Continuous Professional Education Programme for Registered Nurses and Midwives to Administer Gardasil 9 Vaccine

Under the Medicine Protocol to students in Second Level Schools (or equivalent) through a Schools Immunisation Programme

Changing practice to support service delivery
Medicine Protocol

This Medicine Protocol is a specific written instruction for the administration of Gardasil 9 Vaccine to students who may not be individually identified before presentation for treatment.
Clinical Criteria

Active immunisation against and prevention of:

- Premalignant and malignant genital lesions (cervical, vulvar, vaginal, and anal) causally related to Human Papillomavirus (HPV)
  - types 16, 18, 31, 33, 45, 52, 58.

- External genital warts (condyloma acuminata) causally related to HPV types 6 and 11
Circumstances in which the Medicine Protocol applies

• HPV immunisation programme will be delivered annually by the Health Service Executive (HSE) mainly via school based immunisation programme.

• All students in first year in second level schools or age equivalent (in special schools and home schooled), as recommended by NIAC in a 0, and 6 month schedule within the academic year.

Circumstances in which the Medicine Protocol applies

For 2019/2020 Gardasil 9 will be given to:

- All **students**, in first year of second level schools and age equivalent in special schools and home schooled students including in a mop up clinic:
- All **girls** in school outside first year (in 2019/2020) less than 16 years of age whose parents/legal guardians request vaccination if eligible and HPV4 not available
- All **girls** in school outside first year (in 2019/2020) age 16 years of age or older if eligible and HPV4 not available
Interrupted immunisation schedule

• “If an immunisation course is interrupted, it should be resumed as soon as possible”.

• It is NOT necessary to repeat an interrupted immunisation schedule

https://www.hse.ie/eng/health/immunisation/hcpinfo/guidelines/chapter2.pdf
Inclusion Criteria for Gardasil 9 Vaccine

• Students in first year of second level school or age equivalent in special schools and home schooled students (NIAC, 2014)

• Girls older than first year of second level school who are eligible for the vaccine and where HPV (Gardasil) is no longer available

• Students with valid consent
Exclusion Criteria for Gardasil 9 Vaccine

• Any student who has had an anaphylactic or hypersensitivity reaction to a previous dose of Gardasil 9 or any of its constituents.

• Pregnancy

• Contraindication to intramuscular injection (haematological disorder/coagulation disorder)
Exclusion Criteria cont....

- Acute febrile illness. The presence of a minor infection such as a mild upper respiratory infection or low grade fever is not a contraindication for immunisation.

- Students who are immunocompromised either due to disease or treatment.
Gardasil 9 Vaccine: Product Information

• Details of the most current and update information of the SmPC and other data is available on the website https://www.hpра.ie
Possible Side Effects – Gardasil 9

- **Very Common:** (more than 1 per 10 doses of vaccine)
  - Pain, swelling and redness at injection site
  - Headache

- **Common:** (more than 1 in 100 doses and less than 1 in 10 doses)
  - Itching and bruising at the injection site
  - Dizziness
  - Fever
  - Nausea
  - Fatigue

- Allergic reactions have also been reported. Some of these reactions have been severe. Symptoms may include difficulty breathing, wheezing, hives and/or rash.

  - For a full list of side effects refer to [https://www.hpра.ie](https://www.hpра.ie)
Gardasil 9 Constituents

**Antigen:** L1 virus like particles for HPV Type 16, 18, 31, 33, 45, 52, 58

**Adjuvent:** aluminium hydroxyphosphate sulphate adjuvant (0.5 milligrams Al)

**Excipients:**
- Sodium chloride
- L-histidine
- Polysorbate 80
- Sodium borate
- Water for injection
Nature and Contents of Pack-Gardasil9

- Gardasil 9 is only available in single packs of pre-filled syringes ready for use for intramuscular injection

- Vaccine contains two needles –
  - 23G x 25mm – should be used,

- Prior to agitation, Gardasil9 may appear as a clear liquid with a white precipitate.
- After thorough agitation, it is a white, cloudy liquid
Frequency of Administration

- The person to be vaccinated will receive 2 or 3 individual doses of the vaccine. All 2 or 3 doses should aim to be given within a 12-month period.

- For those who commence vaccine under 15 year of age
  - 1<sup>st</sup> dose: 0 month (Sept- Nov)
  - 2<sup>nd</sup> dose: 6 months (Feb-May) after first injection

- The second dose can be given least five, but ideally six months after the first dose. NIAC recommends that “two doses should ideally be separated by 6 to 12 months. The minimum interval between doses is 5 calendar months”. The 4 day rule applies.
Frequency of Administration- Those aged 15 years +

- Students aged 15 years and older at time of first HPV vaccine (Gardasil 9) require 3 doses of HPV vaccine.
- The minimum interval between the first and second doses is 4 weeks.
- The minimum interval between the second and third doses is 12 weeks.
- The minimum interval between the first and third doses is 5 calendar months.
Gardasil 9 for those who have started with Gardasil HPV4

- For girls older than first year of second level school, HPV 4 Gardasil should be given to those starting or completing a course of vaccine.
- When HPV 4 Gardasil stocks are no longer available, these girls may receive Gardasil 9.
- Those who have completed a course of HPV 4 vaccine (Gardasil) vaccination do not require revaccination with HPV vaccine (Gardasil 9) as part of the routine schools programme.
Any Questions