

**GUIDELINES FOR STAFF:  
SECOND LEVEL SCHOOL  
HUMAN PAPILOMAVIRUS VACCINATION CAMPAIGN**

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## **1.0 INTRODUCTION**

These guidelines have been prepared to inform relevant Health Service Executive (HSE) staff in relation to the procedures to be followed during the Human Papillomavirus (HPV) vaccination campaign.

The HPV vaccination programme is part of the national strategy to protect females from cervical cancer. The impact of the programme in the prevention of cervical cancer will not be seen for 20 to 30 years.

This campaign aims to vaccinate all 12 year old girls by targeting girls in first year of second level schools nationally and girls 12 years of age who are outside of the traditional school system.

HPV vaccines will be administered in accordance with the recommendations of the National Immunisation Advisory Committee (NIAC) of the Royal College of Physicians (RCPI), as set out in an updated chapter (July 2009) of the Immunisation Guidelines for Ireland, 2008, available at [http://www.immunisation.ie/en/Downloads/PDFFile\\_16134\\_en.pdf](http://www.immunisation.ie/en/Downloads/PDFFile_16134_en.pdf), <http://www.hpsc.ie>, or at <http://www.rcpi.ie>

A completed immunisation course to protect against HPV requires three doses of HPV vaccine. The HSE programme aims to achieve a high uptake of greater than 80% for a completed three dose vaccine course.

## **2.0 SCOPE**

These guidelines apply to all HSE medical officers, nurses and administrative staff involved in the HPV vaccination campaign for girls in first year of second level schools in Ireland.

## **3.0 RESPONSIBILITY**

- It is the responsibility of the Principal Medical Officer to ensure that all medical officers are aware of the processes described in these guidelines.
- It is the responsibility of the Directors of Public Health Nursing to ensure that all nurses are aware of the processes described in these guidelines.
- It is responsibility of the Local Health Managers to ensure that all relevant administrative persons are aware of the processes described in these guidelines.
- It is the responsibility of the medical, nursing and administrative staff to ensure that they are familiar with and are adhering to the practices as set out in these guidelines.
- Reporting relationships of any non HSE staff involved in the programme will need to be defined in advance of the start of the programme.

#### 4.0 EPIDEMIOLOGY OF HPV INFECTION

Human papillomavirus (HPV) is a virus that infects squamous epithelium including the skin, and mucous membranes of the upper respiratory and anogenital tract.

- There are over 100 types of HPV.
- HPV can exist within its host in an active or latent form.
- Some types are responsible for common warts (verrucae).
- Around 40 types can infect the genital tract. Some of these are low-risk types (e.g. HPV 6 and 11) which cause genital warts, while others are high-risk types (e.g. HPV 16 and 18) which are associated with various cancers such as cancer of the cervix, vulva, vagina, anus, penis and oropharynx.

The clinical spectrum of disease caused by HPV ranges from asymptomatic infection, to benign warts, to invasive cancer, depending on the virus type, the route of infection, and the body's immune response.

- Genital HPV infection is the most common sexually transmitted disease worldwide.
- Risk factors associated with genital HPV infection include younger age at sexual initiation, number of sexual partners, and the sexual history of the partner (number of previous sexual partners).
- An estimated 80% of sexually active women become infected with at least one strain of HPV by age 50 years.
- In Ireland, ano-genital warts account for approximately 30% of all sexually transmitted infection notifications annually and the largest proportion of cases occurs in young adults in the 20-29 year age group.
- HPV types 6 and 11 are associated with over 90% of genital warts.

Persistent genital HPV infection can lead to cervical cancer.

- HPV types 16 and 18 are responsible for over 70% of cervical cancers.
- HPVs associated with cancer are called oncogenic or 'high risk' types. HPVs that do not cause cancer are termed 'low risk' types. Two of these 'low risk' types cause genital warts. HPV types are referred to by number (assigned in the order in which they were discovered).
- In Ireland in 2007 there were 286 new cases of cervical cancer in Ireland and 81 women died from the disease. .

## 5.0 HPV VACCINE

Two HPV vaccines are licensed for use in Ireland and contain virus-like particles (VLPs) produced using recombinant DNA technology. *Cervarix*, manufactured by GSK, is a bivalent vaccine containing VLPs for two HPV types (16 and 18). Gardasil®, manufactured by Sanofi Pasteur MSD, is a quadrivalent vaccine containing VLPs for four HPV types (6, 11, 16 and 18). The HSE has procured Gardasil® vaccine for the school HPV programme.

Gardasil

- contains no viral DNA and is not infectious or oncogenic
- is not a live vaccine
- cannot cause HPV infection
- cannot cause cancer

## 5.1 Gardasil® Vaccine constituents

Virus-like Particles

- HPV Type 6
- HPV Type 11
- HPV Type 16
- HPV Type 18

Other constituents:

- Sodium chloride
- L-histidine
- Polysorbate 80
- Sodium borate
- Water for injection
- Amorphous aluminium hydroxyphosphate sulphate adjuvant

The vaccine may contain traces of yeast as the production process involves yeast cells.

These constituents are present in many other vaccines and other authorised products

Examples are outlined below

- L-histidine is a component of some hepatitis vaccines
- Polysorbate 80 is a component of several of the childhood vaccines and other medication e.g. mycostatin used for oral thrush, feldene gel used as an anti-inflammatory medication
- Sodium borate is a component of some vaccines and medicinal compounds such as Optrex eye drops
- Aluminium hydroxyphosphate sulphate is a component of several of the childhood vaccines

## **5.2 Gardasil ® Vaccine Presentation**

- Gardasil is presented as a suspension for injection in a pre-filled syringe with no needle attached.
- Prior to agitation it may appear as a clear liquid with a white precipitate. After thorough agitation it is a white, cloudy liquid.
- Two needles are included in the packaging – a 23G needle (0.6x25mm) and a 25G needle (0.5x16mm).
- Gardasil is provided in a single dose presentation.

Whilst the manufacturer's Summary of Product Characteristics (SPC) states that the vaccine comes with a needle guard the vaccine supplied to the Irish market will not have a needle guard.

## **5.3 Gardasil ® Vaccine Licence**

The vaccine has been licensed by the Irish Medicines Board (IMB) and the European Medicines Agency (EMA). The SPC for Gardasil was updated in September 2010 and is available at <http://www.medicines.ie/medicine/11524/SPC/GARDASIL/>. Based on current scientific evidence Gardasil is now licensed for use from the age of 9 years for the prevention of:

- premalignant genital lesions (cervical, vulvar and vaginal) and cervical cancer causally related to certain oncogenic Human Papillomavirus (HPV) types
  - external genital warts (condyloma acuminata) causally related to specific HPV types

## **5.4 Gardasil ® Vaccine Schedule**

Gardasil ® has a recommended routine schedule of 3 doses at 0, 2 and 6 months. The schedule complies with the SPC, the IMB, and the NIAC. An alternate vaccination schedule is possible but should be administered only in exceptional circumstances. For example, when a girl misses a scheduled dose the alternate schedule may be used to enable completion of the vaccine course. The alternative schedule states that there should be at least 1 month between Dose 1 and 2, at least 3 months between Dose 2 and 3, and all three doses should be given within 12 months.

## **6.0 TARGET COHORT**

The programme in the main will be delivered in second level schools. Review of data from other countries strongly suggests that provision of the vaccine through a school based programme results in a significantly greater uptake of the vaccine. A school setting is an appropriate and safe setting to enable the vaccination of a large number of girls therefore enabling the entire cohort of First Year girls to complete a course of vaccination. From a logistical and safety perspective all three doses will be administered during one academic school year.

To ensure the 2009/2010 cohort are included the HSE plans to vaccinate a double cohort of students (2009/2010 and 2010/2011 1st year students) will commence the programme in September 2010.

Girls attending special schools may be vaccinated at school or at a HSE clinic. Girls who are outside of the traditional school system, e.g. home-schooled girls and early school leavers, will be invited to attend a HSE clinic. In the first year of the programme, both for girls attending special school or those who are outside the school system, vaccination will be offered to those girls who turn 12 between 1<sup>st</sup> September 2009 and 31<sup>st</sup> August 2011. Thereafter girls who turn 12 between September and August of the academic year will be vaccinated.

## **7.0 OUTLINE PLAN FOR THE ANNUAL VACCINATION PROGRAMME**

Most schools will commence the HPV programme in September 2010 and continue on an annual basis.

All girls will require two doses before Christmas of the academic year and a third dose 6 months after the first.

A 'Blitz and Mop' approach will be adopted to enable adherence with the recommended schedule, the vaccination of the entire cohort, the completion of the full vaccine course within one academic year, and provision for school holidays and examination periods.

### **7.1 Schedule**

The following schedule will apply (with local variation where necessary):

- The first dose will be given during a three week 'Blitz' period in September and early October in second level schools countrywide.
- This will be followed by a one week 'Mop' period, vaccinating girls in HSE clinics who missed their first dose in school. These clinics may also facilitate the vaccination of those girls attending special schools or who are outside the school system.
- The second dose will be given during a three week 'Blitz' period in November and early December in second level schools countrywide.
- This will be followed by a one week 'Mop' period, vaccinating girls in HSE clinics who missed their second dose in school. These clinics may also facilitate the vaccination of those girls attending special schools or who are outside the school system.
- The third dose will be given during a three week 'Blitz' period in March and early April of the following calendar year (this will depend on when Easter falls) in second level schools countrywide.

- This will be followed by a one week 'Mop' period, vaccinating girls in HSE clinics who missed their third dose in school. These clinics may also facilitate the vaccination of those girls attending special schools or who are outside the school system

## 8.0 PROCEDURES

### 8.1 Operational aspects of the programme prior to the 1<sup>st</sup> school visit

- Parents of the students to be vaccinated will receive the following documentation through the schools in advance of the planned vaccination session in the school:
  - Letter of invitation for vaccination
  - Fact sheet for parents on HPV vaccination
  - Consent Form (Appendix A)
- This documentation will be prepared centrally and distributed to the Local Health Offices (LHOs) along with vaccination record cards. This documentation will be delivered to the schools as far in advance of the proposed visit by the team as possible.
- The composition of vaccination teams will be agreed locally in advance and will depend on the number of girls in first year of second level schools in the catchment area.
- Vaccinations will be delivered by both medical officers and nurses. Nurses may administer vaccine under doctor prescription or medication protocol within their scope of practice.
- All staff should be familiar with the following documents:
  - Immunisation Guidelines for Ireland, 2008 Edition  
<http://www.immunisation.ie/en/HealthcareProfessionals/ImmunisationGuidelines2008>  
and any subsequent amendments
  - A Practical Guide to Immunisation, National Immunisation Office, 2008.  
<http://www.immunisation.ie/en/HealthcareProfessionals/TrainingManual/>
  - HPV school vaccination campaign information for Health Professionals, National Immunisation Office, 2010  
<http://www.immunisation.ie>
- Each medical officer and nurse must be familiar with techniques for resuscitation of a patient with anaphylaxis.
- Each medical officer and nurse should be familiar with the "Anaphylactic Reactions: Treatment in the Community" protocol, updated in December 2009, and available in the Immunisation Guidelines for Ireland at  
[http://www.immunisation.ie/en/Downloads/NIACGuidelines/PDFFile\\_16148\\_en.pdf](http://www.immunisation.ie/en/Downloads/NIACGuidelines/PDFFile_16148_en.pdf)
- Each medical officer and nurse should be familiar with the Medication Protocols for nurse administration of Gardasil and Adrenaline without individual prescription

## **8.2 Operational aspects of the programme on the day of the school visit**

- The team will be at the school in advance of the immunisation session to ensure that it commences promptly at the appointed time.
- Each medical officer and nurse on the teams will be accountable for his/her own practice.
- Each member of staff will report to their relevant line manager.
- Each member of the team has a responsibility to ensure the smooth through-flow and safety of students and staff at all times.
- 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 and all the documentation required by the team are available at the school every day.
- A designated person will ensure that sufficient vaccine is brought to each vaccination session and that vaccines are stored and maintained within Cold Chain conditions-see Section 8.10 and 8.11
- A designated person will take responsibility for bringing the resuscitation kit to the schools and for ensuring that all the necessary resuscitation equipment and drugs are available. These will be checked at the start of each vaccination session.
- At the beginning of each vaccination session two members of the team will verify the identity, expiry dates and batch numbers of the vaccine for use on the day.
- This will be recorded on a locally agreed form, together with the temperature of the cool boxes at the beginning and end of the vaccination session.
- 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.
- A medical practitioner and a nurse must remain at the vaccination venue for at least 30 minutes following the last vaccination.
- At the end of the vaccination session a HPV Campaign Vaccination Session Report Form should be completed. This may be a manual form or may run off the ICT system.
- All members of the Team will be responsible for cleaning/tidying up after the vaccination session so as to ensure that the vaccination venue is left as it was found.
- Students who are absent or whose vaccination is deferred will be given an appointment to attend a HSE mop-up clinic.

## **8.3 Specific responsibilities of individual disciplines:**

The person providing **administrative support** will:

- Collect and return students to their classrooms in association with a designated liaison person from the school.
- Guide students in an orderly fashion to the vaccination venue.

- Record on the list of students to be targeted (if available from the school at vaccination session) those who have attended for vaccination on the day.
- Check that each consent form is completed (see section 8.4) before directing a student to the medical practitioner for prescription of the HPV vaccine.
- Collect the consent forms/vaccination records from each vaccinator at the end of the vaccination session.
- Collate the statistics required for the HPV Campaign Vaccination Session Report Form

The **Medical Officers** will:

- Ensure that informed consent has been given by a parent/guardian (see section 8.5).
- Assess each student's suitability for immunisation on the day (see section 8.6).
- Prescribe the HPV vaccine by signing the appropriate section on the consent form (including Medical Council registration number).
- Administer the vaccine or refer the girl to the team's vaccinator for vaccination.
- Be present while vaccinations are being given by nurse vaccinators, and for 30 minutes after the last vaccine is administered so that he/she is available to deal with anaphylaxis or other any other adverse events that might occur.
- Manage any syncopal episodes that may occur after vaccination (see Section 8.7).

The **Vaccinators** (Nurses or Medical Officers) will:

- Ensure that the number of vaccines that will be required by each vaccinator to complete a one hour vaccination session are removed from the cool box- this number may vary depending on the experience of the vaccinator
- As the session draws to a close ensure that the vaccinators have removed only the required number of vaccine to complete the vaccination session.
- Before administration of the HPV vaccine
  - check that the vaccine has been prescribed by the medical officer
  - record the name of vaccine, batch number and expiry date on the consent form before each student is vaccinated.
- Administer a single dose of 0.5ml of vaccine by intramuscular (IM) injection at a 90° angle to the skin in the densest part of the deltoid muscle of either arm.
- Wash their hands or use the disinfectant gels provided after each vaccination.
- Dispose of sharps immediately, without recapping the needle, into the sharps containers provided.
- In exceptional circumstances vaccine may have been removed from the cool box and from its packaging (e.g. where a girl presents for vaccination and then refuses). In order to comply

with the vaccine license Gardasil should be kept in its outer box to protect from it from light. If not used in a timely fashion this vaccine should be discarded

- Complete the administration details 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.
- Complete the student's vaccination record card and give it to the student.
- Each student should be observed for 15 minutes before being allowed to return to the classroom, and should not leave the vaccination venue / school for 30 minutes after vaccination.
- Manage any syncopal episodes that may occur after vaccination (see Section 8.8).

**Note:**

- The skin does not require cleaning before the vaccine is administered unless visibly dirty. In this instance the skin can be cleaned with soap and water. If an alcohol wipe is used the skin should be allowed to dry before the vaccine is injected.
- Gloves are not required when administering intramuscular injections

**8.4 Administration of HPV vaccine under Medication Protocol**

- An Bord Altranais defines medication 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 medication protocol involves the authorisation of the nurse/midwife to supply and administer a medication 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.
- The Gardasil medication protocol enables registered nurses employed in the HSE who have undertaken the required education and training programmes to administer HPV vaccine without individual prescription.

**8.5 Consent**

- Vaccination is not compulsory.
- Informed consent must be obtained prior to vaccination.
- For girls aged under 16, consent must be obtained from one parent or guardian.
- For girls aged 16 years of age and over they can consent on their own behalf.
- Consent is given by the girl/parent/guardian to a course of vaccination therefore it covers all three doses necessary to complete a course and consent remains valid until the course has been completed or unless consent is withdrawn by a parent or guardian.

- If a parent consents but the girl refuses vaccination on the day of the school clinic the girl should not be vaccinated.
- If a parent refuses but the girl expresses a desire to be vaccinated on the day of the school clinic, the girl may be vaccinated if she is aged 16 years or over as she can provide her own consent. If the girl is less than 16 years of age she cannot be vaccinated.
- The team will keep a record of those students where consent was withheld and the reasons stated if given.

Further guidance on consent, if required, is contained in “A Practical Guide to Immunisation” which is available at [http://www.immunisation.ie/en/Downloads/PDFFile\\_15165\\_en.pdf](http://www.immunisation.ie/en/Downloads/PDFFile_15165_en.pdf)

### **8.6 Assessment of the student for vaccination**

Vaccines will 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, 2008.

The student’s temperature will not be checked 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 medical officer to require deferral of the vaccine, will be offered an appointment for the mop-up clinic.

#### Contra-indications to vaccination

- Known hypersensitivity to any of the vaccine constituents including a severe reaction (anaphylaxis) to yeast. (Gardasil is manufactured using yeast cells and anybody with a severe allergic reaction to yeast should not receive the vaccine).
- Previous allergic reaction to Gardasil ®
- Pregnancy

#### Pregnancy

Parent(s) are advised to discuss the possibility of pregnancy with their daughter prior to vaccination and are asked to indicate on the consent form whether or not the girl is pregnant (see Appendix A). If the parent(s) indicate that their daughter is pregnant then vaccination should be withheld. If they indicate that their daughter is not pregnant then vaccination is appropriate. Questioning the girl about her last menstrual period is not indicated.

At each visit the vaccinator should ask the girl the following:

- Have you read on the consent form where it says that the HPV vaccine 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.

If there is any possibility of pregnancy vaccination should be postponed

If the female student is under 16 years of age inform the parent, 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.

However, if the girl is adamant that her parents are not to be informed as to the reason for deferral the medical officer should notify their line manager and seek further advice. Refer to GP, by phone or a referral letter with the consent of the girl and her parents seeking further advice if necessary.

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. This should be reported as an adverse event to the IMB. The course of Gardasil ® HPV vaccination may be finished when the pregnancy is completed.

#### Precautions for vaccination

- Acute severe febrile illness; defer until recovery.
- Vaccine 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) needle and to apply pressure to the vaccine site for 1-2 minutes after the injections. Some authors have suggested that narrower 25 gauge needle might produce an injection jet under greater pressure and that this can cause increased trauma and local reaction rates. In those with a severe bleeding tendency vaccination can be scheduled shortly after administration of clotting factor replacement or similar therapy. There are no data with HPV vaccines using the subcutaneous route. Administration by the subcutaneous route may be considered in those with severe bleeding disorders. However, immunogenicity of vaccines recommended for IM administration may not be as long-lasting if they are given subcutaneously. The patient or parent should be advised of this.
- There is no data on the use of Gardasil ® in individuals with impaired immune responsiveness, whether due to treatment or illness. These individuals may not respond as effectively to the vaccine.

When there are doubts as to whether or not to give a vaccine contact a Principal Medical Officer or a Specialist in Public Health Medicine.

### **8.7 Reactions to HPV vaccine**

HPV vaccines are considered safe and well tolerated.

#### Side Effects

The side effect profile of Gardasil ® is outlined below:

- Very common (1/10): Pyrexia, and erythema, pain, or swelling at the injection site
- Common (1/100, <1/10): Pain in extremity, and bruising and pruritus at the injection site
- Rare (1/10,000, <1/1,000): Urticaria
- Very rare (<1/10,000): Bronchospasm
- Syncope has occurred after vaccination with Gardasil ®, especially in adolescents.

The HPV fact sheet for parents contains details on adverse reactions and their management. Parents should inform the school immunisation team of any adverse reactions to the vaccine by contacting the Local Health Office.

The medical officers will report all serious adverse reactions to the Irish Medicines Board

Adverse events can be reported online at:

<http://www.imb.ie/EN/Safety--Quality/Online-Forms/Human-Medicine-Adverse-Drug-Reaction.aspx>

Or an adverse event form can be downloaded, and returned by FREEPOST, from:

<http://www.imb.ie/EN/Publications/Safety--Quality/Reporting-Suspected-Product-Problems/Safety-Related-Problems/Adverse-Reaction-Form.aspx?page=1&year=0&categoryid=58&letter=&q=>

### **8.8 Syncope following vaccination**

Post-vaccination fainting has been reported with most vaccines. Based on data from the USA, syncope is most common after three adolescent vaccines HPV, MCV4 (4<sup>th</sup> dose Meningococcal vaccine), and Tdap. It is not known whether this is due to the vaccines or if the increased incidence in this age group merely reflects that adolescents are generally more likely to experience fainting. The onset of syncope is usually immediate. A review of syncope after vaccination found that 89% occurred within 15 minutes of vaccination.

#### Preventing syncope:

- Experience from Australia suggests that the organisation of clinics can be a key factor in reducing the number of fainting episodes.
  - Girls should be brought in small groups (less than 10 girls) to the area where vaccination is occurring
  - The ideal clinic layout is an area of the school where girls go in one door to be vaccinated and exit via another door so that they cannot increase anxiety levels in girls waiting to be vaccinated
- Ensure patient is sitting or lying for vaccination.
- Observe patient for 15 minutes after vaccination.
- Further advice on reducing the incidence of syncope during school vaccination programmes is contained in Appendix B.

#### Management of syncope:

- Patient should be placed in the recumbent position and observed until they are fully recovered.
- Recovery of consciousness occurs within a minute or two, but patients may take some more time to recover fully.
- Fainting is sometimes accompanied by brief clonic seizure activity (i.e. rhythmic jerking of the limbs), but this requires no specific treatment or investigation.

### **8.9 Defaulters**

For girls who have their vaccination deferred by the medical officer they should be given an appointment for the next mop-up clinic.

School Principals will be given information about the next mop up clinic which they can provide to students who are absent from school on the day.

Where possible following attendance at the mop up clinics every effort should be made to schedule subsequent doses in the school setting.

### **8.10 Vaccine Storage**

- Vaccines will be stored in the vaccine fridges at the main health centres in accordance with the local Vaccine Fridge Standard Operating Procedure (SOP).
- All medical, nursing and administrative staff involved in handling vaccines for the School Immunisation Programme will be aware of their respective responsibilities as set out in these guidelines, so as to ensure that the vaccines remain safe and effective.

### **8.11 Maintenance of the Cold Chain during School Visits**

The designated person collecting the vaccine from the health centre will be responsible for:

- Appropriately completing the routine stock removal form at the health centre each day in accordance with the Vaccine Fridge SOP.
- Ensuring that only vaccine that is in date is brought to the school.
- Ensuring that, if possible, vaccine to be used on a day is all the same batch.
- Recording the temperature in the cool box
  - before leaving the health centre
  - at the beginning of the vaccination session
  - at the end of the vaccination session
  - on returning the vaccines to the fridge.
- Maintaining the vaccines at a temperature range from 2 to 8°C (Appendix C: Maintenance of cool-box temperature).
- Ensuring that vaccines that are maintained under Cold Chain conditions and in their original packaging not used on a particular day are marked and kept separately so that they are used first on the next vaccinating day.
- Any vaccine that has been removed from its packaging and is not used in a timely manner should be discarded. This vaccine should NOT be marked and NOT be used at a subsequent session.

## **9.0 DATA COLLECTION AND RECORDING**

### **9.1 Client Records**

Girls will be given a vaccination record card after their first dose which will record the vaccine manufacturer, date given, batch number, expiry date, route and site of injection, and name of vaccinator.

They should be told to keep this safe and to bring it with them when they get their next dose.

### **9.2 HSE Records**

Consent forms for students whose vaccination is deferred or who are absent on the day should be put aside for the next mop-up clinic.

Consent forms for students who have been vaccinated should be set aside for the next school clinic.

When students have completed the vaccination course their records will be filed in accordance with the HSE Records Retention Policy.

### **9.3 Clinic Data Recording**

Data should be recorded for statistical purposes at the end of each session (Appendix D). This should include

- The target number of female students in First Year and Second year for the programme commencing in 2010 and thereafter for the target number of females in First Year.
- The number of students vaccinated in school on the day by year and by stage of vaccination.
- The number of students for whom vaccination has been refused and reasons for same (where known).
- The number of students for whom vaccination has been deferred and reasons for deferral e.g. absence, illness/medical reason, inadequate information, lack of proper consent.

### **9.4 Data Entry Standards**

Data accuracy is very important. Care should be given to the correct spelling of client demographic details and GP details. All Mandatory Fields must be completed correctly with meaningful and accurate data. In addition to the mandatory fields, users should make every effort to input as much client information as possible. If additional information is entered on forms in notes fields or on the back of the form where there is no data entry field available this information should be entered into the notes field. Appendix E provides further guidance on the correct recording of client data.

## **11.0 FURTHER INFORMATION**

Further information regarding HPV, cervical cancer and HPV vaccine can be found on the following websites.

- National Immunisation Office available at <http://www.immunisation.ie>
- Immunisation Guidelines for Ireland 2008 Edition HPV chapter available at <http://www.immunisation.ie/en/HealthcareProfessionals/ImmunisationGuidelines2008/>
- Department of Health and Children available at [www.dohc.ie](http://www.dohc.ie)
- Health Protection Surveillance Centre available at <http://www.hpsc.ie>
- Irish Medicines Board available at <http://www.imb.ie>
- Medicines Information online available at <http://www.medicines.ie>
- National Cancer Screening Service available at <http://www.cancerscreening.ie>
- National Cancer Registry Ireland available at <http://ncri.ie/ncri/index.shtml>
- Irish Cancer Society available at <http://www.cancer.ie>
- World Health Organisation HPV information available at <http://www.who.int/immunization/topics/hpv/en/>

- Centre for Disease Control and Prevention – HPV information available at <http://www.cdc.gov/hpv/>
- Australian Government, Department of Health and Education HPV programme available at <http://www.health.gov.au/internet/immunise/publishing.nsf/Content/immunise-hpv>
- New Zealand, Ministry of Health HPV programme available at <http://www.moh.govt.nz/moh.nsf/indexmh/immunisation-diseasesandvaccines-hpv-programme>
- United Kingdom HPV programme available at <http://www.nhs.uk/Conditions/HPV-vaccination/Pages/Introduction.aspx>
- Canadian HPV programme available at <http://www.phac-aspc.gc.ca/std-mts/hpv-vph/fact-faits-eng.php>
- European Medicines Agency available at <http://www.ema.europa.eu/>

# APPENDIX A: HUMAN PAPILLOMAVIRUS (HPV) VACCINATION CONSENT FORM

FOR OFFICIAL USE ONLY

Class Name: \_\_\_\_\_ School Roll Number: \_\_\_\_\_ Client ID Number: \_\_\_\_\_



## Human Papillomavirus (HPV) Vaccination Consent Form



If you wish to give consent please fill in Parts 1, 2 and 3. If you do not wish to give consent please fill in parts 1, 2 and 4.

### PART 1 Complete this part for all girls

Forename: \_\_\_\_\_ Middle Name: \_\_\_\_\_ Surname: \_\_\_\_\_

Girl's PPSN (Optional): \_\_\_\_\_ Birth date: \_\_\_\_\_  
D O M M Y Y Y Y

Girl's surname at birth: \_\_\_\_\_ Mother's maiden name: \_\_\_\_\_

Home Address: \_\_\_\_\_

County: \_\_\_\_\_

Parent/Guardian home phone: \_\_\_\_\_ Parent/Guardian mobile: \_\_\_\_\_

School or college name: \_\_\_\_\_ 1<sup>st</sup> year:  2<sup>nd</sup> year:

If not at school or college (please tick): Home schooled  Outside School System

GP name and address: \_\_\_\_\_  
 \_\_\_\_\_ GP phone number: \_\_\_\_\_

### PART 2 Complete this part if this girl has previously been given a HPV vaccine (include each dose)

	Vaccine Name (Gardasil or Cervarix)	Batch Number	Date Given
Dose 1			
Dose 2			
Dose 3			

**PRIVACY STATEMENT:** The HSE will use the information you provide to monitor the HPV vaccination programme and health care provision. HSE Staff are aware of their obligations under the Data Protection Acts, 1988 and 2003.

Do you wish to have her HPV vaccination records linked with:

her other HSE immunisation records (please tick) Yes  No

her future cervical cancer screening records with the National Cancer Screening Service (please tick) Yes  No

### PART 3 Complete this part if you want to have this girl vaccinated

Before you give consent please complete these questions. The doctor or nurse may decide to vaccinate, delay or withhold vaccination.

Has she had a previous severe reaction to Gardasil? Yes  No

Is she allergic to any of the vaccine constituents (aluminium hydroxyphosphate sulphate, L-histidine, Polysorbate 80, yeast)? Yes  No

Is she pregnant? Yes  No

Has she an illness/condition that increases her risk of bleeding? Yes  No

I have read and understand the information about vaccination to be administered, including risks and side effects. I understand that I am giving consent for three doses of Gardasil over 6-12 months. I am authorised to give consent for this girl to be vaccinated. (Those over 16 years of age are legally entitled to consent for themselves.)

Name (please print): \_\_\_\_\_ (please tick): Parent  Guardian  Self

Signature: \_\_\_\_\_ Date: \_\_\_\_\_ (DD/MM/YY)

## Human Papillomavirus (HPV) Vaccination Consent Form

**PART 4** Complete this part if you do not want to have this girl vaccinated

**NO, I do not consent to the vaccinations.**

After reading the information provided, I do not wish to have this girl vaccinated with the Gardasil vaccine.

(Those over 16 years of age are legally entitled to consent for themselves.)

Name (please print): \_\_\_\_\_ (Please tick): Parent  Guardian

Signature: \_\_\_\_\_ Date: \_\_\_\_\_ (DD/MM/YY)

**FOR OFFICE USE ONLY – GARDASIL VACCINATION**

Dose	Date Given	Batch Number	Site Given	Prescribed by signature and MCRN	Vaccinator's signature and MCRN/Nurse PIN	Vaccination location (school name or roll number or clinic name)
<b>1</b>	/ /					

If Dose 1 not given please tick reason: Absent  Unwell  Refused  Clinical reason  Other

Comment: \_\_\_\_\_

Signature: \_\_\_\_\_ Adverse Reaction Reported to IMB: Yes  No

Dose	Date Given	Batch Number	Site Given	Prescribed by signature and MCRN	Vaccinator's signature and MCRN/Nurse PIN	Vaccination location (school name or roll number or clinic name)
<b>2</b>	/ /					

If Dose 2 not given please tick reason: Absent  Unwell  Refused  Clinical reason  Other

Comment: \_\_\_\_\_

Signature: \_\_\_\_\_ Adverse Reaction Reported to IMB: Yes  No

Dose	Date Given	Batch Number	Site Given	Prescribed by signature and MCRN	Vaccinator's signature and MCRN/Nurse PIN	Vaccination location (school name or roll number or clinic name)
<b>3</b>	/ /					

If Dose 3 not given please tick reason: Absent  Unwell  Refused  Clinical reason  Other

Comment: \_\_\_\_\_

Signature: \_\_\_\_\_ Adverse Reaction Reported to IMB: Yes  No

## **APPENDIX B: TIPS FOR CONDUCTING A SCHOOL IMMUNISATION SESSION TO REDUCE THE INCIDENCE OF SYNCOPE**

*Adapted from the Immunisation Programme in Victoria, Australia\**

- Organise sessions to be run in a venue that allows privacy for each student being vaccinated so that other students are not watching the procedure prior to their vaccine being administered.
- Have a separate entry and exit point so students arriving for vaccination do not cross paths with students leaving after vaccination.
- Arrange for students to be seated when being administered their vaccines in case of an immediate faint.
- Provide a nearby area for adolescents to wait following the vaccination. This area needs to be readily accessible to immunisation staff in the event of a faint or other immediate adverse event.
- Supervision may be required to ensure students remain seated while waiting the 15 minutes after being vaccinated in case of fainting.
- The vaccination area should be free of staircases and concrete as these areas can contribute to injury following a fainting episode.
- It is important for a person familiar to each class to be present at the venue in order to assist with identification of students control their behaviour and create a calm environment.
- Ensure the vaccine session is run with only one class present at a time to minimise the sense of mass anxiety that a few students can engender in other vulnerable students.
- Following vaccination, students are required to wait a minimum of 15 minutes in a nearby location; however, this time should be longer if a student is feeling dizzy or unwell after vaccination.
- Following vaccination, adolescents should refrain from strenuous activity for up to 30 minutes in case of a delayed fainting episode.

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\* Immunisation Programme, Department of Human Services. Immunisation Newsletter 2009;37:2

## **APPENDIX C: MAINTENANCE OF COOL-BOX TEMPERATURE**

Cool-box temperature should be maintained between 2 and 8 °C **at all times**

- Ice packs should be wrapped unless they have their own cover.
- Frozen ice packs should be placed in the cool box for a minimum of 15 minutes before the vaccines are packed into the cool-box.
- The number of packs used should be as per cool box manufacturer's instructions /best practice recommendations
- The ice packs used should be rotated to ensure maximum coldness.
- The ice packs should be positioned appropriately above, below and around the vaccines as space in the cool-box allows.
- The temperature probe should be 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 should be transported in their original packaging, wrapped in bubble-wrap 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
- The cool-box thermometer should be sent back to the manufacturer for calibration on an annual basis.
- Vaccines returned to the health centre fridge following school vaccination session should be marked and used first on their next excursion to a school.

### **Procedures following breakdown in the "Cold Chain"**

Check position of temperature probe. The temperature probe should be placed in the middle of the vaccines. Reset probe ensure positioned correctly away from ice packs. Close box firmly and recheck temperature in 10 minutes.

### **If temperature too low (< 2°C)**

Vaccine should not be used - Safety issue as risk of fracture to glass vial

Unimpaired product cannot be guaranteed if storage temperature falls below 2°C.

**If temperature high (>8°C)**

If there are any queries with respect to vaccine storage, cold chain, etc., please contact the Chief Pharmacist at the National Immunisation Office for further advice. He/She can be contacted at 087 9915452 or 01 8676108

**APPENDIX D Session Report Form**

This form should be completed at the end of each vaccination session.

<b>LHO AREA</b>	
<b>School Roll Number</b>	
<b>School Name</b>	
<b>School Address</b>	
<b>Tel No:</b>	
<b>Fax No:</b>	
<b>Email:</b>	
<b>Principal</b>	
<b>Date of Vaccination Session</b>	

<b>Vaccine</b>	<b>Expiry Date</b>	<b>Batch Number</b>

	Secondary Schools		Special schools		<b>TOTAL</b>
	<b>First Year</b>	<b>Second Year</b>	<b>Aged 12 outside 1<sup>st</sup> or 2<sup>nd</sup> yr</b>	<b>Age 13 outside 1<sup>st</sup> or 2<sup>nd</sup> yr</b>	
<b>Total number in Cohort</b>					
<b>Number with consent not returned</b>					
<b>Number previously vaccinated*</b>					
<b>Total No. who refused consent</b>					
<b>Number Vaccinated: 1st Dose</b>					
<b>Number Vaccinated: 2nd Dose</b>					
<b>Number Vaccinated: 3rd Dose</b>					
<b>Absent</b>					
<b>Unwell</b>					
<b>Refused on the day</b>					
<b>Clinical reason</b>					
<b>Other</b>					
<b>Total Activity (No. of vaccines given)</b>					
<b>No. referred to mop up clinic</b>					

\*Completed course of either Gardasil or Cervarix given by GP

## APPENDIX E: DATA ENTRY STANDARDS

### Data entry of names:

Ensure that the name entered in the Surname field is the family name and that the name entered in the First Name field is the first or given name of the client.

### ***Surname Data Entry Convention to be followed***

Surname should be input without any spelling abbreviations, commas, apostrophes, dashes etc.

No characters other than alpha characters (letters) are acceptable in the surname field.

Names prefixed with **AI** should be entered as AI space Hussain i.e. **AI Hussain**

Names prefixed with **MC** should be entered as MC space i.e. **Mc Carthy**

Names prefixed with **MAC** should be entered as Mac space i.e. **Mac Amhlaigh**

Names prefixed with **O'** should be entered as O space i.e. **O Connor**

Names prefixed with **D'** should be entered as D space i.e. **D Eathe**

Names prefixed with **Ní** should be entered as Ni space i.e. **Ni Bhroin**

Names prefixed with **Nic** should be entered as Nic space i.e. **Nic Ailin**

Names prefixed with **De** should be entered as De space i.e. **De Burca**

**Double barrel names** should also be entered without commas, apostrophes, dashes etc. Enter with a space between names i.e. **Tierney Monahan** not Tierney-Monahan

### ***First Name Data Entry Convention to be followed***

Forenames must be entered in full. Initials or spelling abbreviations are not acceptable e.g. type Michael not MI, Margaret not Mags, Patrick Joseph and not Patk J. etc. Junior/Senior: Where the suffix is used in a client's name, it must be typed in full with brackets directly after the forename e.g. Michael (Junior) or Patrick (Senior).

Ensure that the **proper** first name is given and recorded not the "known as" name i.e. **Margaret rather than Mags**. Where the client uses an alias name which differs considerably from their official forename, this may need to be recorded for correspondence and identification purposes. In such cases, the alias name should be type in brackets directly after the official forename e.g. Margaret (Peggy). Please note that aliases are not to be confused with name abbreviations such as Robert (Bobby).

**Date of Birth** should be entered in the European way i.e. DD/MM/YYYY

**Mobile Numbers** may be used to send short SMS messages therefore it is important that they are collected and recorded accurately. Enter number as nnn nnnnnn e.g. 086 2549801 (do not enter anything else into this field)

**Address**

Abbreviations for addresses are not acceptable. All mandatory address fields must be completed correctly and information typed in the appropriate fields. All elements of the address must be typed in full without any dashes, hyphens etc. e.g. Saint Marys Street. The following common address must be entered in full: Avenue, Apartments, Circular, Cottages, Court, Crescent, Drive, East, Estate, Garden, Glade, Grove, Heights, House, Lawn, Lower, Middle, North, Parade, Park, Place, Road, Saint, Square, Terrace, Upper, Walk, West .

**Apartment No.** If the client address contains an apartment number, type the word Apartment and the appropriate number in the Apartment field e.g. Apartment 7

**Care of** – Some clients may be residing 'care of' someone or somewhere. This should be entered as c/o. When entering a c/o location, type this information in the first line of address i.e. c/o Mary Burke.