

Medical & Allied Branch  
Dr Lorraine Doherty



Department of  
**Health, Social Services  
and Public Safety**

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AN ROINN

**Sláinte, Seirbhísí Sóisialta  
agus Sábháilteachta Poiblí**

MÁNNYSTRIE O

**Poustie, Resydènter Heisin  
an Fowk Siccar**

**HSS (MD) 16/2008**

To:  
Chief Executives, HSS Boards and Trusts  
Directors of Public Health, HSS Boards (*for onward distribution to screening leads and sexual health leads*)  
Director of Nursing, HSS Boards  
Directors of Pharmaceutical Services, HSS Boards/HSC Trusts/CSA  
GP Medical Advisers, HSS Boards  
Consultants in Communicable Disease Control, HSS Boards  
All Community Pharmacists  
Medical Directors, HSC Trusts (*for onward distribution to Consultants in Genito-urinary medicine, Gynaecology and Family Planning*).  
Nursing Directors, HSC Trusts (*for onward distribution to all Community Nurses and School Health Staff*)  
All General Practitioners (*for onward distribution to practice staff including practice nurses*)  
Regional Epidemiologist, CDSC (NI)  
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Our Ref: HSS (MD) 16/2008  
Date: 22<sup>nd</sup> May 2008

Dear Colleague,

## **INTRODUCTION OF HUMAN PAPILLOMAVIRUS VACCINE INTO THE CHILDHOOD IMMUNISATION PROGRAMME: FURTHER GUIDANCE ON PROGRAMME IMPLEMENTATION**

I am writing to provide further guidance on the introduction of the human papillomavirus (HPV) vaccination programme.

The Chief Medical Officer's letter of 22nd May has set out the key features of the programme, and further background information on HPV is provided in the final draft of a new chapter for 'Immunisation against Infectious Disease 2006' ([www.dh.gov.uk/greenbook](http://www.dh.gov.uk/greenbook)). This guidance should be read in conjunction with those documents.

This letter is aimed at those health professionals who will be responsible for implementing the new programme. I would encourage you to share this guidance with all those who will be involved in helping to deliver the new programme in your area.

The benefits of introducing HPV vaccination will be felt by women and their families for generations to come. The Department of Health, Social Services and Public Safety will continue to work closely with Health and Social Services Boards and Health and Social Care Trust colleagues to make the introduction of this new programme a success.

Any queries on the programme should be addressed to Health Protection Branch, DHSSPS, Castle Buildings, Stormont, Belfast BT3 2SQ. Email: [health.protection@dhsspsni.gov.uk](mailto:health.protection@dhsspsni.gov.uk)

Yours sincerely,



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cc Dr Michael McBride, Chief Medical Officer  
Dr E Mitchell, Deputy Chief Medical Officer  
Ms C Jendoubi, Director Primary Care DHSSPS  
Mr A Elliott, Director of Health Development, DHSSPS  
Mr S Camplisson, Health Protection Team, DHSSPS  
Ms K Simpson, Health Protection Team, DHSSPS  
Mr J Farrell, Principal, GMS Contract Unit, DHSSPS  
Directors of Primary Care, Health & Social Services Boards  
Local Health & Social Care Groups – Chairs/Managers  
Dr B Dunn, Chair, GPC, BMA  
Dr B Gaffney, Chief Executive, HPA NI  
Ms C Baxter, Information Office, DHSSPS  
Members of the RACCDC Regional Immunisation Committee

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## 1. Outline of the immunisation programme

### 1.1 Routine programme start date and cohort to be immunised

From the beginning of the 2008/2009 school year, the routine childhood immunisation programme will include HPV immunisation for all 12- to 13-year old girls (school year 9). The first cohort to be immunised will be all girls born between 1 July 1995 and 30 June 1996.

### 1.2 Catch-up campaign and immunisation of older girls and young women

An outline of the catch-up programme is provided in the Chief Medical Officer's letter of 22nd May 2008. The timing of the routine programme and catch-up campaign is summarised in the table below.

	School year 8	School year 9	School year 10	School year 11	School year 12	School year 13	School year 14
2008/09		■					
2009/10		■				■	■
2010/11		■			■	■	
2011/12		■					



Routine programme for Year 9 girls



Catch-up campaign for older girls

The successful introduction of routine immunisation for 12 to 13 year old girls is the priority in the first year of the HPV vaccination programme. Further information on the catch-up campaign will follow the implementation of the routine programme.

JCVI has recommended that a catch-up campaign for all women aged 18 years and over is not cost effective, but that immunisation could benefit some individual women. The four UK Health Departments are considering the issues around this matter. Any individual woman who feels she may benefit can discuss the issue with her GP.

### 1.3 Vaccine to be supplied and the immunisation schedule

Details of the brand of vaccine to be provided for this programme will follow. For both the currently available vaccines:

- three doses of vaccine are needed; and
- a 0, 1-2, 6 months schedule should be used for planning purposes.

All three doses should be given within a 12-month period. Further information on scheduling is available in the final draft of a new chapter for '*Immunisation against Infectious Disease 2006*' ([www.dh.gov.uk/greenbook](http://www.dh.gov.uk/greenbook)).

## **2. Funding and service arrangements**

£400k will be allocated to the Health and Social Care Trusts to support the implementation of the programme through the school health service. £340k will be recurrent funding and £60k non recurrent funding for 2008-09 only and will cover training and management costs.

The £340k recurrent funding will support Trusts in making suitable arrangements including:

- Vaccination administration costs
- Child Health System administration costs
- Preparatory work in schools
- Information sessions & dealing with questions from parents, schools and pupils
- Pharmacy costs
- Mop-up clinic costs

**The following central costs will be met by the Department:**

- **Purchase of the Vaccine**
- **Promotion and support information materials**
- **Publicity for the programme by the Health Promotion Agency**

## **3. Delivery of the routine programme**

JCVI has recommended that the routine HPV immunisation programme would be most efficiently delivered through schools. This is recommended because that approach is likely to provide higher vaccine coverage and to be more acceptable to parents and pupils. In Northern Ireland the HPV programme will be delivered by the School Health Service within each Health and Social Care Trust areas. The Department has been working closely with the HSC Trusts on this matter.

The Chief Medical Officer on 22nd May 2008 has written to the Chief Executives of the Education and Library Boards seeking their support and cooperation, along with that of the school principals in each of the Education and Library Board areas. This support will be crucial for the effective delivery of the programme.

Arrangements should be made for girls who miss a scheduled immunisation. 'Mop-up' sessions for those girls who miss their vaccination appointment will be provided through the school health service. School Health Service can decide on the location and timing of these 'mop-up' clinics.

## 4. HPV vaccines, and the supply and management of vaccine stocks

There are two licensed HPV vaccines in the UK. Cervarix™ is manufactured and licensed by GlaxoSmithKline. Gardasil™ is manufactured by Sanofi Pasteur MSD. The brand of HPV vaccine that will be purchased nationally (and also what pack size will be supplied) will be announced in June 2008, following the completion of the current procurement exercise.

### 4.1 Available vaccines

Both the currently available vaccines are given as a course of three 0.5ml doses, over a period of about six months. The schedule for administration of HPV vaccines is discussed in section 1.3. The two vaccine brands must not be interchanged. One brand of vaccine must be used for the entire course.

Cervarix™ is supplied as a turbid white suspension in a single dose 0.5ml pre-filled syringe with a blue needle (23g x 25mm). The vaccine may appear as a clear colourless supernatant with a fine white deposit after storage. The vaccine should be shaken well before use. A single syringe pack measures 42mm x 24mm x 133mm.

Gardasil™ is supplied in a single dose 0.5ml pre-filled syringe with both a blue needle (23g x 25mm) and an orange needle (25g x 16mm). The blue needle should be used for HPV vaccine administration (see chapter four, '*Immunisation against Infectious Disease 2006*' ([www.dh.gov.uk/greenbook](http://www.dh.gov.uk/greenbook))). Prior to agitation, the vaccine may appear as a clear liquid with a white precipitate. The vaccine should be shaken well before use and, after thorough agitation is a white, cloudy liquid. A single syringe pack measures 47mm x 23mm x 150mm.

The administration of HPV vaccines, their adverse reactions, and their use in pregnancy are explained in detail in the final draft of a new chapter for '*Immunisation against Infectious Disease 2006*' ([www.dh.gov.uk/greenbook](http://www.dh.gov.uk/greenbook)).

### 4.2 Patient Group Directions

A template Patient Group Direction (PGD), for use with HPV vaccines (Gardasil™ or Cervarix™) will be made available at [www.immunisation.nhs.uk/hpv](http://www.immunisation.nhs.uk/hpv). Boards and HSC Trusts may wish to tailor this to reflect local needs. The use of PGDs is described in detail in '*Immunisation against Infectious Disease 2006*' (pages 35 to 39, [www.dh.gov.uk/greenbook](http://www.dh.gov.uk/greenbook)).

### 4.3 Supply of HPV vaccine

Stocks of HPV vaccines will be supplied via designated Trust Pharmacy Departments. Trust Pharmacy Departments will be able to order supplies of HPV vaccine via Movianto Ireland.

Trust Pharmacy departments should ensure that vaccine is stored appropriately, distributed in the correct expiry date order, and liaise with their Board to ensure that vaccine is only provided for girls in the recommended cohort.

Further information on supply arrangements and stock availability will be issued to Trust Pharmacy Departments by the Regional Pharmaceutical Procurement Service (Tel: 028 9055 2386).

#### **4.4 Vaccine storage**

Vaccines should be stored in the original packaging at +2°C to +8°C and protected from light. All vaccines may be sensitive to some extent to heat and cold. Freezing may cause increased reactogenicity and loss of potency for some vaccines. It can also cause hairline cracks in the container, leading to contamination of the contents.

Please ensure sufficient fridge space is available for the new vaccine. Each site holding vaccine is asked to review current stocks of all vaccines. Trust Pharmacy Departments should ensure that have sufficient stocks of the new HPV vaccine in place for the start of the campaign. However then only hold optimum stock levels to meet demand and liaise with healthcare professionals to minimise local stockholding and wastage. . A review of available fridge space will be necessary to ensure adequate storage capacity at the start of the programme.

It is imperative that Trusts have robust arrangements in place for maintenance of “cold chain” for vaccine transport.

#### **4.5 Vaccine wastage**

**Effective management of vaccines throughout the supply chain is essential to reduce vaccine wastage.** Trusts should ensure that they have robust stock management systems in place to minimise waste.

Each 1% of vaccine supplied in the current childhood immunisation programme is worth approximately £2m. This could increase to nearer £3m with the introduction of the HPV vaccine. Even small percentage reductions in vaccine wastage will have a major impact on the financing of vaccine supplies.

Trusts are asked to advise the Department what systems they have implemented to manage and control vaccine wastage.

#### **4.6 Transporting and storing vaccine at immunisation sessions**

More information will be provided regarding transporting and storing HPV vaccine at immunisation sessions when details of the vaccine to be used with the national programme are announced in June 2008.

Any queries on local Trust supply and distribution arrangements should be made to the relevant Trust Pharmacy Department.

The Regional Pharmaceutical Procurement Service (Tel: 028 9055 2386) will provide information on availability and distribution of central supplies of the HPV vaccine to Trust Pharmacy Departments.

## 5. Communication

All information and guidance resources to support the HPV programme are being posted on the DHSSPS website at [www.dhsspsni.gov.uk](http://www.dhsspsni.gov.uk) as they become available.

Materials to support the training of health professionals are available, including: the final draft of a new chapter on HPV for 'Immunisation against Infectious Disease 2006' (at [www.dh.gov.uk/greenbook](http://www.dh.gov.uk/greenbook)); and a fact sheet and a training slide set for professionals (at [www.immunisation.nhs.uk/hpv](http://www.immunisation.nhs.uk/hpv)).

### 5.1 Information pack

The information pack will comprise the following items:

- information leaflet for girls and their parents/guardians;
- Q&A for parents/guardians;
- fact sheet for health professionals;
- new HPV chapter for 'Immunisation against Infectious Disease 2006' (the Green Book);
- sample consent form/data capture form;
- poster to advertise the vaccination programme
- letter from Chief Medical Officer, Chief Pharmaceutical Officer and Chief Nursing Officer.

Information packs will be sent to the following health professional groups:

- Directors of Public Health, HSS Boards (*for onward distribution to screening leads and sexual health leads*)
- Director of Nursing, HSS Boards
- Directors of Pharmaceutical Services, HSS Boards/HSC Trusts/CSA
- GP Medical Advisers, HSS Boards
- Consultants in Communicable Disease Control, HSS Boards
- Community Pharmacists
- Medical Directors, HSC Trusts (*for onward distribution to Consultants in genito-urinary medicine, gynaecology and family planning*).
- Nursing Directors, HSC Trusts (*for onward distribution to all Community Nurses and School Health Staff*)
- All General Practitioners (*for onward distribution to practice staff including practice nurses*)

**A modified pack will also be sent to head teachers of post primary schools.**

### 5.2 Information for girls and their parents/guardians

The HPV information leaflet for girls and their parents/guardians and a Q&A sheet for parents/guardians will be available for the start of the school year. Translated versions of the leaflet in a number of languages will be available (in electronic format only) on the DHSSPS website.

Prior to the start of the immunisation programme, information material and consent form should be given to each pupil to be vaccinated, to take home and share with their parents/guardians.

### **5.3 Advertising and media support**

Starting in September 2008, an advertising campaign will publicise the introduction of HPV vaccination. The media used will include TV, radio and national press.

## **6. Consent**

As with all other forms of health care, valid consent must be obtained before the administration of vaccines. The legal situation is described below.

There are three scenarios, which can be summarised as follows:

- For girls under 16 years of age not considered competent to give consent, consent must be sought from a parent or guardian.
- For girls under 16 years of age who demonstrate *Gillick* competence<sup>i</sup>, and who are appropriately informed, consent from parents/guardians is not required.
- Girls over 16 years of age are presumed to be capable of self-consenting unless there are specific reasons otherwise.

For girls who are *Gillick* competent, it is still good practice to involve the girl's family in the decision-making process, taking into account her right to confidentiality. There is no legal requirement for consent to be in writing. Valid consent means the person giving consent has the capacity to make that decision, has enough information to make it, and must not be acting under duress.

Health professionals must ensure that parents/guardians and girls are properly informed of the benefits and risks of the HPV vaccine, possible side effects and how to treat them, and also provide sufficient opportunities to discuss any issues that arise. The information leaflet is designed to support this process.

For reasons of efficiency, it is recommended that consent is sought at the outset for all three doses of the vaccine. The health professional providing the vaccine should ensure that valid consent is in place at the time that the vaccine is given.

## **7. Monitoring vaccine uptake**

The Northern Ireland the PfA target for HPV is by 31st March 2009 Trusts will have delivered the second dose of the HPV vaccination to 90% of girls who are in Year 9 in 2008/09. Therefore monitoring vaccine uptake is crucial to ascertain the success of the programme.

Monitoring vaccine uptake will be done through capturing data from the Child Health System, but uptake levels will not be known until December 2008 at the earliest. This is the first year of the programme and interest from the assembly, media and health professionals will be high. A further additional monitoring template will need to be used

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<sup>i</sup> *Gillick v West Norfolk and Wisbech AHA* [1986] AC 112. The court held that children who have sufficient understanding and intelligence to enable them to understand fully what is involved in a proposed intervention will also have the capacity to consent to that intervention.

by the school health service alongside the form for the Child Health system until December 2008. This would allow provision of the following information:

- The numbers of first and second doses given during a particular month
- The uptake of first and second doses
- The cumulative coverage of first and second doses

Details of this data capture form and guidance on its use will issue in due course.