

Medicine Protocol for the Administration of HPV vaccine (Gardasil) by registered nurses and registered midwives




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 2017/2018 HSE School Immunisation Programme.**

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

- An Bord Altranais (2007) *Guidance to Nurses and Midwives on Medication Management* Dublin: An Bord Altranais
- Health Services Executive (2016) *Directions for Nurses and Midwives for the Management of a Patient who Develops Anaphylaxis*. Dublin: Health Service Executive
- Health Service Executive (2017) Guidelines for Staff: Schools Immunisation Programme 2017/2018 available at <http://www.hse.ie/eng/health/immunisation/pubinfo/schoolprog/4in1mmr/schoolguidelines.pdf>
- Health Service Executive National Immunisation Office (2008) *A Practical Guide to Immunisation*. Dublin: Health Service Executive available at <http://www.hse.ie/eng/health/immunisation/hcinfo/trainingmanual/>
- 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 <http://www.hse.ie/eng/health/immunisation/hcinfo/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>
- Nursing and Midwifery Board of Ireland (2016) e-learning Guide to Medicine Management. Available at <http://www.hseland.ie>

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

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

Document reference number:	ONMSD 2017-006
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 school through a School Immunisation Programme.
Date the protocol comes into effect	September 2017
Date for review of protocol	May 2018
Document prepared by:	Office of the Nursing and Midwifery Services Director (ONMSD) HSE, in collaboration with the National Immunisation Office (NIO) at the request of Dr Kevin Kelleher, Assistant National Director, Health and Wellbeing – Public Health and Child Health, 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. Kevin Kelleher Assistant National Director, Health and Wellbeing – Public Health and Child Health, HSE</p> <p>Signature:  <i>McK 19719</i></p> <p>Name: Dr Áine Carroll, National Director of Clinical Strategy and Programmes, HSE</p> <p>Signature: </p> <p>Name: Ms Mary Wynne, Nursing and Midwifery Services Director, HSE</p> <p>Signature:  <i>NMBI 26108</i></p>

2.0 Clinical Criteria	
Clinical Condition for use of the protocol	The clinical condition for which this medicine protocol has been developed is for the active immunisation against and prevention of premalignant genital lesions (cervical, vulvar, and vagina) and cervical cancer related to Human Papillomavirus (HPV) types 16 and 18 and external genital warts (condyloma acuminata) causally related to HPV types 6 and 11.
Circumstances in which the medicine protocol applies	<p>The School Immunisation Programme (SIP) will be delivered annually by the Health Service Executive (HSE).</p> <p>Gardasil is given as a vaccination for girls in first year of second level schools and or age equivalent in special schools and home schooled. The aim of the immunisation programme is to provide the HPV vaccine (Gardasil) schedule, as recommended in the Immunisation Guidelines for Ireland within the academic year.</p> <p>http://www.hse/eng/health/immunisation/hcpinfo/guidelines/</p> <p>For the 2017/2018 school year girls in school outside first year less than 16 years of age whose parents/legal guardians request HPV vaccine.</p> <p>Girls in school outside first year (in 2017/2018) age 16 years or older who request HPV vaccine.</p> <p>Girls will require one dose in September/October and a second dose six months (183 days) later.</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>http://www.hse.ie/eng/health/immunisation/pubinfo/schoolprog/4in1mmr/schoolguidelines.pdf</p>
Inclusion criteria for girl using the medicine protocol	<p>Girls in first year of second level school or age equivalent in special schools and home schooled students (NIAC, 2014) in</p> <p>http://www.hse.ie/eng/health/immunisation/pubinfo/schoolprog/4in1mmr/schoolguidelines.pdf</p> <p>For the 2017/2018 school year girls in school or age equivalent outside first year less than 16 years of age whose parents/legal guardians request HPV vaccine.</p> <p>Girls in school or age equivalent outside first year (in 2017/2018) age 16 years or older who request HPV vaccine.</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</p> <p>Girls who are immunocompromised either due to disease or treatment.</p>

<p>Actions to be taken for those girls who are excluded from the Protocol</p>	<ul style="list-style-type: none"> • All girls meeting exclusion criteria must be referred to the medical practitioner for an individual assessment. • Document action in clinical notes • Where HPV Vaccine (Gardasil) is prescribed following medical assessment, the nurse or midwife may administer HPV Vaccine (Gardasil) 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>
<p>Description of circumstances and referral arrangements when further advice or consultation is required</p>	<p>Refer the girl to the Medical Practitioner in the event of:</p> <ul style="list-style-type: none"> • Adverse reaction • Other clinical concerns
<p>Documentation required to support implementation of the medicine protocol</p>	<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 available 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 (NIRF,2017) • Tear pads for post vaccination • It is the responsibility of each nurse or midwife to be familiar with the appropriate documentation to support the safe administration of Gardasil vaccine which includes the following: <ul style="list-style-type: none"> • Guidelines for Staff: School Immunisation Programme 2017/2018 • Medicine Protocol for the administration of Gardasil vaccine by registered nurses and registered midwives through the School Immunisation Programme to <ol style="list-style-type: none"> 1. Girls in second level schools and age equivalent in special schools and home schooled students including , in a mop up clinic, girls in school outside first year (in 2017/2018) less than 16 years of age whose parents/legal guardians request vaccination 2. Girls in school outside first year (in 2017/2018) age 16 years of age or older who request vaccination. • Directions for nurses and midwives for the management of a patient who develops 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 (HSE 2016)</i>, available at http://www.hse.ie/eng/health/immunisation/hcpinfo/fluinfor/adrenalineprotocol.pdf
<p>3.0 Name of Medicine</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>HPV Vaccine (Gardasil) 2017/2018</p> <p>Link to Summary of Product Characteristics: https://www.hpra.ie/docs/default-source/3rd-party-documents/spc-gardasil-09062011.pdf?sfvrsn=2</p> <p>Link to Patient Information Leaflet: http://www.ema.europa.eu/docs/en_GB/document_library/EPAR_-_Product_Information/human/000703/WC500021142.pdf</p>
<p>Procedure for the management, reporting and documentation of errors and near misses involving the medication</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 medical practitioner.</p> <p>The incident must be reported to the relevant line manager as soon as possible.</p> <p>The incident and all sections taken must be promptly recorded and the relevant National Incident Management Report Form completed (National Incident Report Form (NIRF-01-V09)) (Jan 2017):https://www.hse.ie/eng/about/QAVD/Incident-Management/NIRF-01-V09-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.</p> <p>Any suspected adverse reactions associated with medication errors should be reported to the HPRA as outlined below.</p>
<p>Procedure for reporting Adverse Drug Reactions to the Health Products Regulatory Authority (HPRA)</p>	<p>All adverse drug reactions or suspected adverse drug reactions following administration of the vaccine must be reported as soon as possible in accordance with criteria outlined by the Health Products Regulatory Authority (HPRA).</p> <p>Reporting of suspected adverse reactions may be carried out on line at http://www.hpra.ie or through use of the yellow card system which is available in a 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 <i>Management of a Patient with Anaphylaxis HSE (2016)</i> – available online at</p>

	http://www.hse.ie/eng/health/immunisation/hcpinfo/guidelines/Anaphylaxis.pdf
Resources and equipment required	<ul style="list-style-type: none"> • Vaccine (pre-filled syringe) • Fridge/Cooler box with minimum/maximum thermometer to maintain cold chain temperature between +2° to +8°C • Disposable kidney dishes/coloured trays • Gauze swabs/Plasters • Sharps bins, and bags for disposal of other hazardous material • Alcohol hand rinse • Access to telephone • Resuscitation equipment and drugs in accordance with the <i>Management of a Patient with Anaphylaxis</i>, (HSE, 2016) available at http://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	All documentation will be held for review and audit purposes as per local policy.
4.0 Information for the girl/parent/guardian	
Advice to be given to girl/parent/guardian before treatment Advice to be given to the girl/parent/guardian after treatment	<p>HPV vaccine Gardasil 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 Information outlined on the Tear Pad must be explained to girl, and stating date and time of vaccination given for parental/guardian's attention. This 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	In the event of an adverse reaction the nurse/midwife must ensure that all procedures are adhered to as outlined in Section 3.
5.0 Staff authorised to use this medicine protocol	
Professional qualifications, training, experience and competence required prior to working under this medicine protocol	<p>Registered nurse or registered midwife on the live register of The Nursing and Midwifery Board of Ireland.</p> <p>Education programme for nurses and midwives on the use of <i>Medicine Protocol for the Administration of HPV Vaccine (Gardasil) through a School Immunisation Programme</i>.</p>

Basic Life Support for Health Care Workers within the last two years.

Approved Anaphylaxis Treatment Training programme initially, with updates as required to maintain individual competence.

Competency Injection Technique

Recommended:

Nursing and Midwifery Board of Ireland eLearning programme on *Medicines Management Standards for Nurses and Midwives* (2016).

References

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

European Medicines Agency available at www.EMA.europa.eu.

Health Products Regulatory Authority (2015) available at www.hpra.ie (accessed 9th March 2017).

Health Service Executive (2016) *Directions for Nurses and Midwives for the Management of a Patient who Develops 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.

HPV Vaccine (Gardasil) MSD Ireland Limited *Summary of Product Characteristics*,

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 2007, Statutory Instruments No.200 of 2007. Dublin: Stationery Office.

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

National Immunisation Office (2008) *A Practical Guide to Immunisation*. Dublin: Health Service Executive (available at www.immunisation.ie).

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>

Nursing and Midwifery Board of Ireland (2015) *Practice Standards for Midwives* Dublin: Nursing and Midwifery Board of Ireland.

Nursing and Midwifery Board of Ireland (2016) *e-learning Guide to Medication Management*. Available at www.hseland.ie



An Bord Altranais
Nursing Board

29 July 2011

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

Dear Mr. Shannon,

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

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

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

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

I hope this information is of assistance to you.

Yours sincerely,

Dr Mauna Piggott
Chief Executive Officer

Office of Nursing Services Director

- 3 AUG 2011

RECEIVED

¹ Tetravac vaccine, IPV Infanrix vaccine, Priorix vaccine, M-M RVAXPRO vaccine and Boostrix vaccine