



Medicine Protocol for the administration of Gardasil 9 (HPV) vaccine by registered nurses and registered midwives to students in second level school through a School Immunisation Programme


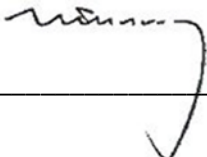

This medicine protocol is a specific written instruction for the administration of Gardasil 9 (HPV) vaccine, Human Papillomavirus vaccine (HPV Types 6, 11, 16, 18, 31, 33, 45, 52 and 58) to students in Second Level School who are not individually identified before presentation for treatment by registered nurses and registered midwives. This medicine protocol is valid for the 2023/2024 Health Service Executive (HSE) School Immunisation Programme (SIP).

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 Gardasil 9 (HPV) vaccine with reference to and guidance from Nursing & Midwifery Board of Ireland (NMBI), National Nursing and Midwifery Immunisation Working Group, National Immunisation Advisory Committee (NIAC), National Immunisation Office (NIO), HSE and in accordance with the Summary of Product Characteristics (SmPC) for Gardasil 9 (HPV) vaccine as detailed by the European Medicines Agency (EMA) at www.ema.ie

- National Immunisation Advisory Committee (2023) *Anaphylaxis: Immediate Management in the Community* available at:
https://rcpi.access.preservica.com/uncategorized/IO_a36f9e4b-4c80-432d-8264-546089359925/
- National Immunisation Advisory Committee *Immunisation Guidelines for Ireland*: Royal College of Physicians of Ireland National Immunisation Advisory Committee available at:
<https://www.rcpi.ie/Healthcare-Leadership/NIAC/Immunisation-Guidelines-for-Ireland>
- National Immunisation Office (2023/2024) *Supporting Information for Staff: Schools Immunisation Programme* available at:
<https://www.hse.ie/eng/health/immunisation/hcpinfo/schoolproghcp/supportingdoc.pdf>
- Nursing and Midwifery Board of Ireland (2021) *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/NMBI/media/NMBI/Code-of-Professional-Conduct-and-Ethics.pdf>
- Nursing and Midwifery Board of Ireland (2020) *Guidance for Registered Nurses and Midwives on Medication Administration* available at:
<https://www.nmbi.ie/NMBI/media/NMBI/NMBI-Medication-Administration-2020.pdf?ext=.pdf>
- Nursing and Midwifery Board of Ireland (2022) *Practice Standards for Midwives*. Dublin: Nursing and Midwifery Board of Ireland available at:
<https://www.nmbi.ie/Standards-Guidance>
- Nursing and Midwifery Board of Ireland (2015) *Recording Clinical Practice. Guidance to Nurses and Midwives*. Dublin: Nursing and Midwifery Board of Ireland available at:
<https://www.nmbi.ie/Standards-Guidance/More-Standards-Guidance/Recording-Clinical-Practice>
- Nursing and Midwifery Board of Ireland (2015) *Scope of Nursing and Midwifery Practice Framework*. Dublin: Nursing and Midwifery Board of Ireland available at:
<https://www.nmbi.ie/Standards-Guidance/Scope-of-Practice/Nursing-Practice-Scope-Definition>

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

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Document reference number	ONMSD 2023-006
1.0 Critical Elements	
Name of Organisation where protocol applies	Health Service Providers across the voluntary and statutory services of HSE. This Medicine Protocol applies to: Registered nurses and midwives involved in the supply and administration of the Gardasil 9 (HPV) vaccine to students in second level schools through a SIP.
Date the protocol comes into effect	September 2023 (For the school year of September 2023 – September 2024)
Date for review of protocol	May 2024
Document prepared by:	Office of the Nursing and Midwifery Services Director (ONMSD) HSE, in collaboration with the NIO at the request of Dr Éamonn O' Moore, Director of National Health Protection, HSE.
<p>Names and Signatures of the employing authority who is authorising the implementation of the protocol</p> <p><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>	<p>Name: Dr Éamonn O'Moore Director of National Health Protection, , HSE</p> <p style="text-align: center;"></p> <p>Signature: _____</p> <p>Name: Dr Colm Henry, Chief Clinical Officer, HSE</p> <p style="text-align: center;"></p> <p>Signature: _____</p> <p>Name: Dr Geraldine Shaw, Nursing and Midwifery Services Director, , HSE</p> <p style="text-align: center;"></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 premalignant lesions and cancers affecting the cervix, vulva, vagina and anus caused by vaccine HPV types 16, 18, 31, 33, 45, 52 and 58 and external genital warts (condyloma acuminata) causally related to HPV types 6 and 11.

Circumstances in which the medicine protocol applies

The SIP will be delivered annually by the HSE.

Gardasil 9 (HPV) vaccine is administered as a vaccination for students in first year of second level schools and or age equivalent in special schools and home schooled.

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 2023/2024 school year.

<https://www.hse.ie/eng/health/immunisation/hcpinfo/schoolproghcp/>

NIAC recommends a single dose of HPV 9 vaccine for those aged 9-24 years of age (unless they are immunocompromised, when three doses are required). Therefore, students with a healthy immune system require only one dose of Gardasil 9 (HPV) vaccine

<https://www.hse.ie/eng/health/immunisation/hcpinfo/guidelines/chapter10.pdf>

Students with a healthy immune system who have had a single dose of any HPV vaccine are considered fully vaccinated as per the latest NIAC recommendations. Therefore, there is no need for them to receive further doses of Gardasil 9 (HPV9) vaccine.

Those who have completed a course of HPV vaccine (Gardasil 4) vaccination are considered fully vaccinated so they do not require revaccination with Gardasil 9 (HPV) vaccine as part of the routine schools programme.

Girls (currently in 2nd year – 6th year of secondary school, or in age-equivalent special schools or educated at home) and Boys (currently in 2nd year – 5th year of secondary school/6th year if they did not do transition year, or in age-equivalent special schools or educated at home) with a healthy immune system who have received a single dose of Gardasil 9 (HPV9) vaccine are considered fully vaccinated. Therefore, there is no need for them to receive further doses of Gardasil 9 (HPV9) vaccine.

Students who meet the inclusion criteria using this protocol outlined below, that have also been advised by their treating Specialist/Consultant that they require 3 doses of HPV vaccine due to immunocompromised, require a three dose HPV vaccination schedule at 0, 2 and 6 months.

Immunocompromised:

Those with the following conditions require a three dose schedule at 0, 2 and 6 months **regardless of age.**

- Haematopoietic stem cell or solid organ transplant recipients
- HIV infection
- Malignant haematological disorders affecting the bone marrow or lymphatic systems, e.g., leukaemia, lymphomas, blood dyscrasias up to 5 years from diagnosis
- Non-haematological malignant solid tumours
- Primary immunodeficiency (includes those who have Down Syndrome)
- Within two weeks of commencing, on or within three to six months of receiving significant immunosuppressive therapy – CONTACT specialist.

<p>Inclusion criteria for Students using the medicine protocol</p>	<p>Students in first year of second level school or age equivalent in special schools and home schooled students.</p> <p>Students with valid consent.</p> <p>All students with a valid consent form who did not receive a HPV Vaccine during the 2023/2024 school year.</p>
<p>Exclusion criteria for Students using the medicine protocol</p>	<ul style="list-style-type: none"> • Anaphylaxis to any of the vaccine constituents. • Pregnancy – HPV vaccine is not recommended during pregnancy <p>Note:</p> <ul style="list-style-type: none"> • Yeast allergy is not a contraindication to HPV4 or HPV9 vaccines. Although the vaccines are grown in yeast cells, the final product does not contain any yeast. <p>Precautions</p> <p>Acute severe febrile illness; defer until recovery.</p> <p>Syncope has been reported among adolescents before or following vaccination, particularly with the first dose. Recipients should be seated or lying down during vaccine administration.</p> <p>Note: COVID-19 vaccines and other vaccines may be administered at the same time or at any interval.</p>
<p>Actions to be taken for those students who are excluded from the Protocol</p>	<ul style="list-style-type: none"> • All students meeting exclusion criteria (excluding pregnancy) must be referred to a medical practitioner for an individual assessment. • Document action in clinical notes • Where Gardasil 9 (HPV) vaccine is prescribed following medical assessment, the nurse or midwife may administer Gardasil 9 (HPV) vaccine within their scope of practice. <p>Note: In determining their scope of practice, nurses and midwives must make judgements about their competency to carry out a role or activity (NMBI, 2022).</p>
<p>Description of circumstances and referral arrangements when further advice or consultation is required</p>	<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
<p>Documentation required for the implementation of this medicine protocol</p>	<p>A consent form must be completed by the parent /legal guardian for all students who receive the Gardasil 9 (HPV) vaccine. Relevant 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 Health Records/Vaccine passport • HPRA adverse reaction reporting forms • HSE Incident/Near Miss report forms • Tear pads for post vaccination and advice

	<p>It is the responsibility of each nurse or midwife to be familiar with the appropriate documentation to support the safe administration of Gardasil 9 (HPV) vaccine which includes the following:</p> <ul style="list-style-type: none"> • Supporting Information for Staff: SIP (2023/2024). • Medicine Protocol for the administration of HPV vaccine (Gardasil 9) NIAC (2023) <i>Anaphylaxis: Immediate Management in the Community</i> available at: https://rcpi.access.preservica.com/uncategorized/IO_a36f9e4b-4c80-432d-8264-546089359925/ • National Consent Policy(HSE2022) • https://www.hse.ie/eng/about/who/national-office-human-rights-equality-policy/consent/hse-national-consent-policy.pdf
<p>3.0 Name of Medicine</p>	<p>Gardasil 9 (HPV) Vaccine Dose: 0.5ml Route: Intramuscular injection Site: Deltoid (Left side recommended)</p>
<p>Link to Medicine Details of product information and other data including instructions for supply and administration is available from the European Medicines Agency (EMA) at www.ema.ie</p>	<p>Link to Summary of Product Characteristics and Patient Information Leaflet: https://www.ema.europa.eu/en/documents/product-information/gardasil-9-epar-product-information_en.pdf</p>
<p>Procedure for the 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 medication/patient/dose/route being administered or another medication 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 in the student’s documentation/notes and the relevant incident report form completed.</p> <p>https://www.hse.ie/eng/about/who/nqpsd/qps-incident-management/nims/nirf-01-v12-person-interactive.pdf</p> <p>The student’s parent and/or legal guardian should be informed of the incident.</p> <p>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/).</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 online 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>Resources and equipment required</p>	<ul style="list-style-type: none"> • Gardasil 9 (HPV) 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) • Vaccination cool packs • Disposable kidney dishes/coloured trays • Gauze swabs/Plasters • Sharps bins, and bags for disposal of healthcare risk and non risk waste • Alcohol hand sanitizer • Face masks • Access to telephone • Resuscitation equipment and drugs in accordance with the NIAC (2023) <i>Anaphylaxis: Immediate Management in the Community</i> available at: https://rcpi.access.preservica.com/uncategorized/IO_a36f9e4b-4c80-432d-8264-546089359925/ <p>Access to medical support</p> <ul style="list-style-type: none"> • Safe storage areas for medicines and equipment • Current medicine protocol for Gardasil 9 (HPV) Vaccine for SIP • HSE Policy on the Management of Sharps and Prevention of Sharp Injuries 2022 https://healthservice.hse.ie/filelibrary/staff/policy-on-the-management-of-sharps-and-prevention-of-sharp-injuries.pdf
<p>Audit process to identify appropriate use of the protocol or unexpected outcome</p>	<p>All documentation will be held for review and audit purposes as per local policy.</p>
<p>4.0 Information for the student/parent/guardian</p>	
<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 first 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 who is present.</p>

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

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

5.0 Staff authorised to use this medicine protocol

Professional qualifications, training, and competence required prior to using this medicine protocol Professional Qualifications

Registered nurse or registered midwife must have completed all of the following:

1. Be a Registered Nurse or Registered Midwife, on the active register maintained by the NMBI
2. Education programme for nurses and midwives on *Schools Immunisation Programme* and any updates for nurses and midwives accessible on www.HSELand.ie
3. An approved *Basic Life Support for Health Care Providers Course* within the last two years (i.e. Irish Heart Foundation (IHF))
4. Initial *National Anaphylaxis Education Programme for Health Care Professionals* accessible on www.HSELand.ie followed by a two hour classroom based skills workshop. Recertification is required every two years by completing the on-line *National Anaphylaxis Education Programme for Health Care Professionals* accessible on www.HSELand.ie
5. Immunisation Foundation Programme available on www.HSELand.ie
6. Module 1 - The HPV Vaccine: About HPV and the vaccine available on www.HSELand.ie
Module 2 - The HPV Vaccine: Giving the vaccine available on www.HSELand.ie
7. The registered nurse/midwife must complete the Competency Self-Assessment Form available at www.immunisation.ie

References

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

Health Products Regulatory Authority available at www.hpra.ie

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

HSE Policy on the Management of Sharps and Prevention of Sharp Injuries (2022).

HPV Vaccine (Gardasil9) MSD Ireland Limited *Summary of Product Characteristics and Patient Information Leaflet* available at www.ema.ie

HSE *National Consent Policy* (2022)

<https://www.hse.ie/eng/about/who/national-office-human-rights-equality-policy/consent/>

National Immunisation Advisory Committee (2023) *Anaphylaxis: Treatment in the Community*. Available at https://rcpi.access.preservica.com/uncategorized/IO_a36f9e4b-4c80-432d-8264-546089359925/

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.rcpi.ie/Healthcare-Leadership/NIAC/Immunisation-Guidelines-for-Ireland>

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

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

Nursing and Midwifery Board of Ireland (2021) *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 (2022) *Practice Standards for Midwives* Dublin: Nursing and Midwifery Board of Ireland available at:

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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-Practice-Scope-Definition>

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<https://www.nmbi.ie/Standards-Guidance/More-Standards-Guidance/Recording-Clinical-Practice>

