

## 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


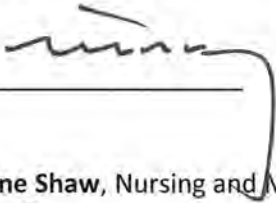

This medicine protocol is a specific written instruction for the administration of Gardasil , Human Papillomavirus vaccine (Type 6, 11, 16, 18) (HPV) to girls in Second Level School who are not individually identified before presentation for treatment by registered nurses and registered midwives. **This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

Document reference number:	ONMSD 2020 - 012
<b>1.0 Critical Elements</b>	
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"> <li>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.</li> </ul>
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: <b>Dr Lorraine Doherty</b>, National Clinical Director Health protection, HSE</p> <p>Signature: </p> <p>Name: <b>Dr Colm Henry</b>, National Director of Clinical Strategy and Programmes, HSE</p> <p>Signature: </p> <p>Name: <b>Dr. Geraldine Shaw</b>, Nursing and Midwifery Services Director, HSE</p> <p>Signature: </p>

<b>2.0 Clinical Criteria</b>	
<b>Clinical Condition for use of the protocol</b>	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.
<b>Circumstances in which the medicine protocol applies</b>	<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 1<sup>st</sup> and 3<sup>rd</sup> 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><a href="https://www.hse.ie/eng/health/immunisation/pubinfo/schoolprog/school.html">https://www.hse.ie/eng/health/immunisation/pubinfo/schoolprog/school.html</a></p>
<b>Inclusion criteria for girl using the medicine protocol</b>	<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><a href="https://www.hse.ie/eng/health/immunisation/pubinfo/schoolprog/school.html">https://www.hse.ie/eng/health/immunisation/pubinfo/schoolprog/school.html</a></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>

	<p>equivalent age 16 years or older who requested HPV vaccine before September 2020.</p> <p>Girls with valid consent.</p>
<b>Exclusion criteria for girl using the medicine protocol</b>	<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>
<b>Actions to be taken for those girls who are excluded from the Protocol</b>	<ul style="list-style-type: none"> <li>• All girls meeting exclusion criteria must be discussed with the medical practitioner for an individual assessment.</li> <li>• Document action in clinical notes</li> <li>• 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.</li> </ul> <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>
<b>Description of circumstances and referral arrangements when further advice or consultation is required</b>	<p>Discuss the girl with the Medical Practitioner or lead Nurse in the event of:</p> <ul style="list-style-type: none"> <li>• Previous adverse reaction</li> <li>• Other clinical concerns</li> </ul>
<b>Documentation required for the implementation of this medicine protocol</b>	<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"> <li>• Vaccination session report form</li> <li>• Blank Vaccine consent forms</li> <li>• Vaccine Information Leaflets</li> <li>• Patient Immunisation Passport</li> <li>• Health Products Regulatory Authority Adverse Reaction Reporting forms</li> <li>• HSE Incident/near miss report forms (NIRF, 2020)</li> <li>• Tear pads for post vaccination</li> </ul> <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"> <li>• Supporting Information for Staff: School Immunisation Programme 2020/2021</li> <li>• Medicine Protocol for the administration of (Gardasil 4, Type 6, 11, 16, 18) vaccine</li> <li>• Directions for nurses and midwives for the management of a patient who develops anaphylaxis incorporating <i>Medication Protocol for the Administration</i></li> </ul>

	<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><a href="https://www.hse.ie/eng/health/immunisation/hcpinfo/fluinfo/adrenalineprotocol.pdf">https://www.hse.ie/eng/health/immunisation/hcpinfo/fluinfo/adrenalineprotocol.pdf</a></p>
<p><b>3.0 Name of Medicine: Gardasil</b>  <b>Dose: 0.5ml</b>  <b>Route: Intramuscular Injection</b>  <b>Site: Deltoid (Left side recommended)</b></p>	
<p><b>Link to Medicine</b></p> <p><b>Details of product information and other data including instructions for supply and administration is available from the Health Products Regulatory Authority at <a href="http://www.hpra.ie">www.hpra.ie</a></b></p>	<p>HPV Vaccine (Gardasil , Type 6, 11, 16, 18) 2020/2021</p> <p><b>Link to Summary of Product Characteristics and Patient Information Leaflet:</b>  <a href="https://www.ema.europa.eu/docs/en_GB/document_library/EPAR_-_Product_Information/human/000703/WC500021142.pdf">https://www.ema.europa.eu/docs/en_GB/document_library/EPAR_-_Product_Information/human/000703/WC500021142.pdf</a></p>
<p><b>Procedure for the reporting and documentation of errors and near misses involving the medicine</b></p>	<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):  <a href="https://www.hse.ie/eng/about/qavd/incident-management/nirf-01-v11-person.pdf">https://www.hse.ie/eng/about/qavd/incident-management/nirf-01-v11-person.pdf</a></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' (<a href="https://www.hpsc.ie/a-z/EMIToolkit/">https://www.hpsc.ie/a-z/EMIToolkit/</a>).</p>
<p><b>Procedure for reporting Adverse Drug Reactions</b></p>	<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>

<p><b>to the Health Products Regulatory Authority (HPRA)</b></p>	<p>reporting may be carried out in line at <a href="https://www.hpra.ie">https://www.hpra.ie</a> 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><a href="https://www.hse.ie/eng/health/immunisation/hcpinfo/guidelines/Anaphylaxis.pdf">https://www.hse.ie/eng/health/immunisation/hcpinfo/guidelines/Anaphylaxis.pdf</a></p>
<p><b>Resources and equipment required</b></p>	<ul style="list-style-type: none"> <li>• Vaccine (pre-filled syringe)</li> <li>• Fridge/Cool box with minimum/maximum temperature recording device to monitor the cold chain temperature (between +2°C and +8°C)</li> <li>• Disposable kidney dishes/coloured trays</li> <li>• Gauze swabs/Plasters</li> <li>• Sharps bins, and bags for disposal of other hazardous material</li> <li>• Alcohol hand rinse</li> <li>• Access to telephone</li> <li>• Resuscitation equipment and drugs in accordance with the <i>Management of a Patient with Anaphylaxis</i>, (National Immunisation Advisory Committee, 2019) available at <a href="https://www.hse.ie/eng/health/immunisation/hcpinfo/guidelines/Anaphylaxis.pdf">https://www.hse.ie/eng/health/immunisation/hcpinfo/guidelines/Anaphylaxis.pdf</a></li> <li>• Access to medical support</li> <li>• Safe storage areas for medicines and equipment</li> <li>• Current medicine protocol for HPV Vaccine (Gardasil ).</li> </ul>
<p><b>Audit process to identify appropriate use of the protocol or unexpected outcomes</b></p>	<p>All documentation will be held for review and audit purposes as per local policy.</p>
<p><b>4.0 Information for the girl/parent/guardian</b></p>	
<p><b>Advice to be given to girl/parent/guardian before treatment</b></p> <p><b>Advice to be given to the girl/parent/guardian after treatment</b></p>	<p><b>HSE vaccination programme information leaflet must have been supplied with the consent form to each parent/legal guardian prior to administration of the vaccine</b></p> <p><b>After Treatment</b> 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>
<p><b>Details of any necessary follow-up, action and referral arrangements</b></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>

<b>5.0 Staff authorised to use this medicine protocol</b>	
<p><b>Professional qualifications, training, experience and competence required prior to working under this medicine protocol</b></p> <p><b>Professional Qualifications</b></p> <p><b>Training, Experience, Competence</b></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 <a href="http://www.hse.ie">www.hse.ie</a>.</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><b>Recommended:</b></p> <p><i>E-learning Guide to Medicine Management</i>, available at <a href="http://www.hseland.ie">www.hseland.ie</a></p> <p><i>Introduction to Immunisation</i>, available at <a href="http://www.hseland.ie">www.hseland.ie</a></p>

**References**

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

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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.

HPV Vaccine (Gardasil 4) MSD Ireland Limited *Summary of Product Characteristics and Patient Information Leaflet Updated May 2017* Available at [www.hpra.ie](http://www.hpra.ie)

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*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.

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