Supporting Information for Staff
School Immunisation Programme
2019-2020 academic year
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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) of the Royal College of Physicians of Ireland (RCPI) and contained in the Immunisation Guidelines for Ireland, available at http://www.hse.ie/eng/health/immunisation/hcpinfo/guidelines/

The SIP is carried out by staff from each CHO area.

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 Tdap/IPV vaccine.

First year of second level school

- Tetanus, diphtheria, pertussis with Tdap vaccine.
- Human papillomavirus (HPV) with HPV9 vaccine.
- Meningococcal ACWY infection with MenACWY vaccine.

The programme aims to vaccinate on an annual basis;

- All four to five year olds with MMR and Tdap/IPV by targeting students in junior infants of primary schools and age equivalent in special schools (i.e. born between 01/09/2014 and 31/08/2015) or aged 6 years and home schooled (i.e. born between 01/09/2013 and 31/08/2014).

- All 12 to 13 year olds with Tdap, MenACWY and HPV9 by targeting students in first year in second level schools for the 2019/2020 academic year and age equivalent students born between 01/09/2006 and 31/08/2007 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.
School Immunisation Schedule and Target Cohort

The programme will be delivered in primary, second level and special schools.

All information packs for second level schools will be sent to each CHO so they can be sent as soon as the school year starts for immediate distribution to parents and legal guardians.

The target uptake for the Tdap/IPV, MMR2, MenACWY vaccine and Tdap is 95% and the target for HPV9 vaccine is 85%.

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 and Sligo/Leitrim GPs provide the MMR and Tdap/IPV vaccines to children aged four and five years.

Primary Schools

MMR and Tdap/IPV immunisation schedule for Junior Infants

- This will be provided by HSE staff through the schools. Parents may not choose to attend the GP for vaccination in areas where the programme is provided by HSE staff through the schools. In Donegal and Sligo/Leitrim GPs provide the MMR and Tdap/IPV vaccines to children aged four and five years.
- Parents should not be routinely invited to attend school vaccinations. There is no requirement to have a parent present at the time of vaccination.
- If parents have signed a valid consent form, all children should be vaccinated regardless of whether a parent is present or not. Children should be treated in the same manner regardless of whether a parent is present or not.
- Where children present for MMR vaccination in junior infants and their parents 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.
Second Level Schools

All second level schools now require 2 visits

- Visit 1: HPV9 and Tdap
- Visit 2: HPV9 and MenACWY

As per NIAC guidelines, Gardasil 9 for those who start the vaccination series before their 15th birthday, the two doses should ideally be separated by 6 to 12 months. The minimum interval between doses is 5 calendar months and the 4 day rule applies. A six month gap between doses is preferable, but the minimum interval may be used if necessary.

Additional Information resources:

- Summary of Product Characteristics (SmPCs) for each of the vaccines available at [www.hpra.ie](http://www.hpra.ie) and also available under the relevant schools vaccination programme at [http://bit.ly/SchProg](http://bit.ly/SchProg)
- Medicine Protocols for each of the vaccines in the schools immunisation programme are available under the relevant schools vaccination programme at [http://bit.ly/SchProg](http://bit.ly/SchProg)
- Each medical officer and nurse must be familiar with techniques for resuscitation of a patient with anaphylaxis and have completed a Basic Life Support training course within two years.
- Each medical officer and nurse should be familiar with the medicine protocols for nurse administration of the relevant vaccines and epinephrine/adrenaline, without individual prescription.
Useful Information before, during and after the session

Templates for Standard Operating Procedures (SOP’s) have been provided in Appendix B to document how schools based immunisation sessions should run. These can be adapted for use in local areas.

Consent

- Informed consent must be obtained prior to vaccination. The person providing consent to a vaccination should be offered as much information as they reasonably need to make their decision.
- Consent remains valid unless consent is withdrawn by a parent, legal guardian or student aged 16 years or older.
- The Guide to Professional Conduct & Ethics for Registered Medical Practitioners, 8th Edition, 2016 (Medical Council) states in section 11.1
  
  “(You must) give patients enough information, in a way that they can understand, to enable them to exercise their right to make informed decisions about their care.
- Consent is not valid if the patient has not been given enough information to make a decision”
- Under normal circumstances, the parent(s) of a child can give consent for vaccination on their child’s behalf. For students aged under 16, consent must be obtained from a parent or legal guardian.
- Under The Guardianship of Infants Act, 1964, the mother is given automatic parental responsibility for the child. The father is also given parental responsibility if he is married to the mother at the time of the child’s birth or if they marry after the birth of the child or if both adults adopt the child together. However, if a child is born outside marriage the mother is given automatic responsibility for all decisions relating to the child. Under certain circumstances guardianship of the child may be changed e.g. if one parent dies the remaining parent will automatically assume sole guardianship of the child or another guardian can also be appointed by the court.
- Students aged 16 years of age and over can consent on their own behalf.
- Special consideration needs to be given to children who are in care of the HSE either on a voluntary or statutory basis and contact should be made with the appropriate social worker.
- In the case of the HPV vaccine, consent is given by the parent/legal guardian/student to a course of vaccination, therefore it covers all doses necessary to complete a course and consent remains valid until the course has been completed or unless consent is withdrawn by a parent, legal guardian or student aged 16 years or older.
- If a parent/legal guardian contacts the local health office to withdraw consent they should speak to the administrative staff looking after the vaccine programme.
• The necessary information can be taken and the required changes made to the consent form – a double line should be drawn through the vaccine administration details section and ‘refused dose’
• HSE consent policy can be found at: https://www.hse.ie/eng/about/who/qid/other-quality-improvement-programmes/consent/

When vaccination is delayed or refused
For those in first year of second level school from September 2019, the schools vaccine programme will only be available to them in first year and they will not be able to opt back into the programme at a later date if they have refused consent.
For those girls who are older than first year in 2019, but are still in school- they may start or complete a course of HPV vaccines. They should be offered HPV4 while stocks are still available and may complete with HPV9 if HPV4 is no longer available.
Tdap and Men C vaccines for older students who missed the vaccine in first year should only be offered in mop up clinics if the student missed the vaccine in first year for medical reasons or other exceptional circumstances.
If parents/legal guardians refuse consent for all three vaccines, they should, where possible, be contacted and advised that if they refuse one vaccine they can still give consent for the other vaccines to protect their child from serious diseases.

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/student aged 16 years and older.
• Address any clinical issues raised on the consent form.
• Check that any interval between vaccinations is appropriate.
• For HPV9 vaccine check that the interval since the previous HPV9 vaccine is appropriate for this dose i.e. for 2nd dose it is at least 5 calendar months since 1st dose (the 4 day rule applies). Access to a calendar is recommended.

NIAC guidelines state ‘If a vaccine is given before the minimum age or interval recommended, it should not be considered as part of the primary series as there may be a sub-optimal immune response. The dose should be disregarded and another dose given at the recommended time…. However, giving a
dose 4 days or less before the minimum age or interval is unlikely to have a significant adverse effect on the immune response to that dose, and does not need to be repeated' see http://bit.ly/NIACCh2

If the second dose of HPV9 is given too early in a student who started the course before the age of 15 years, NIAC guidelines state that if the second dose is given <5 months after the first dose, a third dose should always be administered. This should be given 6–12 months after the first dose and at least 12 weeks after the second dose.

If a dose of HPV is given too early and the student needs to be revaccinated an additional consent form must be completed. Please contact the NIO for a copy of the dose 3 consent form. 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 http://bit.ly/NIACGuidelines

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 medical officer to require deferral of the vaccine, should be offered an appointment for the mop-up clinic.

**Administration of two vaccines at the same vaccination session**

- When two vaccines are being administered, one vaccinator should where possible administer both vaccines.
- Where there are two vaccines to be administered to students at the same vaccination session, each vaccine should be kept in a separate colour coded container.
- When two 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.
- In the case of junior infants MMR is given in the right deltoid and Tdap/IPV in the left deltoid.
- In the case of second level students, the first dose of HPV vaccine is given in the left deltoid and Tdap is given in the right deltoid.
- The second dose of HPV vaccine is given in the left deltoid and MenACWY is given in the right deltoid.
- Where two vaccines are scheduled for students at the same vaccination session but a student is only getting one of these vaccines the following should be done;
- The vaccinator should draw a double line through the box where vaccination details are entered
and write “NOT FOR VACCINATION” between the double lines.

- The vaccinator should double check the required vaccine with a nurse/medical colleague before administering the vaccine.

Vaccine storage and handling

- All vaccines must be stored and transported between +2°C and +8°C.
- The SmPCs for Gardasil9, Boostrix, Priorix, MMRVaxPro, Nimenrix and IPV Boostrix all recommend that the vaccine should be stored in the original package in order to protect from light.
- SmPC for Adrenaline BP 1:1,000 advises that it should not be stored above 25°C and it should be kept in the outer carton.
- See Appendix K for additional information about maintaining the cold chain
- Record the current temperature of the probe in the cool box:
  - Before leaving the health centre.
  - At the beginning of the vaccination session.
  - At the end of the vaccination session.
  - On returning the vaccines to the fridge.
- Ensure that the cool box is placed in,
  - An appropriately ventilated room,
  - Away from any heat source,
  - Away from direct sunlight.
  - Ensure that the cool box remains closed as much as possible.
  - Ensure that where vaccines are not used on a particular day and are in their original packaging and have been maintained under cold chain conditions, these vaccines may be returned to the vaccine fridge. They should be clearly marked so that they are used first at the next vaccinating session. The temperature of the vaccine being returned to the vaccine fridge should be recorded as well as the time of return to the fridge.
  - If these marked vaccines are taken to a second vaccination session and are not used providing the cold chain has been maintained these vaccines can be returned to the vaccine fridge again, for administration at the next session. These marks should differ from the marks used during a cold chain breach. Vaccines which have remained in temperature at all times and have not been used after 1 or 2 transportations to school have not experienced a cold chain breach. However, it is important not to take more vaccines than will be required to a vaccination session so the return of vaccines without being used more than twice should be exceptional.
  - If a temperature deviation has occurred, contact the Chief Pharmacist or the Medical Officer of the National Immunisation Office (at 087 9915452 or 01 8676108) for further advice. The National Immunisation Office will carry out a risk assessment and will advise
on a case by case basis whether it is appropriate to use the vaccines later or whether they should be discarded.

- 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.

- MMR vaccines must be used within one hour of reconstitution or discarded safely into a sharps bin. It is not appropriate to return reconstituted MMR vaccine to the cool box. Reconstituted Nimenrix should be used promptly and must be discarded if reconstituted but not used after 8 hours. It is not appropriate to return reconstituted Nimenrix vaccine to the cold box.

- Once Tdap/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. HPV9 should be used straight away after removal from packaging.

- Prefilled vaccine syringes which have been removed from their packaging should not be returned to the cool box.

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.

**HSE Paper Records**

- Reasons for not vaccinating should be recorded on the consent form and on SIS.

- Consent forms for students whose vaccination is deferred or who are absent on the day should be put aside for the next mop-up clinic.

- Students who fail to return a completed consent form should also be offered an appointment at a mop up clinic – if they can be identified from the school list or by the school staff.

- Consent forms for students who have been vaccinated but require further doses to complete a course should be set aside for the next school clinic. However, the information on the first vaccine must be put into SIS as soon as possible after the first vaccine is given. Please do not wait until the second vaccine is given.

- When students have completed the vaccination course their records should be filed in accordance with the “Policy for Health Boards on Record Retention Periods including outline of issues in records management / National Freedom of Information Liaison Group” 1999 available at [http://bit.ly/RetRec](http://bit.ly/RetRec)

- All clinical notes on events around vaccination should be stored with the consent form. Ensure that all information recorded is in block capitals and is clear and legible and recorded on SIS as appropriate, written in and the date of refusal added.

- 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 consents but the student refuses vaccination on the day of the school session the student should not be vaccinated. This must be recorded on the consent form and on SIS.
- If a parent refuses but the student expresses a desire to be vaccinated on the day of the school session, the student may be vaccinated if they are aged 16 years and over as the student can provide their own consent. If the student is less than 16 years of age they cannot be vaccinated.
- The team should keep a record of those students where consent was withheld and the reasons stated if given.
- 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 very clear refusal, parents/legal guardians should not be contacted.
- Where a consent form is returned a parent/legal guardian leaves the consent blank or fills in the Yes and No sections, a clinical member of the team should phone parent/legal guardian to seek clarification and determine if they actually consent or not. The date and time of the phone call should be recorded on the consent form and the consent or refusal witnessed by two members of staff.

General Immunisation Information

Interrupted immunisation schedule

“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.


Incomplete immunisation schedule

Where children are identified as having had no previous immunisations or an incomplete primary course, vaccines should be given on the day and arrangements should be made to ensure completion of appropriate vaccination in line with the guidance for “catch up immunisation schedule” available at [http://bit.ly/LateEntrant](http://bit.ly/LateEntrant)

Contraindications to vaccination

- Confirmed anaphylactic reaction to the vaccine itself or to a constituent of that vaccine is an absolute contraindication.
- Pregnancy in the case of HPV and MMR vaccines.
- 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
Pregnancy and HPV vaccine

Pregnancy could be an issue for some female students in second level schools. Parent(s) are advised to discuss the possibility of pregnancy with their daughter prior to vaccination. The HPV vaccine consent form includes the statement “I understand that HPV is not recommended in pregnancy” (Appendix D). If the parent(s) 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. Before the second dose of Gardasil is given the vaccinator should ask the girl the following questions:

- Have you read on the consent form where it says that 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. The medical officer or nurse should notify their line manager and seek further advice in relation to their legal obligations under child protection legislation. For further detail, see http://bit.ly/C1stTusla

However, if the girl is adamant that her parents are not to be informed as to the reason for deferral the medical officer or nurse should again notify their line manager and seek further advice in relation to their legal obligations under child protection legislation. For further detail, see http://bit.ly/C1stTusla

If a girl 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. Reports of pregnancy occurring in association with HPV vaccination should only be reported to the HPRA if there is harm to the patient or foetus/infant/child (Appendix I). This means that the outcome of pregnancy should be followed up with the girl when completing her course of HPV vaccine or when the pregnancy is completed. If further vaccines are required then vaccination may be given when the pregnancy is completed.
Precautions for vaccination

- **Acute severe febrile illness**: defer until recovery.
- **Bleeding disorders**: Vaccines should be administered with caution to individuals with coagulation defects. 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 MMR which can be given SC. The patient or parent should be advised of this.
- **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 [http://bit.ly/NIACGuidelines](http://bit.ly/NIACGuidelines)
- **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 [http://bit.ly/NIACGuidelines](http://bit.ly/NIACGuidelines)

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**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.**

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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

_Tdap/IPV_

• There should be an interval of at least six months between the booster dose of Tdap/IPV and the completion of a primary course of tetanus containing vaccine.
• Tdap/IPV can be given at any interval following Td vaccine.

_MMR_

• Vaccination should be deferred for between three and eleven months following the administration of an antibody product (for full details see Table 2.4 in Chapter 2 of Immunisation Guidelines for Ireland available at [http://bit.ly/NIACGuidelines](http://bit.ly/NIACGuidelines))
• MMR is a live vaccine and must not be administered within four weeks of varicella, zoster or yellow fever live vaccines. MMR can be given on the same day or at any interval before or after any other live vaccine.
• **MMR and Chickenpox:** 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.
• MMR is contraindicated in significantly immunocompromised persons due to disease or treatment.

1st Years

• Fainting is a recognised side effect of vaccines given in adolescence.

_Tdap_

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

_Men ACWY_

• 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 polysaccarride Men ACWY vaccine, they should receive the conjugate vaccine in the schools programme
• Anyone who has received a dose of Men C vaccine (e.g. as part of an outbreak response) an at least two month interval should be left before Men ACWY is given.

When there are doubts about giving a vaccine contact a Principal Medical Officer, a Specialist 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 www.hpra.ie.

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.
- 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 Immunisation Guidelines for Ireland. http://bit.ly/NIACAnA
- 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.

Tdap/IPV/ Tdap/IPV 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 they should not be given further routine or emergency booster doses of tetanus or diphtheria containing vaccines 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 of children who receive the booster dose of a Tdap/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

- Mini measles (fever and rash) can occur 6-10 days post vaccination. This is non-infectious and self-limiting.
• Swelling of the salivary glands “mini mumps” can also occur three weeks post vaccination. This is non-infectious.
• A very rare side effect of MMR is the occurrence of thrombocytopenia 15-35 days post vaccination.

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 area office.

**Reporting of adverse reactions**

The medical officers/vaccinators should report all suspected adverse reactions to the HPRA. Details of adverse events may be recorded on the adverse event clinical record *(Appendix H)*.

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:

3. By using the traditional “yellow card” report which can be requested in bulk from the HPRA. The “yellow card” also utilises the free post system.
4. By telephoning the HPRA Pharmacovigilance Section 01-6764971.

Children that 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.

**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 error, e.g. an incorrect vaccine is administered to one or more students, the National Immunisation Office must also be informed.
References

- Guidance for providers of health and social care services Communicating in plain English HIQA and NALA 2015 www.hiqa.ie
- HSE Guidelines for maintaining the vaccine cold-chain including maintenance of vaccine fridges and management of vaccine stock http://bit.ly/SOP01
- Summary of Product Characteristics for the vaccines used in the Schools Immunisation Programme
- Information on HSE’s open disclosure policy http://bit.ly/OpenDis
- Data protection Commission website www.dataprotection.ie
- Information on Subject Access Requests (SAR) http://bit.ly/SARhse

For other useful links and resources (Appendix L)
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 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 provides specific product information for prescribers and healthcare professionals on how to use that medicine safely and effectively. The content of a SmPC is agreed between the manufacturer and the relevant licensing authority during the licensing process. Any update to the SmPC must be approved by the licensing authority. The date of the most recent revision is included at the end of the text. The SmPC has an agreed standard template; the same format of SmPC is applicable in all European Union member states.

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, administered to induce immunity and thereby prevent infectious disease. Non live vaccine is a vaccine that contains killed or fractions of bacteria or viruses. The response may be weaker than for a live vaccine and so repeated doses are often needed. Live attenuated vaccine is a vaccine that contains a weakened strain of live bacteria or viruses that replicate in the body and induce a longer-lasting immunity than non-live vaccines.

Vaccine abbreviations:
- Tdap/IPV: Tetanus, low dose diphtheria, low dose pertussis and inactivated polio
- MMR: Measles, Mumps and Rubella
- HPV: Human papillomavirus
- MenACWY: Meningococcal ACWY
- Tdap: Tetanus, low dose diphtheria and low dose pertussis

Vaccination is the term used to refer to the administration of any vaccine or toxoid.
APPENDIX A: Packshots of vaccines used in school immunisation programme

Primary School Vaccines

IPV-BOOSTRIX (Tdap/IPV)

MMRVAXPRO (MMR)
PRIORIX (MMR)

Second Level School Vaccines

BOOSTRIX (Tdap)
GARDASIL 9(HPV)

NIMENRIX (MenACWY)
Appendix B 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 or first year of second level parent pack through the schools in advance of the planned vaccination session in the school. The pack contains a letter, information leaflets and consent form.

- For home schooled students parents/legal guardians/students should receive an information pack consisting of
  - Letter advising how to access the schools immunisation programme.
  - Information leaflet on the relevant vaccine(s).
  - Appropriate vaccination consent form

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 at 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. [http://bit.ly/ConCQs](http://bit.ly/ConCQs)

For 2019-20 the NIO will be sending the letters and packs to home schooled children, based on information provided by TUSLA. NIO will register these children on SIS so local areas will be able to run a report on those home schooled in their area and can make contact with the parents if they do not contact the team.

- 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 medical officers and nurses. Nurses may administer vaccine under doctor or Registered Nurse Practitioner prescription or under a medicine protocol within their scope of practice.

All staff should be familiar with the following documents:

- Summary of Product Characteristics (SmPCs) for each of the vaccines available at [www.hpra.ie](http://www.hpra.ie)
and also available under the relevant schools vaccination programme at http://bit.ly/SchProg

- Medicine Protocols for each of the vaccines in the schools immunisation programme are available under the relevant schools vaccination programme at http://bit.ly/SchProg
- Healthcare professionals FAQs are available at http://bit.ly/FAQImm and also available under the relevant schools vaccination programme at http://bit.ly/FAQImm
- Each medical officer and nurse must be familiar with techniques for resuscitation of a patient with anaphylaxis and have completed a Basic Life Support training course within two years.
- Each medical officer and nurse should be familiar with the medicine protocols for nurse 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 (Appendix A).
- A designated person will ensure that sufficient vaccine, for each of the two or three vaccines in the vaccination programme is 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 J). 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:

- liaison with school staff
- calling "Time Out" to check all is in order before vaccinations begin
- ensuring all designated roles are covered
- ensuring the vaccination session report form is completed at the end of the vaccination session
- ensuring that the Chief Pharmacist or Senior Medical Officer in the National Immunisation Office is contacted (at 087 9915452 or 01 8676108) if there is a break in the cold chain.
- 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 vaccines to be administered to the students at the same vaccination session, each vaccine should be kept 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 (Tdap/IPV and MMR).

- The immunisation passport is retained by the HSE after the first dose of HPV and Tdap vaccine and is given to first year students after their second HPV and Men ACWY vaccine.

- Ensure that each student is provided with the appropriate tear pad stating date and time vaccine was given.

- Parents/legal guardians/students should be provided with the appropriate contact details so that they can inform the school immunisation staff about any concerns following vaccination.


- At the end of the vaccination session the school vaccination session report form should be completed by a designated person. (Appendix F).

- 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.

- A medical practitioner and a nurse 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 kept so they can be given 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 give letters to school for onward distribution to parents/legal guardians of these students.

• 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.

• Consent forms for those students who require further vaccine doses to complete a course should be kept for the next vaccination session.

Operational aspects after school/clinic vaccination session

o 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.

o 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.

o Students who are identified as having no previous vaccines or an incomplete course should have arrangements made to complete their immunisations as per guidance for late entrants available at http://bit.ly/LateEntrant

o 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.

o Client set up, consent and vaccination recording on the SIS should take place as close to the vaccination event as possible at the latest within a month of the vaccination administration.

o 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

o 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.

o 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.
Area Managers should ensure that all administrative staff in the Schools Immunisation Programme are aware of these guidelines and should facilitate any training required.

Reporting relationships of any non-HSE staff involved in the programme will need to be defined in advance of the start of the programme.

SIS System National Administrators and CHO Administrators are responsible for overseeing the access, use, and quality of the data entered on to the SIS System. Local school teams are responsible for obtaining denominator data for each vaccine type for each cohort for each year as close to September 30th as is practical (when the school census is carried out). These figures must be sent to their CHO Administrator and set up on the system by the end of December (at the latest). If no denominator is entered for a school then no uptake can be calculated. The administrator is responsible for monitoring the system use, data collection, inputting, and data accuracy. Administrators must run system validation and activity reports and follow up where required.

Administrative role 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 these guidelines.
- Each clerical officer should ensure they are 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.
- Contact each school to get the target cohort (denominator data) details. The specifications for this are in Section 6.7.4.
- The target cohort number (denominator) (this is the number of students on the school roll for that class/year in this academic year) on the 30th September 2018 (when the school census is carried out) for each vaccination type should be confirmed with schools immediately after this date. The specifications for this are in Section 6.7.4. (This is required by the SIS system to calculate uptake.) These target cohort number must be provided to the CHO system administrator as soon as possible after 30th September each year. Denominator data can only be set up once on SIS for each school. If the cohort needs to be changed details need to be sent to the central administrators stating reasons why the change is required.
- Ensure special schools are aware of relevant birth cohort.
- Schedule vaccination date/s with each school as far in advance of the vaccination date/s as possible.
- Distribute consent packs/forms (Appendix B), information leaflets and invitation letters to all parents/legal guardians/students through the school as far in advance of the proposed vaccination date as possible.
- Collect completed consent forms from the school as agreed with Principal or School Secretary (or other appropriate person designated by the Principal) prior to the school vaccination day, collate the
forms by school and bring the relevant forms to the school on the day of vaccination.

- Collect those consent forms that are returned directly to the school on the day of vaccination.
- Check with the school those in the target group who are absent on the day and put aside their consent forms. Record the students in the target group, who are present, on the class lists (if lists are available on the day).
- Check all consent forms for omissions and other issues (see Section 6.4) 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 avoid multiple calls to parents.
- Clinical queries should be referred to the nurse or doctor for follow-up.
- Organise the collection and return of students to their classrooms in small groups in association with a designated liaison person from the school (as agreed with the School Principal).
- 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 teacher or appropriate liaison person (as agreed with the School Principal) from the school. Give consent forms to students after confirming their identity.
- Direct student to the Medical Practitioner or Registered Nurse Prescriber for prescription of the relevant vaccine or to the Nurse Vaccinator operating under a medicine protocol.
- Ensure that student is provided with the appropriate tear pad stating date and time vaccine given (Appendix E).
- Collect the consent forms from each vaccinator at the end of the vaccination session. Collate the statistics required for the School Vaccination Session Report Form (Appendix F).
- Keep the consent forms of those who were absent, refused or deferred on the day. These students should be given one appointment to attend a mop up clinic. If the school team is notified that the student cannot attend the mop up clinic, one further appointment should be arranged.
- Children from junior infants should be vaccinated by the school immunisation team and only in exceptional circumstances be referred to their GP for vaccination.
- Collect the consent forms, of those students in junior infants whose school MMR dose constituted their first dose and arrange for them to receive a second dose at least one month later either at a mop up clinic or with their GP.
- Carry out a search on the SIS system to locate the client record, if not found set up a new client record. Input all school vaccinations i.e. Tdap/IPV, MMR, HPV, Tdap and MenC data on to the SIS system (see Section 6.7).
- Ensure all data entered is accurate and in accordance with data entry standards.
- Once a record is entered onto the SIS system, write the system client ID and the school roll number on the top of the consent form in the space provided.
- Carry out validation tasks and maintenance in conjunction with the CHO/Central SIS System Administrator.
In the event of an incident occurring during a vaccination session an incident report must be completed by the person 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.

If errors are made on the SIS System, inform the CHO system administrator as soon as possible so that the errors can be rectified (see Section 6.7).

**Vaccinators role and responsibilities (Nurses, Registered Nurse Prescribers or Medical Officers)**

- 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.
  - MMR (Priorix or MMRvaxPro) must be used within one hour of reconstitution or discarded, Nimenrix should be used as soon as possible after reconstitution and discarded if not used within eight hours.
- 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 vaccine identification label to ensure that 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/student aged 16 years and older
Any clinical issues raised on the consent form should be addressed prior to vaccination.

For Tdap/IPV check that there is an interval of at least six months between the booster dose of Tdap/IPV and the completion of a primary course of tetanus containing vaccine (if applicable).

For HPV vaccine check that the interval since the previous HPV vaccine is appropriate for this dose, i.e. for HPV9 the interval is at least 5 calendar months and the 4 day rule applies.

For dose 2 of MMR vaccine check that it is at least 1 month 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 as appropriate. See guidelines on holding child during immunisation in Chapter 2 of the Immunisation Guidelines for Ireland available at http://bit.ly/NIACCh2

- 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.
  Since 2014 all HSE vaccine tenders have required information from the manufacturers on their compliance with the European Sharps Directive OJ:L:2010:134:0066:0072 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, see http://bit.ly/NIACCh1
- Complete the administration details including the trade name of vaccine, batch number 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 pre printed labels recording batch numbers and/or expiry date is not recommended.
- 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 (see Section 5.3 and Section 5.4).
- When recording the administration of a vaccine under medicine protocol the nurse should enter “Med P” in the prescriber box and enter signature and PIN in the vaccinator box (see Section 5.6).
- All vaccinators (doctors, RNP’s and nurses) 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 (Tdap/IPV and MMR). The immunisation passport is retained by the HSE after the first dose of HPV vaccine and is given to students after completion of the 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 nurse observing students post vaccination will manage any students experiencing symptoms within their scope of practice and consult with the Medical Officer 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.

• One doctor and another vaccinator 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:
  o Prescribe the relevant vaccine by signing in the prescriber box on the consent form (including Medical Council Registration Number - MCRN).
  o Carry out an individual medical assessment for students if requested by nurse working under a medicine protocol.
  o Be present while vaccines are being given by nurse vaccinators, and for 30 minutes after the last vaccine is administered to deal with anaphylaxis or any other adverse events, including syncope that might occur. An adverse event clinical record may be completed.
Registered nurse prescribers should additionally

- Prescribe the relevant vaccine by signing in the prescriber box on the consent form (including ABA 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 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 C: Medicine Protocols

Administration of vaccines under Medicine Protocol

- Registered nurses and midwives working under medicine protocols will be accountable for their own clinical practice and should be familiar with and adherent to the practices as set out in these guidelines.
- Registered nurses and midwives 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 nurse or midwife to supply and administer a medicine to groups of patients in a defined situation meeting specific criteria and who may not be individually identified before presentation for treatment.
- An individually named prescription is not required for the supply and administration of medicine when a medicine protocol is in effect.
- 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.
- In assessing the student’s suitability for vaccination the nurse working under medicine protocol should also pay particular attention to Section 6.5 of these guidelines.
- All students meeting the exclusion criteria of a medicine protocol must be referred to the medical practitioner for an individual medical assessment.
- Where the Medical Officer prescribes the vaccine following individual medical assessment a nurse may administer the vaccine within the nurse’s scope of practice.
- When recording the administration of a vaccine under medicine protocol the nurse should enter “Med P” in the prescriber box and enter signature and PIN in the vaccinator box.
Medicine Protocol for the Administration of IPV Boostrix (Diphtheria, Tetanus, Pertussis and Poliomyelitis) vaccine (adsorbed, reduced antigen(s) content) by registered nurses and registered midwives

This medicine protocol is a specific written instruction for the administration of IPV Boostrix Vaccine Tdap/ IPV (diphtheria, tetanus, pertussis (acellular, component) and poliomyelitis (inactivated) vaccine (adsorbed, reduced antigen(s) content), to children in Primary School by registered nurses and registered midwives. This medicine protocol is valid for the 2019/2020 HSE School Immunisation Programme. This medicine protocol enables registered nurses and midwives employed in the voluntary and statutory services of the HSE who have undertaken the required education and training programmes to administer IPV Boostrix (diphtheria, tetanus, pertussis (acellular, component) and poliomyelitis (inactivated) vaccine (adsorbed, reduced antigen(s) content)), with reference to and guidance from Nursing & Midwifery Board of Ireland, National Immunisation Group, National Immunisation Office, HSE and in accordance with the Summary of Product Characteristics for IPV Boostrix vaccine as detailed by the Health Products Regulatory Authority at www.hpra.ie:

- Health Services Executive (2019) Directions for Nurses and Midwives for the Management of a Patient who Develops Anaphylaxis or suspected anaphylaxis incorporating Medicine Protocol for the Administration of Epinephrine (Adrenaline) injection BP 1:1000 by intramuscular injection for nurses and midwives for the management of anaphylaxis or suspected anaphylaxis. Dublin: Health Service Executive.

The Nursing and Midwifery Board of Ireland defines medicine protocols as “written directions that allow for the supply and administration of a named medicinal product by a nurse or midwife in identified clinical situations. A medicine protocol involves the authorisation of the nurse/midwife to supply and administer a medicine to groups of patients in a defined situation meeting specific criteria and who may not be individually identified before presentation for treatment. An individually named prescription is not required for the supply and administration of medication when a medicine protocol is in effect” (An Bord Altranais, 2007).
**Medicine Protocol for the Administration of IPV Boostrix Vaccine by registered nurses and midwives to children/students in Primary Level School through a School Immunisation Programme**

|----------------------------|--------------------------------|

### 1.0 Critical Elements

**Name of Organisation where protocol applies**: Health Service Providers across the voluntary and statutory services of the Health Service Executive (HSE). This Medicine Protocol applies to:
- Registered nurses and midwives involved in the supply and administration of the IPV Boostrix vaccine to children/students in primary school through a School Immunisation Programme.

**Date the protocol comes into effect**: September 2019

**Date for review of protocol**: May 2020

**Document prepared by**: Office of the Nursing and Midwifery Services Director (ONMSD) HSE, in collaboration with the National Immunisation Office (NIO) at the request of Dr Kevin Kelleher, Assistant National Director Public Health, National Office for Public Health/Child Health Strategic Planning and Transformation, HSE

**Names and Signatures of the employing authority who is authorising the implementation of the protocol**: 

- Name: Dr. Kevin Kelleher, Assistant National Director Public Health, National Office for Public Health/Child Health Strategic Planning and Transformation, HSE

  Signature: [Signature]

- Name: Dr Colm Henry, National Director of Clinical Strategy and Programmes, HSE

  Signature: [Signature]

- Name: Ms Mary Wynne, Nursing and Midwifery Services Director, HSE

  Signature: [Signature]

*On behalf of the authority employing professionals authorised to administer under this medicine protocol, I have read this medicine protocol and authorise its implementation*
## 2.0 Clinical Criteria

<table>
<thead>
<tr>
<th>Clinical Condition for use of the protocol</th>
<th>The clinical condition for which this medicine protocol has been developed is for the active immunisation against and prevention of diphtheria, tetanus, pertussis (whooping cough) and poliomyelitis (polio) disease. IPV Boostrix is given as a booster vaccination to children who have previously received DTaP/IPV containing vaccines in the primary childhood immunisation schedule.</th>
</tr>
</thead>
<tbody>
<tr>
<td>Circumstances in which the medicine protocol applies</td>
<td>The School Immunisation Programme (SIP) will be delivered annually by the Health Service Executive (HSE). The aim of the immunisation programme is to provide a booster dose of diphtheria, tetanus, pertussis (acellular, component) and poliomyelitis (inactivated) vaccine, vaccine to children who previously completed primary vaccination against these diseases as recommended in the Immunisation Guidelines for Ireland. <a href="https://www.hse.ie/eng/health/immunisation/hcpinfo/guidelines/">https://www.hse.ie/eng/health/immunisation/hcpinfo/guidelines/</a>.</td>
</tr>
<tr>
<td>Inclusion criteria for children/students treatment using the medicine protocol</td>
<td>All children in primary school usually delivered in junior infants and age equivalent in e.g. special schools and home schooled students. <a href="https://www.hse.ie/eng/health/immunisation/pubinfo/schoolprop/4in1mmr/schoolguidelines.pdf">https://www.hse.ie/eng/health/immunisation/pubinfo/schoolprop/4in1mmr/schoolguidelines.pdf</a> Children with valid consent.</td>
</tr>
<tr>
<td>Exclusion criteria for children/students using the medicine protocol</td>
<td>Children who have not commenced or completed immunisation course. A known history of anaphylactic or hypersensitivity reaction to IPV Boostrix or any of the vaccine's constituents including neomycin or polymyxin. Acute febrile illness: The presence of a minor infection such as a mild upper respiratory infection or low grade fever is not a contraindication to immunisation. Children with a contraindication to intramuscular injection (haematological disorder/coagulation disorder e.g. haemophilia, severe thrombocytopenia. Children who are immunocompromised either due to disease or treatment.</td>
</tr>
<tr>
<td>Actions to be taken for those who are excluded from the Protocol</td>
<td>• All children meeting exclusion criteria must be referred to the medical practitioner for an individual medical assessment. • Document action in clinical notes. • Where IPV Boostrix vaccine is prescribed following medical assessment, the nurse or midwife may administer IPV Boostrix vaccine within their scope of practice. Note: in determining their scope of practice, nurses and midwives must make judgements about their competency to carry out a role or activity (NMBI, 2015).</td>
</tr>
<tr>
<td>Description of</td>
<td>Refer the student to the Medical Practitioner</td>
</tr>
</tbody>
</table>

---

Medicine Protocol for the Administration of IPV Boostrix (Diphtheria, Tetanus, Pertussis, and Poliomyelitis) vaccine (adsorbed, reduced antigen(s) content), 2019
<table>
<thead>
<tr>
<th>circumstances and referral arrangements when further advice or consultation is required</th>
<th>in the event of:</th>
</tr>
</thead>
<tbody>
<tr>
<td></td>
<td>Adverse reaction</td>
</tr>
<tr>
<td></td>
<td>Other clinical concerns</td>
</tr>
</tbody>
</table>

**Documentation required to support implementation of the medicine protocol**

A consent form must be completed by the parent/legal guardian for all children who receive the IPV Boostrix vaccine. Appropriate details including the batch number must be recorded on the consent form. The following documents will be available at each school vaccination session:

- Vaccination session form
- Blank Vaccine consent forms
- Vaccine Information Leaflets
- Patient held record cards
- Health Products Regulatory Authority Adverse Reaction Reporting forms
- HSE Incident/near miss report forms (NRIF, 2018)
- Tear pads for after vaccination

It is the responsibility of each nurse or midwife to be familiar with the appropriate documentation to support the safe administration of IPV Boostrix vaccine which includes the following:

- Information for Staff: School Immunisation Programme 2019/2020
- Medicine Protocol for the administration of IPV Boostrix
- Directions for nurses and midwives for the management of a patient who develops anaphylaxis or suspected anaphylaxis incorporating Medication Protocol for the Administration of Epinephrine (adrenaline) Injection BP 1:1000 by intramuscular injection by nurses and midwives for the management of a patient with anaphylaxis or suspected anaphylaxis (HSE 2019), available at [https://www.hse.ie/eng/health/immunisation/hcpinfo/fluinfo/adrenalineprotocol.pdf](https://www.hse.ie/eng/health/immunisation/hcpinfo/fluinfo/adrenalineprotocol.pdf)

### 3.0 Name of Medicine

**IPV Boostrix 2019/2020**

**Link to Summary of Product Characteristics**


**Link to Patient Information Leaflet**

[https://www.hpra.ie/img/uploaded/swedocuments/2177440.PA1077_101_001.30520b2e-7fdd-4bfc-8784-63a77e38b2ed.000001plipv.170109.pdf](https://www.hpra.ie/img/uploaded/swedocuments/2177440.PA1077_101_001.30520b2e-7fdd-4bfc-8784-63a77e38b2ed.000001plipv.170109.pdf)

**Procedure for the reporting and documentation of errors and near misses involving the medicine**

In the case of medicine errors that directly involve the child, i.e. wrong medicine/patient/dose/route being administered or another medicine error, the registered nurse or registered midwife must remain with the child and closely monitor them for any adverse reactions.

Vital signs should be recorded and the student should be reviewed by the registered nurse/midwife and/or medical practitioner.

The incident must be reported to the relevant line manager as soon as possible.

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Medicine Protocol for the Administration of IPV Boostrix (Diphtheria, Tetanus, Pertussis, and Poliomyelitis) vaccine (adsorbed, reduced antigen(s) content), 2019
The incident and all actions taken must be promptly recorded in the child's documentation/notes and the relevant report form completed.

The incident and all actions must be promptly recorded and the National Incident Management Report Form completed (National Incident Report Form (NIRF 01-V10)) (May 2018) available at: https://www.hse.ie/eng/about/gavd/incident-management/nirf-01-v10-person1.pdf

The child's parent and/or legal guardian must be informed of the incident.

An incident report form must be completed by the registered nurse or registered midwife and forwarded to the relevant line manager as per local policy.

Any suspected adverse reactions associated with medication errors should be reported to the HPRA as outlined below. (As per local policy).

Any errors and near misses not involving medications, the incident and all actions taken must be promptly recorded on the relevant National Incident Management Report form and forwarded to the relevant line manager

### Procedure for reporting Adverse Drug Reactions to the Health Products Regulatory Authority (HPRA)

The relevant nursing or midwifery staff should report to the HPRA any suspected adverse reactions, in accordance with criteria outlined by the HPRA. This reporting may be carried out in line at https://www.hpra.ie or through the use of the yellow card system which is available in the downloadable format from the HPRA website, or on the request from the HPRA.

The incident and all actions taken must be promptly recorded in accordance with the criteria outlined by the HPRA: *Management of a Patient with Anaphylaxis: Treatment in the Community.* (National Immunisation Advisory Committee, 2019) available online at https://www.hse.ie/eng/health/immunisation/hcpinfo/guidelines/Anaphylaxis.pdf

### Resources and equipment required

- Vaccine (pre-filled syringe)
- Fridge/Cooler box with minimum/maximum thermometer to maintain cold chain temperature between +2° to +8°
- Disposable kidney dishes/coloured trays
- Gauze swabs/Plasters
- Sharps bins, and bags for disposal of other hazardous material
- Alcohol hand rinse
- Access to telephone
- Access to medical support
- Safe storage areas for medicines and equipment
- Current medicine protocol for IPV Boostrix Vaccine.

### Audit process to identify

Medicine Protocol for the Administration of IPV Boostrix (Diphtheria, Tetanus, Pertussis, and Poliomyelitis) vaccine (adsorbed, reduced antigen(s) content), 2019
<table>
<thead>
<tr>
<th>appropriate use of the protocol or unexpected outcomes</th>
<th>All documentation will be held for review and audit purposes as per local policy.</th>
</tr>
</thead>
</table>

### 4.0 Information for child/student/parent/guardian

**Advice to be given to the child/student/parent/guardian before treatment**

The HSE 4in1 and MMR vaccine Information for parents of children in Junior infant's booklet must have been supplied with the consent form to each parent/legal guardian prior to administration of the Tdap/IPV vaccine.

**Advice to be given to the child/student/parent/guardian after treatment**

After Treatment

An Information Tear Pad, stating date and time of vaccination must be given to all students for parental/guardian’s attention. The Tear Pad includes advice about contacting relevant medical personnel in the event of adverse reaction occurring following administration of the vaccination.

The child/student must be advised to remain seated in the post vaccination observation area for 15 minutes to allow monitoring of any immediate reaction including possible anaphylactic reaction and must be advised to report any side effects to the registered nurse or registered midwife who is present.

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

In the event of an adverse reaction the nurse/midwife must ensure that all procedures are adhered to as outlined in Section 3.

### 5.0 Staff authorised to use this medicine protocol

<table>
<thead>
<tr>
<th>Professional qualifications, training, experience and competence required prior to working under this medicine protocol</th>
<th>Registered nurse or registered midwife, on the live register of The Nursing and Midwifery Board of Ireland. Education programme for nurses and midwives on the use of Medicine Protocol for the Administration of IPV Boostrix Vaccine (Diphtheria, Tetanus, Poliomyelitis) through a School Immunisation Programme.</th>
</tr>
</thead>
<tbody>
<tr>
<td><strong>Professional Qualifications:</strong></td>
<td></td>
</tr>
</tbody>
</table>
- Basic Life Support for Health Care Workers within 2 years. 
- "National Anaphylaxis Education Programme for Health Care Professionals", initially attends a classroom based programme. Updates available on [www.hseland.ie](http://www.hseland.ie) "National Anaphylaxis Education Programme for Health Care Professionals" within 2 years. 
- Injection technique education programme. (Local CNME/CNE) 
- "Hand Hygiene for HSE Clinical Staff" [www.hseland.ie](http://www.hseland.ie) 
- "Aseptic Non Touch Technique" (ANTT) [www.hseland.ie](http://www.hseland.ie) 
- "Immunisation Foundation Programme" [www.hseland.ie](http://www.hseland.ie) 
- GDPR Guidelines [www.hseland.ie](http://www.hseland.ie) |
| **Training, Experience, Competence** | 
- "Immunisation Foundation Programme" [www.hseland.ie](http://www.hseland.ie) 
- GDPR Guidelines [www.hseland.ie](http://www.hseland.ie) |
References


Health Products Regulatory Authority available at www.hpra.ie (accessed 31st January 2019)


Health Service Executive (2019) Directions for Nurses and Midwives for the Management of a Patient who Develops Anaphylaxis or suspected anaphylaxis incorporating Medicine protocol for the administration of Epinephrine (Adrenaline) injection BP 1:1000 by intramuscular injection by nurses and midwives for the management of a patient with anaphylaxis or suspected anaphylaxis. Dublin: Health Service Executive.


IPV Boostrix GlaxoSmithKline, Ireland Limited Summary of Product Characteristics and Patient Information Leaflet, text revised January 2019. Available at www.hpra.ie


Irish Medicines Board (Miscellaneous Provision) Act 2006 (No. 3 of 2006) (Section 10(1(iii)). Dublin: Stationery Office.


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


Nursing and Midwifery Board of Ireland (2015) Practice Standards for Midwives Dublin: Nursing and Midwifery Board of Ireland and Midwifery Board of Ireland. And Midwifery Board of Ireland available at http://www.nmbi.ie/Standards-Guidance/Midwives-Standards

Medicine Protocol for the Administration of IPV Boostrix (Diphtheria, Tetanus, Pertussis, and Poliomyelitis) vaccine (adsorbed, reduced antigen(s) content), 2019
29 July 2011

Mr. Michael Shannon
Assistant National Director,
Clinical Strategy and Programme Directorate, Health Service Executive
Dr. Steeven’s Hospital
Dublin 8

Dear Mr. Shannon,

Thank you for informing An Bord Altranais of the current work undertaken by the Office of the Nursing and Midwifery Services Director in relation to the national programme for the administration of the immunisations by nurses and midwives as part of the school immunisation programmes provided by the Health Service Executive. I note your request for professional guidance from An Bord Altranais regarding the scope of practice of nurses and midwives administering vaccines under medication protocol.

An Bord Altranais has published detailed guidance for developing medication protocols and general information about the professions' role in vaccinations in Guidance to Nurses and Midwives on Medication Management (2007) and the e-learning programme Guide to Medication Management (An Bord Altranais and the National Council, 2007).

The Nursing Board recognises and supports the role of the registered nurse and midwife in utilising the medication protocol for the administration of immunisations to children as part of the school immunisation programme. We note the key supports for registrants' scope of practice in implementing these medication protocols have been incorporated in the individual content of the medication protocols in association with reference to the education and clinical supports as you have outlined in your letter.

An Bord Altranais recognise that the HSE medication protocols complement the guidance of the Nursing Board and facilitate the achievement and maintenance of professional competency and outline the accountability of the nurse/midwife asked to participate with this medication protocol.

I hope this information is of assistance to you.

Yours sincerely,

Dr. Mairead O’Riordan
Chief Executive Officer

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1 Tetervac vaccine, IPV Infanrix vaccine, Priorix vaccine, M-M RVAXPRO vaccine and Boostrix vaccine
Medicine Protocol for the Administration of MMR (Measles, Mumps and Rubella) live vaccine
MMRVaxPRO by registered nurses and registered midwives

This medicine protocol is a specific written instruction for the administration of MMRVaxPRO vaccine to
children/students in first year in Primary and Second Level School by registered nurses and registered
midwives. This medicine protocol is valid for the 2019/2020 HSE School Immunisation Programme.

This medicine protocol enables registered nurses and midwives employed in the voluntary and statutory
services of the HSE who have undertaken the required education and training programmes to administer
MMRVaxPRO measles, mumps and rubella (live) vaccine with reference to and guidance from Nursing &
Midwifery Board of Ireland, National Immunisation Group, National Immunisation Office, HSE and in
accordance with the Summary of Product Characteristics for MMRVaxPRO vaccine as detailed by the Health
Products Regulatory Authority at www.hpra.ie:

  Altranais
- Health Services Executive (2019) Directions for Nurses and Midwives for the Management of a Patient
  who Develops Anaphylaxis or suspected anaphylaxis incorporating Medicine Protocol for the
  administration of Epinephrine (Adrenaline) injection BP 1:1000 by intramuscular injection for nurses and
  midwives for the management of a patient with anaphylaxis or suspected anaphylaxis. Dublin: Health
  Service Executive
- National Immunisation Advisory Committee Immunisation Guidelines for Ireland Dublin: Royal College
  of Physicians of Ireland National Immunisation Advisory Committee (Online Update available at
  https://www.hse.ie/eng/health/immunisation/hcupinfo/guidelines/
- Nursing and Midwifery Board of Ireland (2014) Code of Professional Conduct and Ethics for Registered
  Nurses and Registered Midwives. Dublin: Nursing and Midwifery Board of Ireland available at:
- Nursing and Midwifery Board of Ireland (2015) Practice Standards for Midwives. Dublin: Nursing and
  Midwifery Board of Ireland available at: https://www.nmbi.ie/Standards-Guidance/Midwives-Standards.
- Nursing and Midwifery Board of Ireland (2015) Recording Clinical Practice. Guidance to Nurses and
  Midwives. Dublin: Nursing and Midwifery Board of Ireland available at: https://www.nmbi.ie/Standards-
  Guidance/More-Standards-Guidance/Recording-Clinical-Practice
- Nursing and Midwifery Board of Ireland (2015) Scope of Nursing and Midwifery Practice Framework.
  Dublin: Nursing and Midwifery Board of Ireland available at: https://www.nmbi.ie/Standards-
  Guidance/Scope-of-Practice/Nursing-Practice-Scope-Definition

The Nursing and Midwifery Board of Ireland defines medicine protocols as “written directions that allow for the supply
and administration of a named medicinal product by a nurse or midwife in identified clinical situations. A medicine
protocol involves the authorisation of the nurse/midwife to supply and administer a medicine to groups of patients in a
deﬁned situation meeting speciﬁc criteria and who may not be individually identiﬁed before presentation for treatment.
An individually named prescription is not required for the supply and administration of medication when a medication
protocol is in effect” (An Bord Altranais, 2007).
**Medicine Protocol for the Administration of MMRVaxPRO vaccine by registered nurses and midwives to children/students in Primary/Second Level School through a School Immunisation Programme**

|---------------------------|----------------------------------|

**1.0 Critical Elements**

**Name of Organisation where protocol applies**: Health Service Providers across the voluntary and statutory services of the Health Service Executive (HSE). This Medicine Protocol applies to:
- Registered nurses and midwives involved in the supply and administration of the MMRVaxPRO vaccine to children/students in primary/second level school through a School Immunisation Programme.

**Date the protocol comes into effect**: September 2019

**Date for review of protocol**: May 2020

**Document prepared by**: Office of the Nursing and Midwifery Services Director (ONMSD) HSE, in collaboration with the National Immunisation Office (NIO) at the request of Dr. Kevin Kelleher, Assistant National Director Public Health, National Office for Public Health/Child Health, Strategic Planning and Transformation, HSE

**Names and Signatures of the employing authority who is authorising the implementation of the protocol**

"On behalf of the authority employing professionals authorised to administer under this medicine protocol, I have read this medicine protocol and authorise its implementation"

**Name**: Dr. Kevin Kelleher, Assistant National Director Public Health, National Office for Public Health/Child Health, Strategic Planning and Transformation, HSE

**Signature**: [Signature]

**Name**: Dr Colm Henry, National Director of Clinical Strategy and Programmes, HSE

**Signature**: [Signature]

**Name**: Ms Mary Wynne, Nursing and Midwifery Services Director, HSE

**Signature**: [Signature]
## 2.0 Clinical Criteria

| Clinical Condition for use of the protocol | The clinical condition for which this medicine protocol has been developed is for the active immunisation against and prevention of Measles, Mumps and Rubella infection. |
| Circumstances in which the medicine protocol applies | The School Immunisation Programme (SIP) will be delivered annually by the Health Service Executive (HSE). The aim of the immunisation programme is to complete the measles, mumps and rubella vaccination programme. The MMR vaccine is recommended for all children at 12 months of age and at 4-5 years in the Immunisation Guidelines for Ireland [https://www.hse.ie/eng/health/immunisation/hcpinfo/guidelines/](https://www.hse.ie/eng/health/immunisation/hcpinfo/guidelines/). If a child has not received a 1st dose of MMR vaccine, MMRVaxPRO (MMR) should be given, under this protocol, to a child in junior infants or age equivalent. A 2nd dose of MMR vaccine should then be given at least 4 weeks after the 1st MMR (MMRVaxPRO) dose. Preferably in a SIP mop up clinic. This medicine protocol also applies in MMRVaxPRO catch up campaigns and outbreaks situations as recommended by NIAC (2014). |
| Inclusion criteria for children/service user treatment using the medicine protocol | Children/students in primary/second level school or age equivalent in special schools and home schooled students. [https://www.hse.ie/eng/health/immunisation/pubinfo/schoolprog/4in1mmr/schoolguidelines.pdf](https://www.hse.ie/eng/health/immunisation/pubinfo/schoolprog/4in1mmr/schoolguidelines.pdf) Children/Students with valid consent. |
| Exclusion criteria for children using the medicine protocol | A known history of anaphylactic or hypersensitivity reaction to MMRVaxPRO or any of the MMRVaxPRO vaccine constituents including neomycin or gelatin. Acute febrile illness: The presence of a minor infection such as a mild upper respiratory infection or low grade fever is not a contraindication to immunisation. Child/student with a history of thrombocytopenia within six weeks of receiving first dose MMRVaxPRO vaccine. Child/student with a contraindication to intramuscular injection (haematological disorder/coagulation disorder e.g. haemophilia, severe thrombocytopenia). Child/student who are immunocompromised either due to disease or treatment. Child/student who received low-dose immunoglobulin within the previous 5 months or red-cell transfusion within 6 months or high-dosage immunoglobulin within 11 months. Child/student who have received varicella or yellow fever live vaccine within the previous 4 weeks. Active untreated tuberculosis. Pregnancy where applicable. |
| Actions to be taken for those who are excluded from the Protocol | • All children/students meeting exclusion criteria must be referred to the medical practitioner for an individual medical assessment. • Document action in clinical notes. |
- Where MMR (VaxPRO) vaccine is prescribed following medical assessment, the nurse or midwife may administer MMRVaxPRO vaccine within their scope of practice.

*Note: In determining their scope of practice, nurses and midwives must make judgements about their competency to carry out a role or activity (NMBI, 2015).*

| Description of circumstances and referral arrangements when further advice or consultation is required |
| Refer the student to the Medical Practitioner in the event of: |
| - Adverse reaction |
| - Other clinical concerns |

| Documentation required to support implementation of the medicine protocol |
| A Consent form must be completed by the parent/legal guardian for all children/students who receive the MMRVaxPRO vaccine. Students aged 16 years and over consent on their own behalf. Appropriate details including the batch number must be recorded on the Consent Form. The following documents will be available at each school vaccination session: |
| - Vaccination session forms |
| - Blank Vaccine consent forms |
| - Patient held record cards |
| - Health Products Regulatory Authority Adverse Reaction Reporting forms |
| - HSE Incident/near miss report forms (NIRF, 2017) |
| - Tear pads for after vaccination |
| It is the responsibility of each nurse or midwife to be familiar with the appropriate documentation to support the safe administration of MMRVaxPro vaccine which includes the following: |
| - Information for Staff: School Immunisation Programme 2019/2020 |
| - Medicine Protocol for the administration of measles, mumps, and mumps (live) vaccine, MMRVaxPro by registered nurses and registered midwives to children/students in primary/second level school or equivalent (e.g. home schooled, special schools) through the School Immunisation Programme. |
| - Directions for nurses and midwives for the management of a patient who develops anaphylaxis or suspected anaphylaxis incorporating Medication Protocol for the Administration of Epinephrine (adrenaline) Injection BP 1:1000 by intramuscular injection by nurses and midwives for the management of a patient with anaphylaxis or suspected anaphylaxis (HSE 2019) available at [https://www.hse.ie/eng/health/immunisation/hcpinfo/fluinfo/adrenalineprotocol.pdf](https://www.hse.ie/eng/health/immunisation/hcpinfo/fluinfo/adrenalineprotocol.pdf) |

## 3.0 Name of Medicine

**Link to Medicine**

Details of product information and other data including instructions for supply and administration is available from the Health Products Regulatory Authority at [www.hpра.ie](http://www.hpра.ie)

**MMRVaxPRO : 2019/2020**


| Procedure for the reporting and documentation of errors and near misses involving the medication | In the case of medicine errors that directly involve the child/student, i.e. wrong medicine/patient/dose/route being administered or another medicine error, the registered nurse or registered midwife must remain with the child/student and closely monitor them for any adverse reactions. Vital signs should be recorded and the student should be reviewed by the registered nurse/midwife and/or medical practitioner. The incident must be reported to the relevant line manager as soon as possible. The incident and all actions taken must be promptly recorded and the relevant National Incident Management Report Form completed (National Incident Report Form (NIRF-01-V10)) (May 2018) available at:  
The incident and all actions taken must be promptly recorded in the child/student’s documentation/notes and the relevant report form completed. The child/student’s parent and/or legal guardian must be informed of the incident. An incident report form must be completed by the registered nurse or registered midwife and forwarded to the relevant line manager as per local policy. Any suspected adverse reactions associated with medication errors should be reported to the HPRA as outlined below. Any errors and near misses not involving medication, the incident and all actions taken must be promptly recorded on the relevant National Incident Management Report form and forwarded to the relevant line manager as per local policy. |
| Procedure for reporting Adverse Drug Reactions to the Health Products Regulatory Authority (HPRA) | The relevant nurse or midwifery staff should report to the HPRA any suspected adverse reactions, in accordance with criteria outlined by the HPRA. This reporting may be carried out in line at https://www.hpra.ie or through use of the yellow care system which is available in the downloadable format from the HPRA website, or on request from the HPRA. The incident and all actions taken must be promptly recorded in accordance with the criteria outlined by the HPRA:- Management of a Patient with Anaphylaxis HSE (2019) – available online at  
https://www.hse.ie/eng/health/immunisation/hcpinfo/guidelines/Anaphylaxis.pdf |
<p>| Resources and equipment required | • Vaccine (pre-filled syringe). • Fridge/Cooler box with minimum/maximum thermometer to maintain cold chain temperature between +2° to +8°C. • Disposable kidney dishes/clopped trays. • Gauze swabs/Plasters. • Sharps bins and bags for disposal of other hazardous material • Alcohol hand rinse. • Access to telephone. • Resuscitation equipment and drugs in accordance with the Management of a Patient with anaphylaxis (National Immunisation Advisory Committee, 2019) available at |</p>
<table>
<thead>
<tr>
<th>Audit process to identify appropriate use of the protocol or unexpected outcomes</th>
<th>All documentation will be held for review and audit purposes as per local policy.</th>
</tr>
</thead>
</table>

### 4.0 Information for child/student/parent/guardian

**Advice to be given to the child/student/parent/guardian before treatment**

HSE 4 in 1 and MMR vaccine Information for parents of children in Junior infants booklet must have been supplied with the consent form to each student/parent/legal guardian prior to administration of the vaccine.

- Obtain informed consent and a signed consent form.

**After Treatment**

Information Tear Pad, stating date and time of vaccination must be given to all children/students for parental/guardian’s attention. The Tear Pad includes advice about contacting relevant medical personnel in the event of adverse reaction occurring following administration of the vaccine.

The child/student must be advised to remain seated in the post vaccination observation area for 15 minutes to allow monitoring of any immediate reaction including possible anaphylactic reaction and must be advised to report any side effects to the registered nurse or registered midwife.

Adverse reactions are considerably less common (less than 1%) after the 2nd dose of MMR vaccine.

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

In the event of an adverse reaction the nurse/midwife must ensure that all procedures are adhered to as outlined in Section 3.

### 5.0 Staff authorised to use this medicine protocol

**Professional qualifications, training, experience and competence required prior to working under this medicine protocol**

Registered nurse or registered midwife on the live register of The Nursing and Midwifery Board of Ireland.

- Education programme for nurses and midwives on the use of Medicine Protocol for the Administration of MMR (Measles, Mumps and Rubella) live vaccine MMRVaxPRO by registered nurses and registered midwives through a schools immunisation programme
- Basic Life Support for Health Care Workers within 2 years.
- “National Anaphylaxis Education Programme for Health Care Professionals”, initially attends a classroom based programme. Updates available on [www.hseland.ie](http://www.hseland.ie) “National Anaphylaxis Education Programme for Health Care Professionals” within 2 years.
- Injection technique education programme. (Local CNME/CNE)
- “Hand Hygiene for HSE Clinical Staff” [www.hseland.ie]
- “Aseptic Non Touch Technique” (ANTT) [www.hseland.ie]
- “Immunisation Foundation Programme” [www.hseland.ie]
- GDPR Guidelines [www.hseland.ie]
References


Health Products Regulatory Authority available at [www.hpra.ie](http://www.hpra.ie) (accessed 1st February 2019)


Health Service Executive (2019) *Directions for Nurses and Midwives for the Management of a Patient who Develops Anaphylaxis or suspected anaphylaxis incorporating Medicine Protocol for the Administration of Epinephrine (Adrenaline) injection BP 1:1000 by intramuscular injection by nurse and midwives for the management of a patient with anaphylaxis or suspected anaphylaxis*. Dublin: Health Service Executive


MMRVaxPRO Vaccine MSD Ireland Limited *Summary of Product Characteristics and Patient Information Leaflet*. Available at [www.hpra.ie](http://www.hpra.ie)


Irish Medicines Board *(Miscellaneous Provision)* Act 2006 (No. 3 of 2006) (Section 10(1)(ii)). Dublin: Stationery Office


29 July 2011

Mr. Michael Shannon  
Assistant National Director,  
Clinical Strategy and Programme Directorate, Health Service Executive  
Dr. Steeven’s Hospital  
Dublin 8

Dear Mr. Shannon,

Thank you for informing An Bord Altranais of the current work undertaken by the Office of the Nursing and Midwifery Services Director in relation to the national programme for the administration of the immunisations by nurses and midwives as part of the school immunisation programmes provided by the Health Service Executive. I note your request for professional guidance from An Bord Altranais regarding the scope of practice of nurses and midwives administering vaccines under medication protocol.

An Bord Altranais has published detailed guidance for developing medication protocols and general information about the professions’ role in vaccinations in Guidance to Nurses and Midwives on Medication Management (2007) and the e-learning programme Guide to Medication Management (An Bord Altranais and the National Council, 2007).

The Nursing Board recognises and supports the role of the registered nurse and midwife in utilising the medication protocol for the administration of immunisations to children as part of the school immunisation programme. We note the key supports for registrants’ scope of practice in implementing these medication protocol have been incorporated in the individual content of the medication protocols in association with reference to the education and clinical supports as you have outlined in your letter.

An Bord Altranais recognise that the HSE medication protocols\(^1\) complement the guidance of the Nursing Board and facilitate the achievement and maintenance of professional competency and outline the accountability of the nurse/midwife asked to participate with this medication protocol.

I hope this information is of assistance to you.

Yours sincerely,

Dr. Mairead O’Keeffe  
Chief Executive Officer

Office of Nursing Services Director  
- 3 AUG 2011  
RECEIVED

\(^1\) Tetrawac vaccine, IPV Infantrix vaccine, Priorix vaccine, M-M RVAXPRO vaccine and Boostrix vaccine
Medicine Protocol for the Administration of MMR (Measles, Mumps and Rubella) vaccine (Priorix) by registered nurses and registered midwives

This medicine protocol is a specific written instruction for the administration of Priorix Vaccine (MMR) to children/students in Primary and Second Level School by registered nurses and registered midwives. This medicine protocol is valid for the 2019/2020 HSE School Immunisation Programme.

This medicine protocol enables registered nurses and midwives employed in the voluntary and statutory services of the HSE who have undertaken the required education and training programmes to administer MMR (Priorix) measles, mumps and rubella (live) vaccine with reference to and guidance from Nursing & Midwifery Board of Ireland, National Immunisation Group, National Immunisation Office, HSE and in accordance with the Summary of Product Characteristics for MMR vaccine (Priorix) as detailed by the Health Products Regulatory Authority at www.hpra.ie:

- Health Services Executive (2019) Directions for Nurses and Midwives for the Management of a Patient who Develops Anaphylaxis or suspected anaphylaxis incorporating Medicine protocol for the Administration of Epinephrine (Adrenaline) Injection BP 1:1000 by intramuscular injection for nurses and midwives for the management of anaphylaxis or suspected anaphylaxis. Dublin: Health Service Executive


Immunisation Guidelines for Ireland Dublin: Royal College of Physicians of Ireland

National Immunisation Advisory Committee (Online Update available at https://www.hse.ie/en/health/immunisation/hcpinfo/guidelines/


The Nursing and Midwifery Board of Ireland defines medicine protocols as “written directions that allow for the supply and administration of a named medicinal product by a nurse or midwife in identified clinical situations. A medicine protocol involves the authorisation of the nurse/midwife to supply and administer a medicine to groups of patients in a defined situation meeting specific criteria and who may not be individually identified before presentation for treatment. An individually named prescription is not required for the supply and administration of medication when a medication protocol is in effect” (An Bord Altranais, 2007).
<table>
<thead>
<tr>
<th>Document number:</th>
<th>reference</th>
</tr>
</thead>
<tbody>
<tr>
<td></td>
<td>ONMSD 2018 005 ONMSD 2019 014</td>
</tr>
</tbody>
</table>

### 1.0 Critical Elements

**Name of Organisation where protocol applies**

Health Service Providers across the voluntary and statutory services of the Health Service Executive (HSE). This Medicine Protocol applies to:
- Registered nurses and midwives involved in the supply and administration of the Priorix vaccine to children/students in primary/secondary level school through a School Immunisation Programme.

**Date the protocol comes into effect**

September 2019

**Date for review of protocol**

May 2020

**Document prepared by:**

Office of the Nursing and Midwifery Services Director (ONMSD) HSE, in collaboration with the National Immunisation Office (NIO) at the request of Dr Kevin Kelleher, Assistant National Director Public Health, National Office for Public Health/Child Health, Strategic Planning and Transformation, HSE

**Names and Signatures of the employing authority who is authorising the implementation of the protocol**

"On behalf of the authority employing professionals authorised to administer under this medicine protocol, I have read this medicine protocol and authorise its implementation”

Name: Dr. Kevin Kelleher, Assistant National Director Public Health, National Office for Public Health/Child Health, Strategic Planning and Transformation, HSE

Signature: 

Name: Dr Colm Henry, National Director of Clinical Strategy and Programmes, HSE

Signature: 

Name: Ms Mary Wynne, Nursing and Midwifery Services Director, HSE

Signature: 

### Medicine Protocol for the Administration of MMR Vaccine (Priorix), 2019
| **Clinical Condition for use of the protocol** | The clinical condition for which this medicine protocol has been developed is for the active immunisation against and prevention of measles, mumps and rubella infection. |
| **Circumstances in which the medicine protocol applies** | The School Immunisation Programme (SIP) will be delivered annually by the Health Service Executive (HSE). The aim of the immunisation programme is to complete the measles, mumps and rubella (live) vaccine, schedule for children. The MMR vaccine is recommended for all children at 12 months of age and at 4-5 years in the Immunisation Guidelines for Ireland. [https://www.hse.ie/eng/health/immunisation/hcpinfo/guidelines/](https://www.hse.ie/eng/health/immunisation/hcpinfo/guidelines/). If a child has not received a 1st dose of MMR vaccine, Priorix (MMR) should be given under this protocol, to a child in junior infants or age equivalent in special schools and home schooled. A 2nd dose of Priorix (MMR) should then be given at least 4 weeks after the 1st Priorix (MMR) dose. – Preferably in a SIP mop up clinic. This medicine protocol also applies in MMR catch up campaigns and outbreaks situations as recommended by NIAC (2014). |
| **Inclusion criteria for children/students treatment using the medicine protocol** | Children/Students in primary/second level school or age equivalent in special schools and home schooled students. See [https://www.hse.ie/eng/health/immunisation/pubinfo/schoolprog/4in1mmr/schoolguidelines.pdf](https://www.hse.ie/eng/health/immunisation/pubinfo/schoolprog/4in1mmr/schoolguidelines.pdf) Children/Students with valid consent. |
| **Exclusion criteria for children/ student s using the medicine protocol** | A known history of anaphylactic or hypersensitivity reaction to Priorix or to any of the MMR vaccine constituents including neomycin. Acute febrile illness: The presence of a minor infection such as a mild upper respiratory infection or low grade fever is not a contraindication to immunisation. Child/student with a history of thrombocytopenia within six weeks of receiving the first dose of MMR vaccine. Child/Student with a contraindication to intramuscular injection (haematological disorder/coagulation disorder e.g. haemophilia, severe thrombocytopenia Child/student who is immunocompromised either due to disease or treatment. Child/student who received low-dose immunoglobulin within the previous 5 months or red-cell transfusion within 6 months or high-dosage immunoglobulin within 11 months. Child/student who received Varicella or, Yellow Fever live vaccines within the previous 4 weeks. Active untreated tuberculosis. Pregnancy where applicable. |
| **Actions to be taken for those who are excluded from the Protocol** | • All children/students meeting exclusion criteria must be referred to the medical practitioner for an individual medical assessment. • Document action in clinical notes |
- Where MMR Vaccine (Priorix) is prescribed following medical assessment, the nurse or midwife may administer MMR Vaccine (Priorix) within their scope of practice.

*Note: In determining their scope of practice, nurses and midwives must make judgements about their competency to carry out a role or activity (NMBI, 2015).*

| Description of circumstances and referral arrangements when further advice or consultation is required | Refer the student to the Medical Practitioner In the event of:  
Adverse reaction  
Other clinical concerns |
| --- | --- |
| Documentation required to support implementation of the medicine protocol | Consent form must be completed by the parent/legal guardian for all children/students who receive the MMR (Priorix) vaccine. Students aged 16 years and over consent on their own behalf. Appropriate details including the batch number must be recorded on the consent form.  
The following documents will be available at each school vaccination session:  
- Vaccination session form  
- Blank Vaccine consent forms  
- Patient held record cards  
- Health Products Regulatory Authority Adverse Reaction Reporting forms  
- HSE Incident/near miss report forms (NIHF, 2018)  
- Tear pads for post vaccination |
|  |
| It is the responsibility of each nurse or midwife to be familiar with the appropriate documentation to support the safe administration of MMR (Priorix) vaccine which includes the following:  
- Information for Staff : School Immunisations Programme 2019/2020, Medicine Protocol for the administration of measles, mumps, and mumps (live) vaccine, Priorix by registered nurses and registered midwives to children/students in primary / second level school or equivalent (e.g. home schooled, special schools) through the School Imunisation Programme.  
- Directions for nurses and midwives for the management of a patient who develops anaphylaxis or suspected anaphylaxis incorporating Medication Protocol for the Administration of Epinephrine (adrenaline) Injection BP 1:1000 by intramuscular injection by nurses and midwives for the management of a patient with anaphylaxis or suspected anaphylaxis (HSE 2019), available at [https://www.hse.ie/eng/health/immunisation/hcinfo/fluinfo/adrenalineprotocol.pdf](https://www.hse.ie/eng/health/immunisation/hcinfo/fluinfo/adrenalineprotocol.pdf) |

### 3.0 Name of Medicine

<table>
<thead>
<tr>
<th>Link to Medicine</th>
</tr>
</thead>
<tbody>
<tr>
<td>MMR Vaccine (Priorix): 2019/2020</td>
</tr>
</tbody>
</table>

| Details of product information and other data including instructions for supply and administration is available from the Health Products Regulatory Authority at [www.hpра.ie](http://www.hpра.ie) |

**Link to Summary of Product Characteristics:**  
[https://www.hpra.ie/img/uploaded/swedocuments/LicenseSPC_PA1077-036-001_12102017154037.pdf](https://www.hpra.ie/img/uploaded/swedocuments/LicenseSPC_PA1077-036-001_12102017154037.pdf)

**Link to Patient Information Leaflet:**  
[https://www.hpra.ie/img/uploaded/swedocuments/2191542.PA1077_036_001.5998_d734-4a4e-4a36-85c7-3e7fd3cee78b.000001PIL.171012.pdf](https://www.hpra.ie/img/uploaded/swedocuments/2191542.PA1077_036_001.5998_d734-4a4e-4a36-85c7-3e7fd3cee78b.000001PIL.171012.pdf)
### Procedure for the reporting and documentation of errors and near misses involving the medication

In the case of medication errors that directly involve the child/student, i.e. wrong medication/patient/dose/route being administered or another medication error, the registered nurse or registered midwife must remain with the child/student and closely monitor them for any adverse reactions.

Vital signs should be recorded and the student should be reviewed by the registered nurse/midwife and/or medical practitioner.

The incident must be reported to the relevant line manager as soon as possible. The incident and all actions taken must be promptly recorded and the relevant National Incident Management Report Form completed (National Incident Report Form (NIRF-01-V10)) [May 2018](https://www.hse.ie/eng/about/qavd/incident-management/nirf-01-v10-person1.pdf)

The incident and all actions taken must be promptly recorded in the child/student’s documentation/notes and the relevant report form completed.

The child/student’s parent and/or legal guardian must be informed of the incident.

An incident report form must be completed by the registered nurse or registered midwife and forwarded to the relevant line manager as per local policy.

Any suspected adverse reactions associated with medicine errors should be reported to the HPRA as outlined below.

Any errors and near misses not involving medication, the incident and all actions taken must be promptly recorded on the relevant National Incident Management Report form and forwarded to the relevant line manager as per local policy.

### Procedure for reporting Adverse Drug Reactions to the Health Products Regulatory Authority (HPRA)

The relevant nursing or midwifery staff should report to the HPRA any suspected adverse reactions, in accordance with criteria outlined by the HPRA. This reporting may be carried out in line at [https://www.hpraise.ie](https://www.hpraise.ie) or through use of the yellow card system which is available in the downloadable format from the HPRA website, or on request from the HPRA.

The incident and all actions taken must be promptly recorded in accordance with the criteria outlined by the HPRA: *Management of a Patient with Anaphylaxis: Treatment in the Community* (National Immunisation Advisory Committee, 2019) – available online at [https://www.hse.ie/eng/health/immunisation/hcphiinfo/guidelines/Anaphylaxis.pdf](https://www.hse.ie/eng/health/immunisation/hcphiinfo/guidelines/Anaphylaxis.pdf)

### Resources and equipment required

- Vaccine (pre-filled syringe)
- Vaccine cool packs
- Fridge/Cooler box with minimum/maximum thermometer to maintain cold chain temperature between +2° to +8°C
- Disposable kidney dishes/coloured trays
- Gauze swabs/Plasters
- Sharps bins, and bags for disposal of other hazardous material
- Alcohol hand rinse

---

*Medicine Protocol for the Administration of MMR (Priorix), 2019*
- Access to telephone
- Access to medical support
- Safe storage areas for medicines and equipment
- Current medicine protocol for MMR vaccine Priorix.

<table>
<thead>
<tr>
<th>Audit process to identify appropriate use of the protocol or unexpected outcomes</th>
<th>All documentation will be held for review and audit purposes as per local policy.</th>
</tr>
</thead>
</table>

### 4.0 Information for child/student/parent/guardian

**Advice to be given to the child/student/parent/guardian before treatment**

HSE 4 in 1 and MMR vaccine Information for parents of children in Junior infant’s booklet must have been supplied with the consent form to each student/parent/legal guardian prior to administration of the vaccine.

**Advice to be given to the child/student/parent/guardian after treatment**

**After Treatment**

An Information Tear Pad, stating date and time of vaccination must be given to all children/students for parental/guardian’s attention. The Tear Pad includes advice about contacting relevant medical personnel in the event of adverse reaction occurring following administration of the vaccination.

The child/student must be advised to remain seated in the post vaccination observation area for 15 minutes to allow monitoring of any immediate reaction including possible anaphylactic reaction and must be advised to report any side effects to the registered nurse or registered midwife.

Adverse reactions are considerably less common (less than 1%) after the 2nd dose of MMR vaccine.

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

In the event of an adverse reaction the nurse/midwife must ensure that all procedures are adhered to as outlined in Section 3.

### 5.0 Staff authorised to use this medicine protocol

<p>| Professional qualifications | Registered nurse or registered midwife on the live register of The Nursing and |</p>
<table>
<thead>
<tr>
<th>Professional Qualifications</th>
<th>Midwifery Board of Ireland.</th>
</tr>
</thead>
<tbody>
<tr>
<td>Training, Experience, Competence</td>
<td>Education programme for nurses and midwives on the use of Medicine Protocol for the Administration of MMR (Measles, Mumps and Rubella) vaccine (Priorix) by registered nurses and registered midwives through a School Immunisation Programme.</td>
</tr>
<tr>
<td></td>
<td>- Basic Life Support for Health Care Workers within 2 years.</td>
</tr>
<tr>
<td></td>
<td>- “National Anaphylaxis Education Programme for Health Care Professionals”, initially attends a classroom based programme. Updates available on <a href="http://www.hseland.ie">www.hseland.ie</a> “National Anaphylaxis Education Programme for Health Care Professionals” within 2 years.</td>
</tr>
<tr>
<td></td>
<td>- Injection technique education programme. (Local CNME/CNE)</td>
</tr>
<tr>
<td></td>
<td>- “Hand Hygiene for HSE Clinical Staff” <a href="http://www.hseland.ie">www.hseland.ie</a></td>
</tr>
<tr>
<td></td>
<td>- “Aseptic Non Touch Technique” (ANTT) <a href="http://www.hseland.ie">www.hseland.ie</a></td>
</tr>
<tr>
<td></td>
<td>- “Immunisation Foundation Programme” <a href="http://www.hseland.ie">www.hseland.ie</a></td>
</tr>
<tr>
<td></td>
<td>- GDPR Guidelines <a href="http://www.hseland.ie">www.hseland.ie</a></td>
</tr>
</tbody>
</table>
References

Health Products Regulatory Authority available at www.hpra.ie (accessed 31st January 2019)


Health Service Executive (2019) Directions for Nurses and Midwives for the Management of a Patient who Develops Anaphylaxis or suspected anaphylaxis incorporating Medicine Protocol for the administration of Epinephrine (Adrenaline) injection BP 1:1000 by intramuscular injection by nurses and midwives for the management of a patient with anaphylaxis or suspected anaphylaxis. Dublin: Health Service Executive


MMR Vaccine (Priorix) Glaxo Smith Kline, Ireland Limited Summary of Product Characteristics and Patient Information Leaflet, revised 2017 Available at www.hpra.ie


Irish Medicines Board (Miscellaneous Provision) Act 2006 (No. 3 of 2006) (Section 10(ii)). Dublin: Stationery Office


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


Nursing and Midwifery Board of Ireland (2015) Practice Standards for Midwives Dublin: Nursing and Midwifery Board of Ireland available at https://www.nmbi.ie/Standards-Guidance/Midwives-Standards

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


Medicine Protocol for the Administration of MMR (Priorix), 2019
29 July 2011

Mr. Michael Shannon
Assistant National Director,
Clinical Strategy and Programme Directorate, Health Service Executive
Dr. Steeven’s Hospital
Dublin 8

Dear Mr. Shannon,

Thank you for informing An Bord Altranais of the current work undertaken by the Office of the Nursing and Midwifery Services Director in relation to the national programme for the administration of the immunisations by nurses and midwives as part of the school immunisation programmes provided by the Health Service Executive. I note your request for professional guidance from An Bord Altranais regarding the scope of practice of nurses and midwives administering vaccines under medication protocol.


The Nursing Board recognises and supports the role of the registered nurse and midwife in utilising the medication protocol for the administration of immunisations to children as part of the school immunisation programme. We note the key supports for registrants’ scope of practice in implementing these medication protocol have been incorporated in the individual content of the medication protocols in association with reference to the education and clinical supports as you have outlined in your letter.

An Bord Altranais recognise that the HSE medication protocols complement the guidance of the Nursing Board and facilitate the achievement and maintenance of professional competency and outline the accountability of the nurse/midwife asked to participate with this medication protocol.

I hope this information is of assistance to you.

Yours sincerely,

Dr Máire Ní Chroinin
Chief Executive Officer

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1. TetraVax vaccine, IPV Infanrix vaccine, Priorix vaccine, M-M RVAXPRO vaccine and Boosterrix vaccine
Medicine Protocol for the Administration of HPV vaccine (Gardasil 9) by registered nurses and registered midwives to students in Second Level School through a School Immunisation Programme

This medicine protocol is a specific written instruction for the administration of HPV vaccine (Gardasil 9), Human Papillomavirus vaccine (HPV Types 6, 11, 16, 18, 31, 33, 45, 52 and 58) to students in Second Level School who are not individually identified before presentation for treatment by registered nurses and registered midwives. This medicine protocol is valid for the 2019/2020 HSE School Immunisation Programme.

This medicine protocol enables registered nurses and midwives employed in the voluntary and statutory services of the HSE who have undertaken the required education and training programmes to administer HPV vaccine (Gardasil 9) with reference to and guidance from Nursing & Midwifery Board of Ireland, National Immunisation Group, National Immunisation Office, HSE and in accordance with the Summary of Product Characteristics for HPV vaccine (Gardasil 9) as detailed by the Health Products Regulatory Authority at www.hpра.ie:

- Health Services Executive (2019) Directions for Nurses and Midwives for the Management of a Patient who Develops Anaphylaxis or suspected Anaphylaxis incorporating Medicine Protocol for the administration of Epinephrine (Adrenaline) injection EP1:1000 by intramuscular injection for nurses and midwives for the management of a patient with anaphylaxis or suspected anaphylaxis. Dublin: Health Service Executive
- National Immunisation Advisory Committee Immunisation Guidelines for Ireland Dublin: Royal College of Physicians of Ireland National Immunisation Advisory Committee (Online Update available at http://www.hse.ie/eng/health/immunisation/hcpinfo/guidelines/

The Nursing and Midwifery Board of Ireland defines medicine protocols as “written directions that allow for the supply and administration of a named medicinal product by a nurse or midwife in identified clinical situations. A medicine protocol involves the authorisation of the nurse/midwife to supply and administer a medicine to groups of patients in a defined situation meeting specific criteria and who may not be individually identified
before presentation for treatment. An individually named prescription is not required for the supply and administration of medication when a medicine protocol is in effect" (An Bord Altranais, 2007).
**Medicine Protocol for the Administration of HPV Vaccine (Gardasil 9) by registered nurses and midwives to student’s in Second Level School through a School Immunisation Programme**

|-----------------------------|---------------------------------|

### 1.0 Critical Elements

| Name of Organisation where protocol applies | Health Service Providers across the voluntary and statutory services of the Health Service Executive (HSE). This Medicine Protocol applies to:  
- Registered nurses and midwives involved in the supply and administration of the HPV vaccine (Gardasil 9) to students in second level schools through a School Immunisation Programme. |
<table>
<thead>
<tr>
<th></th>
<th></th>
</tr>
</thead>
<tbody>
<tr>
<td>Date the protocol comes into effect</td>
<td>September 2019</td>
</tr>
<tr>
<td>Date for review of protocol</td>
<td>May 2020</td>
</tr>
<tr>
<td>Document prepared by:</td>
<td>Office of the Nursing and Midwifery Services Director (ONMSD) HSE, in collaboration with the National Immunisation Office (NIO) at the request of Dr Kevin Kelleher, National Office for Public Health/Child Health, Strategic Planning and Transformation, HSE</td>
</tr>
</tbody>
</table>

<table>
<thead>
<tr>
<th>Names and Signatures of the employing authority who is authorising the implementation of the protocol</th>
<th></th>
</tr>
</thead>
<tbody>
<tr>
<td>&quot;On behalf of the authority employing professionals authorised to administer under this medicine protocol, I have read this medicine protocol and authorise its implementation&quot;</td>
<td></td>
</tr>
<tr>
<td>Name: Dr. Kevin Kelleher, Assistant National Director Public Health, National Office for Public Health/Child Health, Strategic Planning and Transformation, HSE</td>
<td>Signature: [Signature Image]</td>
</tr>
<tr>
<td>Name: Dr Colm Henry, National Director of Clinical Strategy and Programmes, HSE</td>
<td>Signature: [Signature Image]</td>
</tr>
<tr>
<td>Name: Ms Mary Wynne, Nursing and Midwifery Services Director, HSE</td>
<td>Signature: [Signature Image]</td>
</tr>
</tbody>
</table>
### 2.0 Clinical Criteria

| Clinical Condition for use of the protocol | The clinical condition for which this medicine protocol has been developed is for the active immunisation against and prevention of premalignant lesions and cancers affecting the cervix, vulva, vagina and anus caused by vaccine HPV types 16, 18, 31, 33, 45, 52 and 58 and external genital warts (condyloma acuminata) causally related to HPV types 6 and 11. |
| Circumstances in which the medicine protocol applies | The School Immunisation Programme (SIP) will be delivered annually by the Health Service Executive (HSE). HPV vaccine (Gardasil 9) is given as a vaccination for students in first year of second level schools and or age equivalent in special schools and home schooled. The aim of the immunisation programme is to provide the HPV vaccine (Gardasil 9) schedule, as recommended in the Immunisation Guidelines for Ireland within the academic year. [http://www.hse.ie/eng/health/immunisation/hcpinfo/guidelines/](http://www.hse.ie/eng/health/immunisation/hcpinfo/guidelines/) Students will require one dose in September-November and a second dose at least five, but ideally six months later. NIAC recommends that “two doses should ideally be separated by 6 to 12 months. The minimum interval between doses is 5 calendar months”. The 4 day rule applies. Students aged 15 years and older at time of first HPV vaccine (Gardasil 9) require 3 doses of HPV vaccine. The minimum interval between the first and second doses is 4 weeks. The minimum interval between the second and third doses is 12 weeks. The Minimum interval between the first and third doses is 5 calendar months. If a dose is administered at less than the recommended minimum interval then the dose should be repeated at or after the recommended minimum interval and at least one month after the discarded dose. [https://www.hse.ie/eng/health/immunisation/hcpinfo/guidelines/chapter10.pdf](https://www.hse.ie/eng/health/immunisation/hcpinfo/guidelines/chapter10.pdf) If the vaccination series is interrupted, the series does not need to be restarted. Those who have completed a course of HPV vaccine (Gardasil 4) vaccination do not require revaccination with HPV vaccine (Gardasil 9) as part of the routine schools programme. Girls who are older than first year and have already started but not completed a course of HPV vaccine (Gardasil 4) should ideally complete the course with HPV vaccine (Gardasil 4) if the vaccine is still available. The HPV vaccine (Gardasil 4) medication protocol should be used for HPV vaccine (Gardasil 4) administration. If a course of HPV vaccine (Gardasil 4) has already been started, the schedule can be completed with HPV vaccine (Gardasil 9) if supplies of HPV vaccine (Gardasil 4) are no longer available, it does not need to be restarted. The schedule for completion with HPV vaccine (Gardasil 9) is the same as the HPV vaccine (Gardasil 9) schedule and the HPV vaccine (Gardasil 9) medication protocol can be used. |
| Inclusion criteria for Students using the medicine protocol | Students in first year of second level school or age equivalent in special schools and home schooled students (NIAC, 2019) Students with valid consent. |
Girls older than first year of second level school who are eligible for the HPV vaccine and where HPV vaccine (Gardasil 4) is no longer available.

**Exclusion criteria for Students using the medicine protocol**

A known history of anaphylactic or hypersensitivity reaction to HPV vaccine (Gardasil 9) or any of vaccines constituents.

Acute febrile illness: The presence of a minor infection such as a mild upper respiratory infection or low grade fever is not a contraindication to immunisation.

Students with a contraindication to intramuscular injection (haematological disorder/coagulation disorder e.g. haemophilia, severe thrombocytopenia).

Pregnancy where applicable.

Students who are immunocompromised either due to disease or treatment.

<table>
<thead>
<tr>
<th>Actions to be taken for those students who are excluded from the Protocol</th>
</tr>
</thead>
<tbody>
<tr>
<td>• All students meeting exclusion criteria must be referred to a medical practitioner for an individual assessment.</td>
</tr>
<tr>
<td>• Document action in clinical notes</td>
</tr>
<tr>
<td>• Where HPV Vaccine (Gardasil 9) is prescribed following medical assessment, the nurse or midwife may administer HPV Vaccine (Gardasil 9) within their scope of practice.</td>
</tr>
</tbody>
</table>

*Note: In determining their scope of practice, nurses and midwives must make judgements about their competency to carry out a role or activity (NMBI, 2015).*

<table>
<thead>
<tr>
<th>Description of circumstances and referral arrangements when further advice or consultation is required</th>
</tr>
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<tbody>
<tr>
<td>Refer the student to the Medical Practitioner in the event of:</td>
</tr>
<tr>
<td>• Adverse reaction</td>
</tr>
<tr>
<td>• Other clinical concerns</td>
</tr>
</tbody>
</table>

<table>
<thead>
<tr>
<th>Documentation required to support implementation of the medicine protocol</th>
</tr>
</thead>
<tbody>
<tr>
<td>A consent form must be completed by the parent/legal guardian for all students who receive the HPV vaccine (Gardasil 9). Appropriate details including the batch number must be recorded on the consent form.</td>
</tr>
<tr>
<td>The following documents will be available at each school vaccination session:</td>
</tr>
<tr>
<td>• Vaccination session form</td>
</tr>
<tr>
<td>• Blank Vaccine consent forms</td>
</tr>
<tr>
<td>• Vaccine Information Leaflets</td>
</tr>
<tr>
<td>• Patient Immunisation Passport</td>
</tr>
<tr>
<td>• Health Products Regulatory Authority Adverse Reaction Reporting forms</td>
</tr>
<tr>
<td>• HSE Incident/near miss report forms (NIRF, 2018)</td>
</tr>
<tr>
<td>• Tear pads for post vaccination</td>
</tr>
<tr>
<td>• It is the responsibility of each nurse or midwife to be familiar with the appropriate documentation to support the safe administration of HPV vaccine (Gardasil 9) vaccine which includes the following:</td>
</tr>
<tr>
<td>• Information for Staff: School Immunisation Programme (2019/2020).*</td>
</tr>
</tbody>
</table>
- Current Medicine Protocol for the administration of HPV vaccine (Gardasil 9)

- Directions for nurses and midwives for the management of a patient who develops anaphylaxis or suspected anaphylaxis incorporating Medication Protocol for the Administration of Epinephrine (adrenaline) Injection BP 1:1000 by intramuscular injection by nurses and midwives for the management of a patient with anaphylaxis or suspected anaphylaxis (HSE, 2019), available at [https://www.hse.ie/eng/health/immunisation/hcpinfo/fluinfo/adrenalineprotocol.pdf](https://www.hse.ie/eng/health/immunisation/hcpinfo/fluinfo/adrenalineprotocol.pdf)

### 3.0 Name of Medicine

<table>
<thead>
<tr>
<th>Link to Medicine</th>
<th>HPV Vaccine (Gardasil 9) 2019/2020</th>
</tr>
</thead>
<tbody>
<tr>
<td>Details of product information and other data including instructions for supply and administration is available from the Health Products Regulatory Authority at <a href="http://www.hp%D1%80%D0%B0.ie">www.hpра.ie</a></td>
<td></td>
</tr>
</tbody>
</table>

<table>
<thead>
<tr>
<th>Procedure for the reporting and documentation of errors and near misses involving the medicine</th>
</tr>
</thead>
<tbody>
<tr>
<td>In the case of medicine errors that directly involve the student, i.e. wrong medicine/patient/dose/route being administered or another medicine error, the registered nurse or registered midwife must remain with the student, and closely monitor them for any adverse reactions.</td>
</tr>
</tbody>
</table>

Vital signs should be recorded and the student should be reviewed by the registered nurse/midwife and/or medical practitioner.

The incident must be reported to the relevant line manager as soon as possible.


The incident and all actions taken must be promptly recorded in the student’s documentation/notes and the relevant report form completed.

The student’s parent and/or legal guardian should be informed of the incident.

An incident report form must be completed by the registered nurse or registered midwife and forwarded to the relevant line manager as per local policy.

Any suspected adverse reactions associated with medication errors should be reported to the HPRA as outlined below.

Any errors and near misses not involving medication, the incident and all actions taken must be promptly recorded on the relevant National Incident Management Report Form and forwarded to the relevant line manager (as per local policy).
<table>
<thead>
<tr>
<th>Procedure for reporting Adverse Drug Reactions to the Health Products Regulatory Authority (HPRA)</th>
<th>The relevant nursing or midwifery staff should report to the HPRA any suspected adverse reactions, in accordance with criteria outlined by the HPRA. This reporting may be carried out in line at <a href="https://www.hpra.ie">https://www.hpra.ie</a> or through use of the yellow card system which is available in the downloadable format from the HPRA website, or on request from the HPRA. The incident and all actions taken must be promptly recorded in accordance with the criteria outlined by the Health Products Regulatory Authority (HPRA) - *Management of a Patient with Anaphylaxis: Treatment in the Community (National Immunisation Advisory Committee, 2019) — available online at <a href="https://www.hse.ie/eng/health/immunisation/hcpinfo/guidelines/Anaphylaxis.pdf">https://www.hse.ie/eng/health/immunisation/hcpinfo/guidelines/Anaphylaxis.pdf</a></th>
</tr>
</thead>
</table>
| Resources and equipment required | • Vaccine  
• Fridge/Cooler box with minimum/maximum thermometer to maintain cold chain temperature between +2° to +8°C  
• Disposable kidney dishes/coated trays  
• Gauze swabs/Plasters  
• Sharps bins, and bags for disposal of other hazardous material  
• Alcohol hand rinse  
• Access to telephone  
• Resuscitation equipment and drugs in accordance with the *Management of a Patient with Anaphylaxis*, (National Immunisation Advisory Committee, 2019) available at: [https://www.hse.ie/eng/health/immunisation/hcpinfo/guidelines/Anaphylaxis.pdf](https://www.hse.ie/eng/health/immunisation/hcpinfo/guidelines/Anaphylaxis.pdf)  
• Access to medical support  
• Safe storage areas for medicines and equipment  
• Current medicine protocol for HPV Vaccine (Gardasil 9). |
| Audit process to identify appropriate use of the protocol or unexpected outcomes | All documentation will be held for review and audit purposes as per local policy. |
| 4.0 Information for the student/parent/guardian | |
| Advice to be given to student/parent/guardian before treatment | HSE 1ˢᵗ year vaccination programme information booklet must have been supplied with the consent form to each parent/legal guardian prior to administration of the vaccine. **After Treatment** An Information Tear Pad, stating date and time of vaccination must be given to all students for parental/legal guardian’s attention. The Tear Pad includes advice about contacting relevant medical personnel in the event of adverse reaction occurring following administration of the vaccination. The student must be advised to remain seated in the post vaccination observation area for 15 minutes to allow monitoring of any immediate reaction including suspected anaphylactic reaction and must be advised to report any unwanted side effects to the registered nurse or registered midwife. |
Details of any necessary follow-up, action and referral arrangements

In the event of an adverse reaction the registered nurse/midwife must ensure that all procedures are adhered to as outlined in Section 3.

<table>
<thead>
<tr>
<th>5.0 Staff authorised to use this medicine protocol</th>
</tr>
</thead>
<tbody>
<tr>
<td>Professional qualifications, training, experience and competence required prior to working under this medicine protocol</td>
</tr>
<tr>
<td>Professional Qualifications: Training, Experience, Competence:</td>
</tr>
<tr>
<td>Registered nurse or registered midwife on the live register of The Nursing and Midwifery Board of Ireland.</td>
</tr>
</tbody>
</table>

**Education programme for nurses and midwives on the use of Medicine Protocol for the Administration of HPV Vaccine (Gardasil 9) through a School Immunisation Programme.**

- Basic Life Support for Health Care Workers within 2 years.
- “National Anaphylaxis Education Programme for Health Care Professionals”, initially attends a classroom based programme. Updates available on [www.hseland.ie](http://www.hseland.ie) “National Anaphylaxis Education Programme for Health Care Professionals” within 2 years.
- Injection technique education programme. (Local CNME/CNE)
- “Hand Hygiene for HSE Clinical Staff” [www.hseland.ie](http://www.hseland.ie)
- “Aseptic Non Touch Technique” (ANTT) [www.hseland.ie](http://www.hseland.ie)
- “Immunisation Foundation Programme” [www.hseland.ie](http://www.hseland.ie)
- GDPR Guidelines [www.hseland.ie](http://www.hseland.ie)
References

Health Service Executive (2019) Directions for Nurses and Midwives for the Management of a Patient who develops Anaphylaxis or Suspected Anaphylaxis incorporating Medicine Protocol for the Administration of Epinephrine (Adrenaline) injection BP 1:1000 by intramuscular injection by nurses and midwives for the management of a patient with anaphylaxis or suspected anaphylaxis. Dublin: Health Service Executive
HPV Vaccine (Gardasil9) MSD Ireland Limited Summary of Product Characteristics and Patient Information Leaflet Updated June 2015 Available at www.hpra.ie
Irish Medicines Board (Miscellaneous Provision) Act 2006 (No. 3 of 2006) (Section 10(1)(ii)). Dublin: Stationery Office.
National Immunisation Advisory Committee Immunisation Guidelines for Ireland Dublin: Royal College of Physicians Ireland (Online Update available at https://www.hse.ie/eng/health/immunisation/hcpinfo/guidelines/
Nursing and Midwifery Board of Ireland (2015) Scope of Nursing and Midwifery Practice Framework. Dublin: Nursing and Midwifery Board of Ireland available at: https://www.nmbi.ie/Standards-Guidance

Medicine Protocol for the Administration of HPV vaccine (Gardasil9) 2019
29 July 2011

Mr. Michael Shannon
Assistant National Director,
Clinical Strategy and Programme Directorate, Health Service Executive
Dr. Steeven’s Hospital
Dublin 8

Dear Mr. Shannon,

Thank you for informing An Bord Altranais of the current work undertaken by the Office of the Nursing and Midwifery Services Director in relation to the national programme for the administration of the immunisations by nurses and midwives as part of the school immunisation programmes provided by the Health Service Executive. I note your request for professional guidance from An Bord Altranais regarding the scope of practice of nurses and midwives administering vaccines under medication protocol.


The Nursing Board recognises and supports the role of the registered nurse and midwife in utilising the medication protocol for the administration of immunisations to children as part of the school immunisation programme. We note the key supports for registrants’ scope of practice in implementing these medication protocol have been incorporated in the individual content of the medication protocols in association with reference to the education and clinical supports as you have outlined in your letter.

An Bord Altranais recognise that the HSE medication protocols complement the guidance of the Nursing Board and facilitate the achievement and maintenance of professional competency and outline the accountability of the nurse/midwife asked to participate with this medication protocol.

I hope this information is of assistance to you.

Yours sincerely,
Dr. Maria Peelo
Chief Executive Officer

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1. Tetrasac vaccine, IPV Infantrix vaccine, Priorix vaccine, M-M EVAXPRO vaccine and Boostrix vaccine
**Medicine Protocol for the Administration of Tdap vaccine (Boostrix) adsorbed, reduced antigen(s) content by registered nurses and registered midwives**

This medicine protocol is a specific written instruction for the administration of Boostrix Vaccine (a low dose Tetanus, Diphtheria, and Pertussis (acellular) vaccine (adsorbed, reduced antigen(s) content) (Tdap) to students in Second Level School by registered nurses and registered midwives. This medicine protocol is valid for the 2019/2020 HSE School Immunisation Programme.

This medicine protocol enables registered nurses and midwives employed in the voluntary and statutory services of the HSE who have undertaken the required education and training programmes to administer Tdap vaccine (Boostrix) with reference to and guidance from Nursing & Midwifery Board of Ireland, National Immunisation Advisory Committee, National Immunisation Office, HSE and in accordance with the Summary of Product Characteristics for Tdap vaccine (Boostrix) as detailed by the Health Products Regulatory Authority at [www.hpra.ie](http://www.hpra.ie):

- Health Services Executive (2019) *Directions for Nurses and Midwives for the Management of a Patient who Develops Anaphylaxis or suspected anaphylaxis incorporating Medicine Protocol for the administration of Epinephrine (Adrenaline) injection BP 1:1000 by intramuscular injection for nurses and midwives for the management of anaphylaxis or suspected anaphylaxis*. Dublin: Health Service Executive available at [www.immunisation.ie](http://www.immunisation.ie)

The Nursing and Midwifery Board of Ireland defines medicine protocols as “written directions that allow for the supply and administration of a named medicinal product by a nurse or midwife in identified clinical situations. A medicine protocol involves the authorisation of the nurse/midwife to supply and administer a medicine to groups of patients in a defined situation meeting specific criteria and who may not be individually identified before presentation for treatment. An individually named prescription is not required for the supply and administration of medication when a medication protocol is in effect” (An Bord Altranais, 2007).
<table>
<thead>
<tr>
<th>Document reference number:</th>
<th><strong>ONMSD 2019 010</strong></th>
</tr>
</thead>
<tbody>
<tr>
<td><strong>ONMSD to add</strong></td>
<td></td>
</tr>
</tbody>
</table>

### 1.0 Critical Elements

**Name of Organisation where protocol applies**
Health Service Providers across the voluntary and statutory services of the Health Service Executive (HSE). This Medicine Protocol applies to:
- Registered nurses and midwives involved in the supply and administration of the Boostrix vaccine to first year students in second level school through a School Immunisation Programme.

**Date the protocol comes into effect**
September 2019

**Date for review of protocol**
May 2020

**Document prepared by:**
Office of the Nursing and Midwifery Services Director (ONMSD) HSE, in collaboration with the National Immunisation Office (NIO) at the request of Dr Kevin Kelleher, Assistant National Director Public Health, National Office for Public Health/Child Health, Strategic Planning and Transformation HSE

**Names and Signatures of the employing authority who is authorising the implementation of the protocol**

"On behalf of the authority employing professionals authorised to administer under this medicine protocol, I have read this medicine protocol and authorise its implementation"

- **Name:** Dr. Kevin Kelleher, Assistant National Director Public Health, National Office for Public Health/Child Health, Strategic Planning and Transformation HSE
  
  **Signature:** [Signature]

- **Name:** Dr Colm Henry, National Director of Clinical Strategy and Programmes, HSE
  
  **Signature:** [Signature]

- **Name:** Ms Mary Wynne, Nursing and Midwifery Services Director, HSE
  
  **Signature:** [Signature]
### 2.0 Clinical Criteria

| **Clinical Condition for use of the protocol** | The clinical condition for which this medicine protocol has been developed is for the active immunisation against and prevention of tetanus, diphtheria, and pertussis disease. Tdap (Boostrix) vaccine is given as a booster dose of tetanus, diphtheria, and pertussis vaccine to children in first year in second level school. For 2019/2020 Boostrix may also be given, to students who are outside the First year cohort group, but are still in school, who missed the Boostrix vaccine in first year due to medical reasons and whose parents/legal guardians now request Boostrix vaccine. |
| **Circumstances in which the medicine protocol applies** | The School Immunisation Programme (SIP) will be delivered annually by the Health Service Executive (HSE). The aim of the immunisation programme is to offer a booster dose of the Tdap (diphtheria, tetanus and pertussis (acellular) vaccine Boostrix, to all first year students in second level schools and age equivalent in special schools and home schooled students.) as recommended by NIAC in the Immunisation Guidelines for Ireland [https://www.hse.ie/eng/health/immunisation/hcpinfo/guidelines/](https://www.hse.ie/eng/health/immunisation/hcpinfo/guidelines/). For 2019/2020 Boostrix may also be given, to students who are outside the First year cohort group whose parents/legal guardians made contact with the vaccination team and requested that their unvaccinated child receives Boostrix vaccine and students in school outside first year (in 2019/2020) aged 16 years of age or older who request vaccination. |
| **Inclusion criteria for student/service user treatment using the medicine protocol** | Students in 1\textsuperscript{st} year of second level school and age equivalent in special schools and home schooled students. [https://www.hse.ie/eng/health/immunisation/pubinfo/schoolprog/4in1mmr/schoolguidelines.pdf](https://www.hse.ie/eng/health/immunisation/pubinfo/schoolprog/4in1mmr/schoolguidelines.pdf) For whose parents/legal guardians made contact with the vaccination team and requested that their unvaccinated child receives Boostrix vaccine and students in school outside first year (in 2019/2020) aged 16 years of age or older who request vaccination. Students with valid consent. |
| **Exclusion criteria for student/service treatment using the medicine protocol** | A known history of anaphylactic or hypersensitivity reaction to Boostrix or to any of the Boostrix vaccine constituents. Acute febrile illness: The presence of a minor infection such as a mild upper respiratory infection or low grade fever is not a contraindication to immunisation. Students with a contraindication to intramuscular injection (haematological disorder/coagulation disorder e.g. haemophilia, severe thrombocytopenia) Students who are immunocompromised either due to disease or treatment |
| Actions to be taken for those students who are excluded from the Protocol | • All students meeting exclusion criteria must be referred to the medical practitioner for an individual medical assessment.  
• Document action in clinical notes  
• Where Tdap Vaccine (Boostrix) is prescribed following medical assessment, the nurse or midwife may administer Tdap Vaccine (Boostrix) within their scope of practice.  

*Note: In determining their scope of practice, nurses and midwives must make judgements about their competency to carry out a role or activity (NMBI, 2015).*

| Description of circumstances and referral arrangements when further advice or consultation is required | Refer the student to the Medical Practitioner in the event of:  
• Adverse reaction  
• Other clinical concerns

| Documentation required to support implementation of the medicine protocol | A consent form must be completed by the parent/legal guardian for all students who receive the Boostrix vaccine. Appropriate details including the batch number must be recorded on the Consent Form.  
The following documents will be available at each school vaccination session:  
• Vaccination session report adverse form  
• Blank vaccine consent forms  
• Patient held record cards  
• Health Products Regulatory Authority Adverse Reaction Reporting forms  
• HSE Incident/near miss report forms (NIRF, 2018)  
• Tear pads for post vaccination  

It is the responsibility of each nurse or midwife to be familiar with the appropriate documentation to support the safe administration of Boostrix vaccine which includes the following:  
• Information for Staff: School Immunisation Programme 2019/2020  
• Medicine Protocol for the administration of Boostrix vaccine by registered nurses and registered midwives to students in first year in second level school and age equivalent in special schools and home schooled students through the School Immunisation Programme.  
• Directions for nurses and midwives for the management of a patient who develops anaphylaxis or suspected anaphylaxis incorporating Medication Protocol for the Administration of Epinephrine (adrenaline) Injection BP 1:1000 by intramuscular injection by nurses and midwives for the management of a patient with anaphylaxis or suspected anaphylaxis (HSE 2019), available at [https://www.hse.ie/eng/health/immunisation/hcpinfo/guidelines/Anaphylaxis.pdf](https://www.hse.ie/eng/health/immunisation/hcpinfo/guidelines/Anaphylaxis.pdf)
### 3.0 Name of Medicine

<table>
<thead>
<tr>
<th>Link to Medicine</th>
<th>Details of product information and other data including instructions for supply and administration is available from the Health Products Regulatory Authority at <a href="http://www.hpra.ie">www.hpra.ie</a></th>
</tr>
</thead>
<tbody>
<tr>
<td></td>
<td>Link to Patient Information Leaflet <a href="https://www.hpra.ie/img/uploaded/swedocuments/2177440.PA1077_020_001.c3a2a06-8246-4f8b-899b-9f40420f17dd000001pl170109.pdf">https://www.hpra.ie/img/uploaded/swedocuments/2177440.PA1077_020_001.c3a2a06-8246-4f8b-899b-9f40420f17dd000001pl170109.pdf</a></td>
</tr>
</tbody>
</table>

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

In the case of medicine errors that directly involve the student, i.e. wrong medicine/patient/dose/route being administered or another medicine error, the registered nurse or registered midwife must remain with the student and closely monitor them for any adverse reactions.

Vital signs should be recorded and the student should be reviewed by the registered nurse/midwife and/or medical practitioner.

The incident must be reported to the relevant line manager as soon as possible.


The incident and all actions taken must be promptly recorded in the student’s documentation/notes and the relevant report form completed.

The student’s parent and/or legal guardian/teacher/GP should be informed of the incident.

An incident report form must be completed by the registered nurse or registered midwife and forwarded to relevant line manager as per local policy.

Any suspected adverse reactions associated with medication errors should be reported to the HPRA as outlined below.

Any errors and near misses not involving medication, the incident and all actions taken must be promptly recorded on the relevant National Incident Management form and forwarded to the relevant line manager as per local policy.

### Procedure for reporting Adverse Drug Reactions to the Health Products Regulatory Authority (HPRA)

The relevant nursing or midwifery staff should report to the HPRA any suspected adverse reactions, in accordance with criteria outlined by the HPRA. This reporting may be carried out in line at [https://www.hpra.ie](https://www.hpra.ie) or through use of the yellow card system which is available in the downloadable format from the HPRA website or on request from the HPRA.

The incident and all actions taken must be promptly recorded in accordance with the criteria outlined by the HPRA: *Management of a Patient with Anaphylaxis: Treatment in the Community (National Immunisation Advisory Committee) (2019) – available [here](https://www.hpra.ie/).*
online at

https://www.hse.ie/eng/health/immunisation/hcpinfo/guidelines/Anaphylaxis.pdf

**Resources and equipment required**

- Vaccine (pre-filled syringe)
- Fridge/Cooler box with minimum/maximum thermometer to maintain cold chain temperature between +2° to +8°C
- Disposable kidney dishes/coloured trays
- Gauze swabs/Plasters
- Sharps bins and bags for disposal of other hazardous material
- Alcohol hand rinse
- Access to telephone
- Resuscitation equipment and drugs in accordance with the *Management of a Patient with anaphylaxis* (National Immunisation Advisory Committee, 2019) available at

https://www.hse.ie/eng/health/immunisation/hcpinfo/guidelines/Anaphylaxis.pdf

- Access to medical support
- Safe storage areas for medicines and equipment
- Current medicine protocol for Boostrix (Tdap) Vaccine.

4.0 Information for the student/parent/guardian

**Advice to be given to the student/parent/guardian before treatment**

HSE 1st year vaccination programme information booklet must have been supplied with the consent form to each student's parent or legal guardian prior to administration of the vaccine.

**After Treatment**

An Information Tear Pad, stating date and time of vaccination must be given to all students for parental/guardian’s attention. The Tear Pad includes advice about contacting relevant medical personnel in the event of adverse reaction occurring following administration of the vaccination.

The student must be advised to remain seated in the post vaccination observation area for 15 minutes to allow monitoring of any immediate reaction including possible anaphylactic reaction and must be advised to report any side effects to the registered nurse or registered midwife.

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

In the event of an adverse reaction the nurse/midwife must ensure that all procedures are adhered to as outlined in Section 3.

5.0 Staff authorised to use this medicine protocol

**Professional qualifications,** Registered nurse or registered midwife, maintained on the live register of The Nursing
<table>
<thead>
<tr>
<th>Training, experience and competence required prior to working under this medicine protocol</th>
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<tbody>
<tr>
<td>and Midwifery Board of Ireland.</td>
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</table>

Education programme for nurses and midwives on the use of *Medicine Protocol for the Administration of Tdap vaccine (Boostrix) through a School Immunisation Programme*.

- Basic Life Support for Health Care Workers within 2 years.
- "National Anaphylaxis Education Programme for Health Care Professionals", initially attends a classroom based programme. Updates available on [www.hsland.ie](http://www.hsland.ie) "National Anaphylaxis Education Programme for Health Care Professionals" within 2 years.
- Injection technique education programme (Local CNME/CNE)
- "Hand Hygiene for HSE Clinical Staff"  [www.hsland.ie](http://www.hsland.ie)
- "Aseptic Non Touch Technique (ANTT)"  [www.hsland.ie](http://www.hsland.ie)
- "Guide to Medicines Management"  [www.hsland.ie](http://www.hsland.ie)
- "Immunisation Foundation Programme"  [www.hsland.ie](http://www.hsland.ie)
- GDPR Guidelines  [www.hsland.ie](http://www.hsland.ie)
References


Health Service Executive (2019) Directions for Nurses and Midwives for the Management of a Patient who Develops Anaphylaxis or suspected anaphylaxis incorporating Medicine protocol for the Administration of Epinephrine (Adrenaline) injection BP 1:1000 by intramuscular injection by nurses and midwives for the management of a patient with anaphylaxis or suspected anaphylaxis. Dublin: Health Service Executive


Tdap Vaccine (Boostrix) GlaxoSmithKline, Ireland Limited Summary of Product Characteristics and Patient Information Leaflet, SmPC revised January 2018 Available at www.hpra.ie


Irish Medicines Board (Miscellaneous Provision) Act 2006 (No. 3 of 2006) (Section 10(1)(ii)). Dublin: Stationery Office


National Immunisation Advisory Committee Immunisation Guidelines for Ireland Dublin: Royal College of Physicians Ireland https://www.hse.ie/eng/health/immunisation/hcpiinfo/guidelines/


Medicine Protocol for the Administration of Tdap (Boostrix) (adsorbed, reduced antigen(s) content), 2019
29 July 2011

Mr. Michael Shannon
Assistant National Director,
Clinical Strategy and Programme Directorate, Health Service Executive
Dr. Steeven’s Hospital
Dublin 8

Dear Mr. Shannon,

Thank you for informing An Bord Altranais of the current work undertaken by the Office of the Nursing and Midwifery Services Director in relation to the national programme for the administration of the immunisations by nurses and midwives as part of the school immunisation programmes provided by the Health Service Executive. I note your request for professional guidance from An Bord Altranais regarding the scope of practice of nurses and midwives administering vaccines under medication protocol.


The Nursing Board recognises and supports the role of the registered nurse and midwife in utilising the medication protocol for the administration of immunisations to children as part of the school immunisation programme. We note the key supports for registrants' scope of practice in implementing these medication protocol have been incorporated in the individual content of the medication protocols in association with reference to the education and clinical supports as you have outlined in your letter.

An Bord Altranais recognise that the HSE medication protocols complement the guidance of the Nursing Board and facilitate the achievement and maintenance of professional competency and outline the accountability of the nurse/midwife asked to participate with this medication protocol.

I hope this information is of assistance to you.

Yours sincerely,

Dr. Maire Maguire
Chief Executive Officer

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1. Tetravac vaccine, IPV Infanrix vaccine, Priorix vaccine, M-MRVAXPRO vaccine and Boostrix vaccine

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18/20 Aascal Dhún Chaoin, An Charraig Dhubh, County Dublin, Ireland.
Tel: +353 1 639 8500, Fax: +353 1 639 8595.

www.nursingboard.ie

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Medicine Protocol for the Administration of Nimenrix vaccine (MenACWY) by registered nurses and registered midwives

This medicine protocol is a specific written instruction for the administration of Nimenrix (MenACWY) Vaccine to students in Second Level School by registered nurses and registered midwives. This medicine protocol is valid for the 2019/2020 HSE School Immunisation Programme.

This medicine protocol enables registered nurses and midwives employed in the voluntary and statutory services of the HSE who have undertaken the required education and training programmes to administer Nimenrix vaccine (MenACWY) with reference to and guidance from Nursing & Midwifery Board of Ireland, National Immunisation Advisory Committee, National Immunisation Office, HSE and in accordance with the Summary of Product Characteristics for Nimenrix vaccine (MenACWY) as detailed by the Health Products Regulatory Authority at www.hpra.ie:

- Health Services Executive (2019) Directions for Nurses and Midwives for the Management of a Patient who Develops Anaphylaxis or suspected anaphylaxis incorporating Medicine Protocol for the Administration of Epinephrine (Adrenaline) injection BP 1:1000 by intramuscular injection by nurses and midwives for the management of a patient with anaphylaxis or suspected anaphylaxis. Dublin: Health Service Executive
- National Immunisation Advisory Committee Immunisation Guidelines for Ireland Dublin: Royal College of Physicians of Ireland National Immunisation Advisory Committee (Online Update available at https://www.hse.ie/eng/health/immunisation/hcpinfo/guidelines/)
- Nursing and Midwifery Board of Ireland (2015) Practice Standards for Midwives. Dublin: Nursing and Midwifery Board of Ireland available at: https://www.nmbi.ie/Standards-Guidance/Midwives-Standards,
- Nursing and Midwifery Board of Ireland (2015) Scope of Nursing and Midwifery Practice Framework. Dublin: Nursing and Midwifery Board of Ireland available at: https://www.nmbi.ie/Standards-Guidance/Scope-of-Practice/Nursing-Practise-Scope-Definition

The Nursing and Midwifery Board of Ireland defines medicine protocols as “written directions that allow for the supply and administration of a named medicinal product by a nurse or midwife in identified clinical situations. A medicine protocol involves the authorisation of the nurse/midwife to supply and administer a medicine to groups of patients in a defined situation meeting specific criteria and who may not be individually identified before presentation for treatment. An individually named prescription is not required for the supply and administration of medication when a medication protocol is in effect” (An Bord Altranais, 2007).
**Medicine Protocol for the Administration of Nimenrix Vaccine (MenACWY) by registered nurses and midwives to students in second level school through a School Immunisation Programme**

|-----------------------------|--------------------------------|

### 1.0 Critical Elements

**Name of Organisation where protocol applies**

Health Service Providers across the voluntary and statutory services of the Health Service Executive (HSE). This Medicine Protocol applies to:
- Registered nurses and midwives involved in the supply and administration of the Nimenrix (MenACWY) vaccine to students in second level school through a School Immunisation Programme.

**Date the protocol comes into effect**

September 2019

**Date for review of protocol**

May 2020

**Document prepared by:**

Office of the Nursing and Midwifery Services Director (ONMSD) HSE, in collaboration with the National Immunisation Office (NIO) at the request of Dr Kevin Kelleher, Assistant National Director Public Health, National Office for Public Health/Child Health, Strategic Planning and Transformation, HSE

**Names and Signatures of the employing authority who is authorising the implementation of the protocol**

"On behalf of the authority employing professionals authorised to administer under this medicine protocol, I have read this medicine protocol and authorise its implementation"

- **Name:** Dr. Kevin Kelleher, Assistant National Director Public Health, National Office for Public Health/Child Health, Strategic Planning and Transformation, HSE
  - **Signature:** [Signature]

- **Name:** Dr Colm Henry, Chief Clinical Officer, HSE
  - **Signature:** [Signature]

- **Name:** Ms Mary Wynne, Nursing and Midwifery Services Director, HSE
  - **Signature:** [Signature]

2019
2.0 Clinical Criteria

| Clinical Condition for use of the protocol | The clinical condition for which this medicine protocol has been developed is for the active immunisation against and prevention of Meningococcal Group ACWY (Men ACWY) disease. |
| Circumstances in which the medicine protocol applies | The School Immunisation Programme (SIP) will be delivered annually by the Health Service Executive (HSE) |
| | The Nimenrix (MenACWY) vaccine is given as a vaccination for first year students in second level schools (or age equivalent) |
| | https://www.hse.ie/eng/health/immunisation/hcpinfo/guidelines/ |
| | For 2019/2020 MenACWY may also be given, to students who are outside the First year cohort group, but are still in school, who missed the Men C vaccine in first year due to medical reasons/ exceptional circumstances and whose parents/legal guardians now request MenACWY vaccine. |
| | *MenACWY vaccine should only be offered to students who commenced in 1st year since 2019/2020 |

| Inclusion criteria for students treatment using the medicine protocol | Students in 1st year of second level school and age equivalent in special schools and home schooled students |
| | See https://www.hse.ie/eng/health/immunisation/pubinfo/schoolprog/4in1mmr/schoolguidelines.pdf |
| | For 2019/2020 MenACWY may also be given, to students who are outside the First year cohort group, but are still in school, who missed the Men C vaccine in first year due to medical reasons/ exceptional circumstances and whose parents/legal guardians now request MenACWY vaccine |
| | Students with valid consent. |
| | If Men C vaccine has recently been received, defer Men ACWY vaccine until at least 2 months after Men C vaccine. |

<p>| Exclusion criteria for students when using the medicine protocol | A known history of anaphylactic or hypersensitivity reaction to Nimenrix vaccine or any of its components including Sucrose and Trometamol |
| | Already received a dose of conjugated Men ACWY vaccine at the age of 10 years or older. |
| | Acute febrile illness: The presence of a minor infection such as a mild upper respiratory infection or low grade fever is not a contraindication to immunisation. |
| | Students with a contraindication to intramuscular injection (haematological disorder/coagulation disorder e.g. haemophilia, severe thrombocytopenia). |</p>
<table>
<thead>
<tr>
<th>Actions to be taken for those who are excluded from the Protocol</th>
<th>Students who are immunocompromised either due to disease or treatment.</th>
</tr>
</thead>
<tbody>
<tr>
<td>• All students meeting exclusion criteria must be referred to the medical practitioner for an individual assessment, except where excluded due to receipt of Men ACWY vaccine at 10 years or older who therefore do not require further vaccination.</td>
<td></td>
</tr>
<tr>
<td>• Document action in clinical notes</td>
<td></td>
</tr>
<tr>
<td>• Where Nimenrix Vaccine (MenACWY) is prescribed following medical assessment, the nurse or midwife may administer Nimenrix Vaccine (MenACWY) within their scope of practice.</td>
<td></td>
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<tr>
<td><strong>Note:</strong> in determining their scope of practice, nurses and midwives must make judgements about their competency to carry out a role or activity (NMBI, 2015).</td>
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<thead>
<tr>
<th>Description of circumstances and referral arrangements when further advice or consultation is required</th>
<th>Refer the student to the Medical Practitioner in the event of:</th>
</tr>
</thead>
<tbody>
<tr>
<td>• Adverse reaction</td>
<td></td>
</tr>
<tr>
<td>• Other clinical concerns</td>
<td></td>
</tr>
</tbody>
</table>

**Documentation required to support implementation of the medicine protocol**

A consent form must be completed by the parent/legal guardian for all students who receive the vaccine. Appropriate details including the batch number must be recorded on the consent form.

The following documents will be available at each school vaccination session:

- Vaccination session forms
- Blank Vaccine consent forms
- Patient held record cards
- Health Products Regulatory Authority Adverse Reaction Reporting forms
- HSE Incident/near miss report forms (NIRF, 2018)
- Tear pads post vaccination
- It is the responsibility of each nurse or midwife to be familiar with the appropriate documentation to support the safe administration of Menjugate vaccine which includes the following:
  - Information for Staff: School Immunisation programme **2019/2020**
  - Medicine Protocol for the administration of Nimenrix vaccine (MenACWY) vaccine Directions for nurses and midwives for the management of a patient who develops anaphylaxis or suspected anaphylaxis incorporating Medication Protocol for the Administration of Epinephrine (adrenaline) Injection BP 1:1000 by intramuscular injection by nurses and midwives for the management of a patient with anaphylaxis or suspected anaphylaxis (HSE 2019), [https://www.hse.ie/en/health/immunisation/hcpinfo/fluinfo/adrenalineproto

**3.0 Name of Medicine**

<table>
<thead>
<tr>
<th>Link to Medicine Details of product information and other data including instructions for supply and administration</th>
<th>Nimenrix Vaccine (MenACWY)</th>
</tr>
</thead>
</table>

**Medicine Protocol for the Administration of Nimenrix Vaccine (MenACWY), 2019**
### Procedure for reporting and documentation of errors and near misses involving the medication

In the case of medicine errors that directly involve the student, i.e. wrong medicine/patient/dose/route being administered or another medicine error, the registered nurse or registered midwife must remain with the student and closely monitor them for any adverse reactions.

Vital signs should be recorded and the student should be reviewed by the registered nurse/midwife and medical practitioner.

The incident must be reported to the relevant line manager as soon as possible.

The incident and all actions taken must be promptly recorded in the student’s documentation/notes and the relevant report form completed.

The incident and all sections taken must be promptly recorded and the relevant National incident Management Report Form completed (National Incident Report Form (NIRF-01-V10)) (May 2018):


The student’s parent and/or legal guardian must be informed of the incident.

An incident report form must be completed by the registered nurse or registered midwife and forwarded to the relevant line manager as per local policy.

Any suspected adverse reactions associated with medication errors must be reported to the HPRA as outlined below.

Any errors and near misses not involving medication, the incident and all actions taken must be promptly recorded on the relevant National Incident Management form and forwarded to the relevant line manager as per local policy.

### Procedure for reporting Adverse Drug Reactions to the Health Products Regulatory Authority (HPRA)

The relevant nursing or midwifery staff should report to the HPRA any suspected adverse reactions, in accordance with criteria outlined by the HPRA. This reporting may be carried out in line at https://www.hpra.ie or through use of the yellow card system which is available in the downloadable format from the HPRA website, or on request from the HPRA.

The incident and all actions taken must be promptly recorded in accordance with the criteria outlined by the HPRA: Management of a Patient with Anaphylaxis: Treatment in the Community (National Immunisation Advisory Committee,2019) – available online at

https://www.hse.ie/eng/health/immunisation/hcpinfo/guidelines/Anaphylaxis.pdf

### Resources and equipment required

- **Vaccine**
- Fridge/Cooler box with minimum/maximum thermometer to maintain cold chain temperature between +2° to +8°C
- Disposable kidney dishes/coloured trays
- Gauze swabs/Plasters
<table>
<thead>
<tr>
<th>Audit process to identify appropriate use of the protocol or unexpected outcomes</th>
<th>All documentation will be held for review and audit purposes as per local policy.</th>
</tr>
</thead>
</table>

### 4.0 Information for student/parent/guardian

<table>
<thead>
<tr>
<th>Advice to be given to the student/parent/legal guardian before treatment</th>
<th>HSE 1st year vaccination programme information leaflet must have been supplied with the Consent form to each student/parent/legal guardian prior to administration of the vaccine.</th>
</tr>
</thead>
</table>
| Advice to be given to the student/parent/legal guardian after treatment | After Treatment  
An Information Tear Pad, stating date and time of vaccination must be given to all students for parental/guardian’s attention. The Tear Pad includes advice about contacting relevant medical personnel in the event of adverse reaction occurring following administration of the vaccination.  
The student must be advised to remain seated in the post vaccination observation area for 15 minutes to allow monitoring of any immediate reaction including possible anaphylactic reaction and must be advised to report any side effects to the registered nurse or registered midwife. |
| Details of any necessary follow-up, action and referral arrangements | In the event of an adverse reaction the nurse/midwife must ensure that all procedures are adhered to as outlined in Section 3. |

### 5.0 Staff authorised to use this medicine protocol

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Medicine Protocol for the Administration of Nimenrix Vaccine (MenACWY), 2019
<table>
<thead>
<tr>
<th>Professional qualifications, training, experience and competence required prior to working under this medicine protocol</th>
<th>Registered nurse or registered midwife, maintained on the live register of The Nursing and Midwifery Board of Ireland.</th>
</tr>
</thead>
<tbody>
<tr>
<td><strong>Professional Qualifications:</strong></td>
<td>Education programme for nurses and midwives on the use of <em>Medicine Protocol for the Administration of Meningococcal ACWY Vaccine (MenACWY)</em> through a School Immunisation Programme.</td>
</tr>
<tr>
<td>Training, Experience, Competence:</td>
<td>- Basic Life Support for Health Care Workers within 2 years.</td>
</tr>
<tr>
<td></td>
<td>- &quot;National Anaphylaxis Education Programme for Health Care Professionals&quot;, initially attends a classroom based programme. Updates available on <a href="http://www.hseland.ie">www.hseland.ie</a> “National Anaphylaxis Education Programme for Health Care Professionals” within 2 years.</td>
</tr>
<tr>
<td></td>
<td>• Injection technique education programme. (Local CNME/CNE)</td>
</tr>
<tr>
<td></td>
<td>• “Hand Hygiene for HSE Clinical Staff” <a href="http://www.hseland.ie">www.hseland.ie</a></td>
</tr>
<tr>
<td></td>
<td>• “Aseptic Non Touch Technique” (ANTT) <a href="http://www.hseland.ie">www.hseland.ie</a></td>
</tr>
<tr>
<td></td>
<td>• “Guide to Medicines Management” <a href="http://www.hseland.ie">www.hseland.ie</a></td>
</tr>
<tr>
<td></td>
<td>• “Immunisation Foundation Programme” <a href="http://www.hseland.ie">www.hseland.ie</a></td>
</tr>
<tr>
<td></td>
<td>• GDPR Guidelines <a href="http://www.hseland.ie">www.hseland.ie</a></td>
</tr>
</tbody>
</table>
References

Health Products Regulatory Authority available at [www.hpra.ie](http://www.hpra.ie) (accessed 27th June 2019)


Health Service Executive (2019) *Directions for Nurses and Midwives for the Management of a Patient who Develops Anaphylaxis or suspected anaphylaxis incorporating Medicine protocol for the Administration of Epinephrine (Adrenaline) injection BP 1:1000 by intramuscular injection by nurses and midwives for the management of a patient with anaphylaxis or suspected anaphylaxis*. Dublin: Health Service Executive.


Nimenrix Vaccine (MenACWY) Pfizer *Summary of Product Characteristics and Patient Information Leaflet*, Available at [www.hpra.ie](http://www.hpra.ie)


Irish Medicines Board *Miscellaneous Provision* Act 2006 (No. 3 of 2006) (Section 10(1)(ii)). Dublin: Stationery Office


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


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Medicine Protocol for the Administration of Nimenrix Vaccine (MenACWY), 2019
Nursing and Midwifery Board of Ireland (2015) Scope of Nursing and Midwifery Practice Framework. Dublin: Nursing and Midwifery Board of Ireland available at: https://www.nmbi.ie/Standards-Guidance/Scope-of-Practice/Nursing-Practise-Scope-Definition
29 July 2011

Mr. Michael Shannon
Assistant National Director,
Clinical Strategy and Programme Directorate, Health Service Executive
Dr. Steevën’s Hospital
Dublin 8

Dear Mr. Shannon,

Thank you for informing An Bord Altranais of the current work undertaken by the Office of the Nursing and Midwifery Services Director in relation to the national programme for the administration of the immunisations by nurses and midwives as part of the school immunisation programmes provided by the Health Service Executive. I note your request for professional guidance from An Bord Altranais regarding the scope of practice of nurses and midwives administering vaccines under medication protocol.

An Bord Altranais has published detailed guidance for developing medication protocols and general information about the professions’ role in vaccinations in ‘Guidance to Nurses and Midwives on Medication Management’ (2007) and the e-learning programme ‘Guide to Medication Management (An Bord Altranais and the National Council, 2007).’

The Nursing Board recognises and supports the role of the registered nurse and midwife in utilising the medication protocol for the administration of immunisations to children as part of the school immunisation programme. We note the key supports for registrants’ scope of practice in implementing these medication protocols have been incorporated in the individual content of the medication protocols in association with reference to the education and clinical supports as you have outlined in your letter.

An Bord Altranais recognise that the HSE medication protocols complement the guidance of the Nursing Board and facilitate the achievement and maintenance of professional competency and outline the accountability of the nurse/midwife asked to participate with this medication protocol.

I hope this information is of assistance to you.

Yours sincerely,

Dr. Maria O’Mahony
Chief Executive Officer

Office of Nursing Services Director
3 AUG 2011
RECEIVED
Medicine Protocol for the Administration of HPV vaccine (Gardasil 4, Type 6, 11, 16, 18) by registered nurses and registered midwives to students in Second level School through a School Immunisation Programme

This medicine protocol is a specific written instruction for the administration of Gardasil, Human Papillomavirus vaccine (Type 6, 11, 16, 18) (HPV) to girls in Second Level School who are not individually identified before presentation for treatment by registered nurses and registered midwives. **This medicine protocol is valid for the 2019/2020 HSE School Immunisation Programme.**

This medicine protocol enables registered nurses and midwives employed in the voluntary and statutory services of the HSE who have undertaken the required education and training programmes to administer HPV vaccine (Gardasil) with reference to and guidance from Nursing & Midwifery Board of Ireland, National Immunisation Group, National Immunisation Office, HSE and in accordance with the Summary of Product Characteristics for HPV vaccine (Gardasil) as detailed by the Health Products Regulatory Authority at [www.hpra.ie](http://www.hpra.ie):

- Health Services Executive (2019) *Directions for Nurses and Midwives for the Management of a Patient who Develops Anaphylaxis or suspected Anaphylaxis incorporating Medicine Protocol for the administration of Epinephrine (Adrenaline) injection BP1:1000 by intramuscular injection for nurses and midwives for the management of a patient with anaphylaxis or suspected anaphylaxis.* Dublin: Health Service Executive

The Nursing and Midwifery Board of Ireland defines medicine protocols as “written directions that allow for the supply and administration of a named medicinal product by a nurse or midwife in identified clinical situations. A medicine protocol involves the authorisation of the nurse/midwife to supply and administer a medicine to groups of patients in a defined situation meeting specific criteria and who may not be individually identified before presentation for treatment. An individually named prescription is not required for the supply and administration of medication when a medicine protocol is in effect” (An Bord Altranais, 2007).
Medicine Protocol for the Administration of HPV Vaccine (Gardasil 4, Type 6, 11, 16, 18) by registered nurses and midwives to girls in Second Level School through a School Immunisation Programme

|---------------------------|---------------------------------|

### 1.0 Critical Elements

**Name of Organisation where protocol applies**

Health Service Providers across the voluntary and statutory services of the Health Service Executive (HSE). This Medicine Protocol applies to:
- Registered nurses and midwives involved in the supply and administration of the Gardasil HPV vaccine to girls in second level schools through a School Immunisation Programme.

**Date the protocol comes into effect**

September 2019

**Date for review of protocol**

May 2020

**Document prepared by:**

Office of the Nursing and Midwifery Services Director (ONMSD) HSE, In collaboration with the National Immunisation Office (NIO) at the request of Dr Kevin Kelleher, National Office for Public Health/Child Health, Strategic Planning and Transformation, HSE

### Names and Signatures of the employing authority who is authorising the implementation of the protocol

*On behalf of the authority employing professionals authorised to administer under this medicine protocol, I have read this medicine protocol and authorise its implementation*

**Name:** Dr. Kevin Kelleher  
Assistant National Director Public Health, National Office for Public Health/Child Health, Strategic Planning and Transformation, HSE  
**Signature:** [Signature Image]

**Name:** Dr Colm Henry  
National Director of Clinical Strategy and Programmes, HSE  
**Signature:** [Signature Image]

**Name:** Ms Mary Wynne  
Nursing and Midwifery Services Director, HSE  
**Signature:** [Signature Image]
### 2.0 Clinical Criteria

| Clinical Condition for use of the protocol | The clinical condition for which this medicine protocol has been developed is for the active immunisation against and prevention of premalignant genital lesions (cervical, vulvar, and vagina) and cervical cancer related to Human Papillomavirus (HPV) types 16 and 18 and external genital warts (condyloma acuminata) causally related to HPV types 6 and 11. |
| Circumstances in which the medicine protocol applies | The School Immunisation Programme (SIP) will be delivered annually by the Health Service Executive (HSE).

For 2019/2020 Gardasil will be given to:
1. Girls in first year of second level schools and or age equivalent in special schools and home schooled who commenced the HPV vaccine schedule during the 2018/2019 school year to complete the schedule.
2. Girls in school outside first year less than 16 years of age whose parents/legal guardians request HPV vaccine.
3. Girls in school outside first year (in 2019/2020) age 16 years or older who request HPV vaccine.

The aim of the immunisation programme is to provide the HPV vaccine (Gardasil) schedule, as recommended in the Immunisation Guidelines for Ireland within the academic year.
https://www.hse.ie/eng/health/immunisation/hcpinfo/guidelines/

Girls aged under 15 years of age when they commence the programme require a second dose at least six months (183 days) later as per NIAC guidelines.

NIAC “recommends that the minimum interval between HPV1 and HPV2 is 24 weeks (168 days) and the 4 day rule applies.
This means the second dose of HPV vaccine can be considered valid if given at an interval of 168-4=164 days after the first dose”

Girls aged 15 years and older at time of first HPV vaccine require 3 doses of HPV vaccine. These girls should be given dose 1 and 2 as part of the routine school programme i.e. at 0 and 6 months and a third dose should be given at least three months and preferably four months after the second dose.

To accommodate girls aged 15 years and older at the time of their first HPV vaccine. Who are now opting into the programme for the first time the following flexible schedule may be offered as outlined below:

a) 0, 1, and 6 months (National Immunisation guidelines)

b) 1 – 2.5, third dose at 5-12 months after the 1st dose of HPV (National Immunisation guidelines)

c) 0, 1 and 4 months (HPV frequently ask questions & Patient Information Leaflet)

d) 0, 2 and 6 months (Patient Information Leaflet)

https://www.hse.ie/eng/health/immunisation/pubinfo/schoolprog/school.html

| Inclusion criteria for girl using the medicine protocol | Girls in first year of second level school or age equivalent in special schools and home schooled students (NIAC, 2014) |
| https://www.hse.ie/eng/health/immunisation/pubinfo/schoolprog/school.html |
For the 2019/2020 school year girls in school or age equivalent outside first year less than 16 years of age whose parents/legal guardians request HPV vaccine. Girls in school or age equivalent outside first year (in 2019/2020) age 16 years or older who request HPV vaccine.

Girls with valid consent.

<table>
<thead>
<tr>
<th>Exclusion criteria for girl using the medicine protocol</th>
</tr>
</thead>
<tbody>
<tr>
<td>A known history of anaphylactic or hypersensitivity reaction to Gardasil or any of vaccines constituents. Acute febrile illness: The presence of a minor infection such as a mild upper respiratory infection or low grade fever is not a contraindication to immunisation. Girls with a contraindication to intramuscular injection (haematological disorder/coagulation disorder e.g. haemophilia, severe thrombocytopenia). Pregnancy where applicable. Girls who are immunocompromised either due to disease or treatment.</td>
</tr>
</tbody>
</table>

<table>
<thead>
<tr>
<th>Actions to be taken for those girls who are excluded from the Protocol</th>
</tr>
</thead>
<tbody>
<tr>
<td>• All girls meeting exclusion criteria must be referred to the medical practitioner for an individual assessment. • Document action in clinical notes • Where HPV Vaccine (Gardasil 4, Type 6, 11, 16, 18) is prescribed following medical assessment, the nurse or midwife may administer HPV Vaccine (Gardasil 4, Type 6, 11, 16, 18) within their scope of practice. Note: In determining their scope of practice, nurses and midwives must make judgements about their competency to carry out a role or activity (NMBI, 2015).</td>
</tr>
</tbody>
</table>

<table>
<thead>
<tr>
<th>Description of circumstances and referral arrangements when further advice or consultation is required</th>
</tr>
</thead>
<tbody>
<tr>
<td>Refer the girl to the Medical Practitioner in the event of: • Adverse reaction • Other clinical concerns</td>
</tr>
</tbody>
</table>

<table>
<thead>
<tr>
<th>Documentation required to support implementation of the medicine protocol</th>
</tr>
</thead>
<tbody>
<tr>
<td>A consent form must be completed by the parent/legal guardian for all girls who receive the Gardasil vaccine. Appropriate details including the batch number must be recorded on the consent form. The following documents will be available at each school vaccination session: • Vaccination session form • Blank Vaccine consent forms • Vaccine Information Leaflets • Patient Immunisation Passport • Health Products Regulatory Authority Adverse Reaction Reporting forms • HSE Incident/near miss report forms (NIRF,2018) • Tear pads for post vaccination • It is the responsibility of each nurse or midwife to be familiar with the appropriate documentation to support the safe administration of Gardasil vaccine which includes the following: • Guidelines for Staff: School Immunisation Programme 2019/2020</td>
</tr>
</tbody>
</table>
- Current Medicine Protocol for the administration of (Gardasil 4, Type 6, 11, 16, 18) vaccine
  - 1. Girls in second level schools and age equivalent in special schools and home schooled students including, in a mop up clinic, girls in school outside first year (in 2019/2020) less than 16 years of age whose parents/legal guardians request vaccination
  - 2. Girls in school outside first year (in 2019/2020) age 16 years of age or older who request vaccination.

### 3.0 Name of Medicine

**Link to Medicine**

Details of product information and other data including instructions for supply and administration is available from the Health Products Regulatory Authority at [www.hpra.ie](http://www.hpra.ie)

**HPV Vaccine (Gardasil 4, Type 6, 11, 16, 18) 2019/2020**

**Link to Summary of Product Characteristics and Patient Information Leaflet:**


### Procedure for the reporting and documentation of errors and near misses involving the medicine

In the case of medicine errors that directly involve the girl, i.e. wrong medicine/patient/dose/route being administered or another medicine error, the registered nurse or registered midwife must remain with the girl and closely monitor her for any adverse reactions.

Vital signs should be recorded and the girl should be reviewed by the registered nurse/midwife and medical practitioner.

The incident must be reported to the relevant line manager as soon as possible.

The incident and all actions taken must be promptly recorded and the relevant National Incident Management Report Form completed (National Incident Report Form (NIRF-01-V10)) (May 2018)


The incident and all actions taken must be promptly recorded in the girl’s documentation/notes and the relevant report form completed.

The student’s parent and/or legal guardian should be informed of the incident.

An incident report form must be completed by the registered nurse or registered midwife and forwarded to the relevant line manager as per local policy.

Any suspected adverse reactions associated with medication errors should be reported to the HPRA as outlined below.
Any errors and near misses not involving medication, the incident and all actions must be promptly recorded on the National Incident Management Report and forward to the relevant line manager (as per local policy).

**Procedure for reporting Adverse Drug Reactions to the Health Products Regulatory Authority (HPRA)**

The relevant nursing or midwifery staff should report to the HPRA any suspected adverse reactions, in accordance with criteria outlined below by the HPRA. This reporting may be carried out in line at [https://www.hpra.ie](https://www.hpra.ie) or through the use of the yellow card system which is available in the downloadable format from the HPRA website, or on request from the HPRA.

The incident and all actions taken must be promptly recorded in accordance with the criteria outlined by the HPRA: *Management of a Patient with Anaphylaxis: Treatment in the Community* (National Immunisation Advisory Committee 2019) – available online at [https://www.hse.ie/eng/health/immunisation/hcpinfo/guidelines/Anaphylaxis.pdf](https://www.hse.ie/eng/health/immunisation/hcpinfo/guidelines/Anaphylaxis.pdf)

**Resources and equipment required**

- Vaccine (pre-filled syringe)
- Fridge/Cooler box with minimum/maximum thermometer to maintain cold chain temperature between +2° to +8°C
- Disposable kidney dishes/coated trays
- Gauze swabs/Plasters
- Sharps bins, and bags for disposal of other hazardous material
- Alcohol hand rinse
- Access to telephone
- Access to medical support
- Safe storage areas for medicines and equipment
- Current medicine protocol for HPV Vaccine (Gardasil4).

**Audit process to identify**
<table>
<thead>
<tr>
<th>appropriate use of the protocol or unexpected outcomes</th>
<th>All documentation will be held for review and audit purposes as per local policy.</th>
</tr>
</thead>
<tbody>
<tr>
<td><strong>4.0 Information for the girl/parent/guardian</strong></td>
<td></td>
</tr>
<tr>
<td>Advice to be given to girl/parent/guardian before treatment</td>
<td>HSE 1st year vaccination programme information leaflet must have been supplied with the consent form to each parent/legal guardian prior to administration of the vaccine.</td>
</tr>
</tbody>
</table>
| Advice to be given to the girl/parent/guardian after treatment | After Treatment
An Information Tear Pad, stating date and time of vaccination must be given to all students for parental/guardian’s attention. The Tear Pad includes advice about contacting relevant medical personnel in the event of adverse reaction occurring following administration of the vaccination. The girl must be advised to remain seated in the post vaccination observation area for 15 minutes to allow monitoring of any immediate reaction including possible anaphylactic reaction and must be advised to report any unwanted side effects to the registered nurse or registered midwife. |
| Details of any necessary follow-up, action and referral arrangements | In the event of an adverse reaction the nurse/midwife must ensure that all procedures are adhered to as outlined in Section 3. |
| **5.0 Staff authorised to use this medicine protocol** | |
| Professional qualifications, training, experience and competence required prior to working under this medicine protocol | Registered nurse or registered midwife on the live register of The Nursing and Midwifery Board of Ireland. Education programme for nurses and midwives on the use of Medicine Protocol for the Administration of HPV Vaccine (Gardasil 4) through a School Immunisation Programme. |
| Professional Qualifications, Training, Experience, Competence | • Basic Life Support for Health Care Workers within 2 years.
• “National Anaphylaxis Education Programme for Health Care Professionals”, initially attends a classroom based programme. Updates available on www.hseland.ie “National Anaphylaxis Education Programme for Health Care Professionals” within 2 years.
• Injection technique education programme. (Local CNME/CNE)
• “Hand Hygiene for HSE Clinical Staff” www.hseland.ie
• “Aseptic Non Touch Technique” (ANTT) www.hseland.ie
• “Guide to Medicines Management” www.hseland.ie
• “Immunisation Foundation Programme” www.hseland.ie
• GDPR Guidelines www.hseland.ie |
References


Health Service Executive (2019) Directions for Nurses and Midwives for the Management of a Patient who develops Anaphylaxis or suspected anaphylaxis incorporating Medicine Protocol for the Administration of Epinephrine (Adrenaline) injection BP 1:1000 by intramuscular injection by nurses and midwives for the management of a patient with anaphylaxis or suspected anaphylaxis. Dublin: Health Service Executive


HPV Vaccine (Gardasil4) MSD Ireland Limited Summary of Product Characteristics and Patient Information Leaflet Updated May 2017 Available at www.hpra.ie


Irish Medicines Board (Miscellaneous Provision) Act 2006 (No. 3 of 2006) (Section 10(1)(iii)). Dublin: Stationery Office.


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


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

Medicine Protocol for the Administration of HPV vaccine (Gardasil4) , 2019
29 July 2011

Mr. Michael Shannon
Assistant National Director,
Clinical Strategy and Programme Directorate, Health Service Executive
Dr. Steeven’s Hospital
Dublin 8

Dear Mr. Shannon,

Thank you for informing An Bord Altranais of the current work undertaken by the Office of the Nursing and Midwifery Services Director in relation to the national programme for the administration of the immunisations by nurses and midwives as part of the school immunisation programmes provided by the Health Service Executive. I note your request for professional guidance from An Bord Altranais regarding the scope of practice of nurses and midwives administering vaccines under medication protocol.

An Bord Altranais has published detailed guidance for developing medication protocols and general information about the professions’ role in vaccinations in Guidance to Nurses and Midwives on Medication Management (2007) and the e-learning programme Guide to Medication Management (An Bord Altranais and the National Council, 2007).

The Nursing Board recognises and supports the role of the registered nurse and midwife in utilising the medication protocol for the administration of immunisations to children as part of the school immunisation programme. We note the key supports for registrants’ scope of practice in implementing these medication protocol have been incorporated in the individual content of the medication protocols in association with reference to the education and clinical supports as you have outlined in your letter.

An Bord Altranais recognise that the HSE medication protocols complement the guidance of the Nursing Board and facilitate the achievement and maintenance of professional competency and outline the accountability of the nurse/midwife asked to participate with this medication protocol.

I hope this information is of assistance to you.

Yours sincerely,

Dr. Maura Pender
Chief Executive Officer

Office of Nursing Services Director
- 3 AUG 2011
RECEIVED

1 Tetrawac vaccine, IPV Infantrix vaccine, Priorix vaccine, M-M RVAXPRO vaccine and Boostrix vaccine.
Medicine Protocol for the Administration of Meningococcal Group C conjugate vaccine (Menjugate) by registered nurses and registered midwives

This medicine protocol is a specific written instruction for the administration of Menjugate Vaccine to students in Second Level School by registered nurses and registered midwives. This medicine protocol is valid for the 2019/2020 HSE School Immunisation Programme.

This medicine protocol enables registered nurses and midwives employed in the voluntary and statutory services of the HSE who have undertaken the required education and training programmes to administer Meningococcal Group C conjugate vaccine (Menjugate) with reference to and guidance from Nursing & Midwifery Board of Ireland, National Immunisation Advisory Committee, National Immunisation Office, HSE and in accordance with the Summary of Product Characteristics for Meningococcal Group C conjugate vaccine (Menjugate) as detailed by the Health Products Regulatory Authority at www.hpra.ie :

- Health Services Executive (2019) Directions for Nurses and Midwives for the Management of a Patient who Develops Anaphylaxis or suspected anaphylaxis incorporating Medicine Protocol for the Administration of Epinephrine (Adrenaline) injection BP 1:1000 by intramuscular injection by nurses and midwives for the management of a patient with anaphylaxis or suspected anaphylaxis. Dublin: Health Service Executive
- National Immunisation Advisory Committee Immunisation Guidelines for Ireland Dublin: Royal College of Physicians of Ireland National Immunisation Advisory Committee (Online Update available at https://www.hse.ie/eng/health/immunisation/hcpinfo/guidelines/
- Nursing and Midwifery Board of Ireland (2015) Scope of Nursing and Midwifery Practice Framework. Dublin: Nursing and Midwifery Board of Ireland available at: https://www.nmbi.ie/Standards-Guidance/Scope-of-Practice/Nursing-Practise-Scope-Definition

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

**ONMSD 2019 013**  
**ONMSD-2018-018**

## 1.0 Critical Elements

| **Name of Organisation where protocol applies** | Health Service Providers across the voluntary and statutory services of the Health Service Executive (HSE). This Medicine Protocol applies to:  
- Registered nurses and midwives involved in the supply and administration of the Menjugate vaccine to students in second level school through a School Immunisation Programme. |
<table>
<thead>
<tr>
<th></th>
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</tr>
</thead>
<tbody>
<tr>
<td><strong>Date the protocol comes into effect</strong></td>
<td>September 2019</td>
</tr>
<tr>
<td><strong>Date for review of protocol</strong></td>
<td>May 2020</td>
</tr>
<tr>
<td><strong>Document prepared by:</strong></td>
<td>Office of the Nursing and Midwifery Services Director (ONMSD) HSE, in collaboration with the National Immunisation Office (NIO) at the request of Dr Kevin Kelleher, Assistant National Director Public Health, National Office for Public Health/Child Health, Strategic Planning and Transformation, HSE</td>
</tr>
</tbody>
</table>
| **Names and Signatures of the employing authority who is authorising the implementation of the protocol** | Name: Dr. Kevin Kelleher, Assistant National Director Public Health, National Office for Public Health/Child Health, Strategic Planning and Transformation, HSE  
Signature:  
Name: Dr Colm Henry, Chief Clinical Officer, HSE,  
Signature:  
Name: Ms Mary Wynne, Nursing and Midwifery Services Director, HSE  
Signature: |

"On behalf of the authority employing professionals authorised to administer under this medicine protocol, I have read this medicine protocol and authorise its implementation"
### 2.0 Clinical Criteria

<table>
<thead>
<tr>
<th>Clinical Condition for use of the protocol</th>
<th>The clinical condition for which this medicine protocol has been developed is for the active immunisation against and prevention of Meningococcal Group C (Men C) disease.</th>
</tr>
</thead>
</table>
| Circumstances in which the medicine protocol applies | The School Immunisation Programme (SIP) will be delivered annually by the Health Service Executive (HSE)  
Menjugate is given as a vaccination for first year students in second level schools (or age equivalent)  
[https://www.hse.ie/eng/health/immunisation/hcpinfo/guidelines/](https://www.hse.ie/eng/health/immunisation/hcpinfo/guidelines/) |
| Inclusion criteria for students treatment using the medicine protocol | Students in 1st year of second level school and age equivalent in special schools and home schooled students  
See [https://www.hse.ie/eng/health/immunisation/pubinfo/schoolprog/4in1mmr/schoolguidelines.pdf](https://www.hse.ie/eng/health/immunisation/pubinfo/schoolprog/4in1mmr/schoolguidelines.pdf)  
For 2019/2020 Menjugate may also be given to students who are outside the First year cohort group whose parents/legal guardians made contact with the vaccination team and requested that their unvaccinated child receives Menjugate vaccine and students in school outside first year (2019/2020) age 16 years of age or older who request vaccination*.  
*Menjugate vaccine should only be given to those who have been in 1st year in second level school during or since the 2014/15 school year. |
| Exclusion criteria for students when using the medicine protocol | A known history of anaphylactic or hypersensitivity reaction to Menjugate or any of its components  
Acute febrile illness: The presence of a minor infection such as a mild upper respiratory infection or low grade fever is not a contraindication to immunisation.  
Students with a contraindication to intramuscular injection (haematological disorder/coagulation disorder e.g. haemophilia, severe thrombocytopenia).  
Students who are immunocompromised either due to disease or treatment. |
| Actions to be taken for those who are excluded from the Protocol | • All students meeting exclusion criteria must be referred to the medical practitioner for an individual assessment.  
• Document action in clinical notes  
• Where Meningococcal Group C Conjugate Vaccine (Menjugate) is prescribed following medical assessment, the nurse or midwife may administer Meningococcal Group C Conjugate Vaccine (Menjugate) within their scope of practice. |
Note: In determining their scope of practice, nurses and midwives must make judgements about their competency to carry out a role or activity (NMBI, 2015).

<table>
<thead>
<tr>
<th>Description of circumstances and referral arrangements when further advice or consultation is required</th>
<th>Refer the student to the Medical Practitioner in the event of:</th>
</tr>
</thead>
<tbody>
<tr>
<td></td>
<td>• Adverse reaction</td>
</tr>
<tr>
<td></td>
<td>• Other clinical concerns</td>
</tr>
</tbody>
</table>

**Documentation required to support implementation of the medicine protocol**

A consent form must be completed by the parent/legal guardian for all students who receive the vaccine. Appropriate details including the batch number must be recorded on the consent form.

The following documents will be available at each school vaccination session:

- Vaccination session forms
- Blank Vaccine consent forms
- Patient held record cards
- Health Products Regulatory Authority Adverse Reaction Reporting forms
- HSE Incident/near miss report forms (NIRF, 2018)
- Tear pads post vaccination
- It is the responsibility of each nurse or midwife to be familiar with the appropriate documentation to support the safe administration of Menjugate vaccine which includes the following:
  - Information for Staff: School Immunisation programme 2019/2020
  - Current Medicine Protocol for the administration of Menjugate vaccine
  - Directions for nurses and midwives for the management of a patient who develops anaphylaxis or suspected anaphylaxis incorporating Medication Protocol for the Administration of Epinephrine (adrenaline) Injection BP 1:1000 by intramuscular injection by nurses and midwives for the management of a patient with anaphylaxis or suspected anaphylaxis (HSE 2019), [https://www.hse.ie/eng/health/immunisation/hcpinfo/fluinfo/adrenalinprotocol.pdf](https://www.hse.ie/eng/health/immunisation/hcpinfo/fluinfo/adrenalinprotocol.pdf)

**3.0 Name of Medicine**

<table>
<thead>
<tr>
<th>Link to Medicine</th>
<th>Meningococcal Group C Conjugate Vaccine (Menjugate) 2019/2020</th>
</tr>
</thead>
<tbody>
<tr>
<td>Details of product information and other data including instructions for supply and administration is available from the Health Products Regulatory Authority at <a href="http://www.hpra.ie">www.hpra.ie</a></td>
<td></td>
</tr>
<tr>
<td>Link to Summary of Product Characteristics: <a href="https://www.hpra.ie/img/uploaded/swedocuments/Licence_PA0919-004-003_12042019155821.pdf">https://www.hpra.ie/img/uploaded/swedocuments/Licence_PA0919-004-003_12042019155821.pdf</a></td>
<td></td>
</tr>
</tbody>
</table>

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

In the case of medicine errors that directly involve the student, i.e. wrong medicine/patient/dose/route being administered or another medicine error, the registered nurse or registered midwife must remain with the student and closely monitor them for any adverse reactions.
Vital signs should be recorded and the student should be reviewed by the registered nurse/midwife and/or medical practitioner.

The incident must be reported to the relevant line manager as soon as possible.

The incident and all actions taken must be promptly recorded in the student’s documentation/notes and the relevant report form completed.


The student’s parent and/or legal guardian must be informed of the incident.

An incident report form must be completed by the registered nurse or registered midwife and forwarded to the relevant line manager as per local policy.

Any suspected adverse reactions associated with medication errors must be reported to the HPRA as outlined below.

Any errors and near misses not involving medication, the incident and all actions taken must be promptly recorded on the relevant National Incident Management Report form and forwarded to the relevant line manager as per local policy.

### Procedure for reporting Adverse Drug Reactions to the Health Products Regulatory Authority (HPRA)

<table>
<thead>
<tr>
<th>Procedure for reporting Adverse Drug Reactions to the Health Products Regulatory Authority (HPRA)</th>
</tr>
</thead>
<tbody>
<tr>
<td>The relevant nursing or midwifery staff should report to the HPRA any suspected adverse reactions, in accordance with criteria outlined by the HPRA. This reporting may be carried out in line at <a href="https://www.hpra.ie">https://www.hpra.ie</a> or through use of the yellow card system which is available in the downloadable format from the HPRA website, or on request from the HPRA.</td>
</tr>
<tr>
<td>The incident and all actions taken must be promptly recorded in accordance with the criteria outlined by the HPRA: Management of a Patient with Anaphylaxis: Treatment in the Community (National Immunisation Advisory Committee, 2019) – available online at <a href="https://www.hse.ie/eng/health/immunisation/hcpinfo/guidelines/Anaphylaxis.pdf">https://www.hse.ie/eng/health/immunisation/hcpinfo/guidelines/Anaphylaxis.pdf</a></td>
</tr>
</tbody>
</table>

### Resources and equipment required

- Vaccine (pre-filled syringe)
- Fridge/Cooler box with minimum/maximum thermometer to maintain cold chain temperature between +2° to +8°C
- Disposable kidney dishes/coloured trays
- Gauze swabs/Plasters
- Sharps bins and bags for disposal of other hazardous material
- Alcohol hand rinse
- Access to telephone
- Access to medical support
- Safe storage areas for medicines and equipment
- Current medicine protocol for Meningococcal Group C Conjugate Vaccine (Menjugate).
| Audit process to identify appropriate use of the protocol or unexpected outcomes | All documentation will be held for review and audit purposes as per local policy. |

### 4.0 Information for student/parent/guardian

**Advice to be given to the student/parent/legal guardian before treatment**

| HSE 1st year vaccination programme information leaflet must have been supplied with the Consent form to each student/parent/legal guardian prior to administration of the vaccine. |

**After Treatment**

An Information Tear Pad, stating date and time of vaccination must be given to all students for parental/guardian’s attention. The Tear Pad includes advice about contacting relevant medical personnel in the event of adverse reaction occurring following administration of the vaccination.

The student must be advised to remain seated in the post vaccination observation area for 15 minutes to allow monitoring of any immediate reaction including possible anaphylactic reaction and must be advised to report any side effects to the registered nurse or registered midwife.

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

In the event of an adverse reaction the nurse/midwife must ensure that all procedures are adhered to as outlined in Section 3.

### 5.0 Staff authorised to use this medicine protocol

**Professional qualifications, training, experience and competence required prior to working under this medicine protocol**

Registered nurse or registered midwife, maintained on the live register of The Nursing and Midwifery Board of Ireland.

Education programme for nurses and midwives on the use of Medicine Protocol for the Administration of Menjugate Group C Conjugate Vaccine (Menjugate) through a School Immunisation Programme.

- Basic Life Support for Health Care Workers within 2 years.
- “National Anaphylaxis Education Programme for Health Care Professionals”, initially attends a classroom based programme. Updates available on [www.hsland.ie](http://www.hsland.ie) “National Anaphylaxis Education Programme for Health Care Professionals” within 2 years.
- Injection technique education programme. (Local CNME/CNE)
- “Hand Hygiene for HSE Clinical Staff” [www.hsland.ie](http://www.hsland.ie)
- “Aseptic Non Touch Technique” (ANTT) [www.hsland.ie](http://www.hsland.ie)
- “Guide to Medicines Management” [www.hsland.ie](http://www.hsland.ie)
- “Immunisation Foundation Programme” [www.hsland.ie](http://www.hsland.ie)
- GDPR Guidelines [www.hsland.ie](http://www.hsland.ie)
References

Health Products Regulatory Authority available at www.hpra.ie (accessed 28th June 2019)


Health Service Executive (2019) Directions for Nurses and Midwives for the Management of a Patient who Develops Anaphylaxis or suspected anaphylaxis incorporating Medicine protocol for the Administration of Epinephrine (Adrenaline) Injection BP 1:1000 by intramuscular injection by nurses and midwives for the management of a patient with anaphylaxis or suspected anaphylaxis. Dublin: Health Service Executive


Meningococcal Group C Conjugate Vaccine (Menjugate) GlaxoSmithKline Summary of Product Characteristics and Patient Information Leaflet, updated January 2018. Available at www.hpra.ie


Irish Medicines Board (Miscellaneous Provision) Act 2006 (No. 3 of 2006) (Section 10(1(ii)). Dublin: Stationery Office


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


Medicine Protocol for the Administration of Meningococcal Group C Conjugate Vaccine (Menjugate), 2019
29 July 2011

Mr. Michael Shannon  
Assistant National Director,  
Clinical Strategy and Programme Directorate, Health Service Executive  
Dr. Steevens’ Hospital  
Dublin 8

Dear Mr. Shannon,

Thank you for informing An Bord Altranais of the current work undertaken by the Office of the Nursing and Midwifery Services Director in relation to the national programme for the administration of the immunisations by nurses and midwives as part of the school immunisation programmes provided by the Health Service Executive. I note your request for professional guidance from An Bord Altranais regarding the scope of practice of nurses and midwives administering vaccines under medication protocol.


The Nursing Board recognises and supports the role of the registered nurse and midwife in utilising the medication protocol for the administration of vaccinations to children as part of the school immunisation programme. We note the key supports for registrants’ scope of practice in implementing these medication protocol have been incorporated in the individual content of the medication protocols in association with reference to the education and clinical supports as you have outlined in your letter.

An Bord Altranais recognise that the HSE medication protocols¹ complement the guidance of the Nursing Board and facilitate the achievement and maintenance of professional competency and outline the accountability of the nurse/midwife asked to participate with this medication protocol.

I hope this information is of assistance to you.

Yours sincerely,  
Dr Maria Nolan  
Chief Executive Officer

¹ Tetravac vaccine, IPV Infantrix vaccine, Priorix vaccine, M-M EVAXPRO vaccine and Boostrix vaccine

Office of Nursing Services Director  
-3 AUG 2011  
RECEIVED
APPENDIX D: Vaccination Consent Forms

APPENDIX E: Post Vaccination Tear Pads

APPENDIX F: Session Report Forms
APPENDIX G: Tips for Conducting a School Vaccination Session to Reduce the Incidence of Syncope

Adapted from the Immunisation Programme in Victoria, Australia*

Post-vaccination fainting has been reported with most vaccines. Based on data from the USA, syncope is most common after three adolescent vaccines HPV, quadrivalent meningococcal vaccine and Tdap. It is not known whether this is due to the vaccines or if the increased incidence in this age group merely reflects that adolescents are generally more likely to experience fainting. The onset of syncope is usually immediate. A review of syncope after vaccination found that 89% occurred within 15 minutes of vaccination.

*Experience from Australia suggests that the organisation of clinics can be a key factor in reducing the number of fainting episodes.

- Organise sessions to be run in a venue that allows privacy for each student being vaccinated so that other students are not watching the procedure prior to their vaccine being administered.
- Have a separate entry and exit point so students arriving for vaccination do not cross paths with students leaving after vaccination. Students should be brought in small groups (less than 10 students) to the area where vaccination is occurring.
- Arrange for students to be seated or lying down when being administered their vaccines in case of an immediate faint.
- Provide a nearby area for adolescents to wait following the vaccination. This area needs to be readily accessible to immunisation staff in the event of a faint or other immediate adverse event.
- Supervision may be required to ensure students remain seated while waiting the 15 minutes after being vaccinated in case of fainting.
- The vaccination area should be free of staircases and concrete as these areas can contribute to injury following a fainting episode.
- It is important for a person familiar to each class to be present at the venue in order to assist with identification of students, control their behaviour and create a calm environment.
- Ensure the vaccine session is run with only one class present at a time to minimise the sense of mass anxiety that a few students can engender in other vulnerable students.
- Following vaccination, students are required to wait a minimum of 15 minutes in a nearby location; however, this time should be longer if a student is feeling dizzy or unwell after vaccination.
- Following vaccination, adolescents should refrain from strenuous activity for up to 30 minutes in case of a delayed fainting episode.
Management of Syncope:

- Patient should be placed in the recumbent position and observed until they are fully recovered.
- Recovery of consciousness occurs within a minute or two, but patients may take some more time to recover fully.
- Fainting is sometimes accompanied by brief clonic seizure activity (i.e. rhythmic jerking of the limbs, but this requires no specific treatment or investigation.


APPENDIX H: Adverse event clinical record


APPENDIX I: HPRA Adverse Event Report Form

APPENDIX J: Emergency drugs and Equipment

Emergency Anaphylaxis Kit –as per updated section February 2019 in Immunisation Guidelines

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

- Copy of “Anaphylaxis: Treatment in the Community” from Immunisations Guidelines for Ireland
- 3 x 1ml ampoules of Epinephrine (1:1,000, 1mg/ml)
- or
- 6 x Epinephrine auto-injectors, 150 mcg, 300 mcg and/or 3 x 500 mcg* (depending on age of vaccinees)
- 3 x 1 ml syringes
- Needles 3 x 16mm, 3 x 25mm, 3 x 37 – 40mm
- 1 pocket mask
- Sphygmomanometer (optional)
- Stethoscope (optional)
- Pen and paper to record time of administration of Epinephrine

*Ensure that 500mcg auto-injectors have 25mm needles

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

1. Access to a telephone to call an ambulance.
2. Copy of “Anaphylaxis: Treatment in the Community” from Immunisation Guidelines for Ireland.
3. Adverse event clinical record (Appendix H of Supporting Information for Staff) and pen to record time of administration of epinephrine/adrenaline and clinical condition of patient.
4. Headed notepaper to write referral letter for hospital.
5. Sphygmomanometer x 1 with adult and paediatric cuff.
APPENDIX K: Maintenance of Cool Box Temperature

Vaccines should be stored in the vaccine fridges at the main health centres in accordance with the local Vaccine Fridge Standard Operating Procedure (SOP).

Validated cool boxes should be used from a recognised medical supply company and should be used in conjunction with a validated thermometer or data logger device with an external display. Domestic cool boxes should not be used.

Cool box temperature should be maintained between +2°C and +8°C at all times.

- Ice packs should be wrapped completely unless they have their own cover that encloses them completely this is to prevent the ice pack coming in direct contact with vaccine.
- Frozen ice packs should be placed in the cool box for a minimum of 15 minutes before the vaccines are packed into the cool box.
- The number of packs used should be as per cool box manufacturer’s instruction/best practice recommendations.
- The ice packs should be positioned appropriately above, below and around the vaccines as space in the cool box allows.
- The temperature probe should be placed between vaccine boxes in the middle of the cool box.
- 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.
- It may be necessary to add/remove ice packs as the temperature dictates.
- Only the number of vaccines estimated for administration on any particular day should be brought to the school.
- The vaccines must be transported in their original packaging, and placed in the cool box as per the manufacturer’s instructions.
- The time of packing and returning the vaccines should be recorded.
- The cool box should be placed in,
  - An appropriately ventilated room
  - Away from any heat source
  - Away from direct sunlight
- Record the temperature of the probe in the cool box:
  - Before leaving the health centre
  - At the beginning of the vaccination session
  - At the end of the vaccination session
  - On returning the vaccines to the fridge
- Vaccines, in their original packaging that have been maintained under cold chain conditions, and are returned to the health centre fridge following school vaccination session should be marked and
used first on their next excursion to a school.

- If these marked vaccines are taken to a second vaccination session and are not used providing the cold chain has been maintained these vaccines can be returned to the vaccine fridge again, for administration at the next session.

- If a temperature deviation has occurred, contact the Chief Pharmacist or the Medical Officer of the National Immunisation Office (at 087 9915452 or 01 8676108) for further advice. The National Immunisation Office will carry out a risk assessment and will advise on a case by case basis whether it is appropriate to use the vaccines later or whether they should be discarded.

- A battery powered continuous temperature recording device (data logger) may be used in cool boxes where vaccines are stored. This should be removed from the vaccine fridge with the vaccines and placed in the middle of the cool box adjacent to the vaccines. This is an independent device and gives an accurate account of the 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 temperature. This does not replace max/min thermometers which need to be checked when removing vaccines prior to administration.

- The cool box thermometer should be sent back to the manufacturer for calibration on an annual basis.

**Procedures following breakdown in the “Cold Chain”**

Check position of temperature probe. The temperature probe should be placed into a vaccine box in the middle of the vaccines. Reset probe and ensure it is positioned correctly away from ice packs. Close box firmly and recheck temperature in 10 minutes.

If temperatures outside the permitted range are recorded the Chief Pharmacist or Medical Officer of the National Immunisation Office should be contacted (Phone 087 9915452 or 01 8676108) for further advice. The National Immunisation Office 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 the vaccines until notified by the National Immunisation Office.

For any other queries with respect to vaccine storage, cold chain, etc. contact the Chief Pharmacist at the NIO on the numbers above.
APPENDIX L: 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:

- Department of Health available at [www.health.gov.ie](http://www.health.gov.ie)
- Health Protection Surveillance Centre available at [http://www.hpsc.ie](http://www.hpsc.ie)
- Health Products Regulatory Authority available at [http://www.HPRA.ie](http://www.HPRA.ie)
- Medicines Information online available at [http://www.medicines.ie](http://www.medicines.ie)
- Centre for Disease Control and Prevention – immunisation information available at [http://www.cdc.gov/vaccines/](http://www.cdc.gov/vaccines/)
- United Kingdom immunisation website available at [https://www.gov.uk/government/collections/immunisation](https://www.gov.uk/government/collections/immunisation)
- Further information on cervical cancer and cervical cancer screening can be found on the following websites:
  - National Cancer Screening Service available at [http://www.cancerscreening.ie](http://www.cancerscreening.ie)
  - National Cancer Registry Ireland available at [http://ncri.ie](http://ncri.ie)