

To: PCT immunisation coordinators  
SHA immunisation leads  
HPU immunisation leads



2 May 2008

Dear Colleague,

**Introduction of human papillomavirus vaccine into the national immunisation programme: guidance on programme implementation**

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

The Chief Medical Officer's letter of 2 May 2008 sets out the key features of the programme, and further background information on HPV is provided in a draft factsheet ([www.immunisation.nhs.uk/hpv](http://www.immunisation.nhs.uk/hpv)) and 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 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 will continue to work closely with NHS and other colleagues to make the introduction of this new programme a success.

Yours sincerely,

A handwritten signature in black ink, appearing to read 'D M Salisbury', with a horizontal line underneath.

Professor D M SALISBURY CB  
FRCP FRCPCH FFPH  
Director of Immunisation

This document has been authorised by the Department of Health:  
Gateway reference no: 9794

# **Contents**

## **1. Outline of the immunisation programme**

- 1.1 Routine programme start date and cohort to be immunised
- 1.2 Catch-up campaign and immunisation of older girls and young women
- 1.3 Vaccine to be supplied and the immunisation schedule

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

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

- 3.1 Providing services to all girls

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

- 4.1 Available vaccines
- 4.2 Patient Group Directions
- 4.3 Supply of HPV vaccine
- 4.4 Vaccine storage
- 4.5 Vaccine wastage
- 4.6 Transporting and storing vaccine at immunisation sessions

## **5. Communication**

- 5.1 Information pack
- 5.2 Information leaflet for girls and their parents/guardians
- 5.3 Advertising and media support

## **6. Consent**

## **7. Monitoring vaccine uptake**

- 7.1 Monthly data collection
- 7.2 Annual data collection

## **8. Local data management**

## **9. Annex: monthly and annual datasets**

# 1. Outline of the immunisation programme

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

From the beginning of the 2008/09 school year, the routine childhood immunisation programme will include HPV immunisation for all 12- to 13-year old girls (school year 8). The first cohort to be immunised will be all girls born between 1 September 1995 and 31 August 1996 (and corresponding birth date ranges in following years).

All girls in this age cohort should be offered immunisation. For practical reasons, any girl in school year 8, regardless of her date of birth, should be offered HPV immunisation.

## 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 2 May 2008. The timing of the routine programme and catch-up campaign is summarised in the table below.

	School year 7	School year 8	School year 9	School year 10	School year 11	School year 12	School year 13
2008/09							
2009/10							
2010/11							
2011/12							

 Routine programme for Year 8 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. PCTs will be able to build on the lessons learned from the introduction of the routine programme in order to ensure a successful catch-up campaign.

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 Department of Health will provide advice regarding women aged 18 and over in due course. 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**

£8.9m will be transferred to PCTs to support the implementation of the programme, with funding allocated on a per capita basis. This equates to just over £55k for an average sized PCT. This funding will support PCTs in making suitable arrangements including:

- additional remuneration for providers; and
- administrative, training, education, IT and consumables costs.

In line with vaccine supply arrangements, the allocation of funds will be made on the basis of school rolls data (see section 4.3 for further information). PCTs retain the flexibility to determine locally how best to allocate funding.

Each PCT may make contractual arrangements with NHS or any other providers. When making arrangements with contractors, the PCT has the flexibility to decide what services should be delivered, and by whom, to an appropriate standard. The structure of the remuneration package offered to contractors should be determined locally by each PCT. PCTs may consider entering into a franchise arrangement where another organisation is responsible for the delivery of care on that PCT's behalf under a service level agreement.

At the end of 2007, the Department of Health published the *Operating Framework for 2008/09*, setting out what the NHS needed to achieve for the forthcoming year and beyond. As a part of that, the Department of Health has introduced a new approach to setting and managing priorities using 'Vital Signs'. Childhood immunisation is included in tier 2 of 'Vital Signs', which means that all PCTs should cover this in their operational plans for sign-off by their SHA. The degree of national involvement and approach to performance management will be focused on weak areas against the plan (for more information go to [www.dh.gov.uk/en/Publicationsandstatistics/Publications/PublicationsPolicyAndGuidance/DH\\_082542](http://www.dh.gov.uk/en/Publicationsandstatistics/Publications/PublicationsPolicyAndGuidance/DH_082542)).

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

PCTs are responsible for the implementation of the HPV immunisation programme and will already be planning, with partner organisations, how best to deliver the programme in their area.

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 partnership with local education authorities, PCTs will be identifying all schools within their area. PCTs should identify all institutions for this age group, including independent schools, pupil referral units, young offender units and residential units. The website [www.edubase.gov.uk](http://www.edubase.gov.uk), maintained by the Department for Children, Schools and Families, provides an up-to-date database of educational establishments in England.

PCTs will already be considering the logistics of providing immunisation sessions in schools. PCTs will need to agree with schools the timing of the programme within the school year, given the fixed nature of school terms and the need to avoid clashes with events such as examinations, particularly in the summer term. Provision of specific educational input for pupils, parents and staff from school health services is likely to be helpful. This may be provided, for example, as special assemblies, 'drop-in' sessions or at parent evenings.

Arrangements should be made for girls who miss a scheduled immunisation. A 'mop-up' service could be provided as additional immunisation sessions within-year in schools or by other means, such as through GPs or in community clinics. Providing 'mop-up' vaccination at the same time as the school-leaver booster programme for older children may also be considered.

### **3.1 Providing services to all girls**

PCTs should consider conducting a health equity audit (HEA) for immunisation. This can be used to consider how resources are distributed in relation to the needs of different groups in terms of areas, socio-economic groups, gender, the number of children in the household, or ethnicity.<sup>i</sup>

Girls are entitled to NHS services - including girls in private schools - in accordance with their registration with a general practitioner (or their area of residence should they not be registered with a GP). PCTs are encouraged to make arrangements for all girls to be immunised in school, regardless of their area of residence. PCTs should consider putting in place reciprocal agreements with neighbouring areas to ensure provision of services for girls who attend school outside their PCT area of residence.

## **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.

---

<sup>i</sup> Vaccination services – Reducing inequalities in uptake. Department of Health, 2005 (available at [www.dh.gov.uk/en/Publicationsandstatistics/Publications/PublicationsPolicyAndGuidance/DH\\_4105349](http://www.dh.gov.uk/en/Publicationsandstatistics/Publications/PublicationsPolicyAndGuidance/DH_4105349))

## 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 4, *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). 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

A fixed number of doses of HPV vaccine will be reserved for each PCT, based on school rolls data. Each PCT should designate a contact person to order vaccine supplies. This person should ensure that vaccine is stored appropriately, distributed in the correct expiry date order, and that vaccine is only provided for girls in the recommended cohort.

Vaccine supplies can be ordered in three phases - corresponding to the first, second and third doses – from mid-August 2008, then from 1 September, and 1 January 2009. Multiple orders can be made within this timeframe, up to the total amount of vaccine reserved for the PCT. Vaccine orders will only be taken from the named PCT contact.

Supplies can be delivered to multiple points within a PCT area, providing the Movianto UK<sup>ii</sup> account numbers are given for those delivery points when the named person places the order. Delivery points should be made aware of all deliveries that are due. Deliveries will be made within two weeks of ordering.

---

<sup>ii</sup> Movianto UK Limited, who will be responsible for distributing the vaccine, was previously named Healthcare Logistics (and was formerly Farillon)

The same figures that will be used for vaccine supply purposes, school rolls numbers by PCT, will also be used for allocating the additional funding to PCTs (see section 2) and for the denominator for the monthly data returns (see section 7.1).

Further details, including the supply of contact details for each PCT's designated person, will be provided in a letter, to be sent in May, from the Department of Health's Vaccine Supply Manager. The [vaccine.supply@dh.gsi.gov.uk](mailto:vaccine.supply@dh.gsi.gov.uk) mailbox should be emailed before the beginning of June regarding any possible amendments.

#### **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. Two to four weeks of stock is recommended, and higher stock levels should be reduced to this level. A review of available fridge space will be necessary to ensure adequate storage capacity at the start of the programme.

#### **4.5 Vaccine wastage**

Effective management of vaccines throughout the supply chain is essential to reduce vaccine wastage. PCTs should have effective local protocols that reduce vaccine wastage to a minimum. 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.

PCTs will be issued with sufficient vaccine to immunise all girls in the defined cohort. As vaccine uptake is unlikely to be 100%, this allows for some flexibility, but vaccine wastage must be kept to a minimum to ensure sufficient vaccine is available.

The data collected for this immunisation campaign (see section 7) will enable the careful monitoring of the supply, stock levels and wastage of HPV vaccine.

#### **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 vaccine procurement, storage or distribution should be emailed to [vaccine.supply@dh.gsi.gov.uk](mailto:vaccine.supply@dh.gsi.gov.uk).

## 5. Communication

All information and guidance resources to support the HPV programme are being posted on the immunisation website ([www.immunisation.nhs.uk/hpv](http://www.immunisation.nhs.uk/hpv)) 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 draft factsheet 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
- Q&A
- factsheet
- new HPV chapter for *Immunisation against Infectious Disease 2006* (the Green Book);
- template consent form/data capture form
- A3 poster
- patient held record card (credit card sized, for girls to keep an informal record of their three-dose immunisation course) and
- the Department of Health press release, of 26 October 2007, regarding HPV immunisation.

The Department of Health will send the information pack in May 2008 to the following health professional groups:

- PCTs - immunisation coordinators, directors of public health, GP surgeries , practice nurses, school nurses
- HPA - health protection units; Centre for Infections
- community pharmacies
- NHS Direct call-centres and NHS walk-in centres
- professional organisations - RCN, CPHVA, CPA, RCGP, RCOG, MOSA, BMA, FPH, RCPCH
- strategic health authority screening leads
- strategic health authority immunisation leads
- NHS cancer screening programme leads
- cervical cancer quality assurance directors
- sexual health organisations/contacts
- health promotion units and
- via e-bulletins for health professionals.

The pack will also be sent to the following education contacts in June 2008:

- head teachers of state schools
- head teachers of independent schools, hospital schools and faith schools
- local authority directors of children's services and
- healthy schools coordinators.

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

The HPV information leaflet for girls and their parents/guardians, a Q&A sheet and posters for schools, will be available to order, from June onwards, from the Department of Health publications order line: e-mail [dh@prolog.uk.com](mailto:dh@prolog.uk.com); telephone, 08701 555 455; fax, 01623 724 524. Translated versions of the leaflet in a number of languages will be available (in electronic format only) on the [www.immunisation.nhs.uk/hpv](http://www.immunisation.nhs.uk/hpv) website.

PCTs that are delivering a schools-based programme should order sufficient leaflets and posters for schools in their areas. Before the start of the immunisation programme, schools should give a leaflet and consent form 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, national press, magazines and on-line media. A further wave of advertising will run in the New Year, to remind girls and their parents of the need to complete the full immunisation course.

Details of the immunisation website, and a special NHS Direct information line number, will be included in all information materials and advertising, to direct girls and their parents to more detailed information.

## 6. Consent

As with all other forms of health care, valid consent must be obtained before the administration of vaccines. PCTs may wish to consider specific arrangements for obtaining consent for the HPV programme in line with their local consent policies. Department of Health guidance is given at [www.dh.gov.uk/consent](http://www.dh.gov.uk/consent), and in chapter 2 of *Immunisation against infectious disease* 2006 ([www.dh.gov.uk/greenbook](http://www.dh.gov.uk/greenbook)). The legal situation is described below.

There are three scenarios, that 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>iii</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.

---

<sup>iii</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.

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. A consent form template has been produced - which PCTs may choose to use or adapt - and will be available at [www.immunisation.nhs.uk/hpv](http://www.immunisation.nhs.uk/hpv), but PCTs remain responsible for developing local consent guidance.

## **7. Monitoring vaccine uptake**

Vaccine uptake, supply and wastage data will be provided by PCTs to the Department of Health, subject to ROCR approval, in order to ensure the programme is managed effectively. Data collection will be managed through the Health Protection Informatics (HPI) website. The Department of Health will be contacting PCT immunisation coordinators in due course to give further details about accessing this password protected website. Further guidance and supporting resources for data collection and management will be available at [www.immunisation.nhs.uk/hpv](http://www.immunisation.nhs.uk/hpv).

The HPI website, as well as allowing manual on-line returns, also provides facilities for automatic data extraction from Child Health Information Systems (CHIS). That facility is dependent on suppliers providing a suitable service, and on PCTs having populated their CHIS with appropriate data. Automatic data uploading is expected to become more widely available in later years.

The HPI website will facilitate HPV data submission, and the management of local immunisation programmes by PCTs and strategic health authorities, by:

- allowing the validation of data on point of entry, and correction of any errors before submission
- making use of automated and semi-automated data extraction methods (if supplier arrangements allow)
- allowing data extraction of submitted data to Excel, or the viewing of data as geographical maps or bar charts, and
- allowing vaccine uptake rates and vaccine supply/wastage rates to be viewed and compared anonymously with other areas.

An advanced notice of a Data Set Change Notice (DSCN) for the HPV vaccine uptake dataset has been published by the Information Standards Board ([www.connectingforhealth.nhs.uk/dscn/dscn-2008/advance-1/advance](http://www.connectingforhealth.nhs.uk/dscn/dscn-2008/advance-1/advance)). The DSCN will enable the three Local Programmes for IT to specify to their respective local service providers the requirements for incorporating HPV vaccine recording and data management in to CHIS.

### **7.1 Monthly data collection**

Monthly data collection will start on 1 October 2008, collecting data for the period from 1 to 30 September 2008. Subsequent monthly collections will continue until September 2009. Each monthly collection is cumulative and will always include data from 1 September 2008 to the end of the preceding month. The monthly collections

also include data on vaccine supply and wastage – these data are specific to each month and not cumulative. The denominator for the monthly collection will be fixed and will be the same figure used for vaccine supply and additional PCT funding (see end paragraph section 4.3). The draft monthly dataset, which is subject to ISB and ROCR approval, is given in the Annex.

## **7.2 Annual data collection**

Additionally, there will be an annual collection, for data from 1 September 2008 to 31 August 2009 inclusive, which will be collected from 1 October 2008 until 30 October 2009. The annual collection requests final year-end data for vaccine uptake, but excludes data on vaccine supply and wastage. The annual collection includes additional information on where immunisations were provided (for example, school or GP practice etc), and may request optional data on ethnicity. The denominator for the annual collection will be determined by the PCT, and will include the actual school roll figure at the end of the year and any vaccinations not given in schools. The draft annual dataset, also subject to ISB and ROCR approval, is also provided in the Annex.

## **8. Local data management**

A key factor determining the effectiveness of all immunisation programmes is having accurate data on the target population - to call and recall individuals for vaccination, for record keeping purposes, and to share data as necessary across administrative boundaries. It is essential that PCTs have effective information systems in place, preferably electronic, to support the successful implementation of the HPV immunisation programme.

Guidance on the information and IT requirements of the HPV Immunisation programme will be available at [www.immunisation.nhs.uk/hpv](http://www.immunisation.nhs.uk/hpv). This 'HPV Programme – Business and System Requirements' document is designed to be readily understood by PCTs, IT systems suppliers and other stakeholders, and to ensure better consistency across providers and users.

Discussions have been held with the Department for Children, Schools and Families about the need for data sharing, in particular about access to school roll data. PCTs will need to engage with local schools, that 'own' that data.

It is vital that PCTs include a suitable requirement that the provider makes information available to GPs detailing the vaccinations given to young people, and that this information is recorded in the medical record. This information needs to be retained in the longer term for clinical purposes. Where the GP receives a report from a healthcare professional that has provided clinical services to one of its patients that information should be included in the patient's record. PCTs will decide locally how best this might be achieved, in consultation with their Local Medical Committee as appropriate.

## 9. Annex: monthly and annual datasets

### Draft monthly dataset

#### Cohort

Total number in cohort (pre-populated, based on school roll)	A (fixed)
--	-----------

<i>Doses administered (cumulative from 1/9/2008)</i>	Number	% uptake (automatically calculated)
Number received one dose only since 1 September 2008	B	$B/A*100$
Number received two doses only since 1 September 2008	C	$C/A*100$
Number received all three doses since 1 September 2008	D	$D/A*100$

#### Vaccine supply, usage and stock levels

	Number
Number of doses in stock at start of month	E
Number of doses received this month	F
Number of doses wasted/lost this month	G

\* multiplied by

### Draft annual dataset

#### Cohort

Total number in cohort	A
------------------------	---

<i>Doses administered (cumulative from 1/9/2008)</i>	Number	% (automatically calculated)
Number received one dose only since 1 September 2008	B	$B/A*100$
Number received two doses only since 1 September 2008	C	$C/A*100$
Number received all three doses since 1 September 2008	D	$D/A*100$

#### Location where vaccines administered (mandatory)

Location	Number of doses administered	% (automatically calculated)
Schools/colleges	H	$H/(H+I+J+K)*100$
GP practices	I	$I/(H+I+J+K)*100$
Health centres/community clinics	J	$J/(H+I+J+K)*100$
Other	K	$K/(H+I+J+K)*100$

\* multiplied by