staff: Schools Immunisation Programme

<http://www.hse.ie/eng/health/immunisation/pubinfo/schoolprog/4in1mmr/schoolguidelines.pdf>

Guidance on Vaccine Storage and Handling (Version 2.0 August 2013)

Available at <http://www.hps.scot.nhs.uk/Search/guidedetail.aspx?id=45674>

HSE Guidelines for maintenance of cold-chain in vaccine fridges and management of vaccine stock

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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 in order to stimulate production of an immune response.

Passive immunisation is the administration of preformed antibodies (such as HNIG, specific antibody preparation and antitoxins) in order to provide temporary immunity.

Toxoid is a modified bacterial toxin that has been rendered non-toxic but has the ability to stimulate 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 b (Hib), Hepatitis B, acellular Pertussis, inactivated Polio and Tetanus vaccine |
| Hib/MenC | Haemophilus influenzae type b/Meningococcal C conjugate vaccine |
| HPV | Human Papillomavirus vaccine |
| MenB | Meningococcal B conjugate vaccine |
| MenC | Meningococcal C conjugate vaccine |
| MMR | Measles, Mumps, Rubella vaccine |
| PCV | Pneumococcal conjugate vaccine |
| 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 on or after 1 October 2016

| Age | Vaccines |
|---|-------------------------------------|
| 2 months | Rotavirus + 6 in 1 + PCV + MenB |
| 4 months | Rotavirus + 6 in 1 + Men B |
| 6 months | 6 in 1 + PCV + MenC |
| 12 months | MMR + MenB |
| 13 months | Hib/MenC + PCV |
| 4-5 years (Junior Infants) | 4 in 1 + MMR |
| 12-13 years (1st year second level schools) | MenC |
| 12-13 years (1st year second level schools) | Tdap |
| 12-13 years (1st year second level schools) | HPV x 2 doses (girls only) |
| All aged 65 years and older | Seasonal influenza vaccine |
| Those in specific medically at risk groups | +/- |
| Health care workers | Pneumococcal polysaccharide vaccine |

National Immunisation Schedule for those born before 1 October 2016

| Age | Vaccines |
|---|-------------------------------------|
| At Birth | BCG |
| 2 months | 6 in 1 + PCV |
| 4 months | 6 in 1 + Men C |
| 6 months | 6 in 1 + PCV |
| 12 months | MMR + PCV |
| 13 months | Men C + Hib |
| 4-5 years (Junior Infants) | 4 in 1 + MMR |
| 12-13 years (1st year second level schools) | Men C |
| 12-13 years (1st year second level schools) | Tdap |
| 12-13 years (1st year second level schools) | HPV x 2 doses (girls only) |
| All aged 65 years and older | Seasonal influenza vaccine |
| Those in specific medically at risk groups | +/- |
| Health care workers | Pneumococcal polysaccharide vaccine |

Appendix B

Catch up Immunisation Schedule for those born before 1 October 2016

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

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

4 months to <12 months of age

- ▶ 3 doses of 6 in 1 (DTaP/IPV/Hib/Hep B) at 2 month intervals
- ▶ 1 dose of MenC
- ▶ 2 doses of PCV at 2 month intervals

Continue with routine childhood immunisations from 12 months of age

12 months to <4 years of age

- ▶ 3 doses of 6 in 1 (DTaP/IPV/Hib*/Hep B) at 2 month intervals
* 1 dose of Hib may be given if this is the only vaccine that is required
- ▶ 1 dose of MenC
- ▶ 1 dose of PCV (omit if >2 years of age unless at increased risk)
- ▶ 1 dose of MMR

Continue with routine school immunisations from 4 years of age

- ▶ Booster 4 in 1 DTaP/IPV, or low dose Tdap/IPV if unavailable, at least 6 months and preferably 3 years after the primary course
- ▶ Second MMR at least one month after the first dose

If a child aged <18 months receives a second MMR vaccine within 3 months of the first MMR a third MMR should be given at 4 – 5 years of age

4 – <10 years of age

- ▶ 3 doses of 6 in 1 (DTaP/IPV/Hib*/HepB) at 2 month intervals
* 1 dose of Hib may be given if this is the only vaccine that is required
- ▶ 2 doses of MMR separated by at least one month.
- ▶ 1 dose of MenC

Continue with routine school immunisations

- ▶ Booster of 4 in 1 DTaP/IPV, or low dose Tdap/IPV if unavailable, at least 6 months and preferably 3 years after the primary course

10 – <18 years of age

- ▶ 3 doses of Tdap/IPV at 1 month intervals
- ▶ 2 doses of MMR separated by at least one month
- ▶ 1 dose of MenC
- ▶ Booster doses of Tdap/IPV 5 years after the primary course and Tdap 10 years later

18 years and older

- ▶ 1 doses of Tdap/IPV followed 1 month later by 2 doses of Td/IPV at 1 month intervals
- ▶ 1 dose of MenC (up to 23 years of age)
- ▶ 2 doses of MMR (if no documented evidence of previous vaccinations) for
 - ▼ health care workers born in Ireland since 1978 or born outside Ireland
 - ▼ contacts in outbreaks born in Ireland since 1978 or born outside Ireland
 - ▼ adults from low resource countries

There is no MenB vaccine or rotavirus oral vaccine catch up for babies born before 1 October 2016.

Catch up Immunisation Schedule for babies born on or after 1 October 2016

The catch up schedule for babies born on or after 1 October 2016 is as per the above schedule except for MenB vaccine and Rotavirus oral vaccine.

Rotavirus oral vaccine

- ▶ If an infant is late presenting for vaccination, they can receive their first dose of vaccine up until the age of 7 months and 0 days. The final dose can then be given before 8 months and 0 days.
- ▶ The minimum interval between doses is 4 weeks.
- ▶ All doses of rotavirus vaccine must be completed by 8 months and 0 days.

MenB Vaccine

- ▶ 2 - 10 months
 - ▼ 3 doses
 - ▼ 2 doses 2 months apart and booster at 12 months.
- ▶ 10 months - <12 months
 - ▼ 2 doses
 - ▼ 1 dose and booster at 12 months or older, 2 months after the first dose.
- ▶ 12 months and older
 - ▼ 2 doses
 - ▼ 2 doses 2 months apart.

Appendix B Continued

Catch-up schedule for children and adults born before 1 October 2016

| Vaccine | 4 months to <12 months | 12 months to < 4 years | 4 to <10 years | 10 to <18 years | 18 years and older |
|------------------------------------|---|--|---|---|--|
| 6 in 1 (DTaP/IPV/Hib/Hep B) | 3 doses 2 months apart | 3 doses 2 months apart | 3 doses 2 months apart | | |
| Men C | 1 dose | 1 dose | 1 dose | 1 dose (if given after 10 years of age, adolescent MenC booster not required) | 1 dose (up to 23 years of age) |
| PCV | 2 doses 2 months apart | 1 dose (omit if >2 years of age ²) | | | |
| MMR³ | | 1 dose | 2 doses 1 month apart | 2 doses 1 month apart | 2 doses 1 month apart ⁴ |
| Tdap/IPV | | | | 3 doses 1 month apart | 1 dose ⁵ |
| Td/IPV | | | | | 2 doses 1 month apart (1 month after Tdap/IPV) |
| NOTE | Continue with routine childhood immunisation schedule from 12 months. | Continue with routine school immunisations [4 in 1 DTaP/IPV, or low dose Tdap IPV if unavailable,] at least 6 months and preferably 3 years after primary course, MMR at least 1 month after previous dose] | Continue with routine school immunisations [4 in 1 DTaP/IPV, or low dose Tdap IPV if unavailable, at least 6 months and preferably 3 years after primary course] | Boosters of Tdap/IPV 5 years after primary course and Tdap 10 years later | |

- 1 One dose of single Hib vaccine may be given to children over 12 months of age and up to 10 years of age if this is the only vaccine they require
- 2 Unless at increased risk
- 3 The second dose of MMR is recommended routinely at 4-5 years but may be administered from 18 months of age. Children vaccinated before their first birthday should have a repeat MMR vaccination at 12 months of age, at least one month after the first vaccine with a further dose at 4-5 years of age. If a child aged <18 months receives a second MMR vaccine within 3 months of the first MMR a third MMR should be given at 4-5yrs of age.
- 4 For health care workers born in Ireland since 1978 or born outside Ireland; for contacts in outbreaks born in Ireland since 1978 or born outside Ireland and for adults from low resource countries, without evidence of two doses of MMR vaccine
- 5 Only one dose of Tdap/IPV is required due to likely previous exposure to pertussis infection

Appendix C

Professional Development Coordinators for Practice Nurses by CHO area

| Name | Address | Email | Phone | Fax | Mobile | CHO Areas |
|--------------------|--|---------------------------|----------------|----------------|----------------|--|
| Marie Courtney | HSE Primary Care Unit, Block 15 (3rd Floor), St Finbars Hospital, Douglas Road, Cork | Marie.Courtney@hse.ie | 021 4923832 | 021 4923820 | 086 7872408 | Cork, Kerry |
| Rhonda Forsythe | Swords Business Park, Balheary Rd, Swords, Co. Dublin | Rhonda.Forsythe@hse.ie | 01 8908740 | 01 8908707 | 087 2198098 | North Dublin |
| Dr Rita Lawlor | HSE Primary Care Unit, 52 Broomhill Rd, Tallaght, Dublin 24 | Rita.Lawlor@hse.ie | 01 4632866 | 01 4632847 | 086 3837432 | South West Dublin, Kildare, West Wicklow |
| Patricia McQuillan | The Office Complex, Kilcreene Hospital Grounds, Kilkenny | Patricia.McQuillan@hse.ie | 056 7785613 | 056 7785549 | 087 2281548 | Carlow, Kilkenny, South Tipperary, Waterford, Wexford |
| Kathy McSharry | CNE, St. Mary's Campus, Castlebar, Co. Mayo | Kathy.McSharry@hse.ie | 094 9042164 | 094 9042075 | 087 1206184 | Galway, Mayo, Roscommon |
| Kathy Taaffe | HSE West Primary Care Development Unit, JFK House, JFK Parade, Sligo | Kathy.taaffe@hse.ie | 071 9135024 | | 087 1321424 | Sligo, Leitrim, Cavan, Monaghan, Donegal |

Appendix D

GP Practice administration issues

It is good practice to

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

Appendix E

Sample medicine protocol

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

- ▶ The Nursing and Midwifery Board (2010) Practice Standards for Midwives: The Nursing and Midwifery Board
- ▶ The Nursing and Midwifery Board (2007) E-learning Guide to Medication Management. Available at www.nursingboard.ie
- ▶ The Nursing and Midwifery Board (2007) Guidance to Nurses and Midwives on Medication Management Dublin: The Nursing and Midwifery Board.
- ▶ The Nursing and Midwifery Board (2002) Recording Clinical Practice. Guidance to Nurses and Midwives
- ▶ The Nursing and Midwifery Board (2014) The Code of Professional Conduct and Ethics for Registered Nurses and Midwives
- ▶ The Nursing and Midwifery Board (2015) Scope of Nursing and Midwifery Practice Framework Dublin: The Nursing and Midwifery Board www.nmbi.ie/Standards-Guidance/Scope-of-Practice
- ▶ National Immunisation Advisory Committee (2013) Immunisation Guidelines for Ireland. Dublin: Royal College of Physicians Ireland and any subsequent amendments found at www.immunisation.ie
- ▶ National Immunisation Office (2008) A Practical Guide to Immunisation. Dublin: Health Service Executive
- ▶ Summary of Product Characteristics and Patient Information Leaflet as detailed by the Health Products Regulatory Authority I are available at www.hpra.ie.

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

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

Appendix E Continued

| 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 available) | |
| Names and signatures of protocol authors and reviewers | |
| Name(s) and Signature(s) of the employing authority who is authorising the implementation of the protocol | |
| 2.0 Clinical Criteria | |
| Clinical Condition for use of the protocol | |
| Circumstances in which the medicine protocol applies | |
| Inclusion criteria for patient/service user treatment using the protocol | |
| Exclusion criteria for patient/client treatment using the medicine protocol | |
| Actions to be taken for those who are excluded from the Protocol | |
| Precautions | |
| Documentation required to support implementation of the medicine protocol | |
| 3.0 Details of Medication to be supplied | |
| Name of Medication | |
| Instructions for administration of the vaccine | N.B. A General Practitioner must be on the practice premises during the administration of vaccines and during the 15 minute post vaccination observation period to assist with any adverse events which may result from vaccination administration. |

Appendix E Continued

| | |
|--|--|
| Warnings and precautions for use | |
| Possible Side Effects | |
| Potential adverse reactions and procedures for treatment of same | |
| Procedure for reporting Adverse Drug Reactions to the Health Products Regulatory Authority | |
| Procedure for the reporting and documentation of errors and near misses involving the medication | |
| Mechanisms for storage of medications and for obtaining supply | |
| Resources and equipment required | |
| Audit process to identify appropriate use of the protocol or unexpected outcomes | |
| 4.0 Patient/service-user care information | |
| Advice to be given to the patient/ service user and/or carer before and/ or after treatment | |
| Provision of Patient Information Leaflet/Fact Sheet | |
| Details of any necessary follow-up, action and referral arrangements | |
| 5.0 Staff authorised to use protocol | |
| Staff authorised to use protocol | |
| Professional qualifications, training, experience and competence relevant to this medicine protocol | |
| Requirements for staff for continuing training and education for supplying medication using protocol | |

Appendix F

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

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

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

Date of planned training

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

| Domain of Practice | Performance Criteria: Critical Element | Needs Theory Date/Initial | Needs Practice Date/Initial | Competent Date/Initial |
|--------------------|---|---------------------------|-----------------------------|------------------------|
| 1, 4 | I am aware of the correct preparation/reconstitution of vaccines. | | | |
| 2, 4 | I can prepare all vaccines using aseptic technique. | | | |
| 1, 2, 4 | I can follow the correct procedure for the intramuscular administration of vaccine(s). | | | |
| 1, 2, 3 | I am aware of potential adverse reactions in relation to vaccination. | | | |
| 1, 2, 4 | I am aware of the procedures for treatment of adverse reactions | | | |
| 1, 2, 3 | I understand the procedure for reporting and documentation of medication errors/near misses. | | | |
| 1, 2, 3 | I understand the procedure for the reporting and documentation of adverse drug reactions. | | | |
| 1, 2, 3, 4 | I am aware of relevant written/oral instructions to be given to patients, parents/guardians with regard to completion of their vaccination programme. | | | |
| 1, 4 | I dispose of all equipment and sharps in accordance with standard precautions and local policies. | | | |
| 1, 2, 4 | I record the administration of vaccines as required by practice and HSE documents and update patients record as appropriate. | | | |

I have sufficient theoretical knowledge and practice to undertake this role, and I acknowledge my responsibility to maintain my own competence in line with the Scope of Nursing Practice

Practice Nurse's Signature:

Date:

If any deficits in theory and/or practice identified, the nurse must discuss with authorising General Practitioner and implement 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:

Practice Nurse's Signature:

Date:

Appendix G

Roles and responsibilities of HSE staff

1 Introduction

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

2 Managerial role and responsibilities

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

3. Role of HSE clerical/administrative staff

HSE clerical/administrative staff should

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

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

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

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

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

Appendix H

HSE Area Immunisation Unit Directory

| CHO 1 | | | | |
|---|--|--------------------------------|---|---|
| Address | Name | Area | Phone | Email |
| Immunisation Department, Donegal PCCC HQ, St Joseph's Hospital, Stranorlar, Lifford, Co. Donegal | Eileen Clancy | Donegal | 074 919 1757 | Eileen.Clancy@hse.ie |
| Immunisation Dept, Markievicz Hse., Sligo. | Bernie Flatley | Sligo Leitrim West Cavan | 071 915 5148 | Bernie.flatley@hse.ie |
| Primary Care, Railway St., Navan, Co. Meath | Anita Reilly | Cavan, Monaghan | 046 907 6485 | Anita.Reilly@hse.ie |
| CHO 2 | | | | |
| Address | Name | Area | Phone | Email |
| Child Health/ Immunisation Office Community Services 25, Newcastle Rd., Galway | Brid O Connell (PCI) | Galway City & County | 091 546207 | brid.oconnell1@hse.ie |
| Galway Roscommon PCCC, HSE – West, Roscommon Primary Care Centre, Golf Links Road, Roscommon. | Catriona Harrington | Roscommon | 090 66 37514 | catriona.harrington@hse.ie |
| Child Health/ Immunisation Office, Community Services St. Mary's Headquarters, Castlebar, Co. Mayo | Eleanor Loftus – S Mayo Bridie McAndrew – N Mayo Sheila Hayes | Mayo | 094 9042217 096 21511 094 9042519 | eleanor.loftus@hse.ie bridie.mcandrew@hse.ie sheila.hayes2@hse.ie |

| CHO 3 | | | | |
|---|-------------------------|---|--------------|---------------------------|
| Address | Name | Area | Phone | Email |
| Immunisation Office Sandfield Centre Ennis, Co. Clare | Denise Reidy | Co. Clare | 065 6868039 | Denise.Reidy@hse.ie |
| Immunisation Office, Raheen, Limerick | Mary Stokes | Limerick City & County | 061 483935 | mary.stokes@hse.ie |
| Immunisation Dept., Health Centre, Tyone, Nenagh, Co. Tipperary | Orla Cleary | Tipperary North Riding/ East Limerick | 067 46416 | Orla.cleary@hse.ie |
| CHO 4 | | | | |
| Address | Name | Area | Phone | Email |
| Immunisation Unit, HSE – Floor 2, Mallow Primary Healthcare Centre, Gouldshill, Mallow, Co. Cork | Caroline J. Clifford | Cork City & County | 022 58780 | CarolineJ.Clifford@hse.ie |
| Immunisation Unit, Community Services, Rathass, Tralee, Co. Kerry | Catherine Kearney | Kerry | 066 7195682 | Catherine.Kearney@hse.ie |
| CHO 5 | | | | |
| Address | Name | Area | Phone | Email |
| Child Health Office, Community Care Centre, Western Rd., Clonmel, Co. Tipperary | Siobhan McCall | South Tipperary | 052 6177246 | Siobhan.McCall@hse.ie |
| Child Health Office Community Care Centre James' Green, Kilkenny | Siobhan Hennessy | Co. Carlow Co. Kilkenny | 056 7784670 | SiobhanT.Hennessy@hse.ie |
| Child Health Office, Community Care Offices, Georges St., Wexford | Susan O'Hara | Co. Wexford | 053 9185749 | Susan.Ohara@hse.ie |
| Child Health Office, Community Care Centre, Cork Rd., Waterford | Caroline McGrath | Co. Waterford | 051 842908 | Caroline.Mcgrath@hse.ie |

| CHO 6 | | | | |
|--|--|--|--|---|
| Address | Name | Area | Phone | Email |
| Immunisation Section, Glenside Rd. Wicklow | Denis Mangan | Wicklow | 0404 60672 | Denis.Mangan@hse.ie |
| HSE Immunisation Section Tivoli Rd, Dun Laoghaire, Co. Dublin | Annette Barnes | Dublin South | 01 2365244 | Annette.Barnes@hse.ie |
| Immunisation Section, Vergemount Hall, Clonskeagh, Dublin 6 | Mary McKernan | Dublin South East | 01 2680379 | Mary.McKernan@hse.ie |
| CHO 7 | | | | |
| Address | Name | Area | Phone | Email |
| St Marys Craddockstown Road Naas Co. Kildare | Tiarnan O'Brien Derval Glynn | Kildare/ West Wicklow | 045 907 927 045 907 926 045 907 937 | Tiarnan.obrien@hse.ie |
| Immunisation Department, Elinor Lyons Building, Meath Primary Care Centre, Heytesbury Street, Dublin 8 | Noreen Diver Orlagh Hayes Emer Gannon Jacinta McNevin Amanda Carr | Dublin South Central Dublin West | 076 695 8123 076 695 8198 076 695 8192 076 695 8195 | noreen.diver@hse.ie emer.gannon@hse.ie |
| Immunisation Department, Tessa House, Block D, Cookstown Way, Tallaght, Dublin 24 | David Walsh Thomas McKeon | Dublin South West | 01 4141485 01 4141482 | David.Walsh@hse.ie Thomas.McKeon@hse.ie |
| CHO 8 | | | | |
| Address | Name | Area | Phone | Email |
| Immunisation Section, Primary Care Unit, Springfield, Mullingar Co. Westmeath | Olivia Finerty Leanne Murphy Noeleen Deegan Clare Taaffe | Co. Westmeath Co. Laois Co. Longford Co. Offaly | 044 9384423 044 9384422 044 9384432 044 9384425 | Olivia.Finerty@hse.ie Leanne.Murphy@hse.ie Noeleen.Deegan@hse.ie Clare.Taaffe@hse.ie |
| Primary Care, Railway St., Navan, Co. Meath | Anita Reilly | Meath, Louth | 046 9076485 | Anita.Reilly@hse.ie |

| CHO 9 | | | | |
|---|---|-------------------------|---|--|
| Address | Name | Area | Phone | Email |
| HSE-Dublin North West, Units 4/5 Nexus Building, Blanchardstown Corporate Park, Ballycoolin, Dublin 15 | Ciara Davidson Rita Dalton Karen Connolly | Dublin North West A6 | 018975140 018975158 01 8975139 01 8975135 018975197 | Ciara.Davidson@hse.ie Rita.owens@hse.ie Karen.connolly4@hse.ie |
| Primary, Community and Continuing Care Directorate Ground Floor, Unit 4&5 Nexus Building Block 6A Blanchardstown Corporate Park Dublin 15 | Ciara Davidson Rita Dalton Karen Connolly | Dublin North City A7 | 01 8975140 01 8975158 01 8975197 | Ciara.Davidson@hse.ie Rita.owens@hse.ie Karen.connolly4@hse.ie |
| 1st Floor, Northside Civic Centre Bunratty Road, Dublin 17 | Debbie Keegan | Dublin North | 01 8661431 | debbie.keegan@hse.ie |

Appendix I

Departments of Public Health

| HSE SOUTH | | | |
|---|--|---|--|
| Kilkenny/Carlow/ Waterford/Wexford/ South Tipperary | Director of Public Health: Dr John Cuddihy | Department of Public Health Health Service Executive Dublin Road Lacken Kilkenny | Tel: (056) 7784124 Fax: (056) 7784393 ID Fax: (056) 7784599 |
| Cork/Kerry | Director of Public Health: Dr Mary T O'Mahony | Department of Public Health, Health Service Executive South, Floor 2 – Block 8, St. Finbarr's hospital, Douglas Road, Cork. | Tel: (021) 4927601 Fax: (021) 4923257 ID Fax Cork: (021) 4923257 ID Fax Kerry: (066) 7184542 Email: dph@hse.ie |
| HSE WEST | | | |
| Donegal/Sligo/Leitrim | Director of Public Health: Dr Peter Wright | Department of Public Health Health Service Executive Iona House, Upper Main Street Ballyshannon Co. Donegal | Tel: (071) 9852900 Fax: (071) 9852901 |
| Limerick/Clare/North Tipperary | Director of Public Health: Dr Mai Mannix | Department of Public Health Health Service Executive Mount Kennett House Henry Street, Limerick | Tel: (061) 483337 Fax: (061) 464205 |
| Galway/Mayo/ Roscommon | Director of Public Health: Dr Diarmuid O'Donovan | Department of Public Health Health Service Executive Merlin Park Galway | Tel: (091) 775200 Fax: (091) 758283 Email: public.health@hse.ie |

DUBLIN NORTH EAST

| | | | |
|--------------------------------|--|--|--|
| Cavan/Louth/Meath/ Monaghan | Director of Public Health: Dr Bernadette O'Keefe | Department of Public Health Health Service Executive Railway Street Navan Co. Meath | Tel: (046) 9076412 Fax: (046) 9072325 |
|--------------------------------|--|--|--|

HSE DUBLIN MID LEINSTER

| | | | |
|-------------------------------------|---|--|---|
| Laois/Offaly/Longford/ Westmeath | Director of Public Health: Dr Phil Jennings | Department of Public Health Health Service Executive HSE Area Office Arden Road Tullamore Co. Offaly. | Tel: (057) 9359891 Fax: (057) 9359906 ID Fax: (057) 9359907 Email: public-health@hse.ie |
| Dublin/Kildare/Wicklow | Director of Public Health: Dr Margaret Fitzgerald | Department of Public Health Health Service Executive Dr. Steeven's Hospital Dublin 8. | Tel: Main Switch (01) 6352000 Direct telephone lines for Infectious Disease Notifications: Tel: (01) 6352145 (office hours) Fax: (01) 6352103 Email: dph.east@hse.ie |

Appendix J

Data Entry Standards used in HSE school immunisation programme

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

Data entry of names:

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

Surname Data Entry Convention to be followed

Surname 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 **AI** should be entered as AI space Hussain i.e. **AI 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'** 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 **Ní** should be entered as Ni space i.e. **Ni Bhroin**
- ▶ Names prefixed with **Nic** should be entered as Nic space i.e. **Nic Ailin**
- ▶ Names prefixed with **De** should be entered as De space i.e. **De Burca**
- ▶ **Double barrel names** should also be entered without commas, apostrophes, dashes etc. Enter with a space between names i.e. **Tierney Monahan** not Tierney-Monahan

First Name Data Entry Convention to be followed

Forenames must be entered in full. Initials or spelling abbreviations are not acceptable e.g. type Michael not MI, Margaret not Mags, Patrick Joseph and not Patk J. etc. Junior/Senior: Where the suffix is used in a client's name, it must be typed in full with brackets directly after the forename e.g. Michael (Junior) or Patrick (Senior). Ensure that the **proper** first name is given and recorded not the "known as" name i.e. **Margaret rather than Mags**. Where the client uses an alias name which differs considerably 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 way 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 nnnnnnnnnn e.g. 0862549801 leave 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 Marys 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 No. If the client address contains an apartment number, type the word Apartment and the appropriate number in the Apartment field e.g. Apartment 7.

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

Appendix K

Temperature Log

1. Record the current temperature and the minimum/maximum fridge temperature twice daily: when you first open the office and before closing.
 2. Remember to reset your min-max fridge thermometer after recording the temperatures.

| Month: Year 20 | Name/ Initial | Fridge number: | | PM | Location: | | | Note factors which may affect fridge performance e.g. door opening, vaccine delivery |
|-------------------|------------------|----------------|------------|--------|-----------|------------|--------|--|
| | | AM | | | Time | Current C° | Min C° | |
| Day of the Month | | Time | Current C° | Max C° | Time | Current C° | Min C° | Max C° |
| 1 | | | | | | | | |
| 2 | | | | | | | | |
| 3 | | | | | | | | |
| 4 | | | | | | | | |
| 5 | | | | | | | | |
| 6 | | | | | | | | |
| 7 | | | | | | | | |
| 8 | | | | | | | | |
| 9 | | | | | | | | |
| 10 | | | | | | | | |
| 11 | | | | | | | | |
| 12 | | | | | | | | |
| 13 | | | | | | | | |
| 14 | | | | | | | | |
| 15 | | | | | | | | |
| 16 | | | | | | | | |
| 17 | | | | | | | | |
| 18 | | | | | | | | |
| 19 | | | | | | | | |
| 20 | | | | | | | | |
| 21 | | | | | | | | |
| 22 | | | | | | | | |
| 23 | | | | | | | | |
| 24 | | | | | | | | |
| 25 | | | | | | | | |
| 26 | | | | | | | | |
| 27 | | | | | | | | |
| 28 | | | | | | | | |
| 29 | | | | | | | | |
| 30 | | | | | | | | |
| 31 | | | | | | | | |

Appendix L

Report following breakdown in the “Cold Chain”

| | | | |
|-----------------|--|------|--|
| LHO: | | | |
| Address | | | |
| Phone: | | Fax: | |
| Contact person: | | | |

Identification of breakdown in “Cold Chain” incident

Date identified: ___/___/___ Time identified: ___:___am/pm

Fridge temperature at time of incident identification

| Fridge ID | Current | Minimum | Maximum |
|-----------|---------|---------|---------|
| A | | | |
| B | | | |
| C | | | |
| D | | | |

Last record of fridge temperature within the cold chain and reset

| Fridge ID | Date last record | Time last record | Date last reset | Time last reset |
|-----------|------------------|------------------|-----------------|-----------------|
| A | ___/___/___ | ___:___am/pm | ___/___/___ | ___:___am/pm |
| B | ___/___/___ | ___:___am/pm | ___/___/___ | ___:___am/pm |
| C | ___/___/___ | ___:___am/pm | ___/___/___ | ___:___am/pm |
| D | ___/___/___ | ___:___am/pm | ___/___/___ | ___:___am/pm |

Data logger details

| Fridge ID | Time when reading exceeded +8°C or dropped below +2°C | Time when reading dropped below +8°C or exceeded +2°C | Duration |
|-----------|---|---|----------|
| A | | | |
| B | | | |
| C | | | |
| D | | | |

Appendix M

Details of Vaccines in “Cold Chain” breakdown

| Vaccine | Trade Name | Batch Number | Expiry Date | Quantity |
|---|------------|--------------|-------------|----------|
| Primary Immunisation Programme | | | | |
| DTaP/IPV/Hib/HepB (6in1) | | | | |
| Haemophilus influenzae Type b (Hib) | | | | |
| Hib/MenC | | | | |
| Meningococcal B (MenB) | | | | |
| Meningococcal C (MenC) | | | | |
| MMR | | | | |
| Pneumococcal Conjugate Vaccine (PCV) | | | | |
| Rotavirus | | | | |
| School Immunisation Programme | | | | |
| BCG | | | | |
| Tuberculin | | | | |
| DTaP/IPV (4in1) | | | | |
| Tdap /IPV(4in1-low dose) | | | | |
| MMR | | | | |
| HPV | | | | |
| Tdap | | | | |
| Meningococcal C (Men C) | | | | |
| Seasonal | | | | |
| Influenza Vaccine | | | | |
| Pneumococcal Polysaccharide Vaccine (PPV23) | | | | |
| Others | | | | |
| Hepatitis B Renal (higher dose) | | | | |
| Hepatitis B Adult | | | | |
| Hepatitis B Paediatric | | | | |
| Hepatitis A Adult | | | | |
| Hepatitis A Paediatric | | | | |
| Hepatitis A and B Adult | | | | |
| Hepatitis A and B Paediatric | | | | |
| MenACWY | | | | |
| Td | | | | |
| Tdap | | | | |

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