

From the Acting Chief Medical Officer
Dr Elizabeth Mitchell



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

www.dhsspsni.gov.uk

AN ROINN

**Sláinte, Seirbhísí Sóisialta
agus Sábháilteachta Poiblí**

MÄNNYSTRIE O

**Poustie, Resydènter Heisin
an Fowk Siccar**

HSS(MD)23/2009

Chief Executives, Public Health Agency/ Health & Social
Care Board/Trusts
Director of Public Health/Public Health Agency
Director of Nursing, Public Health Agency
Directors of Pharmaceutical Services, Health & Social Care
Board/Trusts/CSA
Family Practitioner Service Leads, Health & Social Care
Board
GP Medical Advisers, Health & Social Care Board
Consultants in Communicable Disease Control, Public
Health Agency
All Community Pharmacists
Medical Directors, HSS Trusts (*for onward distribution to all
Consultants, Occupational Health Physicians*)
Nursing Directors, HSS Trusts (*for onward distribution to all
Community Nurses*)
All General Practitioners (*for onward distribution to practice
staff including practice nurses*)
Regional Epidemiologists, CSDC(NI)
Dr Paul Jackson, Chair, Regional Immunisation Committee

Room C3.16
Castle Buildings
Stormont BELFAST BT4 3SQ
Tel: 028 90520717
Fax: 028 90520718
Email:
lorraine.doherty@dhsspsni.gov.uk

Your Ref:
Our Ref: HSS(MD)23/2009
Date: 3 June 2009

Dear Colleague,

THE HUMAN PAPILOMAVIRUS (HPV) IMMUNISATION ACCELERATED CATCH-UP PROGRAMME: FURTHER GUIDANCE ON PROGRAMME IMPLEMENTATION

I am writing to provide further guidance on the acceleration of the human papillomavirus (HPV) immunisation catch-up programme as announced in the Chief Professionals letter of 30 March 2009.

Our letter of 22nd May 2008 set out the key features of the HPV immunisation programme and further background information on HPV is provided in the 'Green Book' chapter on Human papillomavirus (HPV) (www.dh.gov.uk/greenbook). This guidance on the catch-up programme should be read in conjunction with those documents.

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

CONTENTS

Section A

- 1. The HPV Immunisation Catch-up Programme**
- 2. HPV vaccines, supply and management of vaccine stocks**
 - 2.1 Vaccine to be supplied for programme and immunisation schedule
 - 2.2 Patient Group Directions
 - 2.3 Supply of HPV Vaccine
 - 2.4 Vaccine storage
 - 2.5 Vaccine wastage
- 3. Consent**
- 4. Monitoring vaccine uptake**
- 5. Communication**

Section B

- 1. Delivery of the Catch-up Programme by School Health**
 - 1.1 Funding and Service Arrangements
 - 1.2 Information Materials

Section C

- 1. Delivery of the Catch-up Programme by Primary Care**
 - 1.1 Funding and Service Arrangements
 - 1.2 Information Materials

Section A

1. The HPV Immunisation Accelerated Catch-up Programme

In Northern Ireland, girls to be vaccinated as part of the catch-up programme are those born between 2 July 1991 and 1 July 1995. It was agreed that it would be possible to accelerate the catch-up programme if both primary care and school health were involved and that the older girls would be better immunised in primary care settings, as a proportion of these girls will have left school and it would cause confusion to try and vaccinate some in school and some by GP.

Girls born between 2 July 1991 and 1 July 1993 are therefore to be vaccinated in primary care settings and girls born between 2 July 1993 and 1 July 1995 are to be vaccinated by school health.

For details on delivery of the catch-up programme by school health, see Section B, and for details on delivery of the catch-up programme by primary care, see Section C.

	School year 8	School year 9	School year 10	School year 11	School year 12	School year 13	School year 14
				*2 July 1994 to 1 July 1995	*2 July 1993 to 1 July 1994	*2 July 1992 to 1 July 1993	*2 July 1991 to 1 July 1992
2009/10							
2010/11							
2011/12							

* Girls born between these dates.



Routine programme for Year 9 girls



Catch-up campaign for girls as via school health



Catch-up campaign for girls in primary care settings

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, Social Services and Public Safety is waiting on advice from DH (L)

on this issue. Any individual woman who feels she may benefit can discuss the issue with her GP.

2. 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. Both the currently available vaccines are given as a course of three 0.5ml doses.

2.1 Vaccine to be supplied for programme and immunisation schedule

The contract to provide the vaccine for the routine programme and catch-up programme was awarded to pharmaceutical company GlaxoSmithKline in June 2008, for their vaccine Cervarix®. The vaccine supplies are only to be used for the immunisation of those girls eligible for the routine programme and the catch-up programme as defined in this letter.

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.

The schedule for Cervarix® (containing HPV types 16,18)* is as follows;

- First dose of 0.5ml of Cervarix® HPV vaccine.
- Second dose of 0.5ml, one to two months after the first dose.
- A third dose of 0.5ml, at least six months after the first dose.

For planning purposes, a vaccination schedule of 0, 1-2, 6 months is appropriate. All three doses should be given within a 12-month period. If the course is interrupted, it should be resumed but not repeated, ideally allowing the appropriate interval between the remaining doses.

If there is a high likelihood that the third dose of HPV vaccine cannot be given according to the recommended schedule, a third dose of Cervarix® can be given three months after the second. This guidance only applies when there are significant challenges in scheduling the third dose to individuals. For example, where the third dose coincides with examinations or when the second dose is given late.

There is no clinical data on whether the interval between doses two and three can be reduced below three months. Where the second dose is given late and there is a high likelihood that the individual will not return for a third dose after three months or if, for practical reasons, it is not possible to schedule a third dose within this time-frame, then a third dose of Cervarix® can be given at least one month after the second dose. **Whenever possible, immunisations for all individuals should follow the recommended 0, 1-2, 6 month schedule.**

If an individual has started a course of Gardasil®, then this course should be completed by the original provider. In the rare instances where this is not possible, then the vaccination course can be completed with Cervarix® to three doses in total (such as one Gardasil®

and two Cervarix®, or two Gardasil® and one Cervarix®). The course should be completed according to a vaccination schedule of 0, 1-2, 6 months.

There is no evidence on the interchangeability of the two HPV vaccine products, therefore this advice is based on clinical judgement. It is not advisable to complete a three dose course of Cervarix® following one or two doses of Gardasil® as there is no safety data on individuals who receive mixed courses of vaccines that could involve four or even five HPV vaccine doses.

The girl or young woman should be informed that Cervarix® will provide protection against cervical cancer, but not against genital warts.

If a child has a severe latex allergy (eg. anaphylactic) they should not receive Cervarix®. They can however receive Gardasil®. Consultants in Communicable Disease Control within each of the HSS Boards can advise on individual cases. It may be simplest to refer a child to their local GP who can prescribe Gardasil® in exceptional clinical circumstances.

The administration of HPV vaccines, scheduling, their adverse reactions, and their use in pregnancy is explained in detail in the final draft of a new chapter for '*Immunisation against Infectious Disease 2006*' (www.dh.gov.uk/greenbook). This should help inform decisions on administering HPV vaccine where there are difficulties in scheduling the third dose and where some individuals may have already started being vaccinated with Gardasil®

2.2 Patient Group Directions

A template Patient Group Direction (PGD), for the supply and administration of bivalent human papillomavirus vaccine (Cervarix®) is available at [http://www.immunisation.nhs.uk/files/PGD HPV.pdf](http://www.immunisation.nhs.uk/files/PGD_HP.V.pdf). 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).

2.3 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 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).

2.4 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.

2.5 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.

3. Consent

As with all other forms of health care, valid consent must be obtained before the administration of vaccines. Trusts may wish to consider specific arrangements for obtaining consent for the HPV programme in line with their local consent policies. DH guidance is given at www.dh.gov.uk/consent, and in chapter two of ‘*Immunisation against Infectious Disease 2006*’ (www.dh.gov.uk/greenbook). 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* competenceⁱ, 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.

ⁱ *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.

4. Monitoring vaccine uptake

As with the routine school-based programme and the primary care extension programme for 17-18 year olds, monitoring vaccine uptake for the catch-up will be done through the Child Health System.

5. Communication

All information and guidance resources to support the HPV immunisation programme can be found on the DHSSPS website at www.dhsspsni.gov.uk and also the dedicated HPV website for Northern Ireland, www.helpprotectyourself.info.

In addition, materials to support the training of health professionals are available at www.immunisation.nhs.uk/hpv.

The information materials that will be provided for the various catch-up cohorts of girls will be explained in the relevant sections below.

Section B

1. Delivery of the Catch-up Programme by School Health

The Chief Medical Officer, on 30 March 2009, has written to the Chief Executives of the Education and Library Boards seeking their support and cooperation, along with that of the school principles in each of the Education and Library Board areas. This support will be crucial for the effective delivery of the programme.

1.1 Funding and Service Arrangements

Funding will be allocated to the Health and Social Care Trusts to support the implementation of the routine programme and the catch-up through the school health service. Funding will support;

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

As with the routine 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.

1.2 Information Materials

An HPV information leaflet for girls and a Q&A sheet parents/guardians will be provided for those girls receiving the immunisation as part of the catch-up programme in school. This will be in a different colour than those materials provided for the routine programme and should be available for distribution to the Trusts from June. Translated versions of the leaflet in a number of languages (in electronic format only), will be available on the HPV website, www.helpprotectyourself.info, as will further information for girls and their parents/guardians.

Prior to immunisation, information materials and consent forms should be given to each pupil to be vaccinated, to take home and share with their parents/guardians.

Section C

1. Delivery of the Catch-up Programme by Primary Care

1.1 Funding and Service Arrangements

Boards are asked to put in place a Local Enhanced Service (LES) for the accelerated catch up programme for girls born between 2 July 1991 and 1 July 1993. GP practices are therefore being asked to deliver this programme as opposed to school health as some girls in this cohort may have already left school. It is proposed the LES should run from June 2009 to May 2010.

Funding will be provided to support the implementation of the catch-up programme in primary care. The proposed fees are in line with national guidance and would be £7.51 per vaccine administered. As there are 3 doses of vaccine to be given for this programme a fee of £7.51 is payable for each dose. In addition funds will be made available to cover the administrative costs, including entering data on the child health system.

1.2 Information Materials

HPV information leaflets for girls and their parents/guardians will be issued to GP practices, for onward distribution to those girls eligible for the catch-up programme through primary care. These materials should be available in June in order for GP practices to issue to girls as soon as possible, encouraging them to attend an appointment. Translated versions of the leaflet in a number of languages (in electronic format only), will be available on the HPV website, www.helpprotectyourself.info, as will further information for girls and their parents/guardians.

Girls being vaccinated in primary care settings will also be provided with a vaccination card. This is a patient held card (credit-card sized) for girls to keep an informal record of their three-dose immunisation course. These will be delivered to GP practice managers, along with the information leaflets.