



Supporting Information for Staff

School Immunisation Programme

2020-2021 academic year



Version 10.G

Revised September 2020

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| Supporting information for Staff: Schools Immunisation Programme 2020/2021 | | Document developed by: | NIO |
| Revision number | Version 10.G | Document approved by: | NIO |
| Approval date: | Ekim 2020 | Responsibility for dissemination: | All staff in Schools Immunisation Programme |
| Revision date | August 2021 | Responsibility for review | NIO |

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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 DTaP/IPV vaccine.

First year of second level school

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

The programme aims to vaccinate on an annual basis;

- All four to five year olds with MMR and DTaP/IPV vaccines by targeting students in junior infants of primary schools for the 2020/2021 academic year and age equivalent in special schools (i.e. born between 01/09/2015 and 31/08/2016) or aged 6 years and home schooled (i.e. born between 01/09/2014 and 31/08/2015).
- All 12 to 13 year olds with Tdap, MenACWY and HPV9 vaccines by targeting students in first year in second level schools for the 2020/2021 academic year and age equivalent students born between 01/09/2007 and 31/08/2008 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.

All information packs 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.

School Immunisation Schedule and Target Cohort

The programme will be delivered in primary, second level and special schools. The target uptake for the DTaP/IPV, MMR2, MenACWY and Tdap vaccines 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 DTaP/IPV vaccines to children aged four and five years.

Primary Schools

MMR and DTaP/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 DTaP/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 there is a valid consent form from parents, 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.
- Children born between 01/05/2015 and 01/05/2016 have been pre-registered on SIS at a generic school ready to be updated with the school they are attending. Included in their stage status record is the evidence from the regional system of a previous MMR vaccination and the medical record number in that system. This record can assist areas to verify if the child has previously received an MMR vaccine. Those pre-registered from

last year who were not in junior infants last year will still appear in the SIS system this year.

Second Level Schools

All second level schools now require 2 visits

- **HPV9 and Tdap**
- **HPV9 and MenACWY**

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

Catch up vaccinations for those who missed vaccines due to COVID 19 school closures in 2019-2020

Due to COVID-19, schools closed in March 2020 and so routine school based immunisation programmes ceased. Each CHO area put on catch-up clinics over the summer to offer vaccines for those who were eligible but had not yet been vaccinated in school before they closed. Although the majority of children were vaccinated, some may not have been able to attend the summer clinics.

School teams should offer an opportunity to be vaccinated to all those in academic year 2020/2021 in senior infants at primary school and second year of second level school who were due immunisations last academic year but were not able to be vaccinated due to school closures. Ideally these vaccines should be offered in school when the teams visit to immunise the routine cohort of children.

Those in senior infants in 2020/2021, should be offered Tdap/IPV while stocks are available to order, otherwise DTap/IPV can be offered.

Additional Information resources:

- Immunisation Guidelines for Ireland are available at <http://bit.ly/NIACGuideline>
- Immunisation training slides for Health Professionals 2020, available at <http://bit.ly/NIPConf>
- Summary of Product Characteristics (SmPCs) for each of the vaccines available at www.hpra.ie and also available under the relevant schools vaccination programme at <http://bit.ly/SchPHCP>
- Medicine Protocols for each of the vaccines in the schools immunisation programme are available under the relevant schools vaccination programme at <http://bit.ly/SchMedPros>
- Healthcare professionals FAQs are available 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 "Anaphylactic Reactions: Treatment in the Community" protocol, in the Immunisation Guidelines for Ireland available at <http://bit.ly/NIACGuideline>
- 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 available from <http://bit.ly/SchMedPros>
- HSE Communicating Clearly guidelines: <http://bit.ly/CommClear>
- HPV E-Learning Programme available on HSE Land www.hseland.ie

Useful Information before, during and after the session

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

Consent

- The Guide to Professional Conduct & Ethics for Registered Medical Practitioners, 8th Edition, 2019 (Medical Council) states in section 11.1 that:
 - “(You must) give patients enough information, in a way that they can understand, to enable them to exercise their right to make informed decisions about their care.
 - Consent is not valid if the patient has not been given enough information to make a decision” See <http://bit.ly/MC8thEd>
- Informed consent must be obtained prior to vaccination.
- 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/legal guardian. Students aged 16 years and older can consent on their own behalf.
- In the case of the HPV vaccine, consent is given 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.
- Under current Irish law, the mother is given automatic parental responsibility for the child. The father is also given parental responsibility if he is married to the mother at the time of the child’s birth or if they marry after the birth of the child or if both adults adopt the child together. However, if a child is born outside marriage the mother is given automatic responsibility for all decisions relating to the child.
- The child’s father is an automatic legal guardian if he has lived with the child’s mother for 12 consecutive months including at least 3 months with the mother and child following the child’s birth. This provision is not retrospective, so guardianship will only be acquired automatically where the parents live together for at least 12 months after 18 January 2016.
- Under certain circumstances legal guardianship of the child may be changed e.g. an unmarried father can become a joint guardian if both parents sign a statutory

declaration, if one parent dies the remaining parent will automatically assume sole legal guardianship of the child or another legal guardian can also be appointed by the court.

- Those 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.
- There is no maximum duration for consent. Consent remains valid for an indefinite period unless
 - It is withdrawn
 - There has been a change in the client's capacity to give consent
 - There has been a change to the proposed vaccine schedule to which the client has not given consent
- If a parent/legal guardian contacts the local health office to withdraw consent they should speak to the staff member, ideally a clinical staff member looking after the vaccine programme. The information provided should be recorded by the recipient on the consent form by drawing a double line through the vaccine administration details section with the words 'refused dose' with the date and time and name and PIN/staff number of the person taking the information down.
- HSE consent policy is here: <http://bit.ly/ConsentQID>

When vaccination is delayed or refused

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

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

Students older than first year of second level school (2020-2021)

Those students in second year of second level school in 2020-21 and who missed vaccines due to school closures and could not attend the summer mop-up clinics, should be offered an opportunity to be vaccinated in 2020-21

HPV9, Men ACWY and Tdap programme – For students not affected by the COVID-19 school closures, only those who miss these vaccines in first year for medical or other exceptional circumstances can be offered these in mop-up clinics in later years.

Girls who started but have not completed the girls only HPV programme may complete the course. Gardasil4 vaccine must be used for this while it is available to order from NCCS.

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

Assessment of the student for vaccination

Before assessing the suitability of a student for vaccination:

- Confirm student's identity (Confirm name, address, date of birth and parent or legal guardian's name by asking: "What is your full name? When is your Birthday? Where do you live? Who signed the consent form? What is their name?" For younger children it may be necessary to confirm identity with the child's teacher or an appropriate liaison person (as agreed with the School Principal) from the school.
- Confirm that informed consent has been given by a parent/legal guardian/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:

"Giving a dose ≤ 4 days before the minimum age or interval (the four-day rule) is unlikely to have a significant adverse effect on the immune response to that dose and does not need to be repeated.

If a vaccine is given >4 days before the recommended minimum age or interval, it is not a valid dose. The dose should be disregarded and another dose given, at least 1 month after the disregarded dose" 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 "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." see

<http://bit.ly/NIACCh10>

- If a dose of HPV vaccine 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 or nurse prescriber 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 if possible, they should be kept in their original packaging until they are to be used. If they are removed from their original packaging each vaccine should be kept in a separate colour coded container.
- When 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. It is also easier to enter this information uniformly into the electronic record.
 - Junior infants should be given MMR vaccine in the right deltoid and DTaP/IPV vaccine in the left deltoid.
 - Second level students should be given
 - a dose of HPV9 vaccine in the left deltoid and Tdap in the right deltoid.
 - a dose of HPV9 vaccine in the left deltoid and MenACWY 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 procedure should be followed:

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

Vaccine storage and handling

- All vaccines must be stored and transported between +2°C and +8°C.
- The SmPCs for all vaccines in the school immunisation programme recommend that they should be stored in the original package to protect from light.
 - Any vaccine that has been removed from its packaging and is not used in a timely manner within the session should not be returned to the cool box but should be discarded safely into a sharps bin. The sharps bin should be securely sealed when three quarters full or filled to the manufacturer’s fill line.
 - 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.
 - The Nimenrix SmPC states that both the solvent and the reconstituted Nimenrix vaccine are clear colourless liquids. Therefore it may be easy to confuse the solvent and the reconstituted vaccine if multiple vaccines have been prepared. The SmPC also states reconstituted Nimenrix should be used promptly. It is not appropriate to return reconstituted Nimenrix vaccine to the cold box.
 - Once DTaP/IPV, 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. All prefilled vaccine syringes which have been removed from their packaging should not be returned to the cool box.
- 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.

Maintenance of the Cold Chain

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

- See *Appendix B* for additional information about maintaining the cold chain
- Record the current temperature of the probe in the cool box:
 - when vaccines are packed
 - upon arrival at the immunisation clinic
 - throughout the immunisation clinic
 - when returning 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. The vaccines should be marked differently to differentiate them from vaccines which were returned after the previous vaccination session and from 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 Pharmacists or Senior Medical Officer in the National Immunisation Office at 087 9915452, 087 4064810 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.

Do not use or dispose of any vaccine which has been exposed to temperatures outside the permitted range. Quarantine and maintain these vaccines between +2oC and +8oC until advised by the National Immunisation Office.

HSE Vaccination Record Forms (Consent Forms)

- Once the parent completes their part of the Consent Form, and the HSE staff introduce clinical content to the form, it should be considered as a clinical record and treated accordingly.
- Information on the vaccination forms must be put into SIS as soon as possible or within 30 days of vaccination offer. This includes vaccination attendance and non-attendance records.
- Where a second vaccination is required to complete the schedule, the first vaccine record 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 (or all three vaccines if receiving three doses of HPV).
- Vaccination forms for students who have been vaccinated but require further doses to complete a course should be filed for easy retrieval the next school clinic.
- Vaccination forms for students whose vaccination is deferred or who are absent on the day should be filed for easy retrieval for the next mop-up clinic.
- Students who fail to return a completed consent form should also be offered an appointment at a mop up clinic if they have been identified from another route e.g. regional systems.
- Vaccination form movements (individual forms or groups of forms) should be traced in and out of the records store. The trace should show who has signed out forms.
- When students have completed the vaccination course their vaccination forms should be filed in accordance with the Policy for Health Boards on Record Retention Periods, 1999 available at <http://bit.ly/RetRec>
- All clinical notes on events around vaccination should be stored as part of the vaccination record either in the system or on the vaccination form. Ensure that all written information recorded is in black ink, in block capitals and is clear and legible.

Clinical Staff Roles

- If the parent/legal guardian requests further clinical advice about the vaccine they can be referred to a clinical member of the vaccination team.
- If a parent consents but the student refuses vaccination on the day of the session, the student should not be vaccinated. This must be recorded on the consent form and on SIS.
- If a parent refuses but the student expresses a desire to be vaccinated on the day of the session, the student may be vaccinated if they are aged 16 years and over. If the student is less than 16 years of age they cannot be vaccinated.
- If vaccines are refused, the date of refusal and PIN of the person writing the refusal should be added to the form and entered onto SIS. Please record a reason if stated.
- Where parents/legal guardians have refused consent for vaccination, the reason for refusal should be reviewed by a clinical member of the vaccination team. If there is a clear refusal, parents/legal guardians should not be contacted.
- Where a consent form is returned and a parent/legal guardian has left the consent blank or only filled in the Yes/No sections, a clinical member of the team should phone the parent/legal guardian to seek clarification about their consent. The date and time of the phone call should be recorded on the consent form and the clinician's PIN, consent or refusal witnessed by two members of staff.

Interrupted immunisation schedule

NIAC guidelines recommend:

“If an immunisation course is interrupted, it should be resumed as soon as possible. It is not necessary to repeat the course, regardless of the time interval from the previous incomplete course. The course should be completed with the same brand of vaccine if possible.” see <http://bit.ly/NIACCh2>

Incomplete immunisation history

Where children are identified as having had incomplete or no previous immunisations, the standard vaccine schedule should be given during the vaccination session. Arrangements should be made to ensure completion of vaccination schedule in line with the guidance from “catch up immunisation schedule” available at <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.

For MMR: Significantly immunocompromised persons, such as those with untreated malignant disease and immunodeficiency states other than HIV infection, and those receiving immunosuppressive therapy, high-dose x-ray therapy and current high-dose systemic corticosteroids. Please refer to the detailed guidance in Chapter 3 on Immunisation of Immunocompromised Persons in Immunisation Guidelines <http://bit.ly/NIACGuidelines>

- Pregnancy and vaccines

The only vaccines used in the schools programme where pregnancy is a contraindication are HPV and MMR vaccines

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 consent form for students in first year of second level schools includes the statement “I understand that HPV is not recommended in pregnancy” (*Appendix C*). If the 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.

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.
 - There is no recommendation on the subcutaneous administration of the DTaP/IPV, Tdap, MenACWY or HPV9 vaccines.
- **Immunosuppression:** The immune response of individuals who are immunocompromised may be inadequate.
 - In the case of MMR vaccine for those who have immune deficiency or immunosuppression please refer to the detailed guidance in Chapter 3 on

Immunisation of Immunocompromised Persons in Immunisation Guidelines

<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>

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

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

Information on specific vaccines

All pertussis containing vaccines

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

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

Junior Infants

DTaP/IPV

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

- If a 4th dose of diphtheria, pertussis, polio and tetanus containing vaccine has been given at age ≥ 3 years and 4 months, a 5th dose of diphtheria, pertussis, and tetanus containing vaccine is not required until age 12-13 years.

A 5th dose of polio vaccine (as Tdap/IPV) is only recommended if a child, aged 10 years and over, is travelling to polio endemic or epidemic area.

MMR

- MMR is contraindicated in persons who are significantly immunocompromised due to disease or treatment.
- MMR is a live vaccine and must not be administered within four weeks of varicella or yellow fever live vaccines. MMR can be given on the same day or at any interval before or after any other live vaccine, including the Live Attenuated Influenza Vaccine (LAIV/Fluenz).
- 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>)
- 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.
- NIAC guidelines have recently been update to say that any child who has received two doses of MMR vaccine over the age of 12 months and at least one month apart are up to date with their immunisations and do not require another dose in junior infants.

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.

MenACWY

- Those who have had a dose of Men ACWY conjugate vaccine at the age of 10 years or older do not require a further dose of vaccine. If they have received the polysaccharide

Men ACWY vaccine, they should receive the conjugate vaccine in the schools programme

- For anyone who has received a dose of Men C vaccine (e.g. as part of an outbreak response) an interval of at least two months should be left before Men ACWY vaccine is given.
- Parents or students do not need to be questioned about prior Men C or Men ACWY vaccines, but the above information on intervals should be used if a parent has indicated that the student has recently received a meningococcal C or ACWY vaccine.

When there are doubts about giving a vaccine 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. 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. Children who develop reactions in the days after vaccination do not need to be seen by the Medical Officer unless in exceptional circumstances. There is no evidence to date that any of the vaccines used in the school immunisation programme cause long-term adverse events.

General side effects

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

- A local reaction at the injection site which can consist of redness, swelling, pain and increased skin temperature is the most common side effect.
- Systemic symptoms, e.g. fever and malaise.
- Syncope can occur after vaccination, especially in adolescents. See *Appendix D*
- Anaphylaxis is an extremely rare event (about one event/million doses) that could occur with the administration of any vaccine. Detailed advice on the management of

anaphylaxis is contained in the 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.

DTaP/IPV and Tdap specific side effects

- Booster doses of tetanus, diphtheria and pertussis containing vaccines can result in an increase in local reactogenicity and fever compared to the primary course i.e. extensive swelling of vaccinated limb (sometimes involving the adjacent joint);
- In general these reactions begin within 48 hours of vaccination and resolve spontaneously over an average of 4 days without sequelae.
- Such reactions do not contraindicate further doses of diphtheria, tetanus, or pertussis containing vaccines however after such a reaction, further routine or emergency booster doses of tetanus or diphtheria containing vaccines should not be given more frequently than every 10 years
- Antibiotic treatment or the use of anti-inflammatory medication does not reduce the duration or severity of such reactions.
- Parents of children who receive the booster dose of a DTaP/IPV containing vaccine should be informed of the risk of extensive swelling, highlighting that this is not usually associated with significant pain or limitation of movement.

MMR specific side effects

- 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.

Reporting of adverse reactions

The medical officers/vaccinators should report relevant suspected adverse reactions to the HPRA. Details of adverse events may be recorded on the adverse event clinical record (*Appendix E*). When reporting suspected adverse reactions to the HPRA, details of the brand name and batch number of the vaccine should be included in the report. An adverse reaction report form can be accessed by:

- Following the links to the online reporting options accessible from the HPRA website at <http://bit.ly/HPRAar>
- Using a downloadable report form also accessible from HPRA website, which may be completed manually and submitted to the HPRA via “freepost” available from the HPRA website <http://bit.ly/HPRAIssue>
- 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.
- By telephoning the HPRA Pharmacovigilance Section 01-6764971.

Incident reporting

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

If there is a vaccine administration error, e.g. an incorrect vaccine is administered to one or more students, the National Immunisation Office must also be informed. Such an error must be reported to the relevant line manager. The incident and all actions taken must be recorded and the relevant National Incident Management Report Form completed (National Incident Report Form - NIRF-- 01-V 11 March 2020)

<https://www.hse.ie/eng/about/qavd/incident-management/nirf-01-v11-person.pdf>

References

- Children First 2011 – National Guidance for the Protection and Welfare of Children.
<https://www.dcy.gov.ie/docs/EN/Children-First-Guidance/2759.htm>
- Guidance for providers of health and social care services Communicating in plain English HIQA and NALA 2015 www.hiqa.ie
- Healthcare professionals FAQ National Immunisation Office <http://bit.ly/FAQImm>
- Healthcare risk waste management segregation packaging and storage guidelines for healthcare risk waste 4th edition 2010 <http://bit.ly/HCRiskW>
- HSE Guidelines for maintaining the vaccine cold-chain including maintenance of vaccine fridges and management of vaccine stock <http://bit.ly/SOP01>
- HSE Guidelines for maintaining the vaccine cold-chain in vaccine cool boxes.
<http://bit.ly/SOPNIO02>
- Immunisation Guidelines for Ireland. National Immunisation Advisory Committee
<http://bit.ly/NIACGuidelines>
- Immunisation training slides for Health Professionals 2020 <http://bit.ly/NIPConf>
- Policy for Health Boards on Record Retention Periods including outline of issues in records management / National Freedom of Information Liaison Group 1999,
<http://bit.ly/RetRec>
- Patient Information Leaflet (PIL) for the vaccines used in the Schools Immunisation Programme
 - Tetravac PIL <https://bit.ly/TetravacPIL>
 - Priorix PIL <http://bit.ly/PriorixPIL>
 - MMRVaxPro PIL <https://bit.ly/MMRVaxProPIL>
 - Gardasil 9 PIL <https://bit.ly/Gardasil9Pil>
 - Boostrix PIL <http://bit.ly/BoostrixPIL>
 - Nimenrix PIL <http://bit.ly/nimenrixPIL>
- Ten tips for conducting a safe school immunisation session. Victorian Government Health Information. Immunisation Section Newsletter Issue 37 February 2009.
<http://bit.ly/NewsAus>
- Information on HSE ICT security <http://bit.ly/ICTSec>
- Information on HSE electronic communications <http://bit.ly/EIComm>
- Information on HSE encryption policies <http://bit.ly/EncPol>
- Information on how to communicate clearly <http://bit.ly/CommClear>

- Information on HSE's open disclosure policy <http://bit.ly/OpenDis>
- Information on HSE consent policy <http://bit.ly/ConsentP>
- Data protection Commission website www.dataprotection.ie
- HSE Data Protection policies <http://bit.ly/HSEdataprotection>
- Information on Subject Access Requests (SAR) <http://bit.ly/SARhse>
- GDPR Frequently Asked Questions <http://bit.ly/GDPRhse>

For other useful links and resources (*Appendix F*)

Glossary of Terms and Definitions

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

Adverse event following immunisation (AEFI): is an unwanted or unexpected event occurring after the administration of vaccine(s). Such an event may be caused by the vaccine(s) or may occur by chance after vaccination (i.e. it would have occurred regardless of vaccination).

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

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

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

Immunisation denotes the process of artificially inducing or providing immunity. This may be either active or passive.

Active immunisation is the administration of a vaccine or toxoid in order to stimulate production of an immune response.

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

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

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

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

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

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

Toxoid is a modified bacterial toxin that has been rendered non-toxic but has the ability to stimulate the formation of antitoxin.

Vaccine is a suspension of live attenuated or non-live micro-organisms or fractions thereof, or microorganism like particles administered to induce immunity and thereby prevent infectious disease.

Non live vaccine is a vaccine that contains killed or fractions of microorganisms or microorganism like particles. The response may be weaker than for a live vaccine and so repeated doses are often needed.

Live attenuated vaccine is a vaccine that contains a weakened strain of live bacteria or viruses that replicate in the body and induce a longer- lasting immunity than non-live vaccines.

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

Vaccine abbreviations:

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

MMR: Measles, Mumps and Rubella

HPV: Human papillomavirus

MenACWY: Meningococcal ACWY

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

Appendix A Template Operating Procedures and roles and responsibilities

Operational aspects of the programme prior to the school vaccination session

- Prior to the vaccination date all queries should be dealt with so no child attends for vaccination with an outstanding query. A system should be available locally to deal with immunisation queries or concerns from parents/legal guardians/students and schools.
- The target cohorts (denominator) for each vaccination programme should be identified.
- The schedule of school visits by the immunisation team(s) should ideally be decided with the schools a minimum of one month in advance if possible.
- Parents/legal guardian/students should receive the junior infant primary school or first year of second level parent pack through the schools in advance of the planned vaccination session. The pack contains a letter, information leaflets and consent form.
- TUSLA will inform the NIO of the number of home schooled children in the ages eligible for vaccinations. The NIO will send TUSLA immunisation and they will send these packs to parents.
- 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>
- For students who are home schooled, 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.
- 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.

Clinical staff should be familiar with the following documents:

- Immunisation Guidelines for Ireland are available at <http://bit.ly/NIACGuideline>
- Immunisation training slides for Health Professionals 2020, available at <http://bit.ly/NIPConf>
- Summary of Product Characteristics (SmPCs) for each of the vaccines available at www.hpra.ie and also available under the relevant schools vaccination programme at <http://bit.ly/SchPHCP>
- Medicine Protocols for each of the vaccines in the schools immunisation programme are available under the relevant schools vaccination programme at <http://bit.ly/SchMedPros>
- Healthcare professionals FAQs are available at <http://bit.ly/FAQImm>
- "Anaphylactic Reactions: Treatment in the Community" protocol, in the Immunisation Guidelines for Ireland available at <http://bit.ly/NIACGuideline>
- HSE Communicating Clearly with Patients and Service Users guidelines <http://bit.ly/CommClear>

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.
- 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 the correct vaccine type, appropriate quantity of the two or three vaccines being administered are brought to each vaccination session and that vaccines are in date and stored and maintained within cold chain.
- A designated person will take responsibility for bringing the resuscitation kit to the schools and for ensuring that all the necessary resuscitation equipment and drugs are available and in date (*Appendix H*). These should be checked by two clinical members of the team and recorded on the vaccination session report form at the start of each vaccination session.
- Before the vaccination session begins the staff at the session must agree who is to take the “lead role” for the vaccination session and have an overall oversight for the operation of the vaccination session. This oversight role will not diminish the roles and responsibilities of all team members. The “lead role” may be assigned in advance, however if this person is absent or delayed another person must take on this oversight role.

The person in the “lead role” will be responsible for:

- liaison with school staff
 - calling “Time Out” to check all is in order before vaccinations begin
 - ensuring all designated roles are covered
 - ensuring the session report form is completed at the end of the vaccination session, including the lead person’s name and PIN
 - ensuring that the Pharmacists or Senior Medical Officer in the National Immunisation Office is contacted at 087 9915452, 087 4064810 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 their original box or in a separate colour coded container.
- Ensure the student’s immunisation passport is completed and given to all students before they leave the vaccination area (DTaP/IPV and MMR).
- The immunisation passport is retained by the HSE after the first dose of HPV 9 and Tdap vaccine and is given to first year students after their second HPV9 and Men ACWY vaccine.
- Ensure that each student is provided with the appropriate tear pad stating date and time vaccine was given and the appropriate contact details so that parents /legal guardians can inform the school immunisation staff about any concerns following vaccination.
- Each vaccinator is responsible for the secure disposal of sharps and clinical waste in a sharps container and for ensuring that the sharps container is secured at the end of each vaccination session and removed from the school premises as in the HSE guidelines “Healthcare risk waste management segregation packaging and storage guidelines for healthcare risk waste” 4th edition 2010, available at <http://bit.ly/HCRiskW>
- At the end of the vaccination session the school vaccination session report form should be completed by a designated person. (*Appendix I*).
- All members of the Team should be responsible for cleaning/tidying up after the vaccination session so as to ensure that the vaccination venue is left as it was found.
- 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 entered on SIS and given an appointment to attend a HSE mop up clinic.
- In addition, where a completed consent form is provided too late for the school vaccination session, the student should be called to a mop up clinic.
- Students who require further vaccine doses to complete a course should have their school record entered onto SIS and be offered an appointment to attend a HSE mop up clinic.

- If addresses are available send letters to parents/legal guardians of these students by post. If addresses are not available for students the school should be provided with sealed letters for onward distribution to parents/legal guardians of these students.

Operational aspects after school/clinic vaccination session

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

Roles and Responsibilities

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

Managerial role and responsibilities

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

Administrative roles and responsibilities

- Each clerical officer should report to their relevant line manager.
- Each clerical officer should ensure that they are familiar with and adhering to the relevant practices as set out in this document and the SIS user guide (email sis.support@hse.ie).
- Each clerical officer should read and make available as needed the Statement of Information Practices for SIS and be familiar with and adhere to the Data Protection legislation.
- Ensure a copy of school health and safety regulations is obtained and adhered to during each school visit.
- Make their CHO administrator aware of any differences between the school denominator and the Department of Education's published denominator, this may involve contacting each school to get their target cohort (denominator).
- Ensure special schools are aware of relevant birth cohort.
- Schedule vaccination date/s with each school and distribute consent packs /forms (*Appendix C*), information leaflets and invitation letters to all parents/legal guardians through the school as far in advance of the vaccination date/s as possible.
- Collect completed consent forms from the school as agreed with Principal or other person designated by the school principal prior to the school vaccination day and bring the relevant forms to the school on the day of vaccination.
- Collect any additional consent forms that are returned on the day of vaccination.
- Check with the school those who are in the target group but are absent on the day and separate their consent forms. Record the students in the target group, who are present, on the class lists (if lists are available on the day).
- Check all consent forms (see pages 16-21) and contact parents or ask second level students themselves to resolve any administrative queries. Where there are also clinical queries to be resolved, all queries for that student should be referred to a clinical member of the team for follow up, to make one call to parents.
- Organise the collection and return of students to their classrooms in small groups in association with a designated school liaison person.
- Confirm student's identity (confirm name, address, date of birth and guardian's name by asking: "What is your full name? When is your Birthday? Who signed the consent form?

What is their name?" For younger children it may be necessary to confirm identity with appropriate liaison person from the school.

- Give consent forms to students after confirming their identity.
- Direct student to the Medical Officer or Registered Nurse Prescriber.
- Ensure that student is provided with the appropriate tear pad stating date and time vaccine given (*Appendix J*) and the school vaccination team contact details.
- Collect the consent forms and collate the statistics required for the School Vaccination Session Report Form (*Appendix I*) at the end of the session.
- Offer one appointment to attend a mop up clinic to students who were not vaccinated on the day. If the school team is notified that the student cannot attend the mop up clinic, one further appointment should be arranged.
- Carry out a search on the SIS to locate the client record, if not found set up a new client record. Input all school vaccinations i.e. MMR, 4in1, HPV, Tdap and MenACWY data on to the SIS including clients who did not or could not attend.
- For those students in junior infants, check the consent form and SIS (PCI MMR status box) to see if school MMR dose constituted their first dose and if so, arrange for them to receive a second dose at least one month later either at a mop up clinic or with their GP.
- Ensure all data entered is accurate and in accordance with data entry standards by running quality reports after school or clinic data is entered.
- Once a record is entered onto the SIS, write the system's client ID and the school roll number on the top of the consent form so that other users know this record is registered.
- In the event of an incident occurring during a vaccination session an incident report must be completed according to the HSE policy on incidents.
- If there is a vaccine error e.g. an incorrect vaccine is administered to one or more students, the record should be updated by the administrator who becomes aware of the error indicating the actions taken to bring this to the attention of the medical team; and the National Immunisation Office must also be informed.
- If errors are made on the SIS that you cannot be resolved, inform the CHO system administrator as soon as possible so that the errors can be rectified.
- Local school teams are responsible for establishing the school cohort by requesting the school denominator each academic year. Cohort changes are to be made in writing to the National SIS Administrator.

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 promptly after reconstitution.
- Any vaccines removed from their packaging should be used at that vaccination session or discarded.
- Check that the appropriate vaccine(s) for the vaccination session are in the cool box and the expiry date has not passed and record this on the school vaccination session report form
- Check that appropriate drugs and equipment are available for resuscitation and record this on the school vaccination session report form
- Before administration of each vaccine, each vaccinator should:
 - Check the name of the vaccine identification label to ensure that it is the correct vaccine for the student.
 - Check the expiry date on the vaccine box and confirm that the vaccine has not expired.
 - Check there is no evidence of any foreign particulate matter and/or variation of physical aspect of the vaccine. Discard the vaccine if these changes observed.
 - The SmPC for all the vaccines used in the school immunisation programme recommend that each vaccine is well shaken before administration.
 - Confirm student's identity (Confirm name, address, date of birth and parent or legal guardian's name by asking: "What is your full name? When is your

birthday? Where do you live? Who signed the consent form? What is their name?" For younger children it may be necessary to confirm identity with the child's teacher or an appropriate liaison person (as agreed with the School Principal) from the school.

- Confirm that informed consent has been given by a parent/legal guardian/student aged 16 years and older.
- Any clinical issues raised on the consent form should be addressed prior to vaccination
- For DTaP/IPV check that there is an interval of at least six months between the booster dose of DTaP/IPV and the completion of a primary course of tetanus containing vaccine (if applicable).
- 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 if required. See guidelines on holding child during immunisation in Chapter 2 of the Immunisation Guidelines for Ireland available at <http://bit.ly/NIACCh2>
- If a child refuses to be vaccinated, they should be deferred to a mop up clinic and their parents informed, ideally on the day of vaccination.
- Administer a single dose of 0.5ml of the appropriate vaccine by intramuscular (IM) injection at a 90° angle to the skin in the densest part of the deltoid muscle of the arm.
- Vaccinators should wash their hands or use the disinfectant gel after each vaccination.
- Dispose of sharps immediately, without recapping the needle, into the sharps containers provided as in the HSE guidelines "Healthcare risk waste management segregation packaging and storage guidelines for healthcare risk waste" 4th edition November 2010,

available at <http://bit.ly/HCRiskW>. 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 (as per box) and expiry date, clearly at the end of the consent form immediately after the vaccine is given. It is not appropriate to record this at the end of the session.
- Use of 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.
- 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 .
- All vaccinators (doctors, RNPs 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 HPV9 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:

- Prescribe the relevant vaccine by signing in the prescriber box on the consent form (including Medical Council Registration Number - MCRN).
- Carry out an individual medical assessment for students if requested by nurse working under a medicine protocol.
- 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).

Piloting of nurse led clinics

- There is currently a review being undertaken in Ireland to look at the delivery of immunisations to school aged children. If during the academic year 2020-21, an area is piloting nurse led clinics, further guidance will be provided on the roles and responsibilities in these circumstances.

Appendix B: Maintenance of Cool Box Temperature

- Vaccines should be stored in the vaccine fridges at the main health centres in accordance with the NIO Vaccine Fridge Standard Operating Procedure (SOP). See <http://bit.ly/NIOSOP1>
- Solid walled or vaccine specific soft walled insulated cool boxes and ice packs/gel packs from a recognised medical supply company must be used 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 / gel packs should be wrapped completely unless they have their own cover that encloses them completely - to prevent the ice pack coming in direct contact with vaccine.
- Frozen Wrapped 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.
- Thermometer probe (or data logger) should be placed in the middle of vaccines and should not touch ice packs/gel packs. To prevent probe from moving during transport, it can be placed in an empty vaccine box, placed in the middle of the vaccines. 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:
 - when vaccines are packed
 - upon arrival at the immunisation clinic
 - throughout the immunisation clinic
 - when returning 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.
- A data logger should be used in the cool boxes where external temperature display records only current temperature. This will provide an accurate account of temperatures reached and the duration of any temperature breach. The information on the data logger can be downloaded at the end of a vaccination day to confirm that any returned vaccines have remained within temperature. **A data logger does not replace the need to check cool box temperatures each time when removing vaccines prior to administration.**
- The cool box thermometer / data logger should be calibrated annually.

Procedures following breakdown in the “Cold Chain”

- If temperatures outside the permitted range are recorded, first check the position of the temperature probe. The temperature probe should be in a vaccine box in the middle of the vaccines – if it is not correctly positioned reset the probe and ensure it is positioned correctly away from ice packs or at the lid of cool box then close the box firmly and recheck the temperature in 15 minutes.
- If the temperature is still outside the permitted range, place the vaccine under quarantine in the fridge, and contact the Pharmacists or Senior Medical Officer in the National Immunisation Office at 087 9915452, 087 4064810 or 01 8676108 for further advice. The NIO will carry out a risk assessment and will advise on a case by case basis whether it is appropriate to use the vaccines or whether they should be discarded.

- Do not use or dispose of any vaccine which has been exposed to temperatures outside the permitted range. Quarantine and maintain these vaccines between +2°C and +8°C until advised by the National Immunisation Office.

Appendix C: Vaccination Consent Forms

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

Appendix D: Tips for Conducting a School Vaccination Session to Reduce the Incidence of Syncope

Adapted from the Immunisation Programme in Victoria, Australia^a

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.

See at <http://bit.ly/NewsAus>

Appendix E: Adverse event clinical record

Available from: <http://bit.ly/SchPHCP>

Appendix F: List of Useful Links and Resources

Further information regarding the vaccines in the Schools Immunisation Programme and the diseases they protect against can be found on the following websites

- National Immunisation Office available at <http://www.immunisation.ie>
- Immunisation Guidelines for Ireland available at <http://bit.ly/NIACGuidelines>
- Department of Health available at <http://www.health.gov.ie>
- Health Protection Surveillance Centre available at <http://www.hpsc.ie>
- Health Products Regulatory Authority available at <http://www.HPRA.ie>
- Medicines Information online available at <http://www.medicines.ie>
- World Health Organization information available at <http://www.who.int/topics/immunization/en/>
- Centre for Disease Control and Prevention – immunisation information available at <http://www.cdc.gov/vaccines/>
- Epidemiology and Prevention of Vaccine-Preventable Diseases, "Pink Book" available at <http://bit.ly/CDCPinkB>
- Australian Government, Department of Health and Education immunisation website available at <http://www.immunise.health.gov.au/>
- Immunisation Department of Health Victoria Australia available at <http://www.health.vic.gov.au/immunisation/index.htm>
- Secondary School Vaccination Program Guide Victoria available at <https://www.betterhealth.vic.gov.au/health/healthyliving/immunisation-in-secondary-schools>
- New Zealand, Ministry of Health immunisation website available at <https://www.health.govt.nz/our-work/preventative-health-wellness/immunisation>
- United Kingdom immunisation website available at <https://www.gov.uk/government/collections/immunisation>
- Department of Health UK Green Book available at <https://www.gov.uk/government/collections/immunisation-against-infectious-disease-the-green-book>
- Public Health Agency Canada immunisation information available at <https://www.canada.ca/en/public-health/topics/immunization-vaccines.html>
- European Medicines Agency available at <http://www.ema.europa.eu/>

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>
- National Cancer Registry Ireland available at <http://ncri.ie>
- Irish Cancer Society available at <http://www.cancer.ie>

Appendix G: Immunisations during COVID-19

The World Health Organisation state that immunisation services are an essential health service and should be maintained. The Departments of Health and Education are supportive of continuing immunisation services in schools during academic year 2020-21.

Due to COVID-19 guidelines being implemented in schools, it would be advisable to make contact with each school to discuss how this may affect the set up for immunisation sessions. For example, some schools may be using halls as classrooms, and so another space may need to be used for immunisations.

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

Children should not be attending school if they have COVID-19, or have been asked to self-isolate due to contact with COVID-19. Usual check should be made to ensure that the child is feeling well on the day of immunisation.

Infection Prevention and Control Advice

Social distancing measure:

Maintain social distancing between all individuals at all times where possible and ensure that all students spend the minimum possible time at the session.

In the vaccine session, the seat for the student should be placed 1 m away from any table top, shelf or works surface if possible. Social distance signage could be displayed at the entrance and inside the clinic to maintain the physical space between staff members and also between student.s

Standard and transmission precautions

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

- Hand hygiene: Perform hand hygiene with alcohol hand gel immediately before and after each physical contact with the student.

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

PPE requirement:

Administering a vaccine is a low level clinical activity to a healthy student so a surgical mask is adequate as it is recommended by HPSC to all healthcare staff while carry out their clinical activities. There is no requirement of additional PPE as the vaccine is delivered to a healthy student who has no respiratory symptoms or fever.

- Safe use of masks
Always change your mask: i) When you answer the telephone or take a drink/break ii) When leaving a clinical area iii) If your mask is wet, dirty or damaged.
- Staff uniforms/clothes must be laundered daily
- Routine cleaning: The table top and work surfaces must be cleaned thoroughly at the end of the vaccine session with disinfectant wipes.
- Reusable medical equipment must be cleaned after each use.

Please refer to HPSC guidelines for up to date information on infection prevention and control:

<https://www.hpsc.ie/a-z/respiratory/coronavirus/novelcoronavirus/guidance/guidanceforhealthcareworkers/>

Appendix H: 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 Immunisation 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

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

Appendix I: Session Report Forms

Available from <http://bit.ly/SchPHCP>

Appendix J: Post Vaccination Tear Pads

Available here <http://bit.ly/SchPHCP>

Appendix K: Packshots of vaccines used in school immunisation programme

Primary School Vaccines

TETRAVAC (DTaP/IPV)



MMRVAXPRO (MMR)



PRIORIX (MMR)



Second Level School Vaccines

BOOSTRIX (Tdap)



GARDASIL 9 (HPV)



NIMENRIX (MenACWY)



Appendix L: 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 this document.
- 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 pages 16-21 of this document.
- 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.

Primary School Programme

Tetravac Medicine Protocol



Medicine Protocol for the Administration of Tetravac (Diphtheria, Tetanus, Pertussis and Poliomyelitis) vaccine (adsorbed), by registered nurses and registered midwives

This medicine protocol is a specific written instruction for the administration of Tetravac Vaccine DTaP/IPV (diphtheria, tetanus, pertussis (acellular, component) and poliomyelitis (inactivated) vaccine (adsorbed), to children in Primary School by registered nurses and registered midwives. **This medicine protocol is valid for the 2020/2021 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 Tetravac (Diphtheria, tetanus, pertussis (acellular, component) and poliomyelitis (inactivated) vaccine (adsorbed), with reference to and guidance from Nursing & Midwifery Board of Ireland, National Nursing and Midwifery Immunisation Group, National Immunisation Advisory Committee, National Immunisation Office, HSE and in accordance with the Summary of Product Characteristics for Tetravac vaccine as detailed by the Health Products Regulatory Authority at www.hpra.ie :

- An Bord Altranais (2007) *Guidance to Nurses and Midwives on Medication Management* Dublin: An Bord 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 anaphylaxis or suspected anaphylaxis.* Dublin: Health Service Executive.
- National Immunisation Office (2020) Information for Staff: Schools Immunisation Programme 2020/2021 available at available at:
<https://hse.ie/eng/health/immunisation/hcpinfo/guidelines/immunisationguidelines.html>
- 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 (2014) *Code of Professional Conduct and Ethics for Registered Nurses and Registered Midwives.* Dublin: Nursing and Midwifery Board of Ireland available at: <https://www.nmbi.ie/Standards-Guidance/Code>.
- Nursing and Midwifery Board of Ireland (2015) *Practice Standards for Midwives.* Dublin: Nursing and Midwifery Board of Ireland available at: <http://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-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 medicine protocol is in effect” (An Bord Altranais, 2007).

Medicine Protocol for the Administration of Tetravac Vaccine by registered nurses and midwives to children/students in Primary Level School through a School Immunisation Programme

| | |
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| Document reference number: | ONMSD 2020 - 011 |
| 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: <ul style="list-style-type: none"> Registered nurses and midwives involved in the supply and administration of the Tetravac vaccine to children/students in primary school through a School Immunisation Programme. |
| Date the protocol comes into effect | September 2020 |
| Date for review of protocol | May 2021 |
| 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. Lorraine Doherty, National Clinical Director Health Protection, HSE |
| Names and Signatures of the employing authority who is authorising the implementation of the protocol <i>"On behalf of the authority employing professionals authorised to administer under this medicine protocol, I have read this medicine protocol and authorise its implementation"</i> | <p>Name: Dr. Lorraine Doherty, National Clinical Director Health Protection, HSE</p> <p>Signature: </p> <p>Name: Dr Colm Henry, Chief Clinical Officer, HSE</p> <p>Signature: </p> <p>Name: Dr Geraldine Shaw, Nursing and Midwifery Services Director, HSE</p> <p>Signature: </p> |

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| 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 diphtheria, tetanus, pertussis (whooping cough) and poliomyelitis (polio) disease. Tetravac is given as a booster vaccination to children who have previously received DTaP/IPV containing vaccines in the primary childhood immunisation schedule |
| 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 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 https://www.hse.ie/eng/health/immunisation/hcpinfo/guidelines/ . |
| Inclusion criteria for children/students treatment using the medicine protocol | All children in primary school usually delivered in junior infants and age equivalent in e.g. special schools and home schooled students. https://www.hse.ie/eng/health/immunisation/pubinfo/schoolprog/4in1mmr/schoolguidelines.pdf Children with valid consent. |
| Exclusion criteria for children/students using the medicine protocol | <ul style="list-style-type: none"> Children who have not commenced or completed primary immunisation course. Known systemic hypersensitivity reaction to any component of Tetravac or a vaccine containing the same substances or to pertussis vaccines (acellular or whole cell pertussis). 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. |
| Actions to be taken for those who are excluded from the Protocol | <ul style="list-style-type: none"> All children meeting exclusion criteria must be referred to the medical practitioner for an individual medical assessment. Document action in clinical notes Where Tetravac vaccine is prescribed following medical assessment, the nurse or midwife may administer Tetravac vaccine within their scope of practice. <p><i>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).</i></p> |
| Description of circumstances and referral arrangements when further advice or consultation is required | Discuss the student with the Medical Practitioner or lead nurse in the event of: Previous adverse reaction Other clinical concerns |

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| Documentation required for the implementation of this medicine protocol | <p>A consent form must be completed by the parent /legal guardian for all children who receive the Tetravac vaccine. Appropriate details including the batch number must be recorded on the consent form.</p> <p>The following documents will be required at each school vaccination session:</p> <ul style="list-style-type: none"> • 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, 2020) • Tear pads for after vaccination <p>It is the responsibility of each nurse or midwife to be familiar with the appropriate documentation to support the safe administration of Tetravac vaccine which includes the following:</p> <ul style="list-style-type: none"> • Information for Staff: School Immunisation Programme 2020/2021 • Medicine Protocol for the administration of Tetravac • Directions for nurses and midwives for the management of a patient who develops anaphylaxis or suspected anaphylaxis incorporating <i>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 (HSE 2019)</i>, available at https://www.hse.ie/eng/health/immunisation/hcpinfo/fluinfo/adrenalineprotocol.pdf |
| 3.0 Name of Medicine | <p>Tetravac</p> <p>Dose 0.5ml of vaccine, Route Intramuscular only Site Deltoid (left recommended)</p> |
| 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 | <p>Tetravac 2020/2021</p> <p>Link to Summary of Product Characteristics https://www.hpra.ie/img/uploaded/swedocuments/Licence_PA2131-009-001_30102019150653.pdf</p> <p>Link to Patient Information Leaflet: https://www.hpra.ie/img/uploaded/swedocuments/4f63ba70-1e20-462e-b175-7d2b8f8e9dea.pdf</p> |
| Procedure for the reporting and documentation of errors and near misses involving the medicine | <p>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.</p> <p>Vital signs should be recorded and the student should be reviewed by the registered nurse/midwife and/ or medical practitioner.</p> <p>The incident must be reported to the relevant line manager as soon as possible.</p> <p>The incident and all actions taken must be promptly recorded in the child's documentation/notes and the relevant report form completed.</p> <p>The incident and all actions must be promptly recorded and the National Incident</p> |

| | |
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| | <p>(National Incident Report Form (NIRF--01-V 11 March 2020): https://www.hse.ie/eng/about/qavd/incident-management/nirf-01-v11-person.pdf</p> <p>The child's parent and/or legal guardian must be informed of the incident.</p> <p>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.</p> <p>Any suspected adverse reactions associated with medication errors should be reported to the HPRA as outlined below. (As per local policy).</p> <ul style="list-style-type: none"> Any errors and near misses not involving medications (Needle stick injuries etc.), 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. Refer 'EMI Tool Kit' (https://www.hpsc.ie/a-z/EMIToolkit/). |
| Procedure for reporting Adverse Drug Reactions to the Health Products Regulatory Authority (HPRA) | <p>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.</p> <p>The incident and all actions taken must be promptly recorded in accordance with the criteria outlined by the HPRA: <i>Management of a Patient with Anaphylaxis: Treatment in the Community</i>. (National Immunisation Advisory Committee, 2019) – available online at</p> <p>https://www.hse.ie/eng/health/immunisation/hcpinfo/guidelines/Anaphylaxis.pdf</p> |
| Resources and equipment required | <ul style="list-style-type: none"> Vaccine (pre-filled syringe) Fridge/Cool box with minimum/maximum temperature recording device to monitor the cold chain temperature (between +2°C and +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 <i>Management of a Patient with Anaphylaxis or suspected anaphylaxis</i>, (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 Tetravac Vaccine. |
| Audit process to identify appropriate use of the protocol or unexpected outcomes | <p>All documentation will be held for review and audit purposes as per local policy.</p> |

| 4.0 Information for child/student/parent/guardian | |
|---|--|
| <p>Advice to be given to the child/student/parent/guardian before treatment</p> | <p>The HSE 4 in1 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 DTaP/IPV vaccine.</p> |
| <p>Advice to be given to the child/student/parent/guardian after treatment</p> | <p>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.</p> <p>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.</p> |
| <p>Details of any necessary follow-up, action and referral arrangements</p> | <p>In the event of an adverse reaction the nurse/midwife must ensure that all procedures are adhered to as outlined in Section 3.</p> |
| 5.0 Staff authorised to use this medicine protocol | |
| <p>Professional qualifications, training, and competence required prior to using this medicine protocol</p> <p>Professional Qualifications</p> <p>Training and Competence:</p> | <p>Registered nurse or registered midwife on the active register maintained by The Nursing and Midwifery Board of Ireland.</p> <p>National Schools Immunisation programme for registered nurses and registered midwives on the use of this medicine protocol.</p> <p>Basic Life Support for Health Care Providers within the last two years.</p> <p>Initial anaphylaxis programme (<i>"National Anaphylaxis Education Programme for Health Care Professionals"</i>) via HSEland followed by a one and a half hour classroom based skills workshop (replacing the previous four hour classroom based programme). Subsequent updates every two years via HSEland Anaphylaxis e-learning programme available at www.hse.ie.</p> <p>The registered nurse/midwife must complete the <i>"Competency Self - Assessment Tool for registered nurses and registered midwives to supply and administer vaccines under medicine protocols through a schools immunisation programme"</i>.</p> <p>Recommended:</p> <p>E-learning Guide to Medicine Management, available at www.hseland.ie</p> <p>Introduction to Immunisation, available at www.hseland.ie</p> |

References

An Bord Altranais (2007) *Guidance to Nurses and Midwives on Medication Management* Dublin: An Bord Altranais

Health Products Regulatory Authority available at www.hpra.ie (accessed 16th June 2020)

Health Service Executive (2016) E-Learning Guide to Medicines Management. Available at www.hseland.ie

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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/>

National Immunisation Office (2020) Information for Staff: School Immunisation Programme: Health Service Executive, 2020/2021

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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-Practise-Scope-Definition>

MMR VaxPro Medicine Protocol



Medicine Protocol for the Administration of MMR (Measles, Mumps and Rubella) live vaccine MMR VAXPRO by registered nurses and registered midwives

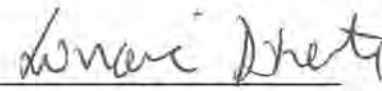

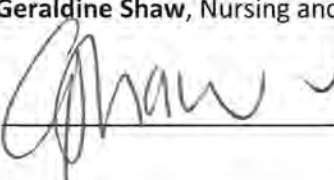
This medicine protocol is a specific written instruction for the administration of MMRVAXPRO vaccine to children/students in first year in Primary and Second Level School by registered nurses and registered midwives. **This medicine protocol is valid for the 2020/2021 HSE School Immunisation Programme.**

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 Nursing and Midwifery Immunisation Working Group, National Immunisation Advisory Committee, 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 :

- An Bord Altranais (2007) *Guidance to Nurses and Midwives on Medication Management* Dublin: An Bord 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 Office 2020. Supporting Information for Staff: Schools Immunisation Programme :Health Service Executive 2020/2021 available at <https://www.hse.ie/eng/health/immunisation/pubinfo/schoolprog/4in1mmr/schoolguidelines.pdf>
- 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 (2014) *Code of Professional Conduct and Ethics for Registered Nurses and Registered Midwives.* Dublin: Nursing and Midwifery Board of Ireland available at: <https://www.nmbi.ie/Standards-Guidance/Code>.
- 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-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 MMRVAXPRO vaccine by registered nurses and midwives to children/students in Primary/ Second Level School through a School Immunisation Programme

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| Document reference number: | ONMSD 2020-008 |
| 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: <ul style="list-style-type: none"> 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 2020 |
| Date for review of protocol | May 2021 |
| 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 Lorraine Doherty, National Clinical Director Health Protection. |
| Names and Signatures of the employing authority who is authorising the implementation of the protocol <i>"On behalf of the authority employing professionals authorised to administer under this medicine protocol, I have read this medicine protocol and authorise its implementation"</i> | <p>Name: Dr. Lorraine Doherty, National Clinical Director Health Protection, HSE</p> <p>Signature: </p> <p>Name: Dr Colm Henry, Chief Clinical Officer, HSE</p> <p>Signature: </p> <p>Name: Dr Geraldine Shaw, Nursing and Midwifery Services Director, HSE</p> <p>Signature: </p> |

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| 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 | <p>The School Immunisation Programme (SIP) will be delivered annually by the Health Service Executive (HSE)</p> <p>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/eng/health/immunisation/hcpinfo/guidelines/.</p> <p>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.</p> <p>This medicine protocol also applies in MMRVAXPRO catch up campaigns and outbreaks situations as recommended by NIAC (2014)</p> |
| Inclusion criteria for children/service user treatment using the medicine protocol | <p>Children/students in primary/second level school or age equivalent in special schools and home schooled students.</p> <p>https://www.hse.ie/eng/health/immunisation/pubinfo/schoolprog/4in1mmr/schoolguidelines.pdf</p> <p>Children/Students with valid consent.</p> |
| Exclusion criteria for children using the medicine protocol | <p>A known history of anaphylactic or hypersensitivity reaction to MMRVAXPRO or any of the MMRVAXPRO vaccine constituents including neomycin or gelatin.</p> <p>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.</p> <p>Child/student with a history of thrombocytopenia within six weeks of receiving first dose MMRVAXPRO vaccine.</p> <p>Child/student with a contraindication to intramuscular injection (haematological disorder/coagulation disorder e.g. haemophilia, severe thrombocytopenia).</p> <p>Child/student who are immunocompromised either due to disease or treatment.</p> <p>MMR vaccine should not be given from 2 weeks before to 3- 11 months after specific immunoglobulins as they may interfere with the immune response</p> <p>MMR should not be given 2 weeks before Human Normal Immunoglobulin (HNIG).</p> <p>Child/student who have received varicella or yellow fever live vaccine within the previous 4 weeks.</p> <p>Active untreated tuberculosis.</p> <p>Pregnancy where applicable.</p> |
| Actions to be taken for those who are excluded from the Protocol | <ul style="list-style-type: none"> • All children/students meeting exclusion criteria must be referred to the medical practitioner for an individual medical assessment. • Document action in clinical notes. • Where MMRVAXPRO vaccine is prescribed following medical assessment, the |

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| | <p>nurse or midwife may administer MMRVAXPRO vaccine within their scope of practice.</p> <p><i>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).</i></p> |
| Description of circumstances and referral arrangements when further advice or consultation is required | <p>Discuss the student with the Medical Practitioner or lead nurse in the event of:</p> <ul style="list-style-type: none"> • Previous Adverse reaction • Other clinical concerns |
| Documentation required for the implementation of this medicine protocol | <p>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.</p> <p>The following documents will be required at each school vaccination session:</p> <ul style="list-style-type: none"> • Vaccination session report forms • Blank Vaccine consent forms • Patient held record cards • Health Products Regulatory Authority Adverse Reaction Reporting forms • HSE Incident/near miss report forms (NIRF, 2020) • Tear pads for after vaccination <p>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:</p> <ul style="list-style-type: none"> • Information for Staff: School Immunisation Programme 2020/2021 • 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 <i>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)</i> available at https://www.hse.ie/eng/health/immunisation/hcpinfo/fluinfo/adrenalineprotocol.pdf |
| 3.0 Name of Medicine | <p>MMRVAXPRO:</p> <p>Dosage 0.5ml</p> <p>Site Deltoid (right side recommended)</p> <p>Route IM</p> |
| <p>Link to Medicine</p> <p>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</p> | <p>2020/2021 Link to Summary of Product Characteristics and PIL https://www.ema.europa.eu/docs/en_GB/document_library/EPAR_-_Product_Information/human/000604/WC500030170.pdf</p> <p>Link to Patient Information Leaflet https://www.hpra.ie/docs/default-source/vaccine-pils/mmrvoxpro-pil.pdf?sfvrsn=6</p> |
| Procedure for the | In the case of medicine errors that directly involve the child/student, i.e. wrong |

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| reporting and documentation of errors and near misses involving the medication | <p>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.</p> <p>Vital signs should be recorded and the student should be reviewed by the registered nurse/midwife and/ or medical practitioner.</p> <p>The incident must be reported to the relevant line manager as soon as possible.</p> <p>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-V 11 March 2020)</p> <p>https://www.hse.ie/eng/about/gavd/incident-management/nirf-01-v11-person.pdf</p> <p>The incident and all actions taken must be promptly recorded in the child/student's documentation/notes and the relevant report form completed.</p> <p>The child/ student's parent and/or legal guardian must be informed of the incident.</p> <p>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.</p> <p>Any suspected adverse reactions associated with medication errors should be reported to the HPRA as outlined below.</p> <p>Any errors and near misses not involving medication e.g. needle stick injuries, 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. Refer 'EMI Tool Kit' (https://www.hpsc.ie/a-z/EMIToolkit/).</p> |
| Procedure for reporting Adverse Drug Reactions to the Health Products Regulatory Authority (HPRA) | <p>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 card system which is available in the downloadable format from the HPRA website, or on request from the HPRA.</p> <p>The incident and all actions taken must be promptly recorded in accordance with the criteria outlined by the HPRA:- <i>Management of a Patient with Anaphylaxis HSE</i> (2019) – available online at</p> <p>https://www.hse.ie/eng/health/immunisation/hcpinfo/guidelines/Anaphylaxis.pdf</p> |
| Resources and equipment required | <ul style="list-style-type: none"> • Vaccine Powder and solvent for solution for injection in a pre-filled syringe • Fridge/Cool box with minimum/maximum temperature recording device to monitor the cold chain temperature (between +2°C and +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 <i>Management of a Patient with anaphylaxis</i> (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 MMRVAXPRO vaccine. |

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| | <i>Introduction to Immunisation</i> , available at www.hseland.ie |
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References

An Bord Altranais (2007) *Guidance to Nurses and Midwives on Medication Management* Dublin: An Bord Altranais.

Health Products Regulatory Authority available at www.hpra.ie (accessed 15th June 2020)

Health Service Executive (2016) E-learning Guide to Medicine Management, available at www.hseland.ie

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

Health Service Executive (2010) *Healthcare Risk Waste Management Segregation Packaging and Storage Guidelines for healthcare Risk Waste*. Dublin: Health Service Executive.

MMRVaxPRO Vaccine MSD Ireland Limited *Summary of Product Characteristics and Patient Information Leaflet*. Available at www.hpra.ie

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

Medicinal Products (Prescription and Control of Supply) (Amendment) Regulations 2007, Statutory Instruments No. 201 of 2007. Dublin: Stationery Office

Misuse of Drugs (Amendment) Regulations 2017, Statutory Instruments No.173 of 2017. Dublin: Stationery Office

National Immunisation Advisory Committee (2019) *Anaphylaxis: Treatment in the Community*. Available at <https://www.hse.ie/eng/health/immunisation/hcpinfo/guidelines/Anaphylaxis.pdf>

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/>

National Immunisation Office (2019) *Information for Staff: School Immunisation Programme: Health Service Executive 2019/2020*

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: <https://www.nmbi.ie/Standards-Guidance/Code>.

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-Practise-Scope-Definition>

Priorix Medicine Protocol

Medicine Protocol for the Administration of MMR (Measles, Mumps and Rubella) live 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 2020/2021 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 Nursing and Midwifery Immunisation Working Group, National Immunisation Advisory Committee, 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 :

- An Bord Altranais (2007) *Guidance to Nurses and Midwives on Medication Management* Dublin: An Bord 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 anaphylaxis or suspected anaphylaxis.* Dublin: Health Service Executive

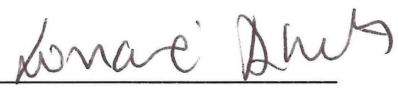

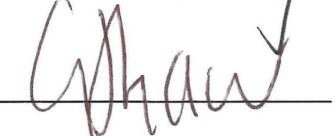
National Immunisation Office 2020. Supporting Guidelines for Staff: Schools Immunisation Programme **2020/2021** available at www.immunisation.ie Royal College of Physicians of Ireland National Immunisation Advisory Committee *Immunisation Guidelines for Ireland* Dublin: Royal College of Physicians of Ireland

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

- Nursing and Midwifery Board of Ireland (2014) *Code of Professional Conduct and Ethics for Registered Nurses and Registered Midwives.* Dublin: Nursing and Midwifery Board of Ireland available at: <https://www.nmbi.ie/Standards-Guidance/Code>.
- 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-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 MMR Vaccine (Priorix) by registered nurses and midwives to children/students in Primary/ Second Level School through a School Immunisation Programme

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| Document reference number: | ONMSD 2020 - 014 |
| 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: <ul style="list-style-type: none"> Registered nurses and midwives involved in the supply and administration of the Priorix vaccine to children/students in primary/second level school through a School Immunisation Programme. |
| Date the protocol comes into effect | September 2020 |
| Date for review of protocol | May 2021 |
| 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 Lorraine Doherty, National Clinical Director Health Protection. |
| Names and Signatures of the employing authority who is authorising the implementation of the protocol <i>"On behalf of the authority employing professionals authorised to administer under this medicine protocol, I have read this medicine protocol and authorise its implementation"</i> | Name: Dr. Lorraine Doherty , National Clinical Director Health Protection, HSE Signature:  Name: Dr Colm Henry , Chief Clinical Officer, HSE Signature:  Name: Dr Geraldine Shaw , Nursing and Midwifery Services Director, HSE Signature:  |

| 2.0 Clinical Criteria | |
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| 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 | <p>The School Immunisation Programme (SIP) will be delivered annually by the Health Service Executive (HSE)</p> <p>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</p> <p>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.</p> <p>This medicine protocol also applies in MMR catch up campaigns and outbreaks situations as recommended by NIAC (2014).</p> |
| Inclusion criteria for children/students treatment using the medicine protocol | <p>Children/Students in primary/ second level school or age equivalent in special schools and home schooled students.</p> <p>See https://www.hse.ie/eng/health/immunisation/pubinfo/schoolprog/4in1mmr/schoolguidelines.pdf</p> <p>Children/Students with valid consent.</p> |
| Exclusion criteria for children/ student s using the medicine protocol | <p>A known history of anaphylactic or hypersensitivity reaction to Priorix or to any of the MMR vaccine constituents including neomycin.</p> <p>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.</p> <p>Child/student with a history of thrombocytopenia within six weeks of receiving the first dose of MMR vaccine.</p> <p>Child/Student with a contraindication to intramuscular injection (haematological disorder/coagulation disorder e.g. haemophilia, severe thrombocytopenia)</p> <p>Child/student who is immunocompromised either due to disease or treatment.</p> <p>MMR vaccine should not be given from 2 weeks before to 3- 11 months after specific immunoglobulins as they may interfere with the immune response</p> <p>MMR should not be given 2 weeks before Human Normal Immunoglobulin (HNIG).</p> <p>Child/student who received Varicella or, Yellow Fever live vaccines within the previous 4 weeks.</p> <p>Active untreated tuberculosis.</p> <p>Pregnancy where applicable</p> |
| Actions to be taken for those who are excluded from the Protocol | <ul style="list-style-type: none"> • 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 |

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| | <p>practice.</p> <p><i>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).</i></p> |
| Description of circumstances and referral arrangements when further advice or consultation is required | <p>Discuss the student with the Medical Practitioner or lead nurse in the event of:</p> <p>Previous adverse reaction</p> <p>Other clinical concerns</p> |
| Documentation required for the implementation of this medicine protocol | <p>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.</p> <p>The following documents will be required at each school vaccination session:</p> <ul style="list-style-type: none"> • 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 (NIRF, 2020) • Tear pads for post vaccination <p>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:</p> <ul style="list-style-type: none"> • Supporting Information for Staff: School Immunisations Programme 2020/2021 • Medicine Protocol for the administration of MMR vaccine Priorix which is a live vaccine 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 <i>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)</i>, available at https://www.hse.ie/eng/health/immunisation/hcpinfo/fluinfo/adrenalineprotocol.pdf |
| 3.0 Name of Medicine | <p>MMR Vaccine (Priorix): 2020/2021</p> <p>Dose 0.5ml</p> <p>Route Intramuscular injection</p> <p>Site Deltoid (right recommended)</p> |
| 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 | <p>Link to Summary of Product Characteristics: https://www.hpra.ie/img/uploaded/swedocuments/Licence_PA1077-036-001_06012020115614.pdf</p> <p>Link to Patient Information Leaflet: https://www.hpra.ie/img/uploaded/swedocuments/28966dfd-33f2-4ed2-9727-917dcb2534f9.pdf</p> |

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| <p>Procedure for the reporting and documentation of errors and near misses involving the medication</p> | <p>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.</p> <p>Vital signs should be recorded and the student should be reviewed by the registered nurse/midwife and/ or medical practitioner.</p> <p>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-V11, March 2020)</p> <p>https://www.hse.ie/eng/about/qavd/incident-management/nirf-01-v11-person.pdf</p> <p>The incident and all actions taken must be promptly recorded in the child/student's documentation/notes and the relevant report form completed.</p> <p>The child/ student's parent and/or legal guardian must be informed of the incident.</p> <p>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.</p> <p>Any suspected adverse reactions associated with medicine errors should be reported to the HPRA as outlined below.</p> <p>Any errors and near misses not involving medication e.g. needle stick injuries, 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. Refer 'EMI Tool Kit' (https://www.hpsc.ie/a-z/EMIToolkit/).</p> |
| <p>Procedure for reporting Adverse Drug Reactions to the Health Products Regulatory Authority (HPRA)</p> | <p>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.</p> <p>The incident and all actions taken must be promptly recorded in accordance with the criteria outlined by the HPRA: <i>Management of a Patient with Anaphylaxis : Treatment in the Community</i> (National Immunisation Advisory Committee, 2019) – available online at</p> <p>https://www.hse.ie/eng/health/immunisation/hcpinfo/guidelines/Anaphylaxis.pdf</p> |
| <p>Resources and equipment required</p> | <ul style="list-style-type: none"> • Vaccine powder and solvent for solution for injection in a pre-filled syringe • Vaccine cool packs • Fridge/Cool box with minimum/maximum temperature recording device to monitor the cold chain temperature (between +2°C and +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 <i>Management of a Patient with Anaphylaxis</i>, (National Immunisation Advisory Committee, 2019) available at |

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| | https://www.hse.ie/eng/health/immunisation/hcpinfo/guidelines/Anaphylaxis.pdf <ul style="list-style-type: none"> • Access to medical support • Safe storage areas for medicines and equipment • Current medicine protocol for MMR vaccine Priorix. |
| 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 child/student/parent/guardian | |
| Advice to be given to the child/student/parent/guardian before treatment Advice to be given to the child/student/parent/guardian after treatment | <p>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.</p> <p>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.</p> <p>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.</p> <p>Adverse reactions are considerably less common (less than 1%) after the 2nd dose of MMR vaccine.</p> |
| 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 and competence required prior to using this medicine protocol. Professional Qualifications Training and Competence: | <p>Registered nurse or registered midwife on the active register maintained by The Nursing and Midwifery Board of Ireland.</p> <p>National Schools Immunisation programme for registered nurses and registered midwives on the use of this medicine protocol.</p> <p>Basic Life Support for Health Care Providers within the last two years.</p> <p>Initial anaphylaxis programme (<i>"National Anaphylaxis Education Programme for Health Care Professionals"</i>) via HSE LanD followed by a one and a half hour classroom based skills workshop (replacing the previous four hour classroom based programme). Subsequent updates every two years via HSE LanD Anaphylaxis e-learning programme available at www.hse.ie.</p> <p>The registered nurse/midwife must complete the <i>"Competency Self - Assessment Tool for registered nurses and registered midwives to supply and administer vaccines under medicine protocols through a schools immunisation programme"</i>.</p> |

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| | <p>Recommended:</p> <p><i>E-learning Guide to Medicine Management</i>, available at www.hseland.ie</p> <p><i>Introduction to Immunisation</i>, available at www.hseland.ie</p> |
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References

An Bord Altranais (2007) *Guidance to Nurses and Midwives on Medication Management* Dublin: An Bord Altranais

Health Products Regulatory Authority available at www.hpra.ie (accessed 16th June 2020)

Health Service Executive (2016) E-Learning Guide to Medicine Management, available at www.hseland.ie

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

Health Service Executive (2010) *Healthcare Risk Waste Management Segregation Packaging and Storage Guidelines for healthcare Risk Waste*. 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 (Commencement) Order 2007. Dublin: Stationery Office

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

Medicinal Products (Prescription and Control of Supply) (Amendment) Regulations 2007, Statutory Instruments No. 201 of 2007. Dublin: Stationery Office

Misuse of Drugs (Amendment) Regulations 2017, Statutory Instruments No.173 of 2017. Dublin: Stationery Office

National Immunisation Advisory Committee (2019) Anaphylaxis: Treatment in the Community. Available at <https://www.hse.ie/eng/health/immunisation/hcpinfo/guidelines/Anaphylaxis.pdf>

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/>)

National Immunisation Office (2020) *Guidelines for Staff: School Immunisation Programme: Health Service Executive, 2020/2021*

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 online <https://www.nmbi.ie/Standards-Guidance/Code>

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>

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>

Second Level School Programme

Gardasil 9 Medicine Protocol



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

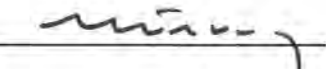
This medicine protocol is a specific written instruction for the administration of HPV vaccine (Gardasil 9), Human Papillomavirus vaccine (HPV Types 6, 11, 16, 18, 31, 33, 45, 52 and 58) to students in Second Level School who are not individually identified before presentation for treatment by registered nurses and registered midwives. **This medicine protocol is valid for the 2020/2021 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 Nursing and Midwifery Immunisation Working Group, National Immunisation Advisory Committee, 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.hpra.ie :

- An Bord Altranais (2007) *Guidance to Nurses and Midwives on Medication Management* Dublin: An Bord 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 BP1:1000 by intramuscular injection for nurses and midwives for the management of a patient with anaphylaxis or suspected anaphylaxis*. Dublin: Health Service Executive
- National Immunisation office 2020 Supporting Information for Staff: Schools Immunisation Programme 2020 available at <http://www.hse.ie/eng/health/immunisation/pubinfo/schoolprog//schoolguidelines.pdf>
- 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/>)
- 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: <http://www.nmbi.ie/Standards-Guidance/Code>.
- Nursing and Midwifery Board of Ireland (2015) *Practice Standards for Midwives*. Dublin: Nursing and Midwifery Board of Ireland available at: <http://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: <http://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: <http://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 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

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| Document reference number: | ONMSD 2020 - 015 |
| 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: <ul style="list-style-type: none"> 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. |
| Date the protocol comes into effect | September 2020 |
| Date for review of protocol | May 2021 |
| 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 Lorraine Doherty, National Clinical Director Health Protection. |
| Names and Signatures of the employing authority who is authorising the implementation of the protocol <i>"On behalf of the authority employing professionals authorised to administer under this medicine protocol, I have read this medicine protocol and authorise its implementation"</i> | Name: Dr. Lorraine Doherty , National Clinical Director Health Protection, HSE Signature:  Name: Dr Colm Henry , Chief Clinical Officer, HSE Signature:  Name: Dr Geraldine Shaw , Nursing and Midwifery Services Director, HSE Signature:  |

| 2.0 Clinical Criteria | |
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| 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 | <p>The School Immunisation Programme (SIP) will be delivered annually by the Health Service Executive (HSE).</p> <p>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.</p> <p>All students with a valid consent form in first year of second level schools and or age equivalent in special schools and home schooled in 2020/21 school year.</p> <p>All students who commenced the HPV vaccination schedule during the 2019/2020 school year to complete the schedule.</p> <p>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.eng/health/immunisation/hcpinfo/guidelines/</p> <p>Students will require one dose in September-November and a second dose at least five, but ideally six months later.</p> <p>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.</p> <p>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</p> <p>If the vaccination series is interrupted, the series does not need to be restarted.</p> <p>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.</p> <p>Girls in second level school outside of 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.</p> <p>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.</p> <p>The schedule for completion with HPV vaccine (Gardasil 9) is the same as the HPV</p> |

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| | vaccine (Gardasil 4) schedule and the HPV vaccine (Gardasil 9) medication protocol can be used. |
| Inclusion criteria for Students using the medicine protocol | <p>Students in first year of second level school or age equivalent in special schools and home schooled students (NIAC, 2020)</p> <p>Students with valid consent.</p> <p>All students who commenced the HPV vaccination schedule during the 2019/2020 school year to complete the schedule.</p> <p>All students with a valid consent form who did not receive a HPV Vaccine during the 2019/2020 school year. Girls in second level school outside of first year and have commenced the vaccine course and where HPV vaccine (Gardasil 4) is no longer available.</p> |
| Exclusion criteria for Students using the medicine protocol | <p>A known history of anaphylactic or hypersensitivity reaction to HPV vaccine (Gardasil 9) or any of vaccines constituents.</p> <p>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.</p> <p>Students with a contraindication to intramuscular injection (haematological disorder/coagulation disorder e.g. haemophilia, severe thrombocytopenia).</p> <p>Pregnancy where applicable.</p> <p>Students who are immunocompromised either due to disease or treatment.</p> |
| Actions to be taken for those students who are excluded from the Protocol | <ul style="list-style-type: none"> • All students meeting exclusion criteria must be referred to a medical practitioner for an individual assessment. • Document action in clinical notes • 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. <p><i>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).</i></p> |
| Description of circumstances and referral arrangements when further advice or consultation is required | <p>Discuss the student with the Medical Practitioner or lead nurse in the event of:</p> <ul style="list-style-type: none"> • Previous adverse reaction • Other clinical concerns |
| Documentation required for the implementation of this medicine protocol | <p>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.</p> <p>The following documents will be required at each school vaccination session:</p> <ul style="list-style-type: none"> • Vaccination session report form • Blank Vaccine consent forms |

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| | <ul style="list-style-type: none"> • Vaccine Information Leaflets • Patient Health Records • Health Products Regulatory Authority Adverse Reaction Reporting forms • HSE Incident/near miss report forms (NIRF, 2020) • Tear pads for post vaccination <p>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:</p> <ul style="list-style-type: none"> • Supporting Information for Staff: School Immunisation Programme (2020/2021). • 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 <i>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</i> (HSE, 2019), available at https://www.hse.ie/eng/health/immunisation/hcpinfo/fluinfo/adrenalineprotocol.pdf |
| 3.0 Name of Medicine HPV Vaccine (Gardasil 9) | <p>Route Intramuscular</p> <p>Site Deltoid (Left side recommended)</p> <p>Dose 0.5ml</p> |
| 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 | <p>HPV Vaccine (Gardasil 9) 2020/2021</p> <p>Link to Summary of Product Characteristics and Patient Information Leaflet: https://www.ema.europa.eu/documents/product-information/gardasil-9-epar-product-information_en.pdf</p> |
| Procedure for the reporting and documentation of errors and near misses involving the medicine | <p>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.</p> <p>Vital signs should be recorded and the student should be reviewed by the registered nurse/midwife and/ or medical practitioner.</p> <p>The incident must be reported to the relevant line manager as soon as possible.</p> <p>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-V 11 March 2020): https://www.hse.ie/eng/about/qavd/incident-management/nirf-01-v11-person.pdf</p> <p>The incident and all actions taken must be promptly recorded in the student's documentation/notes and the relevant report form completed.</p> <p>The student's parent and/or legal guardian should be informed of the incident.</p> <p>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.</p> |

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| | 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, (i.e., needle stick injury) 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). Refer 'EMI Tool Kit' (https://www.hpsc.ie/a-z/EMIToolkit/). |
| Procedure for reporting Adverse Drug Reactions to the Health Products Regulatory Authority (HPRA) | <p>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.</p> <p>The incident and all actions taken must be promptly recorded in accordance with the criteria outlined by the Health Products Regulatory Authority (HPRA) - <i>Management of a Patient with Anaphylaxis: Treatment in the Community (National Immunisation Advisory Committee, 2019)</i> – available online at https://www.hse.ie/eng/health/immunisation/hcpinfo/guidelines/Anaphylaxis.pdf</p> |
| Resources and equipment required | <ul style="list-style-type: none"> • Vaccine (pre-filled syringe) • Fridge/Cool box with minimum/maximum temperature recording device to monitor the cold chain temperature (between +2°C and +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 <i>Management of a Patient with Anaphylaxis</i>, (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 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

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| <p>Advice to be given to student/parent/guardian before treatment</p> <p>Advice to be given to the student /parent/guardian after treatment</p> | <p>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.</p> <p>After Treatment</p> <p>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.</p> <p>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.</p> |
| <p>Details of any necessary follow-up, action and referral arrangements</p> | <p>In the event of an adverse reaction the registered nurse/midwife must ensure that all procedures are adhered to as outlined in Section 3.</p> |
| <p>5.0 Staff authorised to use this medicine protocol</p> | |
| <p>Professional qualifications, training, and competence required prior to using this medicine protocol</p> <p>Professional Qualifications</p> <p>Training and Competence:</p> | <p>Registered nurse or registered midwife on the active register maintained by The Nursing and Midwifery Board of Ireland.</p> <p>National Schools Immunisation programme for registered nurses and registered midwives on the use of this medicine protocol.</p> <p>Basic Life Support for Health Care Providers within the last two years.</p> <p>Initial anaphylaxis programme (<i>"National Anaphylaxis Education Programme for Health Care Professionals"</i>) via HSEland followed by a one and a half hour classroom based skills workshop (replacing the previous four hour classroom based programme). Subsequent updates every two years via HSEland Anaphylaxis e-learning programme available at www.hse.ie.</p> <p>The registered nurse/midwife must complete the <i>"Competency Self - Assessment Tool for registered nurses and registered midwives to supply and administer vaccines under medicine protocols through a schools immunisation programme"</i>.</p> <p>Recommended:</p> <p><i>E-learning Guide to Medicine Management</i>, available at www.hseland.ie</p> <p><i>Introduction to Immunisation</i>, available at www.hseland.ie</p> |

An Bord Altranais (2007) *Guidance to Nurses and Midwives on Medication Management* Dublin: An Bord Altranais

Health Service Executive (2016) *e-learning Guide to Medication Management*. Available at www.hseland.ie

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

Health Products Regulatory Authority, available at www.hpra.ie (accessed 16th June, 2020)

Health Service Executive (2010) *Healthcare Risk Waste Management Segregation Packaging and Storage Guidelines for healthcare Risk Waste*. 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 (Commencement) Order 2007. Dublin: Stationery Office.

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

Medicinal Products (Prescription and Control of Supply) (Amendment) Regulations 2007, Statutory Instruments No. 201 of 2007. Dublin: Stationery Office.

Misuse of Drugs Regulations 2017, Statutory Instruments No.173 of 2017. Dublin: Stationery Office.

National Immunisation Advisory Committee (2019) *Anaphylaxis: Treatment in the Community*. Available at <https://www.hse.ie/eng/health/immunisation/hcpinfo/guidelines/Anaphylaxis.pdf>

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/>)

National Immunisation Office (2020) *Information for Staff: School Immunisation Programme: Health Service Executive, 2020/2021*

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: <https://www.nmbi.ie/Standards-Guidance/Code>.

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>

Boostrix Medicine Protocol

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 2020/2021 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 Nursing and Midwifery Working Group, 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 :

- An Bord Altranais (2007) *Guidance to Nurses and Midwives on Medication Management* Dublin: An Bord 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 anaphylaxis or suspected anaphylaxis*. Dublin: Health Service Executive
- National Immunisation Office) 2020 Supporting Information for Staff: Schools Immunisation Programme 2020/2021 available at www.immunisation.ie
- 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 (2014) *Code of Professional Conduct and Ethics for Registered Nurses and Registered Midwives*. Dublin: Nursing and Midwifery Board of Ireland available at: <https://www.nmbi.ie/Standards-Guidance/Code>.
- 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-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 Tdap Vaccine (Boostrix) by registered nurses and midwives to students in first year in Second Level School through a School Immunisation Programme

Medicine Protocol for the Administration of Tdap Vaccine (Boostrix) by registered nurses and midwives to students in first year in Second Level School through a School Immunisation Programme

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| Document reference number: | ONMSD 2020 - 010 |
| 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: <ul style="list-style-type: none"> 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 2020 |
| Date for review of protocol | May 2021 |
| 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 Lorraine Doherty, National Clinical Director Health Protection. |
| Names and Signatures of the employing authority who is authorising the implementation of the protocol <i>"On behalf of the authority employing professionals authorised to administer under this medicine protocol, I have read this medicine protocol and authorise its implementation"</i> | Name: Dr. Lorraine Doherty , National Clinical Director Health Protection, HSE Signature:  Name: Dr Colm Henry , Chief Clinical Officer, HSE Signature:  Name: Dr Geraldine Shaw , Nursing and Midwifery Services Director, HSE Signature:  |

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| 2.0 Clinical Criteria | |
| Clinical Condition for use of the protocol | <p>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.</p> <p>For 2020/2021 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.</p> |
| Circumstances in which the medicine protocol applies | <p>The School Immunisation Programme (SIP) will be delivered annually by the Health Service Executive (HSE).</p> <p>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/eng/health/immunisation/hcpinfo/guidelines/.</p> <p>For 2020/2021 Boostrix may also be given, to students who are outside the First year cohort group who missed the Boostrix vaccine programme in first year due to exceptional/ medical reasons and whose parents/legal guardians now request it, or who were unable to attend the 2020 summer vaccine catch-up clinics.</p> |
| Inclusion criteria for student/service user treatment using the medicine protocol | <p>Students in 1st year of second level school and age equivalent in special schools and home schooled students.</p> <p>https://www.hse.ie/eng/health/immunisation/pubinfo/schoolprog/4in1mmr/schoolguidelines.pdf</p> <p>For 2020/2021 Boostrix may also be given, to students who are outside the First year cohort group who missed the Boostrix vaccine programme in first year due to exceptional/ medical reasons and whose parents/legal guardians now request it, or who were unable to attend the 2020 summer vaccine catch-up clinics.</p> <p>Students with valid consent.</p> |
| Exclusion criteria for student/service treatment using the medicine protocol | <p>A known history of anaphylactic or hypersensitivity reaction to Boostrix or to any of the Boostrix vaccine constituents.</p> <p>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.</p> <p>Students with a contraindication to intramuscular injection (haematological disorder/coagulation disorder e.g. haemophilia, severe thrombocytopenia)</p> <p>Students who are immunocompromised either due to disease or treatment</p> |
| Actions to be taken for those students who are excluded from the Protocol | <ul style="list-style-type: none"> • 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 |

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| | <p>nurse or midwife may administer Tdap Vaccine (Boostrix) within their scope of practice.</p> <p><i>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).</i></p> |
| Description of circumstances and referral arrangements when further advice or consultation is required | <p>Discuss the student with the Medical Practitioner or lead nurse in the event of:</p> <ul style="list-style-type: none"> • Previous adverse reaction • Other clinical concerns |
| Documentation required for the implementation of this medicine protocol | <p>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.</p> <p>The following documents will be required at each school vaccination session:</p> <ul style="list-style-type: none"> • Vaccination session report form • Blank vaccine consent forms • Patient held record cards • Health Products Regulatory Authority Adverse Reaction Reporting forms • HSE Incident/near miss report forms (NIRF, 2020) • Tear pads for post vaccination <p>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:</p> <ul style="list-style-type: none"> • Supporting Information for Staff: School Immunisation Programme 2020/2021 • 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 <i>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)</i>, available at https://www.hse.ie/eng/health/immunisation/hcpinfo/guidelines/Anaphylaxis.pdf |
| 3.0 Name of Medicine | <p>Tdap Vaccine (Boostrix): 2020/2021</p> <p>Dose 0.5ml</p> <p>Route IM</p> <p>Site Deltoid (right side recommended)</p> |
| 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 | <p>Link to Summary of Product Characteristics:</p> <p>https://www.hpra.ie/img/uploaded/swedocuments/Licence_PA1077-020-001_06062019113754.pdf</p> <p>Link to Patient Information Leaflet</p> <p>https://www.hpra.ie/img/uploaded/swedocuments/2177440.PA1077_020_001.c3a82a06-8246-4f8b-899b-9f40420f17dd.000001pl.170109.pdf</p> |

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| Procedure for the reporting and documentation of errors and near misses involving the medication | <p>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.</p> <p>Vital signs should be recorded and the student should be reviewed by the registered nurse/midwife and/ or medical practitioner.</p> <p>The incident must be reported to the relevant line manager as soon as possible. The incident and all sections taken must be properly recorded and the relevant (National Incident Report Form (NIRF--01-V 11 March 2020): https://www.hse.ie/eng/about/qavd/incident-management/nirf-01-v11-person.pdf</p> <p>The incident and all actions taken must be promptly recorded in the student's documentation/notes and the relevant report form completed.</p> <p>The student's parent and/or legal guardian/teacher/GP should be informed of the incident.</p> <p>An incident report form must be completed by the registered nurse or registered midwife and forwarded to relevant line manager as per local policy.</p> <p>Any suspected adverse reactions associated with medication errors should be reported to the HPRA as outlined below.</p> <p>Any errors and near misses not involving medication (i.e. needle stick injury), 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. Refer 'EMI Tool Kit' (https://www.hpsc.ie/a-z/EMIToolkit/).</p> |
| Procedure for reporting Adverse Drug Reactions to the Health Products Regulatory Authority (HPRA) | <p>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</p> <p>The incident and all actions taken must be promptly recorded in accordance with the criteria outlined by the HPRA: <i>Management of a Patient with Anaphylaxis : Treatment in the Community</i> (National Immunisation Advisory Committee, 2019) – available online at https://www.hse.ie/eng/health/immunisation/hcpinfo/guidelines/Anaphylaxis.pdf</p> |
| Resources and equipment required | <ul style="list-style-type: none"> • Vaccine (pre-filled syringe) • Fridge/Cool box with minimum/maximum temperature recording device to monitor the cold chain temperature (between +2°C and +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 <i>Management of a Patient with anaphylaxis</i> (National Immunisation Advisory Committee, 2019) |

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| | <p>available at https://www.hse.ie/eng/health/immunisation/hcpinfo/guidelines/Anaphylaxis.pdf</p> <ul style="list-style-type: none"> • 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 | |
| <p>Advice to be given to the student/parent/guardian before treatment</p> <p>Advice to be given to the student/parent/guardian after treatment</p> | <p>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.</p> <p>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.</p> <p>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.</p> |
| 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, training, and competence required prior to using this medicine protocol</p> <p>Professional Qualifications</p> <p>Training and Competence:</p> | <p>Registered nurse or registered midwife on the active register maintained by The Nursing and Midwifery Board of Ireland.</p> <p>National Schools Immunisation programme for registered nurses and registered midwives on the use of this medicine protocol.</p> <p>Basic Life Support for Health Care Providers within the last two years.</p> <p>Initial anaphylaxis programme ("<i>National Anaphylaxis Education Programme for Health Care Professionals</i>") via HSEland followed by a one and a half hour classroom based skills workshop (replacing the previous four hour classroom based programme). Subsequent updates every two years via HSEland Anaphylaxis e-learning programme available at www.hse.ie.</p> <p>The registered nurse/midwife must complete the "<i>Competency Self - Assessment Tool for registered nurses and registered midwives to supply and administer vaccines under medicine protocols through a schools immunisation programme</i>".</p> <p>Recommended:</p> <p>E-learning Guide to Medicine Management, available at www.hseland.ie</p> |

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| | <i>Introduction to Immunisation</i> , available at www.hseland.ie |
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References

An Bord Altranais (2007) *Guidance to Nurses and Midwives on Medication Management* Dublin: An Bord Altranais

Health Products Regulatory Authority (2015) available at www.hpra.ie (accessed 16th June 2020)

Health Service Executive (2016) E-Learning Guide to Medicine Management. Available at www.hseland.ie

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

Health Service Executive (2010) *Healthcare Risk Waste Management Segregation Packaging and Storage Guidelines for healthcare Risk Waste*. Dublin: Health Service Executive.

Tdap Vaccine (Boostrix) GlaxoSmithKline, Ireland Limited *Summary of Product Characteristics and Patient Information Leaflet*, SmPC revised June 2019 Available at www.hpra.ie

Irish Medicines Board (*Miscellaneous Provision*) Act 2006 (Commencement) Order 2007. Dublin: Stationery Office

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

Medicinal Products (Prescription and Control of Supply) (Amendment) Regulations 2007, Statutory Instruments No. 201 of 2007. Dublin: Stationery Office

Misuse of Drugs (Amendment) Regulations 2017, Statutory Instruments No.173 of 2017. Dublin: Stationery Office

National Immunisation Advisory Committee (2019) Anaphylaxis: Treatment in the Community. Available at <https://www.hse.ie/eng/health/immunisation/hcpinfo/guidelines/Anaphylaxis.pdf>

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

National Immunisation Office (2020) Information for Staff: School Immunisation Programme: Health Service Executive 2020/2021

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: <https://www.nmbi.ie/Standards-Guidance/Code>.

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-Practise-Scope-Definition>

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>.

Nimenrix Medicine Protocol



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

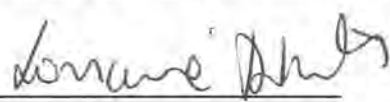
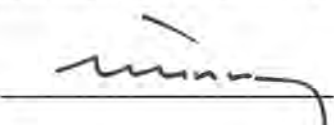
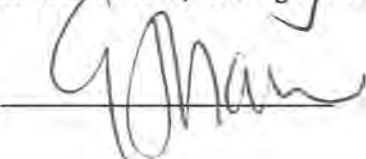
This medicine protocol is a specific written instruction for the administration of Nimenrix (MenACWY) Vaccine to students in Second Level School by registered nurses and registered midwives. **This medicine protocol is valid for the 2020/2021 HSE School Immunisation Programme.**

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 Nursing and Midwifery Immunisation Working Group, 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 :

- An Bord Altranais (2007) *Guidance to Nurses and Midwives on Medication Management* Dublin: An Bord 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 by nurses and midwives for the management of a patient with anaphylaxis or suspected anaphylaxis.* Dublin: Health Service Executive
- National Immunisation Office (2020) Supporting Information for Staff: Schools Immunisation Programme 2020/2021 available at <https://www.hse.ie/eng/health/immunisation/pubinfo/schoolprog/4in1mmr/schoolguidelines.pdf>
- 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 (2014) *Code of Professional Conduct and Ethics for Registered Nurses and Registered Midwives.* Dublin: Nursing and Midwifery Board of Ireland available at: <http://www.nmbi.ie/Standards-Guidance/Code>
- 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-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

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| Document reference number: | ONMSD 2020 -013 |
| 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: <ul style="list-style-type: none"> 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 2020 |
| Date for review of protocol | May 2021 |
| 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 Lorraine Doherty, National Clinical Director Health Protection. |
| Names and Signatures of the employing authority who is authorising the implementation of the protocol <i>"On behalf of the authority employing professionals authorised to administer under this medicine protocol, I have read this medicine protocol and authorise its implementation"</i> | Name: Dr. Lorraine Doherty , National Clinical Director Health Protection, HSE Signature:  Name: Dr Colm Henry , Chief Clinical Officer, HSE Signature:  Name: Dr Geraldine Shaw , Nursing and Midwifery Services Director, HSE Signature:  |

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| 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 | <p>The School Immunisation Programme (SIP) will be delivered annually by the Health Service Executive (HSE)</p> <p>The aim of this immunisation programme is to protect children against four types of meningococcal disease which can cause meningitis (inflammation of the lining around the brain) and /or septicaemia (blood poisoning). The Meningococcal ACWY vaccine will boost child's protection against group C meningococcal disease. It will also provide additional protection against meningococcal groups A, W and Y. In addition, this vaccine also reduces the risk of carrying the disease so can help protect other people too.</p> <p>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/</p> <p>For 2020/2021 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.</p> <p>The Nimenrix (MenACWY vaccine) can be offered to students who commenced in 1st year in 2019/2020 but were unable to attend the summer catch-up clinics and who are consented for the vaccine.</p> |
| Inclusion criteria for students treatment using the medicine protocol | <p>Students in 1st 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</p> <p>For 2020/2021 The Nimenrix (MenACWY vaccine) may also be given, to students who are outside the 1st year second level school 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, or who were in first year in 2019/20 and consented for the vaccine, but could not attend the summer catch-up clinics.</p> <p>Students with valid consent.</p> <p>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 | <p>A known history of anaphylactic or hypersensitivity reaction to Nimenrix vaccine or any of its components including Sucrose and Trometamol</p> <p>Already received a dose of conjugated Men ACWY vaccine at the age of 10 years or older.</p> <p>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.</p> |

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| | <p>Students with a contraindication to intramuscular injection (haematological disorder/coagulation disorder e.g. haemophilia, severe thrombocytopenia).</p> <p>Students who are immunocompromised either due to disease or treatment.</p> |
| Actions to be taken for those who are excluded from the Protocol | <ul style="list-style-type: none"> • 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. • Document action in clinical notes • Where Nimenrix Vaccine (MenACWY) is prescribed following medical assessment, the nurse or midwife may administer Nimenrix Vaccine (MenACWY) within their scope of practice. <p><i>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).</i></p> |
| Description of circumstances and referral arrangements when further advice or consultation is required | <p>Discuss the student with the Medical Practitioner or lead nurse in the event of:</p> <ul style="list-style-type: none"> • Previous adverse reaction • Other clinical concerns |

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| Documentation required for the implementation of this medicine protocol | <p>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.</p> <p>The following documents will be required at each school vaccination session:</p> <ul style="list-style-type: none"> • Vaccination session report forms • Blank Vaccine consent forms • Patient held record cards • Health Products Regulatory Authority Adverse Reaction Reporting forms • HSE Incident/near miss report forms (NIRF, 2020) • Tear pads post vaccination <p>It is the responsibility of each nurse or midwife to be familiar with the appropriate documentation to support the safe administration of Nimenrix Vaccine (MenACWY) vaccine which includes the following:</p> <ul style="list-style-type: none"> • Supporting Information for Staff: School Immunisation programme 2020/2021 • 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 <i>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)</i>, https://www.hse.ie/eng/health/immunisation/hcpinfo/fluinfo/adrenalineprotocol.pdf |
| 3.0 Name of Medicine | Nimenrix Vaccine (MenACWY) |

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| | <p>Dose 0.5ml</p> <p>Route IM</p> <p>Site Deltoid (Right side recommended)</p> <p>Vaccine must be reconstituted</p> |
| <p>Link to Medicine</p> <p>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</p> | <p>Link to Summary of Product Characteristics and Patient Information Leaflet:</p> <p>https://www.ema.europa.eu/en/documents/product-information/nimenrix-epar-product-information_en.pdf</p> |
| <p>Procedure for reporting and documentation of errors and near misses involving the medication</p> | <p>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.</p> <p>Vital signs should be recorded and the student should be reviewed by the registered nurse/midwife and medical practitioner.</p> <p>The incident must be reported to the relevant line manager as soon as possible.</p> <p>The incident and all actions taken must be promptly recorded in the student's documentation/notes and the relevant report form completed.</p> <p>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-V 11 March 2020): https://www.hse.ie/eng/about/qavd/incident-management/nirf-01-v11-person.pdf</p> <p>The student's parent and/or legal guardian must be informed of the incident.</p> <p>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.</p> <p>Any suspected adverse reactions associated with medication errors must be reported to the HPRA as outlined below.</p> <p>Any errors and near misses not involving medication, (i.e. needle stick injury) 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. Refer 'EMI Tool Kit' (https://www.hpsc.ie/a-z/EMIToolkit/).</p> |
| <p>Procedure for reporting Adverse Drug Reactions to the Health Products Regulatory Authority (HPRA)</p> | <p>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.</p> <p>The incident and all actions taken must be promptly recorded in accordance with the criteria outlined by the HPRA: <i>Management of a Patient with Anaphylaxis: Treatment</i></p> |

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| | <p>in the Community (National Immunisation Advisory Committee, 2019) – available online at</p> <p>https://www.hse.ie/eng/health/immunisation/hcpinfo/guidelines/Anaphylaxis.pdf</p> |
| Resources and equipment required | <ul style="list-style-type: none"> • Vaccine , Nimenrix powder & solvent • Fridge/Cool box with minimum/maximum temperature recording device to monitor the cold chain temperature (between +2°C and +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 <i>Management of a Patient with anaphylaxis</i>, (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 Meningococcal ACWY Vaccine (MenACWY). |
| 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 | |
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| <p>Advice to be given to the student/parent/legal guardian before treatment</p> <p>Advice to be given to the student/parent/guardian after treatment</p> | <p>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.</p> <p>After Treatment</p> <p>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.</p> <p>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.</p> |
| Details of any necessary | In the event of an adverse reaction the nurse/midwife must ensure that all procedures |

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| follow-up, action and referral arrangements | are adhered to as outlined in Section 3. |
| 5.0 Staff authorised to use this medicine protocol | |
| Professional qualifications, training, and competence required prior to using this medicine protocol Professional Qualifications Training and Competence: | <p>Registered nurse or registered midwife on the active register maintained by The Nursing and Midwifery Board of Ireland.</p> <p>National Schools Immunisation programme for registered nurses and registered midwives on the use of this medicine protocol.</p> <p>Basic Life Support for Health Care Providers within the last two years.</p> <p>Initial anaphylaxis programme (<i>“National Anaphylaxis Education Programme for Health Care Professionals”</i>) via HSEland followed by a one and a half hour classroom based skills workshop (replacing the previous four hour classroom based programme). Subsequent updates every two years via HSEland Anaphylaxis e-learning programme available at www.hse.ie.</p> <p>The registered nurse/midwife must complete the <i>“Competency Self - Assessment Tool for registered nurses and registered midwives to supply and administer vaccines under medicine protocols through a schools immunisation programme”</i>.</p> <p>Recommended:</p> <p>E-learning Guide to Medicine Management, available at www.hseland.ie</p> <p>Introduction to Immunisation, available at www.hseland.ie</p> |

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An Bord Altranais (2007) *Guidance to Nurses and Midwives on Medication Management* Dublin: An Bord

Altranais

Health Products Regulatory Authority available at www.hpra.ie (accessed 16th June 2020)

Health Service Executive (2016) e-learning Guide to Medicine Management. Available at www.hseland.ie

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Health Service Executive (2010) *Healthcare Risk Waste Management Segregation Packaging and Storage Guidelines for healthcare Risk Waste*. Dublin: Health Service Executive.

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

Irish Medicines Board (*Miscellaneous Provision*) Act 2006 (Commencement) Order 2007. Dublin: Stationery Office

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

Medicinal Products (Prescription and Control of Supply) (Amendment) Regulations 2007, Statutory Instruments No. 201 of 2007. Dublin: Stationery Office

Misuse of Drugs (Amendment) Regulations 2017, Statutory Instruments No.173 of 2017. Dublin: Stationery Office

National Immunisation Advisory Committee (2019) *Anaphylaxis: Treatment in the Community*. Available at <https://www.hse.ie/eng/health/immunisation/hcpinfo/guidelines/Anaphylaxis.pdf>

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/>

National Immunisation Office (2020) *Information for Staff: School Immunisation Programme: Health Service Executive 2020/2021*

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: <https://www.nmbi.ie/Standards-Guidance/Code>.

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>.

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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>

Catch up Programme

Primary school - IPV Boostrix



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

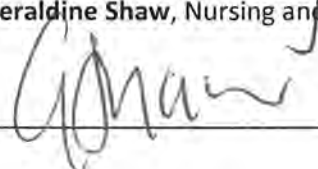
This medicine protocol is a specific written instruction for the administration of IPV Boostrix Vaccine Tdap/IPV (diphtheria, tetanus, pertussis (acellular, component) and poliomyelitis (inactivated) vaccine (adsorbed, reduced antigen(s) content), to children in Primary School by registered nurses and registered midwives. **This medicine protocol is valid for the 2020/2021 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 Nursing and Midwifery Immunisation Working Group, National Immunisation Advisory Committee, 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 :

- An Bord Altranais (2007) *Guidance to Nurses and Midwives on Medication Management* Dublin: An Bord 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 anaphylaxis or suspected anaphylaxis*. Dublin: Health Service Executive.
- National Immunisation Office 2020. Supporting Information for Staff: Schools Immunisation Programme 2020/2021 available at available at:
<https://hse.ie/eng/health/immunisation/hcpinfo/guidelines/immunisationguidelines.html>
- 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 (2014) *Code of Professional Conduct and Ethics for Registered Nurses and Registered Midwives*. Dublin: Nursing and Midwifery Board of Ireland available at: <https://www.nmbi.ie/Standards-Guidance/Code>.
- Nursing and Midwifery Board of Ireland (2015) *Practice Standards for Midwives*. Dublin: Nursing and Midwifery Board of Ireland available at: <http://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-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 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

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| Document number: | reference ONMSD 2020 -009 |
| 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: <ul style="list-style-type: none"> 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 2020 |
| Date for review of protocol | May 2021 |
| 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 Lorraine Doherty, National Clinical Director Health Protection. |
| Names and Signatures of the employing authority who is authorising the implementation of the protocol <i>"On behalf of the authority employing professionals authorised to administer under this medicine protocol, I have read this medicine protocol and authorise its implementation"</i> | Name: Dr. Lorraine Doherty , National Clinical Director Health Protection, HSE Signature:  Name: Dr Colm Henry , Chief Clinical Officer, HSE Signature:  Name: Dr Geraldine Shaw , Nursing and Midwifery Services Director, HSE Signature:  |

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| 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 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 |
| Circumstances in which the medicine protocol applies | <p>The School Immunisation Programme (SIP) will be delivered annually by the Health Service Executive (HSE)</p> <p>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 https://www.hse/eng/health/immunisation/hcpinfo/guidelines/.</p> |
| Inclusion criteria for children/students treatment using the medicine protocol | <p>All children in primary school usually delivered in junior infants and age equivalent in e.g. special schools and home schooled students. https://www.hse.ie/eng/health/immunisation/pubinfo/schoolprog/4in1mmr/schoolguidelines.pdf</p> <p>In 2020-21 academic year, IPV Boostrix should be given to students in senior infants, who had consented to receive the vaccine in junior infants but were unable to attend summer catch-up clinics.</p> <p>If IPV Boostrix is no longer available to order, these students may be given Tetravac.</p> <p>Children with valid consent.</p> |
| Exclusion criteria for children/students using the medicine protocol | <p>Children who have not commenced or completed immunisation course.</p> <p>A known history of anaphylactic or hypersensitivity reaction to IPV Boostrix or any of the vaccine's constituents including neomycin or polymyxin.</p> <p>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.</p> <p>Children with a contraindication to intramuscular injection (haematological disorder/coagulation disorder e.g. haemophilia, severe thrombocytopenia).</p> <p>Children who are immunocompromised either due to disease or treatment.</p> |
| Actions to be taken for those who are excluded from the Protocol | <ul style="list-style-type: none"> • 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. <p><i>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).</i></p> |

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| Description of circumstances and referral arrangements when further advice or consultation is required | <p>Discuss the student with the Medical Practitioner or lead nurse in the event of:</p> <p>Previous adverse reaction</p> <p>Other clinical concerns</p> |
| Documentation required for the implementation of this medicine protocol | <p>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.</p> <p>The following documents will be required at each school vaccination session:</p> <ul style="list-style-type: none"> • Vaccination session report 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, 2020) • Tear pads for after vaccination <p>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:</p> <ul style="list-style-type: none"> • Information for Staff: School Immunisation Programme 2020/2021 • 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 <i>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)</i>, available at https://www.hse.ie/eng/health/immunisation/hcpinfo/fluinfo/adrenalineprotocol.pdf |
| 3.0 Name of Medicine | <p>IPV Boostrix 2020/2021</p> <p>Dose 0.5ml</p> <p>Route IM</p> <p>Site Deltoid (left side recommended)</p> |
| 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 | <p>Link to Summary of Product Characteristics https://www.hpra.ie/img/uploaded/swedocuments/Licence_PA1077-101-001_30012019110555.pdf</p> <p>Link to Patient Information Leaflet: https://www.hpra.ie/img/uploaded/swedocuments/2177440.PA1077_101_001.30520b2e-7fdb-4bfc-8784-63a77e38b2ed.000001plipv.170109.pdf</p> |
| Procedure for reporting and documentation of errors and near misses involving the medication | <p>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.</p> |

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| | <p>Vital signs should be recorded and the student should be reviewed by the registered nurse/midwife and medical practitioner.</p> <p>The incident must be reported to the relevant line manager as soon as possible.</p> <p>The incident and all actions taken must be promptly recorded in the student's documentation/notes and the relevant report form completed.</p> <p>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-V 11 March 2020: https://www.hse.ie/eng/about/qavd/incident-management/nirf-01-v11-person.pdf The student's parent and/or legal guardian must be informed of the incident.</p> <p>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.</p> <p>Any suspected adverse reactions associated with medication errors must be reported to the HPRA as outlined below.</p> <p>Any errors and near misses not involving medication, (i.e. needle stick injury) 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. Refer 'EMI Tool Kit' (https://www.hpsc.ie/a-z/EMIToolkit/).</p> |
| Procedure for reporting Adverse Drug Reactions to the Health Products Regulatory Authority (HPRA) | <p>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.</p> <p>The incident and all actions taken must be promptly recorded in accordance with the criteria outlined by the HPRA: <i>Management of a Patient with Anaphylaxis: Treatment in the Community</i>. (National Immunisation Advisory Committee, 2019) – available online at https://www.hse.ie/eng/health/immunisation/hcpinfo/guidelines/Anaphylaxis.pdf</p> |
| Resources and equipment required | <ul style="list-style-type: none"> • Vaccine (pre-filled syringe) • Fridge/Cool box with minimum/maximum temperature recording device to monitor the cold chain temperature (between +2°C and +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 <i>Management of a Patient with Anaphylaxis or suspected anaphylaxis</i>, (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 IPV Boostrix Vaccine. |
| Audit process to identify appropriate use of the | <p>All documentation will be held for review and audit purposes as per local policy.</p> |

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| protocol or unexpected outcome | |
| 4.0 Information for child/student/parent/guardian | |
| Advice to be given to the child/student/parent/guardian before treatment | The HSE 4 in1 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 | <p>After Treatment</p> <p>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.</p> <p>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.</p> |
| 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, and competence required prior to using this medicine protocol Professional Qualifications Training and Competence: | <p>Registered nurse or registered midwife on the active register maintained by The Nursing and Midwifery Board of Ireland.</p> <p>National Schools Immunisation programme for registered nurses and registered midwives on the use of this medicine protocol.</p> <p>Basic Life Support for Health Care Providers within the last two years.</p> <p>Initial anaphylaxis programme ("<i>National Anaphylaxis Education Programme for Health Care Professionals</i>") via HSEland followed by a one and a half hour classroom based skills workshop (replacing the previous four hour classroom based programme). Subsequent updates every two years via HSEland Anaphylaxis e-learning programme available at www.hse.ie.</p> <p>The registered nurse/midwife must complete the "<i>Competency Self - Assessment Tool for registered nurses and registered midwives to supply and administer vaccines under medicine protocols through a schools immunisation programme</i>".</p> <p>Recommended:</p> <p>E-learning Guide to Medicine Management, available at www.hseland.ie</p> <p>Introduction to Immunisation, available at www.hseland.ie</p> |

References

An Bord Altranais (2007) *Guidance to Nurses and Midwives on Medication Management* Dublin: An Bord Altranais

Health Products Regulatory Authority available at www.hpra.ie (accessed 16th June 2020)

Health Service Executive (2016) E-Learning Guide to Medicines Management. Available at www.hseland.ie

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.

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

Medicinal Products (Prescription and Control of Supply) (Amendment) Regulations 2007, Statutory Instruments No. 201 of 2007. Dublin: Stationery Office.

Misuse of Drugs (Amendment) Regulations 2017, Statutory Instruments No.173 of 2017. Dublin: Stationery Office.

National Immunisation Advisory Committee (2019) Anaphylaxis: Treatment in the Community. Available at <https://www.hse.ie/eng/health/immunisation/hcpinfo/guidelines/Anaphylaxis.pdf> .

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/>

National Immunisation Office (2020) Information for Staff: School Immunisation Programme: Health Service Executive, 2020/2021

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 <https://www.nmbi.ie/Standards-Guidance/Code>

Nursing and Midwifery Board of Ireland (2015) *Practice Standards for Midwives* Dublin: Nursing and Midwifery Board of Ireland. And Midwifery Board of Ireland available at <http://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-Practise-Scope-Definition>

Second level school - Gardasil 4 Medicine Protocol



Medicine Protocol for the Administration of HPV vaccine (Gardasil, Type 6, 11, 16, 18) by registered nurses and registered midwives to students in Second level School through a School Immunisation Programme


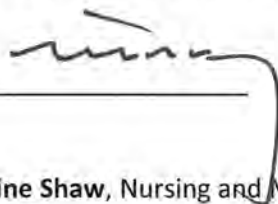

This medicine protocol is a specific written instruction for the administration of Gardasil , Human Papillomavirus vaccine (Type 6, 11, 16, 18) (HPV) to girls in Second Level School who are not individually identified before presentation for treatment by registered nurses and registered midwives. **This medicine protocol is valid for the 2020/2021 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 Nursing and Midwifery Immunisation Working Group, National Immunisation Advisory Committee, 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 :

- An Bord Altranais (2007) *Guidance to Nurses and Midwives on Medication Management* Dublin: An Bord 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 BP1:1000 by intramuscular injection for nurses and midwives for the management of a patient with anaphylaxis or suspected anaphylaxis.* Dublin: Health Service Executive
- National Immunisation office (2020) *Guidelines for Staff: Schools Immunisation Programme 2020/2021* available at <https://www.immunisation.ie>
- 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/>)
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- 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-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 medicine protocol is in effect” (An Bord Altranais, 2007).

Medicine Protocol for the Administration of HPV Vaccine (Gardasil, Type 6, 11, 16, 18) by registered nurses and midwives to girls in Second Level School through a School Immunisation Programme

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| Document reference number: | ONMSD 2020 - 012 |
| 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: <ul style="list-style-type: none"> 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 2020 |
| Date for review of protocol | May 2021 |
| 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 Lorraine Doherty, National Clinical Director Health Protection, HSE |
| Names and Signatures of the employing authority who is authorising the implementation of the protocol <i>"On behalf of the authority employing professionals authorised to administer under this medicine protocol, I have read this medicine protocol and authorise its implementation"</i> | <p>Name: Dr Lorraine Doherty, National Clinical Director Health protection, HSE</p> <p>Signature: </p> <p>Name: Dr Colm Henry, National Director of Clinical Strategy and Programmes, HSE</p> <p>Signature: </p> <p>Name: Dr. Geraldine Shaw, Nursing and Midwifery Services Director, HSE</p> <p>Signature: </p> |

| 2.0 Clinical Criteria | |
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| 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 | <p>The School Immunisation Programme (SIP) will be delivered annually by the Health Service Executive (HSE).</p> <p>The aim of this immunisation programme is to protect young girls against cervical cancer and other cancers caused by the HPV virus infection. This is because the most common cancer caused by the HPV virus is cervical cancer – cancer of the neck of the womb</p> <p>For 2020/2021 Gardasil will be given to :</p> <p>Girls in second level schools and or age equivalent in special schools and home schooled girls who have already commenced the School Immunisation programme Gardasil vaccine under the catch up programme to complete the schedule. Girls who started the HPV vaccine under 15 years of age require a second dose to complete their course.</p> <p>NIAC “recommends that the minimum interval between HPV1 and HPV2 is 24 weeks and the 4 day rule applies.</p> <p>This means the second dose of HPV vaccine can be considered valid if given at an interval of 24 weeks minus 4 days after the first dose”</p> <p>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.</p> <p>To accommodate girls aged 15 years and older at the time of their first HPV vaccine, completing their course, three doses of vaccine, administered at 0, 2 and 6 months are recommended. However, as per NIAC guidelines, if flexibility in the schedule is necessary, the second dose can be administered at a minimum interval of 4 weeks after the first dose or the third dose can be administered at a minimum interval of 12 weeks after the second dose.</p> <p>However, the minimum interval between the 1st and 3rd dose is 5 months.</p> <p>If stocks of Gardasil 4 are no longer available, the schedule can be completed with Gardasil 9 and the Gardasil 9 medicine protocol should be used.</p> <p>https://www.hse.ie/eng/health/immunisation/pubinfo/schoolprog/school.html</p> |
| Inclusion criteria for girl using the medicine protocol | <p>Girls in second level schools and or age equivalent in special schools and home schooled girls, who have already commenced the School Immunisation Programme for Gardasil vaccine under the catch up schedule to complete the Gardasil schedule.</p> <p>https://www.hse.ie/eng/health/immunisation/pubinfo/schoolprog/school.html</p> <p>For the 2020/2021 school year</p> <p>Girls in school outside of first year during 2019/2020 and 2020/2021 school year or age equivalent less than 16 years of age whose parents/legal guardians requested HPV vaccine before September 2020.</p> <p>Girls in school outside first year during 2019/2020 and 2020/2021 school year or age</p> |

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| | <p>equivalent age 16 years or older who requested HPV vaccine before September 2020.</p> <p>Girls with valid consent.</p> |
| Exclusion criteria for girl using the medicine protocol | <p>A known history of anaphylactic or hypersensitivity reaction to Gardasil or any of vaccines constituents.</p> <p>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.</p> <p>Girls with a contraindication to intramuscular injection (haematological disorder/coagulation disorder e.g. haemophilia, severe thrombocytopenia).</p> <p>Pregnancy where applicable.</p> <p>Girls who are immunocompromised either due to disease or treatment.</p> |
| Actions to be taken for those girls who are excluded from the Protocol | <ul style="list-style-type: none"> • All girls meeting exclusion criteria must be discussed with the medical practitioner for an individual assessment. • Document action in clinical notes • Where HPV Vaccine (Gardasil, 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. <p><i>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).</i></p> |
| Description of circumstances and referral arrangements when further advice or consultation is required | <p>Discuss the girl with the Medical Practitioner or lead Nurse in the event of:</p> <ul style="list-style-type: none"> • Previous adverse reaction • Other clinical concerns |
| Documentation required for the implementation of this medicine protocol | <p>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.</p> <p>The following documents will be required at each school vaccination session:</p> <ul style="list-style-type: none"> • Vaccination session report 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, 2020) • Tear pads for post vaccination <p>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:</p> <ul style="list-style-type: none"> • Supporting Information for Staff: School Immunisation Programme 2020/2021 • Medicine Protocol for the administration of (Gardasil 4, Type 6, 11, 16, 18) vaccine • Directions for nurses and midwives for the management of a patient who develops anaphylaxis incorporating <i>Medication Protocol for the Administration</i> |

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| | <p><i>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</i></p> <p>https://www.hse.ie/eng/health/immunisation/hcpinfo/fluinfo/adrenalineprotocol.pdf</p> |
| 3.0 Name of Medicine: Gardasil Dose: 0.5ml Route: Intramuscular Injection Site: Deltoid (Left side recommended) | |
| 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 | <p>HPV Vaccine (Gardasil , Type 6, 11, 16, 18) 2020/2021</p> <p>Link to Summary of Product Characteristics and Patient Information Leaflet: https://www.ema.europa.eu/docs/en_GB/document_library/EPAR_-_Product_Information/human/000703/WC500021142.pdf</p> |
| Procedure for the reporting and documentation of errors and near misses involving the medicine | <p>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.</p> <p>Vital signs should be recorded and the girl should be reviewed by the registered nurse/midwife and/or medical practitioner.</p> <p>The incident must be reported to the relevant line manager as soon as possible.</p> <p>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-V 11 March 2020): https://www.hse.ie/eng/about/qavd/incident-management/nirf-01-v11-person.pdf</p> <p>The incident and all actions taken must be promptly recorded in the girl's documentation/notes and the relevant report form completed.</p> <p>The student's parent and/or legal guardian should be informed of the incident.</p> <p>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.</p> <p>Any errors and near misses not involving medication, (i.e. needle stick injury) 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). Refer 'EMI Tool Kit' (https://www.hpsc.ie/a-z/EMIToolkit/).</p> |
| Procedure for reporting Adverse Drug Reactions | <p>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</p> |

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| to the Health Products Regulatory Authority (HPRA) | <p>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 request from the HPRA.</p> <p>The incident and all actions taken must be promptly recorded in accordance with the criteria outlined by the HPRA : <i>Management of a Patient with Anaphylaxis : Treatment in the Community</i> (National Immunisation Advisory Committee 2019) – available online at</p> <p>https://www.hse.ie/eng/health/immunisation/hcpinfo/guidelines/Anaphylaxis.pdf</p> |
| Resources and equipment required | <ul style="list-style-type: none"> • Vaccine (pre-filled syringe) • Fridge/Cool box with minimum/maximum temperature recording device to monitor the cold chain temperature (between +2°C and +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 <i>Management of a Patient with Anaphylaxis</i>, (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 HPV Vaccine (Gardasil). |
| Audit process to identify appropriate use of the protocol or unexpected outcomes | <p>All documentation will be held for review and audit purposes as per local policy.</p> |
| 4.0 Information for the girl/parent/guardian | |
| <p>Advice to be given to girl/parent/guardian before treatment</p> <p>Advice to be given to the girl/parent/guardian after treatment</p> | <p>HSE vaccination programme information leaflet must have been supplied with the consent form to each parent/legal guardian prior to administration of the vaccine</p> <p>After Treatment</p> <p>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.</p> <p>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.</p> |
| Details of any necessary follow-up, action and referral arrangements | <p>In the event of an adverse reaction the nurse/midwife must ensure that all procedures are adhered to as outlined in Section 3.</p> |

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| 5.0 Staff authorised to use this medicine protocol | |
| Professional qualifications, training, experience and competence required prior to working under this medicine protocol Professional Qualifications Training, Experience, Competence | <p>Registered nurse or registered midwife on the active register maintained by The Nursing and Midwifery Board of Ireland.</p> <p>National Schools Immunisation programme for registered nurses and registered midwives on the use of this medicine protocol.</p> <p>Basic Life Support for Health Care Providers within the last two years.</p> <p>Initial anaphylaxis programme (<i>“National Anaphylaxis Education Programme for Health Care Professionals”</i>) via HSEland followed by a one and a half hour classroom based skills workshop (replacing the previous four hour classroom based programme). Subsequent updates every two years via HSEland Anaphylaxis e-learning programme available at www.hse.ie.</p> <p>The registered nurse/midwife must complete the <i>“Competency Self - Assessment Tool for registered nurses and registered midwives to supply and administer vaccines under medicine protocols through a schools immunisation programme”</i>.</p> <p>Recommended:</p> <p>E-learning Guide to Medicine Management, available at www.hseland.ie</p> <p>Introduction to Immunisation, available at www.hseland.ie</p> |

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Published by: National Immunisation Office

Publication Date: September 2020

