



**Supporting Information for Staff**  
**The Laura Brennan HPV**  
**Catch-up Vaccination Programme**  
**2022 - December 2023**

Version 1.0

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**Supporting Information for Staff - HPV Catch-up Vaccination Programme 2022-2023 – V1.0**

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## The Laura Brennan HPV Catch-up Vaccination Programme

In September 2010, quadrivalent HPV vaccine (HPV4) was introduced for girls in first year of second level school and age-equivalent girls in special schools and those educated at home. Girls in second year or equivalent were also offered HPV4 vaccine. In September 2011, a catch-up programme was introduced, with girls in sixth year or equivalent offered HPV vaccine from 2011 to 2014. In 2019, nonavalent vaccine (HPV9) was introduced into the national immunisation schedule for girls and boys in first year of second level school and age-equivalent students in special schools and those educated at home.

In May 2022, the Minister for Health Stephen Donnelly asked the HSE to prepare to operationalize a programme that would provide for all girls and boys in secondary schools who were previously eligible to receive the HPV vaccine, and who have not yet received it, to be offered the vaccine. He also requested that the HSE provide options to introduce a catch-up programme for young women who have now left secondary school, and who did not receive the vaccine when they were eligible. This programme is now known as The Laura Brennan HPV Catch-up Vaccination Programme.

The Laura Brennan HPV Catch-up Vaccination Programme forms an important part of national efforts to accelerate elimination of cervical cancer in line with WHO targets. Under this programme, the HSE is now providing eligible individuals with a once only opportunity to avail of catch-up HPV vaccination.

Staff from each Community Healthcare Organisation (CHO) are involved in carrying out the programme.

## **Eligibility for vaccination under The Laura Brennan HPV Catch-up Vaccination Programme**

The Department of Health has instructed that this catch-up programme offers HPV vaccination on a once only catch-up basis to:

- All who are still in school who were previously offered HPV vaccination in school and did not take up the offer – both boys and girls. This includes (in academic year 2022/2023):
  - Female students in 2nd – 6th year of secondary school
  - Male students who are in 2nd - 4th year of secondary school (or 5th year if they have skipped Transition year i.e. they were in first year when HPV vaccine was first introduced for boys in 2019/2020)
  
- All females who have left second level education and are under 25 years old on the date of vaccination, provided they have not already received the vaccine.

### **Appeals process for those who are unable to register on the online portal**

When registering on the portal the person will have their records automatically checked to see if a record of receiving at least one HPV vaccine in the past exists, along with checking their age. If a previous record for an HPV vaccine is found or they are 25 years and above they are ineligible. Individuals who are deemed ineligible for the Laura Brennan HPV Catch-up Vaccination Programme will receive a message on the portal stating that they are not eligible for vaccination. Should they wish to appeal this decision, they will be directed to an online consent form – which they can complete and return by post to the relevant LHO indicating their grounds for appeal e.g., if the portal informed them that there is already a record of them having received HPV vaccine in the past and therefore they are not eligible for the catch-up programme and they state that they have never received the HPV vaccine.

LHO staff should then contact the individual to investigate their grounds for appeal.

### **Management of cases of females who register for catch-up HPV vaccination on the online portal and subsequently turn 25 years old by the date of their vaccination clinic appointment**

It is important that vaccinators check that women presenting for vaccination are under the age of 25 on the date of the vaccination clinic (as in some rare instances individuals may have turned 25 since they registered their interest in the Laura Brennan HPV Catch-up Vaccination Programme on the online

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portal). In instances where eligible females have registered for HPV vaccination on the online portal (at age 24) and then subsequently turn 25 years old by the time they receive their vaccination clinic appointment, some discretion may be applied and these individuals vaccinated. However, they will need two doses of HPV vaccine as per the vaccination schedule for those over 25 years old – and they must have completed both doses of the vaccination schedule before the end of 2023 (please see the [NIAC Chapter 10. Human papillomavirus](#) for more information on the HPV vaccination schedule for those over 25 years old).

### Updated National Immunisation Advisory Committee (NIAC) Recommendations

The (NIAC) National Immunisation Advisory Committee have recently updated their recommendations regarding the number of HPV vaccine doses needed to be fully protected. These updated recommendations may be viewed in the NIAC Chapter 10. Human papillomavirus, available here: <https://www.hse.ie/eng/health/immunisation/hcpinfo/guidelines/chapter10.pdf>

#### NIAC Recommendations regarding HPV vaccine dosage (November 2022)

##### **Age 9- 24 years**

A single dose of HPV vaccine is recommended.

##### **Age 25 years and older**

Two doses at 0 and 6-12 months.

If the second dose is given less than five months after the first dose, a third dose should be administered. This should be given 6–12 months after the first dose and at least 12 weeks after the incorrect second dose.

**Immunocompromised persons** (with the conditions outlined below) should be given 3 doses of HPV9 vaccine at 0, 2 and 6 months, **regardless of age**.

Therefore, for most people (i.e. those with healthy immune systems) one dose of the HPV vaccine is recommended. Those who are immunocompromised are advised to get three doses of HPV vaccine over a 6 month period.

## Immunocompromised individuals requiring 3 doses of HPV vaccine

As per updated NIAC recommendations, those with the following conditions require a three dose schedule of HPV vaccine at 0, 2 and 6 months regardless of age

(for further information see the [NIAC Chapter 10. Human papillomavirus](#)).

- 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
- Non-haematological malignant solid tumours
- Primary immunodeficiency
- Within two weeks of commencing, on or within three to six months of receiving significant immunosuppressive therapy\* (for further information see [NIAC Chapter 3](#))

**For those with the above immunocompromising conditions, the three dose HPV vaccination schedule should be recommended by their treating Specialist/Consultant. They/their parent or legal guardian should discuss their case with their Specialist/Consultant and then indicate on their consent form that their Specialist/Consultant advised them to receive three doses of HPV vaccine due to immunocompromise. These immunocompromised individuals can then receive three doses of the HPV9 vaccine as part of the Laura Brennan HPV Catch-up Vaccination Programme.**

**Of note:** Further information from the NIAC to aid immunocompromised individuals and their physicians in making the decision regarding the number of HPV doses required is available on the [National Immunisation Office website](#).

## Advisory Note for parents of children in first year advising of the change to the NIAC recommendations for HPV vaccine dosage

An advisory note is being sent to parents of children currently in first year of secondary school (academic year 2022/2023), advising them of the change to the NIAC recommendations regarding the number of doses of HPV vaccine required. These parents will already have signed a consent form for their children to receive 2 doses of HPV vaccine as per the previous HPV schedule. The advisory note informs parents of the change to the NIAC recommendations, and advises that for most children (i.e. those with healthy immune systems) only one dose of HPV vaccine is now required. There is no need for a formal withdrawal of consent for the second dose of HPV vaccine in these cases.



## Additional Information resources

- Immunisation Guidelines for Ireland are available at <https://bit.ly/NIACGuide>
- Summary of Product Characteristics (SmPCs) for Gardasil 9 HPV vaccine available at [www.hpra.ie](http://www.hpra.ie) and also available under the relevant schools vaccination programme at <http://bit.ly/SchPHCP>
- Each vaccinator should be familiar with the Medicine Protocol for administration of Gardasil 9 vaccine under the Laura Brennan HPV Vaccination Catch-up Programme, available at <http://bit.ly/SchMedPros>
- Each vaccinator should be familiar with the medicine protocol for administration of epinephrine/adrenaline, without individual prescription available from <http://bit.ly/SchMedPros>
- Healthcare professionals FAQs are available at <http://bit.ly/FAQImm>
- Each vaccinator 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 vaccinator should be familiar with the "Anaphylactic Reactions: Treatment in the Community" protocol, in the Immunisation Guidelines for Ireland available at <https://bit.ly/NIACGuide>
- HSE Communicating Clearly guidelines: <http://bit.ly/CommClear>
- HPV E-Learning Programme available on HSELand [www.hseland.ie](http://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 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/Individuals 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/individual aged 16 years or older.
- In the case of an individual who completes the consent form for a one dose schedule of HPV vaccine (or for whom the consent form is completed by a parent or legal guardian), receives one dose of HPV vaccine, and then subsequently consults their treating Specialist/Consultant and are advised that they should receive three doses of HPV vaccine due to being immunocompromised, a new consent form must be completed (and the relevant box ticked stating that: *I have been advised by my treating Specialist/Consultant that I should have 3 doses of HPV vaccine due to having a weak immune system*).
- The first consent form should be appended to the subsequent consent form.

Under current Irish law, the following guardianship rules apply:

- Where a child’s mother and father are married both are the legal guardians.
- Following a separation or divorce, both parents remain the child’s legal guardian even if the child is not living with them and they have not been awarded custody of the child.
- Where a child has been jointly adopted, the adoptive parents are the child’s legal guardians.
- Where a same sex couple is married, the child’s biological parent is a legal guardian. The partner/spouse may apply to become a legal guardian.

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- Where the child's parents are not married:
  - the child's mother is an automatic legal guardian
  - the child's father is an automatic legal guardian if:
    - since 18 January 2016, 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.
  - the mother and father of the child may make a statutory declaration to the effect that they agree to the appointment of the father as legal guardian
  - the father may apply to court to be appointed legal guardian.
- Any adult may apply to court for legal guardianship:
  - if he or she is married to or in a civil partnership with, or has been cohabiting for at least 3 years, with the child's parent and has shared parental responsibility for the child's
  - day-to-day care for at least 2 years.
  - if he or she has provided for the child's day-to-day care for a continuous period of more than 12 months and the child has no parent or guardian who is able or willing to act as guardian.
- A guardian may nominate another person to act as temporary guardian in the event of the guardian's incapacity. This is subject to court approval.
- A guardian may appoint a person to act as the child's guardian in the event of the guardian's death.
- For Children/young people in voluntary care - the usual legal rules of parental consent apply.
- For Children/young people under a care order:
  - Young person over 16 years admitted to the care of Tusla, (i.e. an order of the court), the normal rules apply.
  - For a child/young person under 16 years admitted to the care of Tusla under a care order, the normal rules do not apply (best practice to involve the parents in the decision- making process where possible) when:
    - Under an interim or emergency care order, an application may be made to the District Court in regard to consent to treatment/intervention, including that a social care professional involved with the child's care is permitted to give consent to treatment/intervention.
    - Under a full care order (permanent or temporary), Tusla is authorised by the court to consent to any necessary medical or psychiatric treatment, assessment or examination. Different procedures apply to admission and treatment under the Mental Health Act 2001.

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- 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>
- Read "Who can give consent for vaccination of a young person aged under 16 years?" From <https://bit.ly/ConsentU16>
- Watch this video from Dr. Siobhan Ni Bhriain, HSE National Lead Integrated Care covering Consent for vaccination in 12-15 year olds. <https://youtu.be/vE1X5AcwNgE>

## **Assessment of the student/individual for vaccination**

Before assessing the suitability of a student/individual for vaccination:

- Confirm student's identity (Check ID, 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 adults and those 16 and over providing consent for themselves, confirm individual's identity (Check ID, confirm name, address, date of birth by asking: "What is your full name? When is your Birthday? Where do you live? Who signed the consent form?")
- Confirm that informed consent has been given by a parent / legal guardian for student aged under 16 years
- (Please note: although the initial phase of the Laura Brennan HPV Catch-up Vaccination Programme will enable those eligible for the programme 16 years and over to register for vaccination via the online portal, it is possible that younger siblings/others that are also eligible (but not yet able to register via the online portal) may present in person to the immunisation clinic. The previous HPV vaccination status of these individuals should be checked on SIS and if they have not had a previous HPV vaccine, and capacity allows, they should be facilitated to proceed with vaccination with the informed consent of a parent/legal guardian), provided there are no contraindications to vaccination present.
- Confirm that informed consent has been given by the individual themselves if aged 16 years and over and providing consent for themselves.
- Where practicable, check the vaccination record of the student/individual to be vaccinated on SIS – to confirm that they have not already received a dose of HPV vaccine and are eligible for catch-up HPV vaccination. If live access to SIS is not available in the immunisation clinic, this check of SIS HPV vaccination records should be undertaken prior to the clinic if possible. Although a check of SIS is performed when individuals register on the portal, if an IHI (Individual Health Identifier) match is not found, a small number of people may proceed to booking an appointment even though they have already received a HPV vaccine.
- Address any clinical issues raised on the consent form.
- Ensure there are no contraindications to HPV vaccination.
- If the child/individual has been advised by their treating Specialist/Consultant to receive three doses of HPV9 vaccine due to immunocompromise, check that the intervals between HPV9 vaccinations are appropriate.
  - Immunocompromised persons should be given 3 doses of HPV9 vaccine at 0, 2 and 6 months, regardless of age (the 4 day rule applies). Access to a calendar is recommended.

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NIAC guidelines state:

*“Giving a dose  $\leq 4$  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>

- In the case of an individual who completes the consent form for a one dose schedule of HPV vaccine (or for whom the consent form is completed by a parent or guardian), receives one dose of HPV vaccine, and then subsequently consults their treating Specialist/Consultant and are advised that they should receive 3 doses of HPV vaccine due to being immunocompromised, a new consent form must be completed (and the relevant box ticked stating that: I have been advised by my treating Specialist/Consultant that I should have 3 doses of HPV vaccine due to having a weak immune system).
- The first consent form should be appended to the subsequent consent form.
- For those whose gender identity differs from their gender at birth, the eligibility criteria for the Laura Brennan HPV Catch-up Vaccination Programme should be applied to the gender at birth.
- 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 <https://bit.ly/NIACGuide>
- 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 clinical lead in charge of the vaccination clinic to require deferral of the vaccine should be offered one appointment for the mop-up clinic.

**If they do not attend there is no requirement to send further appointments.**

## Vaccine storage and handling

- HPV9 vaccine must be stored and transported between +2°C and +8°C.
- The SmPC for HPV9 vaccine recommends 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.
  - Once HPV9 vaccines, 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 has published 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

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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 / immunisation clinic 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, please contact the National Immunisation Office immediately.

Contacts include:

- Achal Gupta: mobile 087 4064810
- Cliona Kiersey: mobile 087 9915452
- Email [immunisation@hse.ie](mailto:immunisation@hse.ie)

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 / individual themselves if aged over 16, 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 and third vaccination are required to complete the HPV9 schedule, the first and second vaccine records must be put into SIS as soon as possible after each vaccine is given. Please do not wait until all three vaccines are given if receiving three doses of HPV9.
- Vaccination forms for students / individuals who have been vaccinated but require further doses to complete a course should be filed for easy retrieval the next school clinic / immunisation clinic.
- Vaccination forms for students / individuals whose vaccination is deferred or who are absent on the day should be filed for easy retrieval for the next mop-up clinic.
- If vaccination form movements are required (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 / individuals 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 or individual being vaccinated requests further clinical advice about the HPV9 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 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>

### Contraindications to HPV9 vaccination

- Confirmed anaphylactic reaction to the vaccine itself or to a constituent of that vaccine is an absolute contraindication.
- Pregnancy – HPV vaccination is not recommended in pregnancy.

Pregnancy could be an issue for some female students in second level schools and for older females who have left second level school. Parent(s) are advised to discuss the possibility of pregnancy with their daughter prior to giving consent for vaccination for those aged < 16 years.

The consent form for the *Laura Brennan HPV Catch-up Vaccination Programme* includes the statement "I understand that HPV is not recommended during pregnancy" (Appendix C). If the parent(s) consent is required and they 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 or performing a pregnancy test is not indicated.

If an older female (aged 16 years or older) providing consent for herself indicates on the consent form that she is pregnant, then vaccination should be withheld. Before the HPV9 (Gardasil 9) vaccine is given, the vaccinator should ask the girl / woman 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.
- Performing a pregnancy test in the vaccination clinic prior to vaccination is not indicated.

Before the second and third doses of HPV9 (Gardasil 9) vaccines are given to those recommended to receive three doses on the basis of immunocompromise, the vaccinator should ask the girl/woman 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.
- Performing a pregnancy test in the vaccination clinic prior to vaccination is not indicated.

### **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 vaccinator 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 vaccinator 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 firm pressure to the vaccine site for 5 to 10 minutes after the injection. In those with a severe bleeding tendency vaccination can be scheduled shortly after administration of clotting factor replacement or similar therapy.

- Some vaccines (other than HPV9) can be given by the subcutaneous route in those with severe bleeding disorders. However, there is no recommendation on the subcutaneous administration of HPV9 vaccine.
- **Immunosuppression:** The immune response of individuals who are immunocompromised may be inadequate.
  - Individuals with impaired immune responsiveness, whether due to treatment, illness or other causes may not respond to the HPV vaccine

See HPV chapter 10 and Chapter 3 in the Immunisation Guidelines for Ireland available at

<https://bit.ly/NIACGuide>

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

**HPV9 (Gardasil 9) vaccine does NOT contain latex.**

## Information on HPV9 (Gardasil 9) vaccine

The HPV vaccine currently used in Ireland is:

- Gardasil 9 (manufactured by MSD), a nonavalent vaccine containing VLPs (Virus-Like Particles) for nine HPV types (6, 11, 16, 18, 31, 33, 45, 52 and 58).

The constituents of Gardasil 9 are:

- Virus like particles (VLPs) for HPV types
- Other constituents:
  - Sodium chloride
  - L-histidine
  - Polysorbate 80
  - Sodium borate
  - Water for injection

- Adjuvant (substance that enhances an immune response)
- Amorphous aluminium hydroxyphosphate sulphate (0.5mg Al)

### Of note:

- Fainting is a recognised side effect of vaccines given in adolescence.

When there are doubts about giving a vaccine contact a Principal Medical Officer, a Specialist/Consultant in Public Health Medicine or NIO for further advice.

## Adverse Events

HPV9 (Gardasil 9) vaccine is considered safe and well tolerated. Full details of the side effects of Gardasil 9 vaccine can be found in the summary of product characteristics (SmPC) available on [www.hpra.ie](http://www.hpra.ie). The relevant immunisation leaflet contain details on adverse reactions and their management.

Parents/legal guardians/students/individuals post vaccination should inform the school immunisation team / immunisation team of any adverse reactions to the vaccine by contacting the HSE area office. Children / individuals 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 HPV9 vaccine causes 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 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.

## Reporting of adverse reactions

The vaccinator 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

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 / individuals, 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 12 November 2021)

<https://www.hse.ie/eng/about/who/nqpsd/gps-incident-management/nims/nirf-01-v12-person-interactive.pdf>

## References

- Children First 2011 – National Guidance for the Protection and Welfare of Children.  
<https://www.hse.ie/eng/about/qavd/hr-policies-and-procedures/children-first-2011-%E2%80%93-national-guidance-for-the-protection-and-welfare-of-children.html>
- Guidance for providers of health and social care services Communicating in plain English HIQA and NALA 2015 [www.hiqa.ie](http://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 <https://bit.ly/CCSOP1>
- HSE Guidelines for maintaining the vaccine cold-chain in vaccine cool boxes.  
<https://bit.ly/CCSOP2>
- Immunisation Guidelines for Ireland. National Immunisation Advisory Committee  
<https://bit.ly/NIACGuide>
- 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 Gardasil 9. Visit <https://bit.ly/HPRAHV>
- Gardasil 9 PIL
- Ten tips for conducting a safe school immunisation session. Victorian Government Health Information. Immunisation Section Newsletter Issue 37 February 2009. <https://bit.ly/NLAus>
- Information on HSE ICT security <https://bit.ly/HSEITSec>
- Information on HSE electronic communications <https://bit.ly/HSEITCom>
- Information on HSE encryption policies <https://bit.ly/HSEITEnc>
- 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](http://www.dataprotection.ie)
- HSE Data Protection policies <http://bit.ly/HSEdatapro>
- Information on Subject Access Requests (SAR) <http://bit.ly/SARhse>
- GDPR Frequently Asked Questions <http://bit.ly/GDPRhse>
- Who can give consent for vaccination of a young person aged under 16 years?  
<https://bit.ly/ConsentU16>

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).

**CVC:** Community Vaccination Clinic

**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



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medicinal product by a nurse or midwife or trained vaccinator 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

**A vaccinator** is a trained healthcare professional who has completed training in the administration of vaccinations and is administering vaccinations prescribed by a Registered Nurse Prescriber or Doctor or under a medicine protocol.

### **Vaccine abbreviations:**

HPV: Human papillomavirus

## Appendix A Template Operating Procedures and roles and responsibilities

### Operational aspects of the programme prior to the vaccination session

#### Phase 1:

- Prior to the vaccination date, students and eligible individuals over the age of 16 will be able to register their interest in the Laura Brennan HPV Catch-up Vaccination Programme on an online portal and those eligible will be enabled to book a vaccination appointment online through Swiftqueue.
- Those that book appointments will also be requested to print and complete a consent form in advance of the vaccination clinic if practicable. For those that attend their vaccination appointment and have not completed a consent form, printed consent forms will be available for them to complete on the day of vaccination. They will have been asked to attend their appointment 15 minutes early to facilitate completion of the consent form.
- Each CHO will engage with National Primary Care Operations, CVCs and NIO to provide vaccination clinics in their areas.
- Please note: Clinical governance for the Laura Brennan HPV Catch-up Vaccination Programme remains under Community Operations, Primary Care and not under COVID Operations. Staff assigned from COVID Operations to HPV vaccination will operate and report under Primary Care. Professional governance for nurses participating in the programme will lie with existing community operations structures.

#### Phase 2:

- Prior to the vaccination date, students and eligible individuals under the age of 16 will be able to register their interest in the Laura Brennan HPV Catch-up Vaccination Programme on the online portal and those eligible will be enabled to book a vaccination appointment online through Swiftqueue.
- The NIO will send a letter to Tusla for Tusla to disseminate to home schooled children in the ages eligible for catch-up HPV vaccination. These children will then be able to register their interest in the Laura Brennan HPV Catch-up Vaccination Programme via the online portal and complete a consent form.
- The composition of immunisation teams should be agreed locally in advance.
- Trained Vaccinators may administer vaccine under doctor or Registered Nurse Practitioner prescription or under a medicine protocol within their scope of practice.

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Clinical staff should be familiar with the following documents:

- Immunisation Guidelines for Ireland are available at <https://bit.ly/NIACGuide>
- Summary of Product Characteristics (SmPCs) for Gardasil 9 vaccine available at [www.hpra.ie](http://www.hpra.ie) and also available under the relevant schools vaccination programme at <http://bit.ly/SchPHCP>
- Medicine Protocol for the Laura Brennan HPV Catch-up Vaccination Programme available 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 <https://bit.ly/NIACGuide>
- HSE Communicating Clearly with Patients and Service Users guidelines <http://bit.ly/CommClear>

Each vaccinator 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 administration of the relevant vaccine and epinephrine/adrenaline, without individual prescription.

### **Operational aspects of the programme on the day of the vaccination session**

- The team should be at the vaccination clinic 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 individuals being vaccinated 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 vaccine (i.e. Gardasil 9) has been brought to the vaccination session.
- A designated person will ensure that the correct vaccine type, appropriate quantity of the 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 vaccination clinic 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.

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- 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 clinic 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 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 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
- Ensure the student’s immunisation passport / tear pad is completed and given to all students before they leave the vaccination area.
- The immunisation passport is retained by the HSE after the first dose of HPV9 for those with immunocompromise scheduled to receive three doses of HPV vaccine. It will be given to these immunocompromised vaccinated individuals after they have received their third dose of HPV9 vaccine. All other individuals receiving one dose of HPV vaccine will be given their immunisation passport after receipt of the vaccine on the day of the vaccination clinic.
- Ensure that each vaccinee recipient is provided with the appropriate tear pad stating date and time vaccine was given and the appropriate contact details so that parents /legal guardians/vaccine recipients can inform the immunisation staff about any concerns following vaccination.

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- 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 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.
- Two trained vaccinators must remain at the vaccination venue for at least 30 minutes following the last vaccination.
- Students/individuals who require further vaccine doses to complete a course should have their immunisation record entered onto SIS and be offered an appointment to attend a HSE mop up clinic.

### 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
- Lists of students/individuals for mop-up clinics should be compiled to include all those immunocompromised students/individuals who received dose one (or dose two) of their three dose HPV vaccination schedule on the day and who require further appointment(s) in mop-up clinics to complete their three dose schedule of HPV vaccination.
- 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

- Clinical governance for the Laura Brennan HPV Catch-up Vaccination Programme remains under

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Community Operations, Primary Care and not under COVID Operations. Staff assigned from COVID Operations to HPV vaccination will operate and report under Primary Care. Professional governance for nurses participating in the programme will lie with existing community operations structures.

- 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.
- Any vaccinators from other professions should have appropriate line management and their line manager should ensure that they are aware of this Supporting Information for staff and 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](mailto: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
- 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](mailto:sis.support@hse.ie)).

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- 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.
- Collect the consent forms returned on the day of vaccination.
- Check all consent forms and contact parents or ask second level students/individuals themselves to resolve any administrative queries. Where there are also clinical queries to be resolved, all queries for that student/individual should be referred to a clinical member of the team for follow up, to speak with the individual or to make one call to parents (in the case of those for whom the parents provided consent, or those under 16 years of age) as appropriate.
- Organise the collection and return of students to their classrooms in small groups in association with a designated school liaison person (when vaccination clinics are taking place in schools).
- Confirm student's identity (check ID, 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 adults and those over 16 providing consent for themselves, confirm individual's identity (check ID, confirm name, address, date of birth by asking: "What is your full name? When is your Birthday? Where do you live? Who signed the consent form?")
- Give blank consent forms to students/individuals after confirming their identity (if they do not attend the clinic with a consent form already completed).
- Carry out a search on the SIS to locate the client record and check that the individual to be vaccinated does not have a prior record of receipt of a HPV vaccination in the past. If this search of SIS is not practicable to perform in the vaccination clinic, then perform this search in advance of the clinic where possible. If a record of a previous HPV vaccination is found for an individual on SIS, inform a clinical member of the vaccination team immediately. The clinical member of the vaccination team can explain to the individual that they are not eligible for HPV vaccination under the Laura Brennan HPV Catch-up Vaccination Programme (as they have already received a HPV vaccine according to SIS records). Should they wish to do so; the individual can appeal this decision [by filling out this form](#).
- Direct student/individual to the vaccinator.
- Ensure that student/individual is provided with the appropriate tear pad stating date and time vaccine given (Appendix J) and the vaccination team contact details.
- Collect the consent forms and collate the statistics required for the Vaccination Session Report Form (Appendix I) at the end of the session.
- Carry out a search on the SIS to locate the client record, if not found set up a new client record. Input HPV vaccination(s) data on to the SIS.

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- Ensure all data entered is accurate and in accordance with data entry standards by running quality reports after clinic data is entered.
- Once a record is entered onto the SIS, write the system's client ID and the school roll number (for those in school)/standard CHO roll number (for those not in school) 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/individuals, 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 clinical lead; and the National Immunisation Office must also be informed.
- If errors are made on the SIS that cannot be resolved, inform the CHO system administrator as soon as possible so that the errors can be rectified.

### Vaccinators role and responsibilities

- 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/vaccination clinic's health and safety regulations during each school/vaccination clinic visit
- Be available to answer queries from parents/legal guardians/students/vaccine recipients, teachers and other members of the immunisation team.
- Ensure that all vaccines are used within the recommended time frame.
- 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 vaccination session report form
- Check that appropriate drugs and equipment are available for resuscitation and record this on the 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/vaccine recipient
  - 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 are observed.



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- The SmPC for the Gardasil 9 vaccine recommends that each vaccine is well shaken before administration.
  - Confirm student's identity (Check ID, 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 adults and those over 16 providing consent for themselves, confirm individual's identity (Check ID, confirm name, address, date of birth by asking: "What is your full name? When is your Birthday? Where do you live? Who signed the consent form?")
  - Confirm that informed consent has been given by a parent/legal guardian for students aged under 16 years
  - (Please note: although the initial phase of the Laura Brennan HPV Catch-up Vaccination Programme will enable those eligible for the programme over 16 years old to register for vaccination via the online portal, it is possible that younger siblings/others that are also eligible (but not yet able to register via the online portal) may present in person to the immunisation clinic. The previous HPV vaccination status of these individuals should be checked on SIS and if they have not had a previous HPV vaccine, and capacity allows, they should be facilitated to proceed with vaccination with the informed consent of a parent/guardian), provided there are no contraindications to vaccination present.
  - Confirm that informed consent has been given by the individual themselves if aged over 16 years and providing consent for themselves.
  - Any clinical issues raised on the consent form should be addressed prior to vaccination
  - For those receiving three doses of HPV9 vaccine due to immunocompromise, check that the interval since the previous HPV vaccine is appropriate for this dose, i.e. three doses of HPV9 vaccine should be given at 0, 2 and 6 months, regardless of age (the 4 day rule applies).
  - 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 vaccine recipient is correctly positioned for the safe administration of the vaccine(s) with help from a parent/legal guardian, or other member of the vaccination team, 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 HPV9 vaccine by intramuscular (IM) injection at a 90° angle to the skin in the densest part of the deltoid muscle of the arm.

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- 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 vaccinator should enter “Med P” in the prescriber box and enter signature and PIN in the vaccinator box.
- All vaccinators (doctors, RNPs, nurses) should enter signature and PIN/MCRN in the vaccinator box.
- Ensure the student’s/vaccine recipient’s immunisation passport is completed and given to all students/vaccine recipients before they leave the vaccination area. For those receiving three doses of HPV vaccine due to immunocompromise, 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 i.e. after the third dose has been given.
- Ensure that the student/vaccine recipient is provided with the appropriate tear pad stating date and time vaccine given.
- Ensure that each student/vaccine recipient remains in the vicinity of the vaccination area under observation for 15 minutes after vaccination.
- The vaccinator observing students/individuals post vaccination will manage any students/individuals experiencing symptoms within their scope of practice and consult with the clinical lead 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. Two clinical staff should be

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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/vaccine recipients 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/vaccine recipient 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:**

- Answer any clinical queries when vaccine consent forms are reviewed by nursing staff
- Prescribe the relevant vaccine by signing in the prescriber box on the consent form if required (including Medical Council Registration Number - MCRN).
- Carry out an individual medical assessment for students/vaccine recipients if requested by a vaccinator working under a medicine protocol.

### **Registered nurse prescribers should additionally**

- Prescribe the HPV9 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).

## 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 <https://bit.ly/CCSOP1>
- 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.
- For all packing materials and equipment, ensure that the specifications of each item are adhered in accordance with the manufacturer guidelines. Each site should have SOPs on how to pack a cool box with the ice/gel packs and vaccines. The risk of freezing of vaccines in cool boxes increases if ice/gel packs are not correctly conditioned or separated by insulating material.
- The number of packs used should be as per cool box manufacturer's instruction and local SOP.
- 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 please contact the National Immunisation Office immediately.

Contacts include:

- Achal Gupta: mobile 087 4064810
- Cliona Kiersey: mobile 087 9915452
- or Email [immunisation@hse.ie](mailto:immunisation@hse.ie)

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**

HPV available here <http://bit.ly/SchPHCP>

## **Appendix D: Considerations for Prevention and Management of Syncope in Vaccination Clinics**

Available from <https://bit.ly/MgmtSyncope>

## **Appendix E: Adverse event clinical record**

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

## Appendix F: List of Useful Links and Resources

Further information regarding the HPV vaccine and the diseases it protects against can be found on the following websites

- National Immunisation Office available at <http://www.immunisation.ie>
- Immunisation Guidelines for Ireland available at <https://bit.ly/NIACGuide>
- 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 [https://www.who.int/health-topics/vaccines-and-immunization#tab=tab\\_1](https://www.who.int/health-topics/vaccines-and-immunization#tab=tab_1)
- 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 <https://www.cdc.gov/vaccines/pubs/pinkbook/index.html>
- Australian Government, Department of Health and Education immunisation website available at <https://www.health.gov.au/health-topics/immunisation>
- Immunisation Department of Health Victoria Australia available at <https://www2.health.vic.gov.au/public-health/immunisation>
- 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/services/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 Organization 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 and HSE clinics during academic year 2022-2023.

All staff should follow current HSE infection control guidelines and take every precaution to ensure the safety of pupils/individuals presenting for vaccination and staff when on the school/vaccination clinic premises.

Children/individuals presenting for vaccination should not be attending the vaccination clinic if they have COVID-19. Usual checks should be made to ensure that the child/individual presenting for vaccination is feeling well on the day of immunisation.

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 July 2022 in Immunisation Guidelines

### **NB Updated advice from NIAC no longer recommend the use of autoinjectors**

Adrenaline (epinephrine) auto-injectors are not recommended as first line treatment by health professionals for the immediate management of anaphylaxis or suspected anaphylaxis following vaccination unless they are the only source of adrenaline available, as they may not allow IM delivery of an age appropriate dose.

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)
- 3 x 1 ml syringes
- Needles 3 x 25mm, 3 x 37 – 40mm
- 1 pocket mask
- Sphygmomanometer (optional)
- Stethoscope (optional)
- Pen and paper to record time of administration of Epinephrine

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 HPV Vaccination Tear Pad

Available here <https://bit.ly/HPVCUPVA>

## Appendix K: Packshot of Gardasil 9 vaccine used in the Laura Brennan HPV Catch-up Vaccination Programme

GARDASIL 9 (HPV)



## Appendix L: Medicine Protocols

### Administration of vaccines under Medicine Protocol

- Registered vaccinators 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.
- Vaccinators 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 vaccinator 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.
- Currently, the Laura Brennan HPV Catch-Up Vaccination Programme protocol enables registered nurses employed in the HSE who have undertaken the required education and training programmes to administer HPV9 vaccine without individual prescription.
- In assessing the student’s/individual’s suitability for vaccination the vaccinator working under medicine protocol should also pay particular attention to the advice on vaccine administration included in this document.
- All individuals meeting the exclusion criteria of a medicine protocol must be referred to the medical practitioner or Registered Nurse Prescriber for an individual clinical assessment.
- Where the Medical Officer or Registered Nurse Prescriber prescribes the vaccine, a vaccinator may administer the vaccine within the vaccinator’s scope of practice.
- When recording the administration of a vaccine under medicine protocol the vaccinator should enter “Med P” in the prescriber box and enter signature and PIN in the vaccinator box.