

Supporting Information for Staff
School Immunisation
Programme
2025-2026 academic year

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# Supporting Information for Staff School Immunisation Programme 2025-2026 Academic Year – V15.0

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# **Schools Immunisation Programme**

The Schools Immunisation Programme (SIP) is developed in accordance with the guidance issued by the National Immunisation Advisory Committee (NIAC), hosted by the Health Information and Quality Authority (HIQA) and contained in the Immunisation Guidelines for Ireland, available at <a href="https://www.hiqa.ie/areas-we-work/national-immunisation-advisory-committee/immunisation-guidelines-ireland">https://www.hiqa.ie/areas-we-work/national-immunisation-advisory-committee/immunisation-guidelines-ireland</a>. The SIP is carried out by staff from each Health Region who are responsible for the health of the population in their region.

The Schools Immunisation Programme is part of a national strategy to protect children from infectious diseases through vaccination. Specifically, the Schools Immunisation Programme protects against the following diseases with the named vaccines:

#### **Junior infants**

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

# First year of second level school

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

#### Primary school children

Live Attenuated Influenza vaccine may be provided during September to December each year to children aged 2-17 years old. Regional Immunisation Committees will discuss and agree the administration of LAIV vaccine for school-aged children in their area.

The LAIV vaccine can be given at the same time as MMR and DTaP/IPV, or at **any** interval before or after, if required.

See guidance on the LAIV vaccine programme at <a href="www.immunisation.ie">www.immunisation.ie</a>

The Department of Health Immunisation Policy for the school immunisation programme, supported by the Department of Education, remains that 4 in 1 and MMR vaccines should be delivered on primary school premises and the HPV, Tdap and MenACWY vaccines should be delivered on second level school premises. This applies regardless of the size of the school and the funding provided to RHAs. This is on the basis that the programme is primarily provided on school premises with catch up clinics organised by the Health Regions provided in HSE clinics in the community, as appropriate.

Currently the only exceptions to this is the junior infant MMR and 4 in 1 vaccines, which are delivered by GPs in Donegal, Sligo and Leitrim.

The Programme aims to vaccinate on an annual basis:

- All 4 to 5 year olds with MMR and DTaP/IPV vaccines, by targeting students in junior infants of primary schools for the 2025/2026 academic year and age equivalent in special schools (i.e. born between 01/09/2020 and 31/08/2021) or aged 6 years and home schooled (i.e. born between 01/09/2019 and 31/08/2020).
- All 12 to 13 year olds with Tdap, MenACWY and HPV9 vaccines by targeting students in first year in second level schools for the 2025/2026 academic year and age equivalent students born between 01/09/2012 and 31/08/2013 in special schools and home schooled students. The age cohort for special schools applies to the reported vaccine uptake. Older students who are new entrants into special schools who have never been offered these vaccinations should also be offered them.

Each RHA team will need to order information materials from <a href="healthpromotion.ie">healthpromotion.ie</a> to ensure materials can be sent out as soon as the school year starts for immediate distribution to parents and legal guardians.

# **School Immunisation Schedule and Target Cohort**

The programme will be delivered in primary, second level and special schools. The HSE target uptake for the DTaP/IPV, MMR2, MenACWY and Tdap vaccines is 95% and the HSE target for HPV9 vaccine is uptake of 90% for both boys and girls.

Review of data from other countries strongly suggests that provision of vaccines through school based programmes results in significantly greater uptake of vaccines. A school setting is an appropriate and safe setting to enable the vaccination of a large number of students. In some instances, students may be vaccinated at HSE clinics. Students attending special schools or home schooled may be vaccinated at school or at a HSE clinic. In Donegal, Sligo, and Leitrim, GP practices provide the MMR and DTaP/IPV vaccines to children aged four and five years. MMR catch up is also available in 2025-2026 from GPs for those not age appropriately vaccinated, but it does not replace the school immunisation programme.

## Recommended vaccines and timing for the School Immunisation Programme\*

September 2025 - December 2025

- 1 visit to Primary Schools (Junior Infants)
- Offer: 4 in 1 and MMR

January 2026 - May 2026

- 1 Visit to Second Level Schools (First Year Students)
- Offer: HPV, Tdap and MenACWY

\*It is of vital importance that all schools are offered vaccination during the academic year. Local adjustments to the above timing can be made to ensure the most efficient use of available resources and completion of the programme in the academic year.

#### **Primary Schools**

#### MMR and DTaP/IPV immunisation schedule for Junior Infants

- This will be provided by HSE staff through the schools. Parents and Legal Guardians may not choose to attend the GP for vaccination in areas where the programme is provided by HSE staff through the schools. With the exception of those living in Donegal, Sligo, and Leitrim where GPs provide the MMR and DTaP/IPV vaccines to children aged four and five years.
- Parents/Legal Guardians should not be routinely invited to attend school vaccinations.
   There is no requirement to have a Parent/Legal Guardian to be present at the time of vaccination.
- If there is a valid medical consent form signed and dated from the Parents/Legal Guardians, these children should be vaccinated regardless of whether a Parent/Legal Guardians is present or not. Children should be treated in the same manner regardless of whether a parent is present or not.
- If a Parent/Legal Guardian refuses consent to vaccinate any or all vaccines this
  must be recorded on the consent form and on Schools Immunisation System (SIS).
   This will form part of the child's medical record. In addition, this will also become a
  future immunisation record for the child when they become of age of consenting in
  their own right, and wish to have oversight of their personal immunisation status.
- Where children present for MMR vaccination in junior infants and their Parents/Legal Guardians report that they had no previous dose of MMR, arrangements should be put in place to ensure that they receive a second dose at least one month later. This can be delivered through HSE Clinics or GP services depending on local arrangements.
- The NIO are working with the software suppliers to upload data on children born between 01/07/2012 and 30/06/2013 and between 01/07/2020 and 30/06/2021 so they can be:
  - Pre-registered on SIS at a generic school ready to be updated with the school they are attending.
  - This is planned to be completed before the start of the academic year, if possible.
  - This will include their stage status record from the evidence from the regional system of a previous MMR vaccination and the medical record number in that system.
  - This record can assist areas to verify if the child has previously received an MMR vaccine.
  - o Those pre-registered from last year who were not in junior infants last

year will still appear in the SIS system this year.

Due to the increase in cases of measles in Ireland and across Europe in 2024-25, all areas must prioritise administration of MMR and DTaP/IPV in the first term of the 2025-26 academic year where possible.

#### **Second Level Schools**

All second level schools now require one visit to provide one dose each of HPV9, MenACWY and Tdap vaccines. All three vaccines may be given at the same visit, as per NIAC chapter 13.9. This visit should commence from January 2026

In November 2022, the National Immunisation Advisory Committee (NIAC) issued updated recommendations with respect to HPV vaccine dosage for those who are immunocompetent. A single dose schedule of HPV vaccine is now recommended for all those aged 9 to 24 years of age.

NIAC advise for immunocompromised individuals with the following conditions, they require a three dose schedule at 0, 2 and 6 months regardless of age.

- Haematopoietic stem cell or solid organ transplant recipients
- HIV infection
- Malignant haematological disorders affecting the bone marrow or lymphatic systems, e.g., leukaemia, lymphomas, blood dyscrasias
- Non-haematological malignant solid tumours
- Primary immunodeficiency including Down Syndrome
- Within two weeks of commencing on or within three to six months of receiving significant immunosuppressive therapy (see Chapter 3).

https://www.hiqa.ie/areas-we-work/national-immunisation-advisory-committee/immunisation-guidelines-ireland

Children who are significantly immunocompromised will require 3 doses of HPV9 vaccine at 0, 2 and 6 months. These additional doses can be given in school or at catch-up clinics as appropriate.

NIAC advise 'when there is uncertainty about an individual child about significant immunocompromised NIAC recommend that relevant specialist advice be sought from an appropriate physician.'

Immunisation for children who are Refugees and Applicants Seeking Protection

Children who are refugees and applicants seeking protection and are now living in Ireland are entitled to receive school immunisations in line with their peers. Health Region teams and GPs are

also providing catch-up vaccinations. Materials have been developed by the NIO to support vaccinations and are available from www.immunisation.ie

# **Class Lists**

In December 2024, the Minister for Health enacted <u>S.I. No. 735/2024 - Infectious Diseases</u> (Amendment) (No. 3) Regulations 2024 using his powers under the Health Acts.

This regulation outlines the specific information that publically funded schools under the Department of Education must provide to the HSE to support the effective delivery of the School Immunisation Programme.

Under the regulations Schools Immunisation Teams are authorised to request the following information:

- the name, address, date of birth and sex of the pupil;
- the mother's birth surname;
- contact details including the name, phone number and email address of their parent/guardian;
- the pupil's PPSN (if any);
- the name of the school which the pupil attends and the school roll number

Schools are legally required to provide this information within 10 days of receiving a request.

The Department of Education has advised schools to establish clear procedures for the secure transfer of personal data to the HSE.

Acceptable methods include:

- a hardcopy printed list given directly to a member of the HSE Schools immunisation team
- sending via a secure file sharing system. Principals have been advised that the HSE can provide schools access to the HSE Citrix Share File if required
- sending via email to a member of the HSE Schools immunisation team to an HSE email address only. The data should be supplied in an attachment which is password protected and the password then supplied separately to the HSE Schools immunisation team

With the introduction of this regulation, school immunisation teams can now request class lists from all publically funded schools. These should be requested well in advance of the school visit to allow time for processing and identifying which pupils have not returned consent forms.

The data may be used to:

- Follow up with parents/guardians who have not submitted consent forms
- Clarify consent-related queries
- Confirm consent preferences or complete missing information

To comply with GDPR, Schools Immunisation Teams must securely store class lists until the relevant records are updated in the Schools Immunisation System (SIS). Once data entry is complete, the original files must be securely and permanently destroyed. The National Immunisation Office (NIO) have completed a Data Protection Impact Assessment (DPIA) this outlines the processing of personal data under this regulation. The NIO have made this DPIA available to the Integrated Immunisation Working Group, and the Regional Immunisation Committees. Copies of this can also be requested by emailing <a href="mailto:immunisationdata@hse.ie.">immunisationdata@hse.ie.</a>

# **National Immunisation Information System (NIIS)**

All vaccines provided as part of the national schools programmes are recorded on the Schools Immunisation System (SIS).

Work is underway to develop a National Immunisation Information System to record all vaccines given as part of national programmes. The COVAX platform is being used as the basis for this, with the Primary Childhood Immunisations being the first programme to be added.

It is unlikely that the NIIS platform will be able to capture the schools immunisations for the 2025-26 academic year, so all vaccine records should continue to be entered onto the SIS system as per usual practice.

Information and training will be made available when the schools vaccines transition to NIIS.

#### Irish language materials

The HSE are obliged to provide materials in Irish only, or in Irish and English under a number of different provisions of the Official Languages Acts (OLA).

Under the OLA, the HSE is required to provide public-facing materials, (all official forms and materials that promote or advertise services we provides) such as consent packs, in both Irish and English with equal prominence, ensuring accessibility for Irish speakers. This means the Irish versions of the letter, consent forms, and leaflets must be as accessible as the English versions and convey the same information.

Providing Irish forms only upon request reduces accessibility for Irish speakers is not possible, as it places an additional burden on them to request the forms. As stated in the National Plan for Irish Language Public Services 2024-2030:

'Above almost anything else, the principle of an active offer is one of the most important and central aspects of any effort made to improve the quality of public services available to the people of the country through Irish.' (pg. 111).

#### **Additional Information resources**

- Immunisation Guidelines for Ireland are available at <a href="https://www.hiqa.ie/areas-we-work/national-immunisation-advisory-committee/immunisation-guidelines-ireland">https://mmunisation-guidelines-ireland</a>
   Summary of Product Characteristics (SmPCs) for each of the vaccines available at <a href="https://hpra.com/">https://hpra.com/</a> and also available under the relevant schools vaccination programme at <a href="http://bit.ly/SchPHCP">http://bit.ly/SchPHCP</a>
- Medicine Protocols for each of the vaccines in the schools immunisation programme are available under the relevant schools vaccination programme at <a href="http://bit.ly/SchMedPros">http://bit.ly/SchMedPros</a>
- Healthcare professionals FAQs are available at <a href="http://bit.ly/FAQImm">http://bit.ly/FAQImm</a>
- Each vaccinator must be familiar with techniques for resuscitation of a patient with anaphylaxis and have completed an approved Basic Life Support for Health Care Providers Course (i.e. Irish Heart Foundation (IHF)). Recertification is required every two years.
- Initial National Anaphylaxis Education Programme for Health Care Professionals
  accessible on <a href="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 at <a href="www.HSELanD.ie">www.HSELanD.ie</a>
- Each vaccinator should be familiar with the NIAC "Anaphylaxis: Immediate Management in the Community" protocol, in the Immunisation Guidelines for Ireland available at <a href="https://www.hiqa.ie/areas-we-work/national-immunisation-advisory-committee/immunisation-guidelines-ireland">https://www.hiqa.ie/areas-we-work/national-immunisation-advisory-committee/immunisation-guidelines-ireland</a>
- Each vaccinator should be familiar with the medicine protocols for administration
  of the relevant vaccines and epinephrine/adrenaline, without individual
  prescription available from <a href="http://bit.ly/SchMedPros">http://bit.ly/SchMedPros</a>
- HSE Communicating Clearly guidelines: <a href="http://bit.ly/CommClear">http://bit.ly/CommClear</a>
- HPV E-Learning Programme available on HSELand <u>www.hseland.ie</u>

# Useful information before, during and after the session

Standard Operating Procedures (SOPs) templates have been provided in Appendix A to document how schools-based immunisation sessions should run.

#### Consent

- There is a distinct difference between "clinical" consent and "GDPR" consent (for data processing) which can often create confusion.
  - Clinical consent as outlined in the National Consent Policy (in relation to clinical consent in its broad sense) states; 'Consent is the giving of permission or agreement for a treatment, investigation, receipt or use of a service or participation in research or teaching'. For example, requiring consent to vaccinate is required
  - GPDR or data processing consent is not required to record vaccinations or refusal in their medical record. However, patient information should be sought, stored, shared and used appropriately, proportionately and confidentially for the purposes of the delivery of care. For example completing consent form notes and updating of SIS does not require consent.
  - References on consent above taken from "Memo Consent and Referrals Final" issued by Dr. Siobhán Ní Bhriain, HSE National Clinical Director, Integrated Care, Clinical Design and Innovation, Office of the CCO
- The Guide to Professional Conduct & Ethics for Registered Medical Practitioners,
   9th Edition, 2024 (Medical Council) Chapter 2 give information on consent for doctors.
- Informed consent must be obtained prior to vaccination.
- Only a Parent/Legal Guardian can provide consent for a medical procedure, or refuse consent for a medical procedure for young people under 16 years of age. Young people aged 16 years or older are legally entitled to consent for themselves.
- Consent from one Parent/Legal Guardian is sufficient, unless specified in advance of vaccination taking place. Read more about the HSE Consent Policy on the HSE website.
- In the case of the HPV vaccine, most students require one dose except if immunocompromised. Consent is given to a course of vaccination, if up to three doses are needed the signed consent form covers all these doses and consent remains valid until the course has been completed, or unless consent is withdrawn by a parent/legal guardian, or young person aged 16 years or older.
- There is no maximum duration for consent. Consent remains valid for an indefinite period unless
  - It is withdrawn
  - o 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
- If a Parent/Legal Guardian contacts the HSE school immunisation team to withdraw consent, they should speak to the staff member, ideally a clinical staff member looking after the immunisation programme. The information provided should be recorded by the recipient on the consent form by drawing a double line through the vaccine administration details section with the words 'refused dose' with the date and time and name and PIN/staff number of the person taking the information down. This should also be recorded in SIS.
- HSE Consent Policy 2024 is here:
   <a href="https://assets.hse.ie/media/documents/ncr/20241001\_HSE\_Consent\_Policy.pdf">https://assets.hse.ie/media/documents/ncr/20241001\_HSE\_Consent\_Policy.pdf</a>
- Read: "Who can give consent for vaccination of a young person aged under 16 years?" From https://bit.ly/ConsentU16
- Watch this video from Dr. Siobhan Ni Bhriain, HSE National Lead Integrated Care covering Consent for vaccination: <a href="https://youtu.be/8uKqmkFe8hs">https://youtu.be/8uKqmkFe8hs</a>

# Who are a child's legal guardians?

**Note:** This is a summary of a complex legal position: the relevant provisions are set out in the Guardianship of Children Act 1964 as amended by the Child and Family Relationships Act 2015 (see Appendix 9 HSE consent policy):

- Where a child's mother and father are married both are the legal guardians.
- If a child's mother and father marry after the child's birth, the father automatically becomes the child's legal guardian.
- Where a child has been jointly adopted, the adoptive parents are the child's legal guardians.
- Where a child's mother and father are not married:
  - o The child's mother is an automatic legal guardian;
  - The child's father is an automatic legal guardian if from 18 January 2016, he has
    lived with the child's mother for 12 consecutive months including at least 3 months
    with the mother and child following the child's birth; or
  - If the child's father has not become a guardian by satisfying the cohabitation requirement, he may become a guardian if the mother and father of the child may make a statutory declaration to the effect that they agree to the appointment of the father as legal guardian, or
  - The father may apply to Court to be appointed legal guardian.
- In respect of same-sex couples, the child's biological parent is a legal guardian.
  - The biological parent's partner or spouse may apply to the Court become a legal guardian in accordance with the requirements set out below.

- Where a same-sex couple has a child through Donor Assisted Human Reproduction (not including surrogacy) after 4 May 2020 and has complied with the provisions of Part 2 of the Children and Family
- Relationships Act 2015 (i.e. they have used a recognised fertility clinic and have signed all the relevant consents and declarations), the spouse, civil partner or cohabitant of the mother will be the legal parent of the child. In this situation, the spouse or civil partner of the biological parent will automatically be a legal guardian.
- A cohabitant will be a legal guardian if they fulfil the residence requirement (i.e. have lived with the child's mother for 12 consecutive months including at least 3 months with the mother and child following the child's birth).
- Where a child is born through surrogacy, the surrogate mother is the legal guardian at birth. If the commissioning father's sperm was used in the surrogacy procedure, he may apply to the Court for a declaration of parentage; once granted, this would immediately entitle him to apply to the Court for guardianship. The commissioning mother, or a commissioning father whose sperm was not used in the procedure, may apply to the Court for legal guardianship once she/they have fulfilled the legal requirements set out in the next bullet point.
- Any adult may apply to Court for legal guardianship:
  - If he or she is married to or in a civil partnership with, or has been cohabiting for at least 3 years, with the child's parent and has shared parental responsibility for the child's day-to-day care for at least 2 years, or
  - If he or she has provided for the child's day-to-day care for a continuous period of more than 12 months and the child has no parent or guardian who is able or willing to act as guardian.
- Following a separation or divorce, both parents remain the child's legal guardian even if the child isnot living with them and they have not been awarded custody of the child.
- A guardian may nominate another person to act as temporary guardian in the event of the guardian's incapacity. This is subject to Court approval.
- A guardian may, in their will, appoint a person to act as the child's guardian in the event of the guardian's death.

# **HSE Vaccination Record Forms (Consent Forms)**

- Once the Parent/Legal Guardian completes their part of the Consent Form, and the HSE staff introduce clinical content to the form, it should be considered as a clinical record and treated accordingly.
- Information on the vaccination forms must be put into SIS as soon as possible and within 30 days of vaccination offer. This includes vaccination attendance and nonattendance records.
- Where two or more vaccinations are required to complete the schedule, the first

- vaccine record must be put into SIS as soon as possible after it is given. Please do not wait until all doses of HPV9 vaccines are given before beginning the clinical recording of vaccines given.
- In the case of the HPV vaccine, most students require one dose except if immunocompromised. Consent is given to a course of vaccination, if up to three doses are needed the signed consent form covers all these doses and consent remains valid until the course has been completed, or unless consent is withdrawn by a parent/legal guardian, or young person aged 16 years or older.
- Vaccination forms for students who have been vaccinated but require further doses to complete a course should be filed for easy retrieval the next school clinic.
- Vaccination forms for students whose vaccination is deferred or who are absent on the day should be filed for easy retrieval for the next mop-up clinic.
- Students who fail to return a completed consent form should also be offered one appointment at a mop up clinic if they have been identified from another route e.g. regional systems or lists from education.
- Vaccination form movements (individual forms or groups of forms) should be traced in and out of the records store. The trace should show who has signed out forms.
- When students have completed the vaccination course their vaccination forms should be filed in accordance with the HSE Records Retention Policy available at <u>HSE National</u> Records Retention Policy – Corporate.
- Please note that clinical records, including immunisation records, as a healthcare record now have a retention period of "Lifetime of patient + 8 years after death".
   Therefore, all our clinical records/case notes etc. should be regarded as a healthcare record and the new retention policy period applies.
   <a href="https://healthservice.hse.ie/staff/procedures-guidelines/record-retention-policy/">https://healthservice.hse.ie/staff/procedures-guidelines/record-retention-policy/</a>
- All clinical notes on events around vaccination should be stored as part of
  the vaccination record in the system or on the vaccination form. Ensure that
  all written information recorded is in black ink, in block capitals and is clear
  and legible.

# **Ethnicity and Ethnic Equality Monitoring**

Ethnicity is a measure of a close cultural connection, as opposed to 'race', nationality or citizenship. It involves sharing certain background characteristics, such as a shared history, common ancestors, geographical origin, language, culture and religion. This provides people from an ethnic group with a distinct identity as seen by both themselves and others.

An important issue that influences health is whether a person belongs to a majority or minority ethnic group.

People from minority ethnic groups can often experience poorer health than the rest of the population. Low incomes, poor working and housing conditions, poor social networks and nutrition as well as lack of access to health services can impact the health of those from minority ethnic groups who have immigrated to a new country. This also affects the health of their children and future generations.

Ethnic Equality Monitoring shows the uptake of health services among different ethnic groups. This could help to identify whether discrimination, either direct or indirect, is occurring in the way that services are provided and whether health services are meeting the legal requirements to provide fair and equal service to all ethnic groups under <u>Public Sector Equality and Human Rights Duty</u>

Ethnic or cultural background indicators have been amended and updated to align with the 2022 Census. These have been included in the Schools Immunisation consent forms and will also be added to SIS\*. This will allow for the data to be collected and collated electronically. Unfortunately, it was not possible to add the ethnicity fields to SIS for the 2024-25 academic year, but all efforts will be made to add this for the 2025-26 academic year.

\*Any free text data written on the description "Other and mixed ethnic groups" field will not be entered in SIS for the moment.

It is voluntary for parents and legal guardians to complete this information, but it is important that they are reassured that the information is to ensure fair and equal healthcare services are provided.

The National Social Inclusion Office (NSIO) have a programme of work to support the collection of ethnicity data (Ethnic Equality Monitoring) within a range of health services, including training on HSELanD on how to sensitively ask about ethnicity. See the following links for more detail:

eLearning module on HSELanD:

# Introduction to ethnic equality monitoring

What is Ethnicity and Ethnic Equality Monitoring?

NSIO webinar on Ethnic Equality Monitoring

Report on NSIO online survey of HSE and NGO staff on the collection and use of ethnicity data

Legal requirement for the HSE to provide fair and equal service to all ethnic groups under the Public Sector Equality and Human Rights Duty

More information and resources on Ethnic Equality Monitoring

<u>Posters</u> to explain to patients and clients why they might be asked about their ethnicity, country of birth, language etc. Available in English, Irish, Arabic, Chinese, French, Polish, Russian, Ukrainian.

# When vaccination is delayed

# Junior Infants in primary school - MMR and 4 in 1 vaccines

These children can be recalled to a mop-up clinic or referred to their GP.

# Students older than first year of second level school (2024/2025)

For HPV9, MenACWY and Tdap vaccine programme – only those students who missed these vaccines in first year for medical or other exceptional circumstances and whose Parents/Legal Guardians notified the School Immunisation Team can be offered these vaccines in mop-up clinics in later years.

This guideline is the same for age equivalent students attending special schools.

#### Assessment of the student for vaccination

Before assessing the suitability of a student for vaccination:

- Confirm student's identity (Confirm name, address, date of birth and parent or legal guardian's name by asking: "What is your full name? When is your birthday? Where do you live? Who signed the consent form? What is their name?")
  - For younger children it may be necessary to confirm identity with the child's teacher or an appropriate liaison person (as agreed with the School Principal) from the school.
- Confirm that informed consent has been given by a parent / legal guardian for student aged under 16 years.
- Address any clinical issues raised on the consent form.
- Check that any interval between vaccinations is appropriate.
- For HPV9 vaccine for those requiring a 3 dose schedule:
  - o If the second dose of HPV9 is given too early (i.e. less than the minimum interval of 4 weeks minus 4 days), the dose should be repeated at least one month after the invalid dose with the 3rd dose given so there is an interval of at least 6 months from 1st dose.
  - If the error is the 3<sup>rd</sup> dose is given too early i.e. at < 5 months minus 4 days after the 1<sup>st</sup> dose, a third dose should always be administered at least 12 weeks after the dose that was given too early.
  - If a dose of HPV vaccine is given too early and the student needs to be revaccinated, an additional consent form must be completed. The additional consent and vaccination information must be recorded on SIS.
- Vaccines should only be given to students who are well on the day, and for whom no contraindication is identified as per the Immunisation Guidelines of Ireland available at <a href="https://www.hiqa.ie/areas-we-work/national-immunisation-advisory-committee/immunisation-guidelines-ireland">https://www.hiqa.ie/areas-we-work/national-immunisation-advisory-committee/immunisation-guidelines-ireland</a>
- The student's temperature should not be checked routinely in the school at the time as this is not conclusive and is therefore unhelpful in the decision-making process. Any student feeling unwell on the day or considered by the clinical lead in charge of the vaccination clinic to require deferral of the vaccine, should be offered an appointment for the mop-up clinic.

If they do not attend, there is no requirement to send further appointments.

#### Administration of two or more vaccines at the same vaccination session

- When two or more injectable vaccines are being administered, one vaccinator should where possible administer all the vaccines. This is to ensure that one clinician takes responsibility for the vaccination of each child to reduce the chance of errors.
- The vaccines, if possible, should be kept in their original packaging until they are to be used. If they are removed from their original packaging each vaccine should be kept in a separate colour coded container.
- When three vaccines are administered at the same vaccination session it is
  useful to follow an agreed convention 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. It is also easier to enter this information uniformly
  into the electronic record.
  - Junior infants should be given MMR vaccine in the right deltoid and DTaP/IPV vaccine in the left deltoid.
  - o Second level students should be given:
    - A dose of HPV9 vaccine in the left deltoid.
    - Men ACWY and Tdap vaccines 2.5 cms apart in the right deltoid.
- NIAC advise that: "Multiple vaccines given at the same visit must be given at least 2.5cm (1 inch) apart, and if necessary in different limbs <a href="https://www.hiqa.ie/areas-we-work/national-immunisation-advisory-committee/immunisation-guidelines-ireland">https://www.hiqa.ie/areas-we-work/national-immunisation-advisory-committee/immunisation-guidelines-ireland</a>
- In order to minimize any pain, administer vaccines that are known to be painful when injected (e.g., MMR, HPV9) last. Because pain can increase with each injection, the order in which vaccines are injected matters. Injecting the most painful vaccine last when multiple injections are needed can decrease the pain associated with the injections <a href="https://www.cdc.gov/vaccines/hcp/admin/administer-vaccines.html#multiple-injections">https://www.cdc.gov/vaccines/hcp/admin/administer-vaccines.html#multiple-injections</a>
- For advice about prevention and management of syncope see: <a href="https://bit.ly/MgmtSyncope">https://bit.ly/MgmtSyncope</a>

Where two or more vaccines are scheduled for students at the same vaccination session but a student is not receiving one or more of the vaccines the following procedure should be followed:

- The vaccinator should double check the required vaccine with a nurse/medical colleague before administering the vaccine
- The vaccinator should draw a double line through the box where vaccination details are entered and write "NOT FOR VACCINATION" between the double lines.

## Vaccine storage and handling

- All vaccines must be stored and transported between +2°C and +8°C.
- The SmPCs for all vaccines in the school immunisation programme recommend that they should be stored in the original package to protect from light.
  - Any vaccine that has been removed from its packaging and is not used in a timely manner within the session should not be returned to the cool box but should be discarded safely into a sharps bin. The sharps bin should be securely sealed when three quarters full or filled to the manufacturer's fill line.
  - PRIORIX: The vaccine should be injected promptly after reconstitution. If this is not possible, it must be stored at 2°C – 8°C and used within 8 hours of reconstitution.
  - M-M-RvaxPro: After reconstitution, the vaccine should be used immediately; however, in-use stability has been demonstrated for 8 hours when stored at +2 °C - +8 °C
  - o It is not appropriate to return reconstituted MMR vaccine to the cool box.
  - The Nimenrix SmPC states that both the solvent and the reconstituted Nimenrix vaccine are clear colourless liquids. Therefore, it may be easy to confuse the solvent and the reconstituted vaccine if multiple vaccines have been prepared. The SmPC also states reconstituted Nimenrix should be used promptly. It is not appropriate to return reconstituted Nimenrix vaccine to the cool box.
  - Once DTaP/IPV, Tdap, and HPV9, which come in prefilled syringes, are removed from their packaging they should be used at that vaccination session or discarded safely into a sharps bin. All prefilled vaccine syringes which have been removed from their packaging should not be returned to the cool box.
- SmPC for Adrenaline 1:1,000 Solution for Injection advises that it should not be stored above 25°C and it should be kept in the outer carton.

#### **Maintenance of the Cold Chain**

The National Immunisation Office have published guidance on maintenance of the cold chain including cold boxes. See <a href="http://bit.ly/VaccOrder">http://bit.ly/VaccOrder</a>

- Vaccines should be stored in a pharmaceutical grade fridge at all times at the main health centres.
   These fridges should have the capacity to store all required vaccines between the twice monthly orders, as additional orders cannot be facilitated due to inadequate local storage facilities.
- Current, maximum and minimum temperatures must be checked twice daily with time of reading and sign/initial recorded. Temperature monitoring records should be kept indefinitely unless data logger recordings are being stored indefinitely.
- 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 to 10 minutes intervals.
- Door opening should be kept to a minimum.
- Vaccines should always be stored in their original packaging and should not be removed from their packaging until required for use.
- Vaccine boxes must not touch the sides, back or bottom of the fridge. Air needs to circulate therefore
  the fridge should not be overfilled, as this will prevent proper airflow. Ideally, the fridge should never
  be more than two thirds full.
- The fridge should be serviced and thermometers calibrated annually or in accordance with the manufacturer guideline. Records of servicing and cleaning should be maintained.
- If a vaccines containing fridge records a temperature less than +2° or greater than +8°C quarantine the vaccines between +2 °C and +8 °C and contact the National Immunisation Office by emailing <a href="mailto:pharmacynio@hse.ie">pharmacynio@hse.ie</a>. Please do not use or discard the vaccines until advised by the NIO.
- Vaccine deliveries are twice monthly all year round. Vaccine orders to fulfil the requirements for all planned clinics before the next delivery must be made before the cut off time displayed on the online ordering portal. Emergency deliveries cannot be accommodated for vaccines not ordered for the routine programmes, so a deputy responsible for ordering should be appointed and trained in the event that the designated person in charge of vaccine ordering is unexpectedly unavailable.

# **Transport of Vaccines**

- Domestic cool boxes should not be used to store, distribute or transport vaccines. Cool boxes should be purchased from medical equipment suppliers.
  - Note: Cool boxes (without external power supply) rely on ice/gel packs to maintain correct temperature of +2°C to +8°C. The risk of freezing, or of the temperature of the vaccines in cool boxes dropping to less than +2°C, increases if ice/gel packs are not correctly conditioned or separated by insulating material to prevent direct contact. Each site should have SOPs on how to pack a cool box with the ice/gel packs and vaccines taking into account manufacturer instructions. For all packing materials and equipment, ensure that the specifications of each item are adhered to in accordance with the manufacturer guidelines.

- It is important to test and validate the method of packing vaccines by simulating the process and recording the cold chain for a similar period required for a typical transportation and clinic duration.
- Thermometer probe (or data logger) should be placed in the middle of vaccines and should not touch ice packs/gel packs. To prevent the probe from moving during transport, it can be placed in an empty vaccine box, placed in the middle of the vaccines.
- The vaccines must be transported in their original packaging.
- Only the number of vaccines estimated for administration on any particular day should be brought to the school.
- Record the temperature in the cool box:
  - o when vaccines are packed,
  - o upon arrival at the immunisation clinic,
  - throughout the immunisation clinic,
  - o when returning vaccines to the fridge.
  - The lid of the cool box should be tightly shut and kept closed as much as possible (reducing lid opening helps to keep internal temperatures stable).
  - The cool box should be placed in:
    - o An appropriately ventilated room,
    - Away from any heat source,
    - Away from direct sunlight.
  - A data logger should be used in the cool boxes where external temperature display records only current temperature. This will provide an accurate account of temperatures reached and the duration of any temperature breach. The information on the data logger can be downloaded at the end of a vaccination day to confirm that any returned vaccines have remained within recommended temperature parameters. A data logger does not replace the need to check cool box temperatures each time when removing vaccines prior to administration. A data logger should be set to record at 5 to 10 minutes intervals.
  - If there are any unused vaccines remaining at the end of a vaccination session, providing that the cold chain has been maintained, the vaccines can be returned to the vaccine fridge. They must be marked and should be used first at the next vaccination session.
  - The cool box thermometer / data logger should calibrated annually or in accordance with the manufacturer guidelines.

### Procedures following breakdown in the "Cold Chain"

• If temperatures outside the permitted range are recorded, first check the position of the temperature probe. The temperature probe should be in a vaccine box in the middle of the vaccines – if it is not correctly positioned, reset the probe and ensure it is positioned correctly away from ice packs or at the lid of cool box then close the box firmly and recheck the temperature in 15 minutes.

- If the temperature is still outside the permitted range, place the vaccines under quarantine in the fridge, and contact the NIO (email: <a href="mailto:Pharmacynio@hse.ie">Pharmacynio@hse.ie</a>) for further advice. The NIO will carry out a risk assessment and will advise on a case-by-case basis whether it is appropriate to use the vaccines or whether they should be discarded.
- Do not use or dispose of any vaccine which has been exposed to temperatures outside the
  permitted range. Quarantine and maintain these vaccines between +2°C and +8°C until
  advised by the National Immunisation Office.

# **Clinical Staff Roles**

- If the Parent/Legal Guardian requests further clinical advice about the vaccine they can be referred to a clinical member of the vaccination team.
- If a Parent/Legal Guardian consents but the student refuses vaccination on the
  day of the session, the student should not be vaccinated. This must be recorded
  on the consent form and on SIS and the parent/legal guardian informed if the
  child is aged under 16 years of age.
- If a Parent/Legal Guardian refuses but the student expresses a desire to be vaccinated on the day of the session, the student may be vaccinated if they are aged 16 years and over. If the student is less than 16 years of age they cannot be vaccinated. This must be recorded on the consent form and on SIS. This will form part of a future record for the child when they become of age of consenting in their own right, and wish to have oversight of their personal vaccination status.
- If vaccines are refused, the date of refusal and PIN of the person writing the refusal should be added to the form and entered onto SIS. Please record a reason if stated.
- Where Parents/Legal Guardians have refused consent for vaccination, the
  reason for refusal should be reviewed by a clinical member of the vaccination
  team. If there is a clear refusal, Parents/Legal Guardians should not be
  contacted.
- Where a consent form is returned and a parent/legal guardian has left the consent blank or only filled in the Yes/No sections, a clinical member of the team should phone the parent/legal guardian to seek clarification about their consent. The date and time of the phone call should be recorded on the consent form and the clinician's PIN, consent or refusal witnessed by another member of staff. Which is in line with the <u>HSE Consent policy</u> section 4.2.2 Consent by telephone/electronic means.

#### Interrupted immunisation schedule

NIAC guidelines recommend:

"If an immunisation course is interrupted, it should be resumed as soon as possible. It is not necessary to repeat the course, regardless of the time interval from the previous incomplete course. The course should be completed with the same brand of vaccine if possible." see <a href="https://www.hiqa.ie/reports-and-publications/niac-immunisation-guideline/chapter-02-general-immunisation-procedures">https://www.hiqa.ie/reports-and-publications/niac-immunisation-guideline/chapter-02-general-immunisation-procedures</a>

#### Incomplete immunisation history

Where children are identified as having had incomplete or no previous immunisations, the standard vaccine schedule should be given during the vaccination session. Arrangements should be made to ensure completion of vaccination schedule in line with the guidance from "catch up immunisation schedule" available athttps://www.hiqa.ie/reports-and-publications/niac-immunisation-guideline/chapter-02-general-immunisation-procedures.

#### **Contraindications to vaccination**

- Confirmed anaphylactic reaction to the vaccine itself or to a constituent of that vaccine is an absolute contraindication.
- For MMR: Significantly immunocompromised persons, such as those with untreated malignant disease and immunodeficiency states other than HIV infection, and those receiving immunosuppressive therapy, high-dose x-ray therapy and current high-dose systemic corticosteroids. If there is uncertainty, please advise the parents that the child's specialist should be contacted. Please refer to the detailed guidance in Chapter 3 on Immunisation of Immunocompromised Persons in Immunisation Guidelines <a href="https://www.hiqa.ie/reports-and-publications/niac-immunisation-guideline/chapter-03-immunisation-immunocompromised">https://www.hiqa.ie/reports-and-publications/niac-immunisation-guideline/chapter-03-immunisation-immunocompromised</a>

# **Pregnancy and vaccines**

• The only vaccines used in the Schools Immunisation Programme where pregnancy is a contraindication are HPV and MMR vaccines. Pregnancy could be an issue for some female students in second level schools. Parents/Legal Guardians are advised to discuss the possibility of pregnancy with their daughter prior to vaccination. The consent form for students in first year of second level schools includes the statement "I understand that

HPV is not recommended in pregnancy" (Appendix C). If the Parents/Legal Guardians indicate that their daughter is pregnant then vaccination should be withheld. If the consent form is signed then vaccination is appropriate. Questioning the girl about her last menstrual period is not indicated.

Students who have already received a HPV vaccine are not recommended HPV9 vaccine.

# If a second or third dose of HPV9 vaccine is required the vaccinator should ask the girl the following questions:

- Have you read on the consent form where it says the vaccination is NOT recommended in pregnancy?
- This means that if you think there is any possibility you might be pregnant then you should not be vaccinated today.
- Do you understand this? OR Are you clear about this?
- Do you want to ask me anything more about this before I prescribe the vaccine for you? OR a similar question to check that it is ok to proceed.

# If there is any possibility of pregnancy vaccination should be postponed.

Where there is a possibility of pregnancy and the female student is aged under 17 years of age inform the parents, on the vaccination day, that vaccination has been deferred and the reason for deferral. The parents should be notified that vaccination is not being carried out as they have given consent for it. This decision should be discussed with the student prior to contacting the Parents/Legal Guardians.

The vaccinator should notify their line manager and seek further advice in relation to their legal obligations under child protection legislation. For further detail, see <a href="http://bit.ly/C1stTusla">http://bit.ly/C1stTusla</a>

However, if the female student is adamant that her parents are not to be informed as to the reason for deferral, the vaccinator should again notify their line manager and seek further advice in relation to their legal obligations under child protection legislation. For further detail, see <a href="http://bit.ly/C1stTusla">http://bit.ly/C1stTusla</a>

If a student who was vaccinated subsequently finds out that she was pregnant at or conceived around the time of vaccination, any further HPV vaccination should be postponed.

#### **Precautions for vaccination**

- Acute severe febrile illness: defer until recovery.
- **Bleeding disorders**: Vaccines should be administered with caution to individuals with coagulation defects.
  - o If vaccines are given intramuscularly to those with a bleeding disorder or receiving anticoagulant treatment NIAC has recommended that it is prudent to use a 23 gauge (blue) or wider needle to reduce the pressure gradient and cause less trauma to the tissues. Apply gentle pressure to the vaccine site for 1-2 minutes after the injections. In those with a severe bleeding tendency vaccination can be scheduled shortly after administration of clotting factor replacement or similar therapy.
  - MMR vaccine can be given by the subcutaneous route. Administration by the subcutaneous route may be considered in those with severe bleeding disorders. However, immunogenicity of vaccines recommended for IM administration may not be as long lasting if they are given subcutaneously, except for MMR which can be given SC. The patient or parent should be advised of this.
  - There is no recommendation on the subcutaneous administration of the DTaP/IPV, Tdap, MenACWY or HPV9 vaccines.
- **Immunosuppression:** The immune response of individuals who are immunocompromised may be inadequate.
  - In the case of MMR vaccine for those who have immune deficiency or immunosuppression please refer to the detailed guidance in Chapter 3 on Immunisation of Immunocompromised Persons in Immunisation Guidelines https://www.hiqa.ie/reports-and-publications/niacimmunisation-guideline/chapter-03-immunisation-immunocompromised
  - Individuals with impaired immune responsiveness, whether due to treatment, illness or other causes may not respond to the HPV vaccine.
    - See HPV chapter and Chapter 3 in the Immunisation Guidelines for Ireland available at https://www.hiqa.ie/areas-we-work/national-immunisation-advisory-committee/immunisation-guidelines-ireland

All vaccines (live and non-live) can safely be given to patients being treated with topical calcineural inhibitors (e.g. tacrolimus).

None of the vaccines used in the school immunisation programme contain latex.

## Information on specific vaccines

#### All pertussis-containing vaccines

The following are not contraindications or precautions to giving pertussis-containing vaccines. They have not been shown to cause permanent harm and are significantly less common after acellular than after whole cell pertussis vaccine.

- Temperature of more than 40.5°C within 48 hours of a previous dose of a pertussis containing vaccine
- Hypotonic hyporesponsive episode within 48 hours of a previous dose of a pertussis containing vaccine
- Seizures within 72 hours of a previous dose of a pertussis containing vaccine.
   Persistent, inconsolable crying lasting more than 3hrs within 48 hours of a previous dose of a pertussis- containing vaccine.

#### **Junior Infants**

#### DTaP/IPV

- There should be an interval of at least six months between the booster dose of DTaP/IPV and the completion of a primary course of tetanus containing vaccine.
- DTaP/IPV can be given at any interval following Td vaccine.
- If a 4th dose of diphtheria, pertussis, polio and tetanus containing vaccine has been given at age ≥3 years and 4 months, a 5th dose of diphtheria, pertussis, and tetanus containing vaccine is not required until age 12-13 years.
- A 5th dose of polio vaccine (as Tdap/IPV) is only recommended if a child, aged
   10 years and over, is travelling to polio endemic or epidemic area.

#### **MMR**

- MMR is contraindicated in persons who are significantly immunocompromised due to disease or treatment.
- MMR is a live vaccine and must not be administered within four weeks of varicella or yellow fever live vaccines. MMR can be given on the same day or at any interval before or after any other live vaccine, including the Live Attenuated Influenza Vaccine (LAIV/ Fluenz).
- Immunoglobulin administration may impair the efficacy of MMR and varicella vaccines (Chapters 2, 12, 15 and 20) MMR vaccine can be given at the same time or at any interval before or after washed red blood cells. These vaccines

should be given at least two weeks before and 6 months after the administration of packed red blood cells which may interfere with the immune response (Table 2.6).

**Table 2.6** Recommended intervals between blood products and MMR or varicella vaccines

This table is not intended for determining correct indications and doses for using antibody-containing products.

Preparation	Route	Dose	Estimated IgG mgs/kg	Interval (months)		
Blood products						
Washed RBCs	IV	10mls/kg	Negligible	0		
Packed RBCs and whole blood	IV	10mls/kg	60	6		
Plasma & platelets	IV	10mls/kg	160	7		
HNIG						
Immune deficiencies	SC, IV		300-400	8		
ITP treatment	IV	400mgs/kg/ day	400	8		
		1,000 mgs/kg/ day	1,000	10		
Kawasaki disease	IV		2,000	11		
Measles Immunocompetent contacts	IM		80-200	6		
Immunocompromised contacts	IV		400	8		
Hepatitis A	SC/IM	1-2.5 ml/kg	200-500	6-8		
Specific immunoglobulins						
Cytomegalovirus	IV	3mls/kg	150	6		
Hepatitis B	IM	100-500 IU		3		
Rabies	IM, wound	20 IU/kg	22	4		
Tetanus	IM	250-500 IU	10-20	3		
Varicella	IM	15-25 IU/kg		5		
Respiratory Syncytial Virus monoclonal antibody (palivizumab or nirsevimab) (RSVab)				0		

- Vaccination should be deferred for between three and eleven months following the administration of an antibody product (for full details see Table 2.6 in Chapter 2 of Immunisation Guidelines for Ireland available at
  - https://www.hiqa.ie/sites/default/files/NIAC/Immunisation\_Guidelines/Chapter\_02\_General\_Immunisation\_Procedures.pdf
- If there are cases of chickenpox in the school, the MMR vaccine can be given at any time provided the child does not have an acute febrile illness.
   Any child who has recently had chickenpox can also receive the MMR vaccine (and 4 in 1 or any other vaccine) as long as they are well on the

- day of vaccination.
- NIAC guidelines advise that any child who has received two doses of MMR
  vaccine over the age of 12 months and at least 28 days apart are up to date
  with MMR immunisations and do not require another dose in junior infants.

#### **First Year Vaccines:**

#### **HPV** vaccine

- Fainting is a recognised side effect of vaccines given in adolescence.
- Syncope has been reported among adolescents before or following vaccination, particularly
  with the first dose. Recipients should be seated or lying down during vaccine administration

# **Tdap**

• Tdap can be given at any time interval after a tetanus containing vaccine.

#### **MenACWY**

- Those who have had a dose of Men ACWY conjugate vaccine at the age of 10
  years or older do not require a further dose of vaccine. If they have received the
  polysaccharide Men ACWY vaccine, they should receive the conjugate vaccine
  in the schools programme.
- For anyone who has received a dose of Men C vaccine (e.g., as part of an outbreak response) an interval of at least two months should be left before Men ACWY vaccine is given.
- Parents or students do not need to be questioned about prior Men C or Men
   ACWY vaccines, but the above information on intervals should be used if a parent
   has indicated that the student has recently received a meningococcal C or
   ACWY vaccine.

When there are doubts about giving a vaccine, consult the relevant NIAC chapter or contact a Principal Medical Officer, a Specialist or Consultant in Public Health Medicine or NIO for further advice.

#### **Adverse Events**

The vaccines used in the Schools Immunisation Programme are considered safe and well tolerated. Full details of the side effects of each vaccine can be found in the summary of product characteristics (SmPC) available on <a href="https://www.hpra.ie.">www.hpra.ie</a>. The relevant immunisation leaflets contain details on adverse reactions and their management.

Parents/Legal Guardians/Students should inform the School Immunisation Team of any adverse reactions to the vaccine by contacting the HSE school immunisation team. Children who develop reactions in the days after vaccination do not need to be seen by the Medical Officer unless in exceptional circumstances. There is no evidence to date that any of the vaccines used in the School Immunisation Programme cause long-term adverse events.

#### **General side effects**

These can occur with any of the vaccines used in the Schools Immunisation Programme.

- A local reaction at the injection site, which can consist of redness, swelling, pain and increased skin temperature is the most common side effect.
- Systemic symptoms, e.g., fever and malaise.
- Syncope can occur after vaccination, especially in adolescents. See Appendix D
- Anaphylaxis is an extremely rare event (about one event/million doses) that
  could occur with the administration of any vaccine. Detailed advice on the
  management of anaphylaxis is contained in the <u>Immunisation Guidelines for Ireland.</u>
- Persons who are taking beta-blockers may be vaccinated in the community. In the event
  of anaphylaxis or suspected anaphylaxis, epinephrine (adrenaline) should be given
  promptly and repeated as indicated. As with any episode of anaphylaxis, the patient
  should be transferred to hospital as soon as possible.

# DTaP/IPV and Tdap specific side effects

- Booster doses of tetanus, diphtheria and pertussis containing vaccines can
  result in an increase in local reactogenicity and fever compared to the
  primary course i.e., extensive swelling of vaccinated limb (sometimes
  involving the adjacent joint);
- In general, these reactions begin within 48 hours of vaccination and resolve spontaneously over an average of 4 days without sequelae.
- Such reactions do not contraindicate further doses of diphtheria, tetanus, or
  pertussis containing vaccines however after such a reaction, further routine or
  emergency booster doses of tetanus or diphtheria containing vaccines should not
  be given more frequently than every 10 years

- Antibiotic treatment or the use of anti-inflammatory medication does not reduce the duration or severity of such reactions.
- Parents/Legal Guardian of children who receive the booster dose of a DTaP/IPV
  containing vaccine should be informed of the risk of extensive swelling,
  highlighting that this is not usually associated with significant pain or limitation of
  movement.

# MMR specific side effects

#### Local:

- Very common: erythema at injection site.
- Common: soreness, swelling.

#### General:

- Common: rhinitis, rash.
- "Mini-measles" (fever and rash) may occur 6-10 days after immunisation and consists of mild pyrexia and an erythematous rash. This is non-infectious and self-limiting.
- 'Mini-mumps' with salivary gland swelling may rarely occur during the third week after immunisation. This is non- infectious.
- The rubella component may occasionally produce a rash, mild arthralgia, and lymph-node swelling 2-4 weeks post-vaccination, particularly in postpubertal females (up to 25% of recipients). The incidence is lower than after natural disease. A very rare side effect of MMR is the occurrence of thrombocytopoenia 15-35 days post vaccination.
- Very rarely, erythema multiforme, and nerve deafness have been reported post MMR

# Reporting of adverse reactions

The vaccinator should report relevant suspected adverse reactions to the HPRA. It is not usually necessary to notify the HPRA of the common, short-lived side effects that are already noted in the SmPC of the product. Details of adverse events may be recorded on the adverse event clinical record (Appendix E). 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 http://bit.ly/HPRAar
- You can report directly though a form on the website or via a downloadable report form accessible from HPRA website, which may be completed manually and submitted to the HPRA via email or "freepost"
- By telephoning the HPRA Pharmacovigilance Section 016764971.

# Incident reporting

In the event of an incident occurring during a vaccination session, an incident report must be completed by the professional primarily involved in the incident and forwarded to the relevant manager.

If there is a vaccine administration error, e.g., an incorrect vaccine is administered to one or more students, the National Immunisation Office must also be informed. Such an error must be reported to the relevant line manager. The incident and all actions taken must be recorded and the relevant National Incident Management Report Form completed (National Incident Report Form - NIRF- 01-V 12 November 2021)

https://www.hse.ie/eng/about/who/nqpsd/qps-incident-management/nims/nirf-01-v12-person-interactive.pdf

#### References

- Children First 2011 National Guidance for the Protection and Welfare of Children.
   <a href="https://www.hse.ie/eng/services/list/2/primarycare/childrenfirst/resources/children-first-national-guidance-for-the-protection-and-welfare-of-children-2017.pdf">https://www.hse.ie/eng/services/list/2/primarycare/childrenfirst/resources/children-first-national-guidance-for-the-protection-and-welfare-of-children-2017.pdf</a>
- Guidance for providers of health and social care services Communicating in plain English HIQA and NALA 2015 <a href="https://www.higa.ie">www.higa.ie</a>
- Healthcare professionals FAQ National Immunisation Office <a href="http://bit.ly/FAQImm">http://bit.ly/FAQImm</a>
- Healthcare risk waste management segregation packaging and storage guidelines for healthcare risk waste 4th edition 2010 <u>Healthcare Waste</u> <u>- IWMA</u>
- <u>HSE Guidelines</u> for maintaining the vaccine cold-chain including maintenance of vaccine fridges and management of vaccine stock
- HSE Guidelines for maintaining the vaccine cold-chain in vaccine cool boxes.
   <a href="https://www.hse.ie/eng/health/immunisation/hcpinfo/vaccineordering/sopnio02box.pdf">https://www.hse.ie/eng/health/immunisation/hcpinfo/vaccineordering/sopnio02box.pdf</a>
- Immunisation Guidelines for Ireland. National Immunisation Advisory Committee https://www.hiqa.ie/areas-we-work/national-immunisation-advisorycommittee/immunisation-guidelines-ireland
- Patient Information Leaflet (PIL) for the vaccines used in the Schools Immunisation Programme. Visit <u>Find a medicine (hpra.ie)</u>
  - o Tetravac PIL
  - o Priorix PIL
  - M-M-RvaxPro PIL
  - Gardasil 9 PIL
  - o Boostrix PIL
  - Nimenrix PIL
- Information on HSE ICT security https://bit.ly/HSEITSec
- Information on HSE electronic communications <a href="https://bit.ly/HSEITCom">https://bit.ly/HSEITCom</a>
- Information on HSE encryption policies <a href="https://bit.ly/HSEITEnc">https://bit.ly/HSEITEnc</a>
- Information on how to communicate clearly http://bit.ly/CommClear
- Information on HSE's open disclosure policy <a href="http://bit.ly/OpenDis">http://bit.ly/OpenDis</a>
- Information on HSE Consent Policy HSE National Consent Policy Corporate
- Information on HSE Retention Policy <a href="https://healthservice.hse.ie/staff/procedures-">https://healthservice.hse.ie/staff/procedures-</a>

# guidelines/record-retention-policy/

- Data Protection Commission website https://www.dataprotection.ie/en
- HSE Data Protection policies <a href="http://bit.ly/HSEdatapro">http://bit.ly/HSEdatapro</a>
- Information on Subject Access Requests (SAR) http://bit.ly/SARhse
- GDPR Frequently Asked Questions <a href="http://bit.ly/GDPRhse">http://bit.ly/GDPRhse</a>
- Who can give consent for vaccination of a young person aged under 16 years?
   <a href="https://bit.ly/ConsentU16">https://bit.ly/ConsentU16</a>

For other useful links and resources see Appendix F

#### **Glossary of Terms and Definitions**

A Registered Nurse Prescriber is a nurse or midwife who is registered in the Division of the Register of Registered Nurse Prescribers of the Nursing and Midwifery Board of Ireland (An Bord Altranais, 2007). The Registered Nurse Prescriber will use prescriptive authority in a safe and effective manner in the prescribing of vaccinations in accordance with his/her collaborative practice agreement (CPA) and must adhere to the National Policy for Nurse and Midwife Medicinal Product Prescribing (2012).

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).

**Collaborating Medical Practitioner(s):** the medical practitioner or group of medical practitioners with whom the registered nurse prescriber has a written collaborative practice agreement as part of the requirements to prescribe medicinal products within his/her scope of practice.

Collaborative Practice Agreement (CPA): the CPA is drawn up with the agreement of the registered nurse prescriber, collaborating medical practitioner and the employer outlining the parameters of the registered nurse prescriber's prescriptive authority (i.e., his/her scope of practice). The principles of professional accountability, responsibility, competence and clinical governance underpin the CPA. The medicinal products listing is approved by the Drugs and Therapeutics Committee and authorised by the director of nursing/ midwifery/public health nursing or relevant nurse/midwife manager on behalf of the health service provider (An Bord Altranais, 2012).

**Health Protection Surveillance Centre (HPSC):** the HPSC are responsible for collating, analysing and publishing the national immunisation uptake statistics for all national immunisation programmes in Ireland.

**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.

**Medicine protocols** are written directions that allow for the supply and administration of a named medicinal product by a nurse or midwife or trained vaccinator in identified clinical situations without the requirement for individual prescription.

**School Immunisation Team:** The multidisciplinary team of staff who provide the Schools Immunisation Programme, composition can vary between local areas.

**School Immunisation System (SIS):** All vaccinations administered through the Schools Immunisation Programme must be recorded on the School Immunisation System (SIS). The system is web-based and is accessible from any HSE location. Statistical reports are also generated from SIS allowing local areas to monitor their uptake and target those who are due and overdue vaccinations.

**SmPC:** The Summary of Product Characteristics (SmPC) of a medicine is part of the licensed documentation and provides specific product information for prescribers and healthcare professionals on how to use that medicine safely and effectively. The date of the most recent revision is included at the end of the text.

**School Roll Number:** The unique identifier number given to each school by the Department of Education and Skills (DES). If the school is not registered with the DES it will be assigned a unique HSE ID on the Schools Information System (SIS) system.

**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 non-live micro-organisms or fractions thereof, or microorganism like particles administered to induce immunity and thereby prevent infectious disease. Non live vaccine is a vaccine that contains killed or fractions of microorganisms or microorganism like particles. 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 vaccines

Vaccination is the term used to refer to the administration of any vaccine or toxoid

**A vaccinator** is a trained healthcare professional who has completed training in the administration of vaccinations and is administering vaccinations prescribed by a Registered Nurse Prescriber or Doctor or under a medicine protocol.

#### Vaccine abbreviations:

• DTaP/IPV: Tetanus, diphtheria, pertussis and inactivated polio

• MMR: Measles, Mumps and Rubella

• **HPV**: Human papillomavirus

MenACWY: Meningococcal ACWY

• **Tdap:** Low dose tetanus, diphtheria and low dose pertussis (acellular, component)

## Appendix A: Template Operating Procedures and roles and responsibilities

## Operational aspects of the programme prior to the school vaccination session

- Prior to the vaccination date all queries should be dealt with so no child attends for vaccination with an outstanding query. A system should be available locally to deal with immunisation queries or concerns from parents/legal guardians/students and schools.
- The target cohorts (denominator) for each vaccination programme should be identified.
- The schedule of school visits by the immunisation team(s) should ideally be decided with the schools a minimum of one month in advance if possible.
- Parents/legal guardian/students should receive the junior infant primary school or first year of second level parent pack through the schools in advance of the planned vaccination session. The pack contains a letter, information leaflets and consent form.
- TUSLA will work with the NIO to ensure that the immunisation packs are sent directly to parents of children who are home schooled.
- Students being home schooled are required to register with TUSLA, however
  registration is not required before age 6 years or after age 18 years. The cover
  letter advises parents/legal guardians/students to contact immunisation staff in
  their HSE Area to arrange vaccination. When parent/legal guardian/student
  contacts their HSE Area they should be given an appointment to attend a school
  clinic or mop up clinic. <a href="http://bit.ly/ConCQs">http://bit.ly/ConCQs</a>
- For students who are home schooled, parents/legal guardians/students should receive an information pack consisting of
  - o Letter advising how to access the schools immunisation programme
  - Information leaflet on the relevant vaccine(s)
  - Appropriate vaccination consent form.
- The composition of immunisation teams should be agreed locally in advance and will depend on the number of students in the relevant class in the school.
- Vaccines may be given by trained vaccinators working under a Statutory
  Instrument (SI) to administer vaccines as part of the schools immunisation
  programme. Vaccinators may administer vaccine under doctor or Registered
  Nurse Practitioner prescription or under a medicine protocol within their
  scope of practice.

## Clinical staff should be familiar with the following documents:

- Immunisation Guidelines for Ireland are available at <a href="https://www.hiqa.ie/areas-we-work/national-immunisation-advisory-committee/immunisation-guidelines-ireland">https://www.hiqa.ie/areas-we-work/national-immunisation-advisory-committee/immunisation-guidelines-ireland</a>
- Summary of Product Characteristics (SmPCs) for each of the vaccines available at www.hpra.ie and also available under the relevant schools vaccination programme at http://bit.ly/SchPHCP
- Medicine Protocols for each of the vaccines in the schools immunisation programme are available under the relevant schools vaccination programme at <a href="http://bit.ly/SchMedPros">http://bit.ly/SchMedPros</a>
- Healthcare professionals FAQs are available at http://bit.ly/FAQImm
- NIAC "Anaphylaxis: Immediate Management in the Community" protocol, in the Immunisation Guidelines for Ireland available at <a href="https://www.hiqa.ie/reports-and-publications/niac-immunisation-guideline/anaphylaxis">https://www.hiqa.ie/reports-and-publications/niac-immunisation-guideline/anaphylaxis</a>
- HSE Communicating Clearly with Patients and Service
   Users guidelines <a href="http://bit.ly/CommClear">http://bit.ly/CommClear</a>
- Each vaccinator must be familiar with:
  - Techniques for resuscitation of a patient with anaphylaxis and have completed an approved Basic Life Support for Health Care Providers Course (i.e. Irish Heart Foundation (IHF)). Recertification is required every two years.
  - Medicine protocols for administration of the relevant vaccines and epinephrine/adrenaline, without individual prescription.

#### Operational aspects of the programme on the day of the school vaccination session

- The team should be at the school in advance of the vaccination session to ensure that it commences promptly at the appointed time.
- Each member of the team has a responsibility to ensure the smooth through-flow and safety of students and staff at all times.
- A designated person will take responsibility for ensuring that all necessary documentation and information materials are available for the vaccination session.
- A designated person will take responsibility for ensuring that all the equipment necessary for the administration of the vaccines is in compliance with best practice.
- A designated person must take responsibility for ensuring that the correct and appropriate vaccines for primary and second level schools have been brought to the school vaccination session.
- A designated person will ensure that the correct vaccine type, appropriate quantity

of the two or three vaccines being administered are brought to each vaccination session and that vaccines are in date and stored and maintained within cold chain.

- A designated person will take responsibility for bringing the resuscitation kit to the schools and for ensuring that all the necessary resuscitation equipment and drugs are available and in date (Appendix H). These should be checked by two clinical members of the team and recorded on the vaccination session report form at the start of each vaccination session.
- Before the vaccination session begins the staff at the session must agree who is
  to take the "lead role" for the vaccination session and have an overall oversight
  for the operation of the vaccination session. This oversight role will not diminish
  the roles and responsibilities of all team members. The "lead role" may be
  assigned in advance, however if this person is absent or delayed another person
  must take on this oversight role.
- The person in the "lead role" will be responsible for:
  - o liaison with school staff
  - o calling "Time Out" to check all is in order before vaccinations begin
  - o ensuring all designated roles are covered
  - ensuring the session report form is completed at the end of the vaccination session, including the lead person's name and PIN
  - ensuring that the Pharmacists at the National Immunisation Office is contacted or if there is a break in the cold chain (email pharmacynio@hse.ie).
  - ensuring that an incident report is made if there is an incident at the vaccination session.
- At the beginning of each vaccination session two vaccinators from the team should verify the identity, expiry dates and batch numbers of the vaccine for use on the day, and record it on the school vaccination session report form.
- The current temperature of the probe in the cool boxes at the beginning and end of the vaccination session should be recorded on the school vaccination session report form.
- The person in "lead role" should call a "Time Out" to check all is in order before vaccinations begin.
- The person in "lead role" should also call "Time Out" where there is any
  change to the established routine/flow of the immunisation session/clinic for
  any reason and ensure that all team members are aware of the change
- Where there are two or more vaccines to be administered to the students at

- the same vaccination session, each vaccine should be kept in their original box or in a separate colour coded container.
- Ensure the student's immunisation passport is completed and given to all students before they leave the vaccination area.
- Ensure that each student is provided with the appropriate tear pad stating
  date and time vaccine was given and the appropriate contact details so that
  parents /legal guardians can inform the school immunisation staff about any
  concerns following vaccination.
- Each vaccinator is responsible for the secure disposal of sharps and clinical waste in a sharps container and for ensuring that the sharps container is secured at the end of each vaccination session and removed from the school premises as in the HSE guidelines "HEALTH SERVICE EXECUTIVE WASTE POLICY 2016 <a href="https://www.hse.ie/eng/about/who/healthbusinessservices/national-health-sustainability-office/files/hse-waste-policy-principals.pdf">https://www.hse.ie/eng/about/who/healthbusinessservices/national-health-sustainability-office/files/hse-waste-policy-principals.pdf</a> and also complying with Guide to the European Union Regulations 2014 (Prevention of Sharps Injuries in the Healthcare Sector) <a href="https://www.hse.ie/eng/about/who/healthbusinessservices/national-health-sustainability-office/files/hse-waste-policy-principals.pdf">https://www.hse.ie/eng/about/who/healthbusinessservices/national-health-sustainability-office/files/hse-waste-policy-principals.pdf</a> and also complying with Guide to the European Union Regulations 2014 (Prevention of Sharps Injuries in the Healthcare Sector) <a href="https://www.hse.ie/eng/about/who/healthbusinessservices/national-health-sustainability-office/files/hse-waste-policy-principals.pdf">https://www.hse.ie/eng/about/who/healthbusinessservices/national-health-sustainability-office/files/hse-waste-policy-principals.pdf</a> and also complying with Guide to the European Union Regulations Health and Safety Authority (hsa.ie)
- At the end of the vaccination session the school vaccination session report form should be completed by a designated person. (Appendix I).
- All members of the Team should be responsible for cleaning/tidying up after the vaccination session so as to ensure that the vaccination venue is left as it was found.
- Two trained vaccinators must remain at the vaccination venue for at least 30 minutes following the last vaccination.
- Details of students who failed to return a consent form, did not provide valid consent, were absent, refused vaccination on the day or whose vaccination was deferred should be entered on SIS and given an appointment to attend a HSE mop up clinic.
- In addition, where a completed consent form is provided too late for the school vaccination session, the student should be called to a mop up clinic.
- Students who require further vaccine doses to complete a course should have their school record entered onto SIS and be offered an appointment to attend a HSE mop up clinic.
- If addresses are available send letters to parents/legal guardians of these students by post. If addresses are not available for students the school should be provided with sealed letters for onward distribution to parents/legal guardians of these students.

#### Operational aspects after school/clinic vaccination session

- A designated member of the team is responsible for returning any unused vaccine
  to the fridge. Vaccines that are not used on a particular day and are in their
  original packaging and have been maintained under cold chain conditions should
  be returned to the vaccine fridge. They should be clearly marked so that they are
  used first at the next vaccination session
- Arrangements should be made for a second dose of MMR to be given to those students in junior infants whose school vaccination constituted their first dose of MMR. The information from regional PCI systems will be on SIS in the PCI MMR Stage Status box.
- Students who are identified as having an incomplete course should have arrangements made to complete their immunisations as per guidance for late entrants available at <a href="https://www.hiqa.ie/reports-and-publications/niac-immunisation-guideline/chapter-02-general-immunisation-procedures">https://www.hiqa.ie/reports-and-publications/niac-immunisation-guideline/chapter-02-general-immunisation-procedures</a>
- Lists of students for mop-up clinics should be compiled to include all those students
  who were not vaccinated on the day i.e. who failed to return a consent form, did not
  provide valid consent, were absent or deferred on the day and those students who
  refused vaccination on the day.
- Client set up, consent and vaccination/DNA recording on SIS should take place as
  close to the vaccination event as possible at the latest within a month of the
  vaccination administration.
- Any suspected adverse events that occur during the school vaccination session
  or are subsequently notified by parents, legal guardians or students should be
  reported to the HPRA as appropriate.

## **Roles and Responsibilities**

Roles and responsibilities may be assigned to team members on a local basis according to the professional qualifications and expertise of team members and available resources.

#### Managerial role and responsibilities

- Principal Medical Officers should ensure that all medical officers in the Schools
   Immunisation Programme are aware of this Supporting Information for Staff and should facilitate any training required.
- Directors of Public Health Nursing should ensure that all nurses in the Schools Immunisation Programme are aware of this Supporting Information for staff and should facilitate any training required.

- Any vaccinators from other professions should have appropriate line management and their line manager should ensure that they are aware of this Supporting Information for staff and facilitate any training required.
- Area Managers should ensure that all administrative staff in the Schools
   Immunisation Programme are aware of these guidelines and should facilitate
   any training required. Contact SIS National Administrator for any questions
   about SIS: email <u>SIS.support@hse.ie</u> for training course information.
- Managers are responsible for ensuring that only trained users of the SIS are entering data on the system. Managers should maintain training records for their staff in relation to SIS.
- Reporting relationships and training for any non-HSE staff involved in the programme will need to be defined locally in advance of the start of the programme.
- SIS National Administrator is responsible for maintaining the system lookup tables, reviewing user access controls, providing training materials and devising data quality reporting
- Health Region Administrators are responsible for overseeing the access, administrative processes, use of the system and quality of the data entered on to the SIS. It is important that vaccination records are controlled to ensure:
  - vaccination records are entered on SIS in a timely fashion and only once
  - o records are stored in accordance with local and national policies
  - the location of all records are known at all stages of the immunisation process
- Denominators are brought forward from the previous year to allow reports to show uptake figures. When confirmed school denominators become available from the Department of Education these will also be uploaded to SIS. Health Region administrators may submit a list of schools including any denominator change and an explanation of each change towards the end of the academic year to the SIS National Administrator.
- Health Regions administrators are responsible for managing data quality issues in school teams as they arise.

#### Administrative roles and responsibilities

- Each clerical officer should report to their relevant line manager.
- Each clerical officer should ensure that they are familiar with and adhering to the relevant practices as set out in this document and the SIS user guide (email sis.support@hse.ie).
- Each clerical officer should read and make available as needed the Statement of

- Information Practices for SIS and be familiar with and adhere to the Data Protection legislation.
- Ensure a copy of school health and safety regulations is obtained and adhered to during each school visit.
- Make their health region administrator lead aware of any differences between the school denominator and the Department of Education's published denominator, this may involve contacting each school to get their target cohort (denominator).
- Ensure special schools are aware of relevant birth cohort.
- Schedule vaccination date/s with each school and distribute consent packs /forms (Appendix C), information leaflets and invitation letters to all parents/legal guardians through the school as far in advance of the vaccination date/s as possible.
- Collect completed consent forms from the school as agreed with Principal or other person designated by the school principal prior to the school vaccination day and bring the relevant forms to the school on the day of vaccination.
- Collect any additional consent forms that are returned on the day of vaccination.
- Check with the school those who are in the target group but are absent on the day and separate their consent forms. Record the students in the target group, who are present, on the class lists.
- Check all consent forms and contact parents or ask second level students
  themselves to resolve any administrative queries. Where there are also
  clinical queries to be resolved, all queries for that student should be referred to
  a clinical member of the team for follow up, to make one call to parents.
- Organise the collection and return of students to their classrooms in small groups in association with a designated school liaison person.
- Confirm student's identity (confirm name, address, date of birth and guardian's name by asking: "What is your full name? When is your Birthday? Who signed the consent form? What is their name?" For younger children it may be necessary to confirm identity with appropriate liaison person from the school.
- Give consent forms to students after confirming their identity.
- Direct student to the vaccinator.
- Ensure that student is provided with the appropriate tear pad stating date and time vaccine given (Appendix J) and the school vaccination team contact details.
- Collect the consent forms and collate the statistics required for the School Vaccination Session Report Form (Appendix I) at the end of the session.
- Offer one appointment to attend a mop up clinic to students who were not vaccinated on the day. If the school team is notified that the student cannot attend the mop up clinic, one further appointment should be arranged.

- Carry out a search on the SIS to locate the client record, if not found set up a new client record. Input all school vaccinations i.e. MMR, 4in1, HPV, Tdap and MenACWY data on to the SIS including clients who did not or could not attend.
- For those students in junior infants, check the consent form and SIS (PCI MMR status box) to see if school MMR dose constituted their first dose and if so, arrange for them to receive a second dose at least one month later either at a mop up clinic or with their GP.
- Ensure all data entered is accurate and in accordance with data entry standards by running quality reports after school or clinic data is entered.
- Once a record is entered onto the SIS, write the system's client ID and the school roll number on the top of the consent form so that other users know this record is registered.
- In the event of an incident occurring during a vaccination session an incident report must be completed according to the HSE policy on incidents.
- If there is a vaccine error e.g. an incorrect vaccine is administered to one or more students, the record should be updated by the administrator who becomes aware of the error indicating the actions taken to bring this to the attention of the clinical lead; and the National Immunisation Office must also be informed at <a href="mailto:mai
- If errors are made on the SIS that cannot be resolved, inform the Health Region system administrator as soon as possible so that the errors can be rectified.

## Vaccinators role and responsibilities

- Each vaccinator on the team will be accountable for his/her own clinical practice.
- Each vaccinator should report to their relevant line manager.
- Each vaccinator should ensure that they are familiar with and adhering to the practices as set out in this supporting information.
- Be aware of the school's health and safety regulations during each school visit
- Be available to answer queries from parents/legal guardians/students, teachers and other members of the immunisation team.
- Ensure that all vaccines are used within the recommended time frame.
  - PRIORIX: The vaccine should be injected promptly after reconstitution. If this is not
    possible, it must be stored at 2°C 8°C and used within 8 hours of reconstitution.
  - MMRVAXPRO: After reconstitution, the vaccine should be used immediately; however, in-use stability has been demonstrated for 8 hours when stored at 2 °C – 8 °C
  - Nimenrix should be used promptly after reconstitution.

- Any vaccines removed from their packaging should be used at that vaccination session or discarded.
- Check that the appropriate vaccine(s) for the vaccination session are in the cool box and the expiry date has not passed and record this on the school vaccination session report form
- Check that appropriate drugs and equipment are available for resuscitation and record this on the school vaccination session report form
- Before administration of each vaccine, each vaccinator should:
  - Check the name of the vaccine identification label to ensure that it is the correct vaccine for the student.
  - Check the expiry date on the vaccine box and confirm that the vaccine has not expired.
  - Check there is no evidence of any foreign particulate matter and/or variation of physical aspect of the vaccine. Discard the vaccine if these changes observed.
  - The SmPC for all the vaccines used in the school immunisation programme recommend that each vaccine is well shaken before administration.
  - Confirm student's identity (Confirm name, address, date of birth and parent or legal guardian's name by asking: "What is your full name? When is your birthday? Where do you live? Who signed the consent form? What is their name?" For younger children it may be necessary to confirm identity with the child's teacher or an appropriate liaison person (as agreed with the School Principal) from the school.
  - Confirm that informed consent has been given by a parent/legal guardian for students aged under 16 years or the student if aged 16 years and older.
  - Any clinical issues raised on the consent form should be addressed prior to vaccination
  - For DTaP/IPV check that there is an interval of at least six months between the booster dose of DTaP/IPV and the completion of a primary course of tetanus containing vaccine (if applicable).
  - o For dose 2 of MMR vaccine check that it is at least 28 days since dose 1.
  - Check that the vaccine has been prescribed by the Medical Officer or Registered Nurse Prescriber or in the case of administration, can be given in under medicine protocol.
  - Vaccines should be protected from light and should not be removed from their packaging until required for use.
  - Ensure the student is correctly positioned for the safe administration of the vaccine(s) with help from a parent/legal guardian, other member of the vaccination team, or member of school staff if required. See guidelines on

holding child during immunisation in Chapter 2 of the Immunisation Guidelines for Ireland available at <a href="https://www.hiqa.ie/reports-and-publications/niac-immunisation-guideline/chapter-02-general-immunisation-procedures">https://www.hiqa.ie/reports-and-publications/niac-immunisation-guideline/chapter-02-general-immunisation-procedures</a>

- If a child refuses to be vaccinated, they should be deferred to a mop up clinic and their parents informed, ideally on the day of vaccination.
- Administer a single dose of 0.5ml of the appropriate vaccine by intramuscular (IM) injection at a 90° angle to the skin in the densest part of the deltoid muscle of the arm.
- Vaccinators should wash their hands or use the disinfectant gel after each vaccination.
- Dispose of sharps immediately, without recapping the needle, into the sharps containers provided as per HEALTH SERVICE EXECUTIVE WASTE POLICY 2016 <a href="https://www.hse.ie/eng/about/who/healthbusinessservices/national-health-sustainability-office/files/hse-waste-policy-principals.pdf">https://www.hse.ie/eng/about/who/healthbusinessservices/national-health-sustainability-office/files/hse-waste-policy-principals.pdf</a> and in compliance with the Guide to the European Union Regulations 2014 (Prevention of Sharps Injuries in the Healthcare Sector) "Since 2014 all HSE vaccine tenders have required information from the manufacturers on their compliance with the <a href="European Sharps Directive">European Sharps Directive</a> However to date European vaccine manufacturers continue to plan how to comply with these regulations and no manufacturer is producing vaccines fitted with safety needles.
- At all times ensure that sharps containers are managed in accordance with National Guidelines and located appropriately and safely, off the floor and away from children and the public.
- Complete the administration details including the trade name of vaccine, batch number (as per box) and expiry date, clearly at the end of the consent form immediately after the vaccine is given. It is not appropriate to record this at the end of the session.
- Use of locally pre-printed labels recording batch numbers and/or expiry date is not recommended. You may use the peel off labels supplied with the vaccines.
- The prescriber box should already be completed with either doctor or Registered Nurse Prescriber (RNP) signature and MCRN/PIN if the vaccine has been prescribed by the doctor or RNP.
- When recording the administration of a vaccine under medicine protocol the vaccinator should enter "Med P" in the prescriber box and enter signature and PIN in the vaccinator box.
- All vaccinators (doctors, RNPs, nurses and trained vaccinators) should enter signature and PIN/MCRN in the vaccinator box.
- Ensure the student's immunisation passport is completed and given to all students before they leave the vaccination area. The immunisation passport is retained by

- the HSE after the first dose of HPV9 vaccine and is given to students after completion of the vaccine schedule, if they require a 3 dose HPV vaccine schedule.
- Ensure that student is provided with the appropriate tear pad stating date and time vaccine given.
- Ensure that each student remains in the vicinity of the vaccination area under observation for 15 minutes after vaccination.
- The vaccinator observing students post vaccination will manage any students experiencing symptoms within their scope of practice and consult with the clinical lead as required. As the session draws to a close ensure that only the required number of vaccines to complete the vaccination session has been drawn up/reconstituted. Two clinical staff should be present while vaccinations are being given, and for 30 minutes after the last vaccine is administered to deal with anaphylaxis or any other adverse events, including syncope that might occur.
- Take queries from parents/legal guardians/students about possible adverse reactions that occur after the team has left the vaccination venue.
- Report adverse events to the HPRA. A medication error does not need to be
  routinely reported to the HPRA unless the student experiences harm (i.e. an
  adverse reaction) associated with it. In any such cases involving adverse reactions,
  an adverse reaction report should be submitted to the HPRA, including information
  on the nature of the error involved.
- In the event of an incident occurring during a vaccination session, an incident report must be completed by the professional primarily involved in the incident and forwarded to the relevant manager. If there is a vaccine error, e.g. an incorrect vaccine is administered to one or more students, the National Immunisation Office must also be informed.
- In the event of a student fainting either before or after vaccination, parents/legal guardians should be contacted. Fainting is commoner among adolescents and is likely to recur. Advice should be given about precautionary measures if the student ever needs any further injections.

#### Medical officers should additionally:

- Answer any clinical queries when vaccine consent forms are reviewed by nursing staff
- Prescribe the relevant vaccine by signing in the prescriber box on the consent form if required (including Medical Council Registration Number - MCRN).
- Carry out an individual medical assessment for students if requested by a vaccinator working under a medicine protocol.

#### Registered nurse prescribers should additionally

 Prescribe the relevant vaccine by signing in the prescriber box on the consent form (including NMBI registration number/PIN).

#### Administration of vaccines by Registered Nurse Prescriber

• The Registered Nurse Prescriber should separate the activity of prescribing a medicine and the subsequent actions of supplying and/or administering the medicine. Where possible another registered nurse or midwife or trained vaccinator should undertake the administration of the medicine. "Whilst acknowledging the fundamental principles associated with the separation of responsibilities for prescribing and supplying/administering medicines, the local site specific collaborative practice agreement (CPA) may outline situations where the RNP may in fact be involved in a cross over and merging of these activities as part of her/his provision of patient/service-user care. The CPA should provide for the auditing of such practices as part of the overall audit of prescriptive practices" (Practice Standards and Guidelines for Nurses and Midwives with Prescriptive Authority. An Bord Altranais, 2018, p.21).

## **Appendix B: Vaccination Consent Forms**

(DTaP/IPV and MMR, HPV, Tdap and MenACWY) Available here <a href="http://bit.ly/SchPHCP">http://bit.ly/SchPHCP</a>

# Appendix C: Considerations for Prevention and Management of Syncope in Vaccination Clinics

Available from <a href="https://bit.ly/MgmtSyncope">https://bit.ly/MgmtSyncope</a>

## Appendix D: Adverse event clinical record

Available from: <a href="http://bit.ly/SchPHCP">http://bit.ly/SchPHCP</a>

#### Appendix E: List of Useful Links and Resources

Further information regarding the vaccines in the Schools Immunisation

Programme and the diseases they protect against can be found on the following websites

- National Immunisation Office available at <a href="http://www.immunisation.ie">http://www.immunisation.ie</a>
- Immunisation Guidelines for Ireland available at <a href="https://www.hiqa.ie/areas-we-work/national-immunisation-advisory-committee/immunisation-guidelines-ireland">https://www.hiqa.ie/areas-we-work/national-immunisation-advisory-committee/immunisation-guidelines-ireland</a>
- Department of Health available at <a href="http://www.health.gov.ie">http://www.health.gov.ie</a>
- Health Protection Surveillance Centre available at <a href="http://www.hpsc.ie">http://www.hpsc.ie</a>
- Health Products Regulatory Authority available at <a href="http://www.hpra.ie">http://www.hpra.ie</a>
- Medicines Information online available at <a href="http://www.medicines.ie">http://www.medicines.ie</a>
- World Health Organization information available at https://www.who.int/health-topics/vaccinesand-immunization#tab=tab\_1
- Centre for Disease Control and Prevention immunisation information available at Vaccines and Immunizations | CDC
- Epidemiology and Prevention of Vaccine-Preventable Diseases, "Pink Book" available \_ https://www.cdc.gov/pinkbook/hcp/table-of-contents/index.html
- Australian Government, Department of Health and Education immunisation website available at <a href="https://www.health.gov.au/health-topics/immunisation">https://www.health.gov.au/health-topics/immunisation</a>
- Immunisation Department of Health Victoria Australia available at <a href="https://www2.health.vic.gov.au/public-health/immunisation">https://www2.health.vic.gov.au/public-health/immunisation</a>
- New Zealand, Ministry of Health immunisation website available at <u>Immunisation</u> <u>Health New Zealand | Te Whatu Ora</u>
- United Kingdom immunisation website available at\_ https://www.gov.uk/government/collections/immunisation
- Department of Health UK Green Book available at <u>Immunisation against infectious</u>
   <u>disease GOV.UK (www.gov.uk)</u>
- Public Health Agency Canada immunisation information available at\_ https://www.canada.ca/en/public-health/topics/immunization-vaccines.html
- European Medicines Agency available at <a href="http://www.ema.europa.eu/">http://www.ema.europa.eu/</a>

Further information on cervical cancer and cervical cancer screening can be found on the following websites

- National Cancer Screening Service available at <a href="https://www2.hse.ie/conditions/cervical-screening/">https://www2.hse.ie/conditions/cervical-screening/</a>
- National Cancer Registry Ireland available at <a href="http://ncri.ie">http://ncri.ie</a>
- Irish Cancer Society available at <a href="http://www.cancer.ie">http://www.cancer.ie</a>

### **Appendix F: Immunisations during COVID-19**

The World Health Organization state that immunisation services are an essential health service and should be maintained. The Departments of Health and Education are supportive of continuing immunisation services in schools during academic year 2024/2025.

The school should be reassured that all staff will be following HSE/HPSC infection prevention & control guidelines and will take every precaution to ensure the safety of pupils and staff when on the premises.

Children should not be attending school if they have COVID-19. Usual checks should be made to ensure that the child is feeling well on the day of immunisation.

#### Infection Prevention and Control Advice

All current COVID-19 infection prevention and control (IPC) guidance should be followed

#### **IPC Standard precautions**

Adherence to Standard Precautions with all individuals at all times is paramount to maintain the safety of the students and staff at the vaccine clinic which include:

- Hand hygiene:
  - Perform hand hygiene with alcohol hand gel before vaccine preparation
  - Perform hand hygiene immediately before and after each physical contact with the student.
- Hand gel dispensers: Alcohol hand gel sanitisers can be provided at the entrance and
  exit of the vaccine session, if the school does not have these already, to promote
  the hand hygiene for all staff and students.
- Promotion of respiratory hygiene and cough etiquette: Use tissue or sleeves to cover nose and mouth while coughing /sneezing and followed by hand hygiene.

Please refer to HPSC guidelines for up to date information on infection prevention and control: <u>Guidance for healthcare workers - Health Protection Surveillance</u>

Centre (hpsc.ie)

## Appendix G: Emergency drugs and Equipment

Emergency Anaphylaxis Kit –as per updated section February 2023 in Immunisation Guidelines

#### NB Updated advice from NIAC: the use of autoiniectors is no longer recommended.

Adrenaline (epinephrine) auto-injectors are not recommended as first line treatment by health professionals for the immediate management of anaphylaxis or suspected anaphylaxis following vaccination unless they are the only source of adrenaline available, as they may not allow IM delivery of an age appropriate dose

The availability of protocols, equipment and drugs necessary for the management of anaphylaxis should be checked before each vaccination session

- Copy of "Anaphylaxis: Immediate Management in the Community" from Immunisation Guidelines for Ireland
- 3 x 1ml ampoules of Adrenaline (1:1,000, 1mg/ml)
- 3 x 1 ml syringes
- Needles 3 x 25mm, 3 x 38 40mm
- 1 pocket mask
- Sphygmomanometer (optional)
- Stethoscope (optional)
- Pen and paper to record time of administration of Adrenaline

The kits should be kept closed to ensure the drugs are not exposed to light and stored at room temperature. The kits require regular verification to replace drugs before their expiry date.

There should also be a back-up emergency anaphylaxis kit so that a vaccination session can continue in the event that a student has been treated for anaphylaxis using up the anaphylaxis kit.

## Emergency equipment

- Access to a telephone to call an ambulance.
- Copy of "Anaphylaxis: Immediate Management in the Community" from Immunisation Guidelines for Ireland.
- Adverse event clinical record (Appendix E) and pen to record time of administration of adrenaline and clinical condition of patient.
- Headed notepaper to write referral letter for hospital.
- Sphygmomanometer x 1 with adult and paediatric cuff.
- Stethoscope x 1.

# **Appendix H: Session Report Forms**

Available from <a href="http://bit.ly/SchPHCP">http://bit.ly/SchPHCP</a>

# **Appendix I: Post Vaccination Tear Pads**

Available here <a href="http://bit.ly/SchPHCP">http://bit.ly/SchPHCP</a>

# Appendix J: Packshots of vaccines used in school immunisation programme

# **Primary School Vaccines**

TETRAVAC (DTaP/IPV)



MMRVAXPRO (MMR)



PRIORIX (MMR)



## **Second Level School Vaccines**

BOOSTRIX (Tdap)



GARDASIL 9 (HPV)



NIMENRIX (MenACWY)



#### **Appendix K: Medicine Protocols**

#### **Administration of vaccines under Medicine Protocol**

- Registered vaccinators 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 this document.
- Vaccinators working under medicine protocols should report to their relevant line manager.
- The Nursing and Midwifery Board of Ireland defines medicine protocols as "written directions that allow for the supply and administration of a named medicinal product by a registered nurse or midwife in identified clinical situations".
- A medicine protocol involves the authorisation of the vaccinator 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.
- Currently, the school immunisation medicine protocols enable registered nurses
  employed in the HSE who have undertaken the required education and training
  programmes to administer Schools Immunisation Programme vaccines without
  individual prescription. If appropriate Statutory Instruments and additional
  training and education is in place, other vaccinators currently working in CVCs
  may also administer vaccines for the SIP
- In assessing the student's suitability for vaccination the vaccinator working under medicine protocol should also pay particular attention to the advice on vaccine administration included in this document.
- All students meeting the exclusion criteria of a medicine protocol must be referred to the medical practitioner or Registered Nurse Prescriber for an individual clinical assessment.
- Where the Medical Officer or Registered Nurse Prescriber prescribes the vaccine, a vaccinator may administer the vaccine within the vaccinator's scope of practice.
- When recording the administration of a vaccine under medicine protocol the vaccinator should enter "Med P" in the prescriber box and enter signature and PIN in the vaccinator box.