



Medicine Protocol for the administration of Gardasil 9 (HPV9) vaccine for the Laura Brennan

HPV Vaccine Catch-up Programme

This medicine protocol is a specific written instruction for the administration of Gardasil 9 (HPV9) vaccine for the Laura Brennan HPV Vaccine catch up programme by registered nurses and registered midwives employed by the HSE. This protocol applies to (hereafter referred to as vaccine recipients):

- Females (currently in 2nd year – 6th year of secondary school, or in age-equivalent special schools or educated at home) who have not received the HPV vaccine
- Males (currently in 2nd year – 4th year of secondary school/5th year if they did not do transition year, or in age-equivalent special schools or educated at home) who have not received the HPV vaccine i.e. boys who were in 1st year from 1st September 2019 when the HPV vaccination programme was first extended to boys
- Unvaccinated females who have left second level education and are under 25 years of age on the date of vaccination



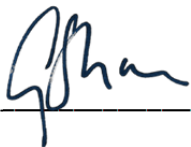
These groups of individuals are currently not eligible to receive the HPV vaccine under the School Immunisation Programme (SIP). This medicine protocol is valid for the duration of the 2022/2023 Health Service Executive (HSE) Laura Brennan HPV Vaccine Catch-up Programme.

This medicine protocol enables vaccinators employed in the voluntary and statutory services of the HSE who have undertaken the required education and training programmes to administer Gardasil 9 (HPV9) 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 (HPV9) vaccine as detailed by the European Medicines Agency (EMA) at www.ema.eu

- An Bord Altranais (2007) *Guidance to Nurses and Midwives on Medication Management*. Dublin: An Bord Altranais
- National Immunisation Advisory Committee (2022) *Anaphylaxis: Immediate Management in the Community* available at: <https://www.hse.ie/eng/health/immunisation/hcpinfo/guidelines/anaphylaxis.pdf>
- National Immunisation Advisory Committee *Immunisation Guidelines for Ireland*: Royal College of Physicians of Ireland National Immunisation Advisory Committee available at: <https://www.hse.ie/eng/health/immunisation/hcpinfo/guidelines/>
- National Immunisation Office (2022/2023) *Supporting Information for Staff: Schools Immunisation Programme* available at: <https://www.hse.ie/eng/health/immunisation/pubinfo/schoolprog/suppinfo4staff.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/MidwivesStandards>
- 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/StandardsGuidance/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 Gardasil 9 (HPV9) vaccine for the Laura Brennan HPV vaccine catch up programme

Document reference number	ONMSD 2022-017
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) and mass vaccination clinic venues. This Medicine Protocol applies to: Registered nurses and registered midwives employed by the Health Service Executive (HSE) who have undertaken the required education and training programmes to administer Gardasil 9 (HPV9) vaccine.
Date the protocol comes into effect	December 2022
Date for review of protocol	December 2023
Document prepared by	National Immunisation Office in collaboration with the Office of the Nursing and Midwifery Services Director (ONMSD) 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 Eamonn 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>

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	<p>Gardasil 9 (HPV9) vaccine is routinely administered to students in first year of second level schools and or age equivalent in special schools and home schooled.</p> <p>However, Department of Health (DoH) has recently announced the Laura Brennan HPV Vaccine Catch-up Programme for females and males who missed the opportunity to avail of the Gardasil (HPV9) vaccine when it was previously offered to them under the HSE School Immunisation Programme (SIP). Therefore, this HPV 9 vaccine catch up medicine protocol applies to this specific cohort of vaccine recipients only (specific eligible groups outlined in further detail in the next section outlining the inclusion criteria for recipients using this medicine protocol).</p> <p>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).</p> <p>COVID-19 Vaccines may be co-administered at the same time or at any interval of this vaccine given.</p>

Inclusion criteria for recipients using the medicine protocol	<ul style="list-style-type: none"> • Females (currently in 2nd year – 6th year of secondary school, or in age-equivalent special schools or educated at home) who have not received the HPV vaccine • Males (currently in 2nd year – 4th year of secondary school/5th year if they did not do transition year, or in age-equivalent special schools or educated at home) who have not received the HPV vaccine i.e. boys who were in 1st year from 1st September 2019 when the HPV vaccination programme was first extended to boys • Unvaccinated females who have left second level education and are under 25 years of age on the date of vaccination <p><u>Note:</u></p> <ul style="list-style-type: none"> • Females under the age of 25 yrs 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. • Males (currently in 2nd year – 4th year of secondary school/5th 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 also no need for them to receive further doses of Gardasil 9 (HPV9) vaccine. • Females and males who have completed the Gardasil 4 vaccine course are considered fully vaccinated. There is no need for them to receive a further dose of Gardasil 9 (HPV9) vaccine. • Individuals that meet the inclusion criteria for recipients using the protocol outlined above, that have also been advised by their treating Specialist/Consultant that they require 3 doses of HPV vaccine due to immunocompromise, require a three dose HPV vaccination schedule at 0, 2 and 6 months.
--	---

<p>Exclusion criteria for recipients 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: Yeast allergy is not a contraindication to Gardasil9 (HPV9) vaccine. Although the vaccines are grown in yeast cells, the final product does not contain any yeast.</p> <p>Precautions</p> <ul style="list-style-type: none"> • Acute severe febrile illness; defer until recovery. • 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>Actions to be taken for those recipients who are excluded from the Protocol</p>	<ul style="list-style-type: none"> • All vaccine recipients (excluding pregnant women) meeting exclusion criteria must be referred to a medical practitioner for an individual assessment. • Document action in clinical notes • Where Gardasil 9 (HPV9) vaccine is prescribed following medical assessment, the nurse or midwife may administer Gardasil 9 (HPV9) vaccine within their scope of practice.
<p>Description of circumstances and referral arrangements when further advice or consultation is required</p>	<p>Discuss the vaccine recipient 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>The following documents will be required at each vaccination session</p> <ul style="list-style-type: none"> • Vaccination session report form • Blank Vaccine consent forms • Vaccine Information Leaflets • Patient Health Records • HPRA adverse reaction reporting forms • HSE Incident/Near Miss report forms • Post vaccination advice <p>It is the responsibility of the vaccinator to be familiar with the appropriate documentation to support the safe administration of Gardasil 9 (HPV9) vaccine which includes the following:</p> <ul style="list-style-type: none"> • Medicine Protocol for the Administration of Gardasil 9 (HPV9) vaccine for the Laura Brennan HPV vaccine catch up programme • NIAC (2022) <i>Anaphylaxis: Immediate management in the Community</i> available at: https://www.hse.ie/eng/health/immunisation/hcpinfo/guidelines/anaphylaxis.pdf

<p>3.0 Name of Medicine</p>	<p>Gardasil 9 (HPV9) Vaccine Dose: 0.5ml Route: Intramuscular injection Site: Deltoid</p>
------------------------------------	--

<p>Link to Medicine</p> <p>Details of product information and other data including instructions for supply and administration is available from the www.ema.ie / www.hpra.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 vaccine recipient vaccinated, i.e. wrong medication/patient/dose/route being administered or another medication error, the vaccinator must remain with the vaccine recipient, and closely monitor them for any adverse reactions.</p> <p>Vital signs should be recorded and the vaccine recipient should be reviewed.</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 vaccine recipient'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>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 vaccinator 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 (HPV9) 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 (2022) <i>Anaphylaxis: Immediate Management in the Community</i> available at: https://www.hse.ie/eng/health/immunisation/hcpinfo/guidelines/anaphylaxis.pdf • Access to medical support • Safe storage areas for medicines and equipment • Medicine Protocol for the Administration of Gardasil 9 (HPV9) vaccine for the Laura Brennan HPV vaccine catch up programme

Audit process to identify appropriate use of the protocol or unexpected outcome	All documentation will be held for review and audit purposes as per local policy.
4.0 Information for the vaccine recipient/parent/guardian	
Advice to be given to the recipient 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/legal guardian’s attention. In the case of older vaccine recipients, they must be given this Information Tear Pad for their own attention and information. 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 recipient 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 vaccinator.</p>
Details of any necessary follow-up, action and referral arrangements	In the event of an adverse reaction, the vaccinator 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	<p>Registered nurse or registered midwife must have completed all of the following:</p> <ol style="list-style-type: none"> 1. Be a Registered Nurse or Registered Midwife, on the active register maintained by the NMBI 2. Education programme for nurses and midwives on <i>Schools Immunisation Programme</i> and any updates for nurses and midwives accessible on www.HSElanD.ie 3. An approved <i>Basic Life Support for Health Care Providers Course</i> within the last two years (i.e. Irish Heart Foundation (IHF)) 4. Initial <i>National Anaphylaxis Education Programme for Health Care Professionals</i> 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 <i>National Anaphylaxis Education Programme for Health Care Professionals</i> 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 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

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

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

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.

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

National Immunisation Advisory Committee (2022) *Anaphylaxis: Immediate Management 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 (2022/2023) *Supporting Information for Staff: Schools Immunisation Programme* available at <https://www.hse.ie/eng/health/immunisation/pubinfo/schoolprog/suppinfo4staff.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 <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-ofPractice/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>