

Dear Colleague

HUMAN PAPILLOMA VIRUS (HPV) IMMUNISATION PROGRAMME: 2010/11

Introduction

1. This letter provides an update for NHS professionals involved in delivering the HPV vaccine, on the arrangements for the third year of this national immunisation programme.

2. The first two years of the HPV immunisation programme presented significant challenges to NHS Boards, and we are grateful for the efforts of all professionals involved. Provisional uptake figures for the schools based element of the second year of the programme indicate that, by February 2010, uptake of the first two doses of the vaccine had reached 89.8% and 81.9% respectively for girls in the routine and catch-up age groups combined. This very good uptake is a direct result of the efforts of NHS Boards and staff should be commended, especially given the demands placed on Boards and members of staff involved in the delivery of the H1N1 vaccination programme.

Eligibility for vaccination in 2010-11

Catch up campaign

3. CEL 5(2008), issued on 6 February 2008 (see: http://www.sehd.scot.nhs.uk/mels/CEL2008_05.pdf), set out the details of the catch-up programme. The programme was planned to last three years from September 1st 2008 to August 31st 2011. September 1st 2010 to August 31st 2011 will therefore be the third and last year of the catch-up programme. Each course of immunisation requires three separate doses. It is important that girls in the eligible age group who have not yet taken up the offer or who have not completed their course, have the opportunity to do so.

4. Girls who were aged 13 to 17 years on 1st September 2008 when the programme began (i.e. girls born on or after 1 September 1990) continue to be eligible for the catch-up programme and can receive the HPV vaccine as part of the national programme until the end of the third year of the catch-up campaign on 31st August 2011.

**From the Chief Medical Officer
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Addresses

For action

NHS Board Chief Executives
NHS Board Immunisation
Co-ordinators
NHS Board Medical Directors
NHS Board Nursing Directors

For information

CHP Managers
NHS Board Communication Directors
Directors of Public Health
General Practitioners
Directors of Pharmacy
Practice Nurses
Health Visitors
Health Scotland
Health Protection Scotland
NHS 24
Local Authority Chief Executives and
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5. Some girls within the original catch-up cohort, will be aged over 18 during the third and final year of the catch-up campaign. They will however remain eligible for vaccination under the national programme by virtue of being within the catch-up cohort at the start of the programme. After August 31st 2011, they will no longer be eligible for HPV immunisation under the national programme.

6. Younger girls in the original catch-up cohort, ie those aged 13 and 14 at the start of the programme on September 1st 2008 will still be aged under 18 on 31st August 2011 but remain eligible to receive the vaccine as part of the national programme beyond the end of the catch-up campaign and up to the age of 18 years (i.e. up to the day before their 18th birthday).

7. The table below lists the eligibility of those included in HPV immunisation catch-up campaign to continue to receive HPV vaccination in Scotland by date of birth and is included for ease of reference.

ELIGIBILITY OF THOSE INCLUDED IN HPV IMMUNISATION CATCH-UP CAMPAIGN TO CONTINUE TO RECEIVE HPV VACCINATION IN SCOTLAND	
Women born between the following dates:	Any women in this group who did not receive the vaccine when scheduled, or have not completed the course of all three doses, can continue to be offered the vaccine until:
01/09/1990 to 31/08/1991	31 st August 2011
01/09/1991 to 31/08/1992	
01/09/1992 to 31/08/1993	
01/09/1993 to 31/08/1994	up to the age of 18 years (i.e. up to the day before their 18th birthday)
01/09/1994 to 31/08/1995	

Routine HPV immunisation programme

8. Girls who have been offered HPV vaccine as part of the ongoing routine immunisation programme in S2 in secondary schools but who did not receive the vaccine when scheduled, or have not completed the course of all three doses, can continue to be offered the vaccine until up to the age of 18 years (i.e. up to the day before their 18th birthday).

9. Based on the above guidance on eligibility, Health Boards should put arrangements in place to offer the vaccine to any girls who are eligible and either did not receive the vaccine when scheduled, or have not completed the course of all three doses.

10. Advice on HPV vaccination of females with unknown or incomplete immunisation status can also be found in the Green Book Chapter on HPV. http://www.dh.gov.uk/prod_consum_dh/groups/dh_digitalassets/@dh/@en/documents/digitalasset/dh_087787.pdf

Non-eligibility for the national programme

11. Having reviewed the cost effectiveness of immunising the whole female population at different ages the Joint Committee of Vaccination and Immunisation (JCVI) recommended that a national programme of HPV immunisation be offered routinely to girls aged 12-13 years (attending S2 in secondary schools in Scotland) and as a one-off catch-up campaign to those aged up to and including 17 years and 364 days. CEL 5 (2008) set out the Scottish Government's acceptance of the recommendation and its position with regard to the catch-up campaign. This is restated and clarified in this letter.

12. Women aged 18 years or over at the start of the catch-up campaign on 1st September 2008 (i.e. with a date of birth before the 1st September 1990), were not covered by the national vaccination programme. After the end of the catch-up campaign i.e. from 1st September 2011 onwards, no woman of 18 years and over in Scotland should be offered the HPV vaccine as part of the national programme.

13. GPs continue to be able to prescribe the vaccine for anyone who is not eligible for the national programme if it is clinically indicated, and according to the product license, under the NHS via GP10.

Funding Arrangements

14. The Scottish Government will continue to fund the full cost of the HPV vaccine for this programme, as well as other central costs relating to communications, surveillance and IT. It has also been agreed that for 2010/11 the funding that had been programmed for national marketing activity will be distributed to Boards to support local marketing or other activity specifically intended to increase uptake of the vaccine by the out-of-school catch up cohort. Boards will be expected to work with NHS Health Scotland in respect of any localised marketing activity to ensure the brand identity of the campaign is maintained and that local activity does not conflict with any of the national information leaflets or web resources that are being maintained. A separate allocation letter will be issued to Boards in respect of this funding shortly.

HPV immunisation out with schools (GPs and community clinics)

15. As with the previous two years of the programme, it is a matter for NHS Boards and local GPs to reach an agreement on whether GPs will provide any immunisation for girls out with the school setting as part of the programme.

Vaccines

16. Following the UK-wide three-year procurement exercise carried out by the Department of Health in 2008, the vaccine supplied for use in the HPV immunisation programme is Cervarix[®]. The administration of HPV vaccines, their adverse reactions, and their use in pregnancy are explained in detail in the HPV chapter for '*Immunisation against Infectious Disease*' (www.dh.gov.uk/greenbook).

17. We are in discussion with colleagues in Department of Health in respect of contracting for HPV vaccine for 2011-12 and beyond. Work is currently underway to assess the quantity of unused vaccine stock available across the UK and how this relates to the requirements for the vaccination cohorts for 2010-11 and 2011-12. It may be that there is sufficient stock available from the initial procurement to support the delivery of the programme in 2011-12 without a further award of contract. We will provide further information on this in due course.

Vaccine Supply

18. HPV vaccine will be supplied by Movianto UK Ltd as part of the national childhood immunisation programme. NHS Boards can order HPV vaccines on and up to a weekly basis.

19. Invoices for the vaccine will be paid directly by the Scottish Government to the UK Government. Boards should continue to ensure that records of vaccine deliveries are sent to Robin Bate in the Health Protection Team of the Scottish Government to enable invoices to be paid. Delivery confirmations should be emailed to Robin.Bate@scotland.gsi.gov.uk or sent by fax (for the attention of Robin Bate) to 0131 244 2157.

Vaccine Storage

20. Vaccines should be stored in the original packaging at +2°C to +8°C and protected from light. All vaccines are 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.

21. NHS Board Vaccine Holding Centres should ensure sufficient fridge space is available for the HPV vaccine. A review of available fridge space will be necessary to ensure adequate storage capacity at the start of year 3 of programme.

Reporting of adverse reactions

22. Cervarix[®] has a Black Triangle status assigned to it by the Medicines and Healthcare products Regulatory Authority (MHRA), which means it is under more intensive monitoring post-marketing. The symbol “▼” denotes this status on product information of a vaccine(s)/medicine(s); and indicates that all suspected adverse drug reactions (ADRs) should be reported to the MHRA. If a doctor, nurse, pharmacist or patient/carer suspects that any adverse reaction has occurred due to the HPV vaccine they should report it via the Yellow Card Scheme, preferably via the electronic Yellow Card reporting facility at <http://yellowcard.mhra.gov.uk/>. Alternatively paper reports can be submitted using either the Yellow Card reporting form (available in the BNF or downloadable from <http://www.mhra.gov.uk/Safetyinformation/Reportingsafetyproblems/Reportingsuspectedadversedrugreactions/Healthcareprofessionalreporting/index.htm>); or reported verbally by telephoning 0808 100 3352. Further advice on reporting of suspected ADRs can be obtained by contacting Yellow Card Centre Scotland on 0131 242 2919.

Patient Group Directions

23. The requirement for Patient Group Directions is described in HDL(2001)7 available from http://www.sehd.scot.nhs.uk/mels/HDL2001_07.HTM. The use of PGDs for administration of vaccines is described in detail in ‘*Immunisation against Infectious Disease*’ (pages 35 to 39), www.dh.gov.uk/greenbook

24. A specimen Patient Group Direction (PGD), for use with HPV vaccine Cervarix[®] is available at <http://www.healthscotland.com/health/topics/immunisation/HPV.aspx>.

Vaccine Wastage

25. Effective management of vaccines throughout the supply chain is essential to reduce vaccine wastage. The HPV vaccine has considerably increased the cost of the childhood immunisation programme. Vaccine wastage must be kept to a minimum - even small percentage reductions in vaccine wastage will have an important impact on the financing of vaccine supplies.

Transporting and storing vaccine at immunisation sessions

26. Validated cool boxes and related items such as cool packs should be used when transporting and storing vaccine for use in situations such as school immunisation sessions. Cool boxes should be used in accordance with manufacturer's guidelines to ensure that vaccines are stored at the correct temperature.

27. A realistic calculation of how much vaccine is needed for a particular immunisation session should be made prior to transporting vaccine to a session. During the session care should be taken to remove only the required amount of vaccine from the cool box.

Communication

28. As detailed in paragraph 11, the national marketing budget for this year will be distributed amongst Health Boards to enable each Board to deliver local marketing or other activity to increase uptake amongst the out-of-school catch-up cohort.

29. All information and guidance for professionals in support of the HPV programme continues to be published on the NHS Health Scotland immunisation website as it becomes available – www.healthscotland.com/immunisation/hpv

30. All public information materials will continue to be available for download from the HPV information website www.fightcervicalcancer.org.uk, by calling 0131 536 5500, or emailing nhs.healthscotland-publications@nhs.net. This includes translations (Chinese, Polish and Urdu) and other alternative formats, including easy read format designed to help support people with learning disabilities

31. Girls eligible for the immunisation refer to a number of national and local sources for information. It is important that the www.fightcervicalcancer.org.uk website and the 0800 22 44 88 helpline advisors are able to signpost enquirers to accurate, local information. **Please ensure your Board maintains arrangements for providing this information to NHS Health Scotland who will ensure the website and helpline are updated.** Girls might only call or look for the information once and rightly expect to be able to access information relevant to the service in their area.

32. NHS Health Scotland has been asked to provide all NHSScotland territorial Boards with the campaign artwork and guidelines on its use in order for them to undertake local marketing activities. It is essential that the identity of the campaign is maintained, so that awareness levels and trust remain strong. Where a Board wishes to develop their own materials using this artwork, NHS Health Scotland will support them by giving advice to ensure consistency of messaging and brand. NHS Health Scotland will be required to sign off the use of the Scotland HPV Immunisation Programme brand including the strapline 'Together we can fight cervical cancer'.

33. Any questions in relation to the public information materials should be directed to the Publications team at NHS Health Scotland on 0131 536 5500 or nhs.healthscotland-publications@nhs.net.

Local data management and monitoring vaccine uptake

34. Maintenance of comprehensive and accurate data is a key factor determining the effective delivery of all immunisation programmes. To this effect, the Child Health Surveillance Programme- School (CHSP-S) has been specifically programmed to:

- provide call/recall,
- minimise duplicate immunisation,
- Health Boards to agree any payments to GP practices for HPV immunisation, locally with GP practices and LMCs,
- support vaccine stock control, and
- measure uptake.

35. NHS Boards (working in partnership with their local education departments and independent schools) should use CHSP-S (or SIRS) to record all HPV immunisations given under the programme, whether administered in school or in GP or community clinics.

36. As with other national immunisation programmes, ISD using data held within CHSP-S (or SIRS) will calculate and publish HPV immunisation uptake rates for the routine and catch-up arms of the programme for each NHS Board and nationally.

Conclusion

37. We recognise that this programme has been a major commitment for all of us, requiring significant time, energy and dedication. We are hopeful that the third year of the programme can build on the very good foundations of strong public awareness and good vaccine uptake that were established through the first two years of activity.

38. We would like to take this opportunity to thank you for your contributions in delivering this successful programme.

Yours sincerely

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Chief Medical Officer

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Chief Nursing Officer

PROFESSOR BILL SCOTT
Chief Pharmaceutical Officer