

Note: This document must be read in conjunction with

- National Immunisation Advisory Committee Immunisation Guidelines for Ireland available at: https://www.rcpi.ie/Healthcare-Leadership/NIAC/Immunisation-Guidelines-for-Ireland
- National Immunisation Office (2022) Guidelines for Vaccinations in General Practice available at: <a href="https://www.hse.ie/eng/health/immunisation/infomaterials/gpsupportingdocpci.pdf">https://www.hse.ie/eng/health/immunisation/infomaterials/gpsupportingdocpci.pdf</a>
- National Immunisation Office (2023/2024) Supporting Information for Staff: Schools Immunisation
   Programme available at:
  - https://www.hse.ie/eng/health/immunisation/hcpinfo/schoolproghcp/supportingdoc.pdf
- National Immunisation Office Clinical Guidance for COVID-19 vaccination available at: https://bit.ly/COVIDClinicalGuidance

#### Updates since last edition

- Removed Section 8.0 Human Papillomavirus (HPV)
- February 2024- Updated COVID-19 Primary dose guidance

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#### 1.0 Introduction

Displaced people entering the EU/EEA from other countries including Ukraine¹ seeking international protection may be vulnerable to developing infectious diseases, including vaccine-preventable diseases, due to the increased incidence of various infectious diseases in their country of origin, disrupted living conditions before or during their displacement that may increase the risk of transmission (e.g. poor shelter, overcrowding with poor ventilation), and challenges accessing healthcare on or after arrival. Displaced people entering Ireland from other countries are dispersing into communities, or accommodated in congregate settings, e.g. hotels, holiday villages, gyms, schools and community centres. Congregate settings have a higher risk of communicable disease outbreaks. The vaccine coverage in Ukraine is sub-optimal for routine childhood immunisations and COVID-19 vaccination. It is a public health priority to ensure that children and adults from other countries are immunised and up to date with all recommended vaccines in Ireland.

Vaccination against COVID-19, measles and polio have been identified as particular priorities by both the World Health Organization (WHO) and the European Centre for Disease Prevention and Control (ECDC) because of the risk of severe clinical outcomes among the most vulnerable, and their outbreak potential.

#### 2.0 Statement:

The Health Service Executive (HSE) provides catch-up vaccination for children and adults coming from other countries. The catch-up vaccination programme aims to protect them from vaccine preventable diseases (VPDs) and prevent outbreaks of VPDs in congregate and other settings.

#### 3.0 Purpose:

The catch-up vaccination programme for children and adults coming from other countries is aligned 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, available at <a href="https://www.rcpi.ie/Healthcare-Leadership/NIAC/Immunisation-Guidelines-for-Ireland">https://www.rcpi.ie/Healthcare-Leadership/NIAC/Immunisation-Guidelines-for-Ireland</a>.

The clinical information in this document has been prepared to inform and support relevant HSE staff, Registered Nurses (RN), Registered Midwives (RMs) and Registered Medical Practitioners (RMPs) on the procedures to be followed for the safe delivery of catch-up vaccination for children and adults coming from other countries.

#### 4.0 Scope:

These guidelines apply to all Registered Nurses (RN), Registered Midwives (RMs) and Registered Medical Practitioners (RMPs) (hereafter referred to as vaccinators) providing catch-up vaccination to Refugees and Applicants Seeking Protection in Ireland and in the event of an outbreak.

#### 5.0 Principles for catch-up vaccination in Ireland

Children and adults coming to Ireland from other countries should follow the Irish immunisation schedule as they are now living in Ireland. This is to protect them from vaccine-preventable diseases that are or were common in Ireland (and hence in our immunisation schedule), or which may have serious consequences including disability and death. Vaccination coverage for other countries is available at <a href="https://bit.ly/WHOVacc">https://bit.ly/WHOVacc</a>

<sup>&</sup>lt;sup>1</sup> European Centre for Disease Prevention and Control. Operational public health considerations for the prevention and control of infectious diseases in the context of Russia's aggression towards Ukraine. 8 March 2022. Stockholm: ECDC; 2022

#### 5.1 Previous immunisation record

The immunisation guidelines advise that people coming to Ireland with no documented or reliable verbal history of immunisation, should be assumed to be unimmunised. This includes those coming from areas of conflict (such as Ukraine). It should be assumed that if doses are not documented (or there is no reliable verbal history) that they have not been received, and the Irish catch-up recommendations for that age should be followed.

- Once a child reaches the age of 2 years of age, NIAC advises they no longer need PCV13 vaccine or MenB vaccine, even if they have never had these vaccines. The exception is children with at-risk conditions who should be vaccinated. For those at-risk conditions, please refer to NIAC chapter 13 for <a href="Meningococcal Infection">Meningococcal Infection</a> and the NIAC chapter 16 for <a href="Pneumococcal Infection">Pneumococcal Infection</a>.
- Once a child has reached the age of 10, they no longer need HIB vaccine
- A child over the age of 1 year needs a single dose of MenC up until the age at which MenACWY is given in school. If they have missed MenACWY in school, they should receive a single dose of MenC up to the age of 23 years.
- There is no catch-up vaccination programme for hepatitis B vaccine unless the person falls into an at-risk group

#### 5.2 NIAC Catch up schedule

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

Please see below NIAC Chapter 2 (updated August 2022) Tables 2.3, 2.4 and 2.4a outlining recommended catch-up vaccination schedules. <a href="https://www.rcpi.ie/Healthcare-Leadership/NIAC/Immunisation-Guidelines-for-Ireland">https://www.rcpi.ie/Healthcare-Leadership/NIAC/Immunisation-Guidelines-for-Ireland</a>

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

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

Details of superscripts are below Table 2.4

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

Vaccine	4 -9 years	10 -17 years	18 years and older	
DTaP/IPV/HepB¹/ Hib² 6 in 1	3 doses ≥8 weeks apart 1,2			
MenC³	nC³ 1 dose		1 dose up to 23 years of age, if Men C containing vaccine not given at age ≥10years	
MMR	2 doses	2 doses	2 doses	
	≥28 days apart <sup>4</sup>	≥28 days apart	≥28 days apart <sup>5</sup>	
Tdap/IPV <sup>6</sup>		3 doses	1 dose <sup>7</sup>	
		≥28 days apart		
Td/IPV			2 doses ≥28 days apart – leave ≥28 day gap after Tdap/IPV	
NOTE	DTaP/IPV at least 6 months and preferably 3 years after primary course and MMR2 ≥ 1 month after MMR1	Booster of Tdap/IPV 5 years after primary course; Tdap 10 years later		

- HepB vaccine is not needed if this is the only vaccine required unless in a risk group (NIAC Chapter 9 <a href="https://www.rcpi.ie/Healthcare-Leadership/NIAC/Immunisation-Guidelines-for-Ireland">https://www.rcpi.ie/Healthcare-Leadership/NIAC/Immunisation-Guidelines-for-Ireland</a>)
- 2. A dose of single Hib vaccine may be given to those from 12 months to < 10 years of age if this is the only vaccine required
- 3. Combined Hib/MenC vaccine can be given up to 10 years of age if these are the only two vaccines required
- 4. One dose if not yet in primary school and second dose will be given in junior infants
- 5. For HCWs or contacts in outbreaks born in Ireland since 1978 or born outside Ireland; and for adults from low resource countries, without evidence of two doses of MMR vaccine
- 6. If Tdap/IPV is unavailable, see Table 2.4a
- 7. Only one dose of Tdap/IPV is required due to likely previous exposure to pertussis infection

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

Vaccine	10-13 years	14 - 17 years	18 years and older	
DTaP/IPV	3 doses ≥28 days apart			
Tdap		1 dose <sup>1</sup>	1 dose <sup>1</sup>	
Td/IPV		3 doses ≥28 days apart – leave ≥28 day gap after Tdap²	3 doses ≥28 days apart – leave ≥28 day gap after Tdap²	
MenC	1 dose up to 23 years of age, if Men C containing vaccine not given at age ≥10 years			
MMR	2 doses ≥28 days apart³			
NOTE	Booster of Td/IPV 5 year Tdap 10 years later			

<sup>&</sup>lt;sup>1</sup>Only one dose of Tdap is required due to likely previous exposure to pertussis infection

#### 5.3 Interrupted immunisation schedule

- If the recommended immunisation schedule is interrupted, it should be resumed as soon as possible.
- It is not necessary to restart the schedule, regardless of the time of interval from the previous vaccination. This is because of immunological memory.
- Intervals longer than routinely recommended between doses do not impair the immunologic response to live and inactivated vaccines that require more than one dose to achieve primary immunity.
- Similarly, delayed administration of recommended booster doses does not adversely affect the antibody response to such doses.

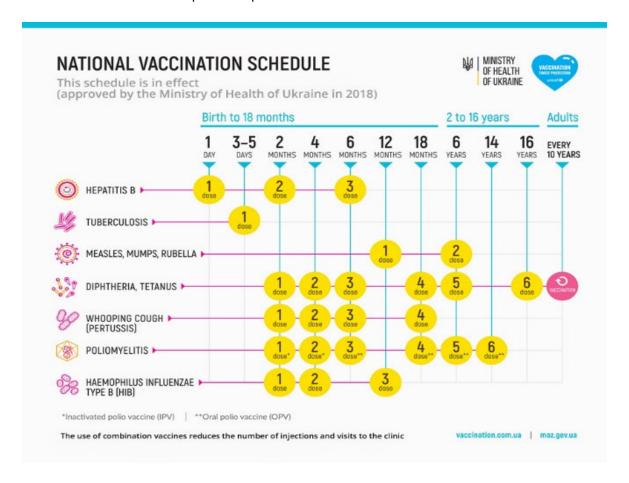
#### 6.0 Childhood Immunisations in Ukraine

• In Ukraine's routine childhood immunisation schedule, children are offered vaccines to protect against Tuberculosis, Diphtheria, Tetanus, Pertussis, Polio, Haemophilus influenzae type b and Hepatitis B before 12 months of age. From 12 months of age they are offered MMR and Haemophilus influenzae vaccines. The schedule from the Ukrainian Ministry of Health is shown below and available. National Immunisation Office (NIO) supportive information for healthcare workers in delivering catch-up vaccinations is also available at https://bit.ly/NIOBOTPIPA

<sup>&</sup>lt;sup>2</sup> There may be increased reactogenicity due to four tetanus containing vaccines in a short time

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

• While vaccine uptake in Ukraine is below 90% for most vaccines, the majority of children <u>are</u> vaccinated. The WHO reports an uptake of 87% for MMR2 and 80% for DTP3



Children coming to Ireland from overseas should have prior immunisation status checked at
every healthcare opportunity (make every contact count). As a priority, pay particular attention
to MMR and Polio-containing vaccines which are particularly important for those coming from
Ukraine. Children should be age-appropriately vaccinated to protect them against vaccine
preventable diseases. Teenagers and adults should also have their vaccination status
checked, again prioritising MMR and polio vaccines.

# 6.1 Primary Childhood Schedule - information sources WHO vaccine preventable disease monitoring system 2020 global summary https://immunizationdata.who.int/listing.html?topic=&location

#### **European Centre for Diseases Control (ECDC)**

Vaccine schedules in all countries in the EU/EEA <a href="https://vaccine-schedule.ecdc.europa.eu/">https://vaccine-schedule.ecdc.europa.eu/</a>

#### **Centre for Diseases Control (CDC)**

Aids to Translating Foreign Immunisation Records

https://www.cdc.gov/vaccines/pubs/pinkbook/downloads/appendices/b/foreign-products-tables.pdf

#### 7.0 COVID-19 vaccination and catch-up vaccination

For details of Clinical Guidance for COVID-19 vaccination please refer to https://rcpi.access.preservica.com/uncategorized/IO c4ceab50-5f9c-44bf-9478-281093016a4b/

#### 8.0 Vaccination in an outbreak situation

In an outbreak situation, vaccinations may be recommended by the Outbreak Control Team outside of the routine immunisation and catch-up schedule. For example MMR vaccine can be given from the age of 6 months, although children vaccinated under the age of 12 months require a further dose at 12 months and a subsequent dose at 4-5 years of age. Please refer to immunisation guidelines for Ireland for further details. In the event of an outbreak, the public health team will provide advice and guidance on its management including any vaccinations to be provided and the group who are recommended to receive them.

## 9.0 Medicine Protocol for Registered Nurses (RNs) and Registered Midwives (RMs):

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

- Registered nurses and registered midwives employed in the voluntary and statutory services of the Health Service Executive (HSE) including Central Vaccination Centres (CVCs), congregated settings, temporary clinics and mobile units who have undertaken the required education and training programmes can administer vaccines under medicine protocol.
  - The medicine protocols for the vaccines used in this NIAC catch-up vaccination programme
    to vaccinate \* Refugees and Applicants Seeking Protection in Ireland and in the event of an
    outbreak by registered nurses and midwives are developed by the NIO in collaboration with
    the Office of the Nursing and Midwifery Services Director (ONMSD)
  - All eligible nurses must read and sign the medicine protocols to vaccinate \* Refugees and Applicants Seeking Protection in Ireland and in the event of an outbreak prior to administering vaccines available at <a href="https://bit.ly/NIOBOTPIPA">https://bit.ly/NIOBOTPIPA</a>
  - All eligible nurses must complete the Self-Assessment of Competency to administer vaccines\* under Medicine Protocol for registered nurses and registered midwives to vaccinate Refugees and Applicants Seeking Protection and on the event of outbreak

\*Health Service Executive (HSE) Primary Childhood Immunisation Programme (PCIP), Schools Immunisation Programmes (SIP) and the National Immunisation Advisory Committee (NIAC) Catch Up Immunisation Programme available at https://bit.ly/NIOBOTPIPA

#### 9.1 Education & training requirements for vaccinators

All vaccinators 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 competent in the correct intramuscular injection technique for administration of vaccines and the injection site used according to age group.

They should be familiar with the following documents:

 National Immunisation Advisory Committee Immunisation Guidelines for Ireland available at: https://www.rcpi.ie/Healthcare-Leadership/NIAC/Immunisation-Guidelines-for-Ireland

- National Immunisation Office (2018) Guidelines for Vaccinations in General Practice available at: https://bit.ly/GPGuidelinesVacc
- National Immunisation Office (2023/2024) Supporting Information for Staff: Schools Immunisation
   Programme available at:
  - https://www.hse.ie/eng/health/immunisation/hcpinfo/schoolproghcp/supportingdoc.pdf
- National Immunisation Office Clinical Guidance for COVID-19 Vaccination available at: https://bit.ly/COVIDClinicalGuidance
- Summary of Product Characteristics (SmPCs) for each of the vaccines available at <a href="www.hpra.ie">www.hpra.ie</a>
   or <a href="www.medicines.ie">www.medicines.ie</a>

#### **Managing Anaphylaxis**

 National Immunisation Advisory Committee (2023) Anaphylaxis: Immediate Management in the Community available at: <a href="https://www.rcpi.ie/Healthcare-Leadership/NIAC/Immunisation-Guidelines-for-Ireland">https://www.rcpi.ie/Healthcare-Leadership/NIAC/Immunisation-Guidelines-for-Ireland</a>

#### (RMs/RNs):

Must have completed the following:

- 1) Be a Registered Nurse or Registered Midwife, on the active register maintained by the NMBI
- 2) Immunisation Foundation Programme accessible on www.HSELanD.ie
- 3) Education programme for nurses and midwives on *Primary Childhood Immunisation Programme* and any updates for nurses and midwives accessible on <a href="https://www.HSELanD.ie">www.HSELanD.ie</a>
- 4) Education programme for nurses and midwives on *Schools Immunisation Programme* and any updates for nurses and midwives accessible on www.HSELanD.ie
- 5) NIO Education programme on *Catch up vaccination for Refugees and Applicants Seeking Protection in Ireland* accessible on www.HSELanD.ie
- 6) An approved *Basic Life Support for Health Care Providers Course* within the last two years (i.e. Irish Heart Foundation (IHF)
- 7) Initial National Anaphylaxis Education Programme for Health Care Professionals accessible on <a href="https://www.HSELanD.ie">www.HSELanD.ie</a> followed by a two hour classroom based skills workshop. Recertification is required every two years by completing the on-line National Anaphylaxis Education Programme for Health Care Professionals accessible on <a href="https://www.HSELanD.ie">www.HSELanD.ie</a>
- 9) The registered nurse/midwife must complete the Competency Self-Assessment Form to vaccinate Refugees and Applicants Seeking Protection in Ireland and in the event of an outbreak available at <a href="https://bit.ly/NIOBOTPIPA">https://bit.ly/NIOBOTPIPA</a>

#### Recommended:

Ensure they are familiar with the following documents

- National Immunisation Advisory Committee Immunisation Guidelines for Ireland available at: https://www.rcpi.ie/Healthcare-Leadership/NIAC/Immunisation-Guidelines-for-Ireland
- National Immunisation Office (2022) Guidelines for Vaccinations in General Practice available at: https://www.hse.ie/eng/health/immunisation/infomaterials/gpsupportingdocpci.pdf
- National Immunisation Office (2023/2024) Supporting Information for Staff: Schools Immunisation Programme available at:
  - https://www.hse.ie/eng/health/immunisation/hcpinfo/schoolproghcp/supportingdoc.pdf
- Summary of Product Characteristics (SmPC) for the individual vaccine used in the catch up vaccination programme available at <a href="https://www.hpra.ie">www.hpra.ie</a>

#### 10.0 Communication tools

The NIO has developed information materials to support the delivery of a vaccination programme for Refugees and Applicants Seeking Protection in Ireland. It includes posters and leaflets for parents about the Primary Childhood Immunisation Programme, the School Immunisation Programme, and about specific recommended vaccines in pregnancy and for adults. Information is available in English, Ukrainian and Russian.

 The NIO webpage available to support Refugees and Applicants Seeking Protection in Ireland is: https://bit.ly/NIOBOTPIPA

#### 11.0 Vaccine administration:

Prior to administration of the vaccine the vaccinator must adhere to the following:

- Follow the Infection Prevention Control (IPC) standard precautions all the time i.e. hand hygiene, sharps management and healthcare risk waste management available at <a href="https://www.hpsc.ie/a-z/respiratory/coronavirus/novelcoronavirus/guidance/infectionpreventionandcontrolguidance/">https://www.hpsc.ie/a-z/respiratory/coronavirus/novelcoronavirus/guidance/infectionpreventionandcontrolguidance/</a>
- Verify the client's name, date of birth and ensure that informed consent for vaccination has been given. The vaccine consent form is available at <a href="https://www.hse.ie/eng/health/immunisation/hcpinfo/botpipa/">https://www.hse.ie/eng/health/immunisation/hcpinfo/botpipa/</a>
- Ensure that there are no contraindications to vaccination present (vaccinators must be familiar
  with the contraindications and precautions for each vaccine to be administered please see the
  appropriate NIAC chapters available at: <a href="https://bit.ly/NIACGuide">https://bit.ly/NIACGuide</a>
- 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.
- Check the name and expiry date of each vaccine to ensure that it is the correct vaccine
- Ensure that the vaccine colour and composition is in accordance with the Summary of Product Characteristics (SmPC) for the vaccine if not discard the vaccine.
- To avoid injecting into subcutaneous tissue in adults, it is necessary to spread the skin of the selected vaccine site taut between the thumb and forefinger in order to isolate the muscle. In small infants and others with little subcutaneous tissue or muscle mass the tissue around the injection site may be gently bunched up.
- The needle should be inserted fully into the muscle at a 90° angle and the vaccine injected into
  the muscle tissue, in the centre of the inverted triangle (see Figure 1). When the needle is
  withdrawn, light pressure should be applied to the injection site for several seconds with a dry
  cotton ball or gauze.
- Give information on common side effects after the vaccination.

  Request the vaccine recipient to wait in the clinic waiting area for 15 minutes following vaccination

#### 11.1 Recommended sites for Intramuscular (IM) injection

There are only two routinely recommended IM sites for administration of vaccines, the Vastus lateralis muscle (anterolateral thigh) and the deltoid muscle (upper arm), (Figures 2.1- 2.4). Using these sites reduces the chance of involving significantly sized nerves or blood vessels. The site depends of the age and muscle mass of the recipient.

#### Vastus lateralis for IM injection

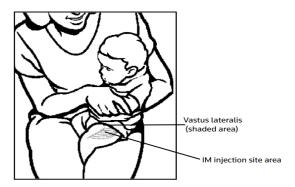
The Vastus lateralis muscle is located on the antero-lateral aspect of the thigh, from one of the patient's hand breadths below the greater trochanter to one hand's breath above the knee. The

middle third of the muscle is the site for injections. The width of the Injection site extends from the mid-line of the thigh anteriorly to the mid-line of the outer thigh.

#### Figure 1: Vastus lateralis site for IM injection, birth to 36 months<sup>2</sup>

Vastus lateralis: The injection site is the middle third of the Vastus lateralis, in the antero-lateral thigh (shaded area below). Either leg can be used.

Figure 1:



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

#### Figure 2: For Older children

- The child is held on the carer's lap or stands in front of the seated parent.
- The carer's arms embrace the child during the process.
- Both legs are firmly between the carer's legs.

Figure 2:



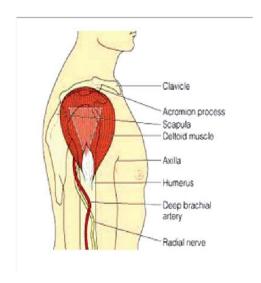
#### **Deltoid site for IM injection**

<sup>&</sup>lt;sup>2</sup> Figure taken from Immunisation Guidelines of the National Immunisation Advisory Committee

The light triangle in Figure 2 indicates site for IM injection into the deltoid muscle for older toddlers, children and adults. The upper border of the triangle is approximately two finger-breadths below the acromion process and the apex is at the midpoint of the humerus.

The recommended site is in the middle of the triangle. To avoid causing an injury, do not inject too high or too low. Insert needle at 90 angle.

Figure: 3 IM injection site is middle of the inverted triangle<sup>3</sup>



<sup>&</sup>lt;sup>3</sup> Figure taken from the Immunisation Guidelines of the National Immunisation Advisory Committee

#### 12.0 Post vaccination documentation & advice

Record the vaccine administration details in the system and recipient's immunisation passport where it is being used including

- Vaccine name, batch number, manufacturer and expiry date
- Dose administered
- Site used
- Date vaccine was given
- Vaccinator must print and sign their name on the consent form and record PIN/MCRN.
- Ensures the <u>vaccination passport is completed and given</u> to the vaccine recipient/parent/legal guardian before they leave.
- Ensures the vaccine recipient remains in the clinic under observation for 15 minutes as most anaphylaxis episodes begin within 15 minutes of vaccination.
- Gives after care information to the vaccine recipient that is available in the immunisation passport.
- Takes any queries about possible adverse reactions that occur post vaccination.
- Provides appropriate contact details if there are any concerns following vaccination.
- Reports adverse events to the HPRA (see Section 13.0).

#### 13.0 Adverse Reaction – Anaphylaxis

The vaccinators should refer to and be familiar with NIAC algorithms/protocol *Anaphalyxis: immediate management in the Community* (2022) available at: <a href="https://www.rcpi.ie/Healthcare-Leadership/NIAC/Immunisation-Guidelines-for-Ireland">https://www.rcpi.ie/Healthcare-Leadership/NIAC/Immunisation-Guidelines-for-Ireland</a>

Algorithms for management of anaphylaxis from the Immunisation Guidelines must be kept with anaphylaxis kits.

#### 13.1 Adverse Reaction - Reporting

The Health Products Regulatory Authority (HPRA) requests that health care professionals report all suspected reactions to all vaccines. When reporting suspected adverse reactions to the HPRA, details of the brand name and batch number of the vaccine should be included in the report. An adverse reaction report form can be accessed by:

- Following the links to the online reporting options accessible from the HPRA website at www.hpra.ie
- Using a downloadable report form also accessible from HPRA website, which may be completed
  manually and submitted to the HPRA via "freepost" available from the HPRA website
  <a href="https://www.hpra.ie/homepage/about-us/report-an-issue">https://www.hpra.ie/homepage/about-us/report-an-issue</a>

#### 14.0 Ordering of Vaccines

Vaccines are prescription-only medicines (POMs) and to maintain their licensed usage should be stored and transported in accordance with the manufacturer instructions (PIL/SmPC) in compliance with the cold chain i.e. between +2°C and +8°C.

Vaccines should be ordered from the HSE National Cold Chain Service (NCCS) and stored in a central site within the CHO with an appropriate facility for cold chain management -including a provision for a pharmaceutical fridge with a data logger. The vaccination team should carry a cool box

to transport vaccines from the central vaccine storage site to the vaccination clinic/site as the National Cold Chain Service will not be supplying vaccines to an individual vaccination clinic /site.

For more information, please refer to the National Immunisation Office (NIO) guidance on maintenance of the cold chain including cold boxes, available at <a href="http://bit.ly/VaccOrder">http://bit.ly/VaccOrder</a> It is recommended to complete the 30 minute HSE e-learning module "Storing and Managing Vaccines" Available at <a href="https://www.hseland.ie">www.hseland.ie</a>

The vaccine forecast form is available for this vaccination programme only at <a href="https://www.hse.ie/eng/health/immunisation/hcpinfo/botpipa/">https://www.hse.ie/eng/health/immunisation/hcpinfo/botpipa/</a>

- 14.1 All services must arrange delivery of required vaccines via the HSE National Cold Chain Service. There should be adequate time for ordering and delivery of vaccines, especially as sites may be ordering vaccines that are not delivered to them as part of routine immunisation programmes.
- 14.2. A "vaccine stock sheet" should be kept to record the date and stock on hand and quantity ordered. Vaccines should be ordered by a specific date as per a prescribed schedule from the National Cold Chain Service (NCCS).
- 14.3. Vaccines should be ordered online at <a href="https://ordervaccines.ie/">https://ordervaccines.ie/</a> from the HSE National Cold Chain Service (NCCS) (current contract holders are United Drug Distributors UDD). Any queries can be sent to E-mail <a href="mailvaccines@udd.ie">vaccines@udd.ie</a> NCCS send a confirmatory email outlining that they have received the order and confirming the vaccine delivery date. If confirmation is not received NCCS should be contacted directly.
- 14.4 On receipt of vaccines, they must be checked against the order for any damage or discrepancy and stored in the vaccine fridge immediately. Vaccines must be placed <u>immediately</u> in the vaccine fridge and must <u>never</u> be left at room temperature.

#### 15.0 Cold Chain Management of Vaccines

- 15.1 The 'Cold Chain 'is the system of correct storage, transport and maintenance of vaccines. All vaccines are sensitive to heat, cold and light. They must be kept at temperatures between +2°C and 8°C to maintain their potency and comply with regulations.
- 15.2 The electricity supply to the vaccine storage fridge should not be accidentally interrupted. This can be achieved by using a switchless socket or by placing cautionary notices on plugs and sockets and using a dedicated circuit for the fridge and also label the fuse.
- 15.3 A temperature monitoring chart should be on each vaccine fridge door. These charts should be kept indefinitely unless data logger recordings are being stored indefinitely.
- 15.4 Current, maximum and minimum temperatures must be checked **twice daily** with time of reading and sign/initial.
- 15.5 A temperature data logger should be placed in the fridge as a second monitor independent of the fridge thermometer. This provides a continuous temperature record and should be set to record at 5 minute intervals.
- 15.6 Vaccines should be stored in the department vaccine fridge at all times. They should not be stored in non-pharmaceutical fridges.
- 15.7 The fridge should not be overfilled to allow air to circulate around the vaccines packages. Vaccines should be stored in containers that will prevent them touching the sides or back of the fridge.
- 15.8 Door opening should be kept to a minimum.
- 15.9 Food and drink should not be stored in this fridge.
- 15.10 Vaccines should always be stored in their original packaging and should not be removed from their packaging until required for use.

- 15.11 The inside of the fridge should be regularly cleaned with warm slightly soapy water. Dry thoroughly and only restock once the temperature is within the recommended range. 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.
- 15.12 If the temperature recorded is less than +2° or greater than +8°C quarantine the vaccines in the fridge if it has returned to the correct temperature or quarantine and move to another fridge at the correct temperature, and do not use them until advice is received from the NIO. Contact the NIO's pharmacists by email <a href="mailto:pharmacynio@hse.ie">pharmacynio@hse.ie</a> for vaccines supplied by the National Cold Chain Service. A risk assessment will be carried out and a recommendation made. The use of a vaccine stored at an incorrect temperature is based on a thorough understanding of the likely impact of the temperature variation on the vaccine and must be made on a case-by-case basis.

#### REMEMBER THE 7Rs

- 1. **Read:** temperature twice daily at clinic/surgery opening and closing times.
- 2. **Record:** maximum, minimum and current temperatures stating date and time of reading and sign/initial and download data logger regularly.
- 3. **React:** if the temperature falls outside +2°C to +8°C, document this action.
- 4. **Review:** temperature records regularly (at least once a month).
- 5. **Rotate:** vaccines after each delivery placing shorter dated vaccines to the front.
- 6. **Remove:** expired stock from fridge immediately and return to NCCS for destruction.
- Reset: reset the max/min thermometer (i.e. clear the thermometer memory) after each
  reading and after a period of high activity once temperatures have stabilised and also at the
  end of every day

#### 16.0 Transport of vaccines

The designated person collecting the vaccines is responsible for:

- 16.1 Appropriately completing the routine stock removal form each day in accordance with the vaccine fridge standard operating procedures (SOP) https://bit.ly/CCSOP1
- 16.2 Ensuring that the cool box is packed and maintained between +2°C to +8°C in accordance with cool box standard operating procedures (SOP) https://bit.ly/CCSOP2
  - Cool packs must be stored in accordance with the manufacturers 'instructions, at +2°C to +8°C to ensure they maintain the cold chain at the right temperature.
  - Ice packs must be stored in accordance with manufacturers 'instructions in a freezer.
     These should never be in direct contact with the vaccines as they will freeze the vaccines. Sufficient barrier layer must be used to prevent this happening
- 16.3 Ensuring that the correct vaccine is in date.
- 16.4 Ensuring that, if possible, vaccine to be used on a day is all the same batch.
- 16.5 Recording the temperature in the cool box,
  - Before leaving storage fridge.
  - At the beginning of the vaccination session
  - At the end of the vaccination session
  - On returning the vaccines to the fridge.
- 16.6 Placing the cool box in,
  - An appropriately ventilated room
  - Away from any heat source
  - · Away from direct sunlight
- 16.7 Monitoring the temperature inside the cool box

- The cool box should remain closed as much as possible
- Only the amount of vaccine needed at one time should be removed for preparation and administration.
- 16.8 Ensuring that where vaccines are not used on a particular day and are in their original packaging and have been maintained under cold chain conditions, these vaccines may be returned to the vaccine fridge but they should be clearly marked so that they are used first on the next vaccinating session.
  - The temperature of the vaccine being returned to the vaccine fridge should be recorded as well as the time of return to the fridge.
- 16.9 If these marked vaccines are taken to a second vaccination session and are not used, providing the cold chain has been maintained, the vaccines can be returned to the vaccine fridge again, for administration at the next session. If a temperature deviation occurs during the vaccination clinic e.g. vaccine is taken out of the +2°C and +8°C temperature for use and for any reason is not used, quarantine the vaccine between +2°C and +8°C and contact the NIO for further advice as explained in section 15.12 as above. The NIO will carry out a risk assessment and will advise on a case by case basis whether it is appropriate to use the vaccines later or whether they should be discarded.

#### 17.0 Data Management & Statistical Reporting

Consent forms must be managed in accordance with the General Data Protection Regulations (GDPR) along with the Data Protection Acts 1988 – 2018. See <a href="https://bit.ly/HSEGDPRInfo">https://bit.ly/HSEGDPRInfo</a> Recording of vaccination should take place, using the agreed process, including ICT systems if applicable.

#### 18.0 Revision

This guidance document will be reviewed and updated as necessary if research, legislation, standards, practice, the environment or role of personnel alters.

#### References

An Bord Altranais 2007 Guidance to Nurses and Midwives on Medication Management. Dublin

Nursing and Midwifery Board of Ireland (2020) Guidance for Registered Nurses and Midwives on Medication Administration. Dublin: Nursing and Midwifery Board of Ireland

Immunisation Guidelines for Ireland. National Immunisation Advisory Committee available at: https://www.rcpi.ie/Healthcare-Leadership/NIAC/Immunisation-Guidelines-for-Ireland

National Immunisation Advisory Committee (2022) Anaphylaxis: Immediate Management in the Community available at: <a href="https://www.rcpi.ie/Healthcare-Leadership/NIAC/Immunisation-Guidelines-for-Ireland">https://www.rcpi.ie/Healthcare-Leadership/NIAC/Immunisation-Guidelines-for-Ireland</a>

National Immunisation Office (2023/2024) Supporting Information for Staff: Schools Immunisation Programme available at:

https://www.hse.ie/eng/health/immunisation/hcpinfo/schoolproghcp/supportingdoc.pdf

Guidelines for Vaccinations in General Practice. National Immunisation Office HSE 2018 available at: https://bit.ly/GPGuidelinesVacc

Guidelines for maintaining the vaccine cold-chain including maintenance of vaccine fridges and management of vaccines. National Immunisation Office HSE 2020 available at: https://bit.ly/CCSOP1

Guidelines for maintaining the vaccine cold-chain in vaccine cool boxes. National Immunisation Office HSE 2020 available at: <a href="https://bit.ly/CCSOP2">https://bit.ly/CCSOP2</a>

Health Services Executive. (2018). GDPR available at: https://bit.ly/HSEGDPRInfo

WHO vaccine preventable disease monitoring system 2020 global summary <a href="https://immunizationdata.who.int/listing.html?topic=&location">https://immunizationdata.who.int/listing.html?topic=&location</a>

## **Appendix 1: Consent Form**

Visit <a href="https://www.hse.ie/eng/health/immunisation/hcpinfo/botpipa/">https://www.hse.ie/eng/health/immunisation/hcpinfo/botpipa/</a> for the English version and for translated materials.

## Appendix 2: Stock Record

This record should be completed for each vaccine and used when any stock is moved in or out.

Fridge ID:									
Date	Vaccine: Trade Name	Batch Number	Expiry date	Number of doses in stock	Number of doses received	Number of doses sent to site <sup>1</sup>	Number of doses returned from site <sup>2</sup>	Number of doses for destruction	Signature

<sup>=</sup> Number of doses sent to school/clinic/unit.

<sup>&</sup>lt;sup>2</sup> = Number of doses returned from school/clinic/unit still in cold chain.