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GUIDELINES FOR STAFF:
HPV SECOND LEVEL SCHOOL VACCINATION CAMPAIGN

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VERSION 2 May 12th 2010

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 HPV (Human Papillomavirus) 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, 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.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.

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 vaccine chosen for the school programme is the Gardasil ® vaccine.

The vaccine,

- contain no viral DNA and are 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

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 will be 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 (EMEA) for use in females aged 9 to 26.

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 child 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

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.

Girls who are outside of the traditional school system, e.g. home-schooled girls and early school leavers, will need to be vaccinated in a non-school setting. In the first year of the programme girls who turn 12 between 1st September 2009 and 31st August 2011 will be vaccinated. Thereafter girls who turn 12 between September and August of the academic year will be vaccinated.

While these guidelines apply nationally there will be local variation in the composition of the school vaccination teams and some processes may vary. This will be due to the varied distribution of females in second level schools across the country.

To comply with the Minister's instructions to vaccinate first year girls, beginning with the 2009/2010 cohort, the HSE recommended the vaccination of a double cohort of students

(2009/2010 and 2010/2011 1st year students) to begin in September 2010 for safety and logistical reasons and to ensure a high vaccine uptake.

To comply with further instruction from the Department of Health and Children, the HSE will begin vaccinating some of the 2009/2010 cohort of 1st year girls in May 2010. These girls will require their second dose in July 2010 and their third dose in November 2010. Thus the first and third doses of the vaccine will be provided in school but alternative arrangements will be required for their second dose during the school holidays.

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.
- 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.
- 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.

8.0 PROCEDURES

8.1 Operational aspects of the programme prior to the 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.
- It is envisaged that in many areas nurses will administer the HPV vaccines. At the outset, all vaccinations delivered by nurses will be prescribed by medical officers. Over time an increasing number of nurse vaccinators will be qualified to administer school vaccines, including HPV vaccines, by following medication protocols. Medical officers will also be vaccinators in some areas.
- All staff should be familiar with the following documents:
    - Immunisation Guidelines for Ireland, 2008 Edition
      http://www.immunisation.ie/en/HealthcareProfessionals/ImmunisationGuidelines2008
    - 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

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 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 the HPV Campaign Vaccination Session Report Form (Appendix B) should be completed.
- 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 (Appendix B) as agreed with the National Immunisation Office.

The **Medical Officers** will:

- Ensure that informed consent has been given by a parent/guardian (see section 8.4).
- Assess each student's suitability for immunisation on the day (see section 8.5).
- Prescribe the HPV vaccine by signing the appropriate section on the consent form (including Medical Council registration number).
- Administer the vaccine or refer the child 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:

- 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.
- 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 8.7).

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 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 child/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.
- If a parent consents but the child refuses vaccination on the day of the school clinic the child should not be vaccinated.
- If a parent refuses but the child expresses a desire to be vaccinated on the day of the school clinic, the child may be vaccinated if she is aged 16 years or over as she can provide her own consent. If the child 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

8.5 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
- Previous allergic reaction to Gardasil ®
- 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 child 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.

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 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. 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 Paediatrician or a Specialist in Public Health Medicine.

8.6 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=

8.7 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 (4th 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 C.

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.

8.8 Defaulters

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

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.

8.9 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.

8.10 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 D: Maintenance of cool-box temperature).
- Ensuring that vaccines not used on a particular day are marked and kept separately so that they are used first on the next vaccinating day.

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 date given, batch number and expiry date.

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

The following data will be recorded for statistical purposes at the end of each session on the Vaccination Session Report Form (Appendix B):

- 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.
- 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
- Health Protection Surveillance Centre available at http://www.hpsc.ie
- Irish Medicines Board available at http://www.imb.ie
- Medicines Information online available at 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.immunisation.nhs.uk/Vaccines/HPV
- 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

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 children**

Child's Forename: ______ Middle Name: ______ Surname: ______

Child's Personal Public Services Number (PPSN): ______ Birth date: D D M M Y Y Y Y

Child's surname at birth: ______ Mother's maiden name: ______

Address: ______

Parent home phone: ______ Parent mobile: ______

School or college name: ______ Class or year: ______

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

GP name and address: ______

PART 2 — **Complete this part if your child has previously been given a HPV vaccine**

Vaccine Name (Gardasil or Cervarix)	Batch Number	Date Given

PRIVACY STATEMENT: We will use the information you provide to monitor the HPV vaccination programme and health care provision. We will send personal information to the National Cancer Screening Service to enable cancer screening services to be offered to this child when she is older. HSE staff are aware of their obligations under the Data Protection Acts, 1988 and 2003. If you do not wish to have your or your child's information recorded by us or by the National Cancer Screening Service, you have the right to write to the local immunisation office to ask for the record to be removed.

PART 3 — **Complete this part if you want to have your child vaccinated**

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 understand that my child's details and vaccination will be recorded on the HSE immunisation systems and will be shared with the National Cancer Screening Service. I am authorised to give consent for the above child/myself to be vaccinated. (Children over 16 years of age are legally entitled to consent/refuse consent for themselves.)

Name (please print): ______ (Please tick): Parent ☐ Guardian ☐ Self ☐

Signature: ______ Date: D D M M Y Y Y Y

PRE-IMMUNISATION CHECKLIST: Before the person is vaccinated, please check this list.
The doctor or nurse may decide to vaccinate, delay or withhold vaccination.

Is the person allergic to aluminium hydroxyphosphate sulphate, L-histidine, Polysorbate 80, yeast?	Yes ☐	No ☐
Has the person had a previous severe reaction to the Gardasil vaccine?	Yes ☐	No ☐
Is the person pregnant?	Yes ☐	No ☐

PTO

Human Papillomavirus (HPV) Vaccination Consent Form

PART 4 Complete this part if you do not want to have your child vaccinated

NO, I do not consent to the vaccinations.
After reading the information provided, I do not wish to have myself/my child vaccinated with the Gardasil vaccine.
(Children over 16 years of age are legally entitled to consent/refuse consent for themselves.)

Name (please print): ______ (Please tick): Parent ☐ Guardian ☐ Self ☐

Signature: ______ Date: D D M M Y Y Y Y

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)
1	/ /					

If **Dose 1** not given please tick reason: Absent ☐ Unwell ☐ Child refused ☐ Clinical reason ☐ Other ☐

Comment:

Signature:

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)
2	/ /					

If **Dose 2** not given please tick reason: Absent ☐ Unwell ☐ Child refused ☐ Clinical reason ☐ Other ☐

Comment:

Signature:

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)
3	/ /					

If **Dose 3** not given please tick reason: Absent ☐ Unwell ☐ Child refused ☐ Clinical reason ☐ Other ☐

Comment:

Signature:

APPENDIX B: HPV CAMPAIGN VACCINATION SESSION REPORT FORM

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

LHO: ___________________________

School Name: ____
Address: ____
____
____
Tel. No.: __________________
Fax No.: __________________
Email: ____________________
Principal: _________________

Date of clinic: ___/___/____

Vaccine	Expiry Date	Batch Number

	First Year	Second Year
Total Number Eligible Students		
Number Vaccinated • 1st Dose • 2nd Dose • 3rd Dose		
Number Deferred		
Number Consent Withheld		

HSE staff present at vaccination session:

Doctors	Nurses	Clerical Officers

APPENDIX C: 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 children, 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 D: 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.
- Three frozen ice packs should be placed in the cool box for a minimum of 15minutes before the vaccines are packed into the cool-box.
- The ice packs used should be rotated to ensure maximum coldness.
- The ice packs should be positioned 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.
- 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 time of packing and returning the vaccines should be recorded.
- 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 (< 2ºC)

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

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

If temperature high (>8ºC)

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 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 **Al** should be entered as Al space Hussain i.e. **Al 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 Ml, 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 nnnnnnn 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.