AN ROINN OIDEACHAIS AGUS SCILEANNA | DEPARTMENT OF EDUCATION AND SKILLS

Circular Letter 0036/2010

To: The Boards of Management and Principals of Post-Primary Schools and the Chief Executive Officers of Vocational Education Committees.

Vaccination Programme against the Human Papillomavirus (HPV) in Post-Primary Schools.

The Department of Education and Skills has been advised by the Health Services Executive (HSE) that it is now commencing the national HPV vaccination programme. This vaccine will reduce the risk of girls getting cervical cancer when they are adults.

The HSE has asked the Department to bring the attached letter to the attention of all post-primary schools (HSE letter).

The HSE has set up a dedicated website (www.hpv.ie) and this website, along with the Department's website (www.education.ie), will provide any supplementary information likely to be required by schools in relation to the support they will provide to the HSE in its management of this vaccination programme.

The Táiniste and Minister strongly encourages' post-primary schools to co-operate with the HSE on this important public health issue.

BRIAN BROGAN
PRINCIPAL OFFICER

May 2010

Feidhmeannacht na Seirbhíse Sláinte
Health Service Executive

National Immunisation Office
Units 8/9 Manor Street Business Park
Manor Street
Dublin 7
www.immmunisation.ie

September 2010

HPV (Human Papillomavirus Vaccination) Programme 2010

Dear Principal,
The Health Service Executive (HSE) has commenced the national HPV vaccination programme, which will reduce the risk of cervical cancer in girls in Ireland.

All girls require three doses of vaccine with a two month interval between the 1st and 2nd dose and a four month interval between the 2nd and 3rd doses.

In keeping with best practice from other countries and to ensure high vaccine uptake the HSE will deliver a school based programme.

For this first year of the programme the vaccine will be given to all girls who will be entering 1st Year AND 2nd Year in September 2010. Vaccination began in a small number of schools in May 2010. The majority of schools will commence the programme in September 2010.

For special schools, vaccination for all girls who reach 12 years of age between 1st September 2009 and 31st August 2011 will start in September 2010.

The HSE vaccination teams will contact you to make arrangements to provide the vaccinations three times on agreed dates between September 2010 and March 2011. It is important for girls to receive all three doses for the vaccine to be fully effective.

The HSE vaccination teams will do all they can to ensure the vaccination sessions take place as efficiently as possible. Should you require further information please contact your local immunisation office (phone numbers overleaf)

Yours sincerely

Dr Kevin Kelleher
Assistant National Director Population Health – Health Protection
Medical Registration Number 19719

Contact phone numbers for HSE Immunisation Offices

South		Dublin North East	
Carlow/Kilkenny SouthTipperary Waterford Wexford	056/7784500 052/6177221 051/842906 053 9123522	Nth Dublin City & Nth Dublin County Dublin North Central Dublin North West	01/8164259 01/8467289 01/8825157
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Longford /Westmeath	044 9395076		

Please note that for vaccination sessions to take place the HSE teams will require

- Use of a large room such as a hall/indoor sports court. In choosing this area it would be very useful if there was a separate entrance and exit.
- Hand-washing facilities
- Tables and chairs for vaccinating teams (depending on size of school and vaccinating team)
- Chairs or mats for students
- A liaison member of staff to call students from class at the appropriate time for vaccination and return them to class in an orderly way after vaccination

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14 September 2010

HPV (Human Papillomavirus Vaccination) Programme 2010

Dear Principal

The HSE is aware of correspondence being sent to principals of second level schools with serious allegations about HPV vaccine. Over 57,000 Irish girls will be offered HPV vaccine this year, and they and their parents deserve to be well informed about the vaccine, its good safety profile and the cancer that it prevents.

Cervical cancer is the second most common cancer in women worldwide. Each year in Ireland around 250 women are diagnosed with cervical cancer and 80 die from the disease. At least 7 out of 10 of these cancers are linked to Human Papillomavirus (HPV).

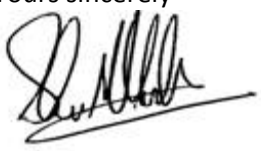
Infection with HPV is common. About 80% of all women will have a HPV infection in their lifetime, most of which will clear naturally. However two high risk types of HPV (16 or 18) are responsible for causing over 70% of cervical cancers.

Thankfully, we now have a vaccine to protect girls from these high risk types of HPV infection and cervical cancer when they are adults. The HSE began providing HPV vaccine during May of this year, and all girls starting 1st Year and 2nd Year in September will be offered this vaccine, mostly in their schools, and all free of charge.

Like Ireland, every one of the many countries implementing HPV vaccination programmes are doing so in the best interest of their citizens, to maximise health, prevent disease and prolong life. Around the world, a failure to implement a HPV vaccination programme would be considered to be a withholding of potentially life-saving preventive treatment.

Please find below Questions and Answers regarding HPV vaccine based on peer reviewed international evidence and vaccine safety data before and after licensing. Further information is available at www.hpv.ie

Yours sincerely



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Dr Kevin Kelleher
Assistant National Director Population Health – Health Protection
Medical Registration Number 19719

HPV VACCINE QUESTIONS AND ANSWERS

HOW LONG IS HPV VACCINE EFFECTIVE FOR?

The exact duration of protection for any HPV vaccine will only be known after decades of follow up of girls who have been vaccinated. This is because there is a very long time frame of usually over 20 years between a girl becoming infected with HPV and possibly developing cervical cancer.

There is definitive clinical evidence that protection lasts at least 5 years (HPV vaccine was licensed in 2006) and clinical trials have shown that the levels of immunity remain high. In addition there is also evidence that there has been a substantial reduction in the numbers of cases of genital warts (also caused by HPV) in countries where Gardasil HPV vaccine has been introduced.

All the current evidence is that immunity from HPV vaccine is long lasting. However there is not sufficient information to determine whether or not a booster dose of HPV vaccine will be needed in the future. Studies and trials are ongoing to determine whether or not a booster dose is required. The results of these will indicate if a booster dose is necessary and if a booster is required the girls will be informed.

WHAT ABOUT GIVING HPV VACCINE TO GIRLS WHO ARE ALREADY SEXUALLY ACTIVE?

HPV vaccine is effective for girls who have not been previously exposed to infection. The vaccine should still be administered to girls who are already sexually active but will not alter the progression of a pre-existing HPV infection or the development of any consequences of this infection. This is why the National Immunisation Advisory Committee advised that the HPV programme should be given to 12 year old girls on the basis that this would be prior to when they become sexually active.

HOW SAFE IS HPV VACCINE?

All vaccines including Gardasil, the vaccine used in the HSE's HPV immunisation programme undergo a series of trials before they can be licensed and these trials can take several years. These trials assess vaccine safety and effectiveness. After vaccines receive a licence their safety and effectiveness profile continues to be assessed.

Internationally, the World Health Organization monitors and reviews the safety of HPV vaccines. By March 2009, over 60 million doses of Gardasil had been distributed either as part of national immunisation programmes or by private doctors.

In the opinion of the US Food and Drug Administration, the European Medicines Agency, and the Therapeutic Goods Administration in Australia Gardasil, has a good safety record.

It has been tried and tested in large clinical studies which lasted more than a decade and which included over 25,000 subjects in 33 countries. These studies are outlined

in section 4.8 of and 5 of the Summary of Product Characteristics which is available at http://www.medicines.ie/medicine/11524/SPC/GARDASIL.

WHAT ARE THE SIDE EFFECTS FROM GARDASIL?
Gardasil is considered safe and well tolerated.

The most frequently reported side effects are local redness and /or swelling at the point of injection, and fever. These are typical and usually mild and temporary reactions to any kind of vaccination.

Fainting has occurred after vaccination with Gardasil, especially in adolescents. Fainting has also been reported with other vaccines in adolescence. 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 fainting is usually immediate. A review of fainting after vaccination found that 89% occurred within 15 minutes of vaccination and that the adolescents recovered quickly.

Less common reported side effects from Gardasil include pain in the injected arm, and bruising and itchiness at the injection site and rarely hives or a wheeze occur.

Like most vaccine severe allergic reactions are extremely rare.

In some countries there have been deaths reported following HPV vaccination – however further investigation has shown that none of these deaths were causally associated with the HPV vaccine and were due to other unrelated causes such as drowning, malaria and an undiagnosed tumour.

The World Health Organisation conducted a review of HPV vaccine safety in 2009 and stated “no concerns with the safety profile were identified”

HOW LONG HAS THE HPV VACCINE BEEN IN USE?
Gardasil which protects against 4 of the common Human Papillomaviruses has been licensed for use since 2006. By March 2009, over 60 million doses of Gardasil had been distributed either as part of national immunisation programmes or by private doctors

WHAT DOES GARDASIL VACCINE CONTAIN?
The vaccine constituents are outlined in the Summary of Product Characteristics (the licensed information about the vaccine) which is available at http://www.medicines.ie/medicine/11524/SPC/GARDASIL/
These are

- Proteins like those that coat the HPV virus known as virus like particles (VLPs) (These VLPs cannot cause HPV infection or cancer).
- Aluminium hydroxyphosphate sulphate which is a component of several of the childhood vaccines
- L-histidine which is a component of some hepatitis vaccines

- Polysorbate 80 – 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 a component of some vaccines and medicinal compounds such as Optrex eye drops

The vaccine is manufactured using yeast cells and anybody with a severe allergic reaction to yeast should not receive the vaccine

DO GIRLS WHO HAVE BEEN VACCINATED STILL REQUIRE CERVICAL SCREENING IN THE FUTURE?

The vaccine does not protect against all HPVs. The vaccine protects against the types of HPV which cause 7 out of 10 cervical cancers so it is still important for girls to have regular smear tests when they are adults.

More information about HPV vaccine is available at www.hpv.ie www.immunisation.ie and in the Gardasil Summary of Product Characteristics (SPC) which is available at http://www.medicines.ie/medicine/11524/SPC/GARDASIL/

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