

Dear Colleague

HUMAN PAPILLOMAVIRUS (HPV) VACCINATION PROGRAMME: CHANGE IN SCHEDULE FROM 3 TO 2 DOSES

1. This letter provides information on forthcoming changes to the HPV vaccination programme.
2. The HPV vaccination programme in Scotland started on 1 September 2008. The programme helps protect girls against cervical cancer later in life by routinely immunising them in early secondary school, at around 11-13 years of age, through a school-based programme.
3. In March 2014, the Joint Committee on Vaccination and Immunisation (JCVI) revised its existing recommendation to change the HPV vaccination schedule from a 3 to a **2 dose schedule**.
4. This change of advice is based on the latest immunological evidence which shows that the antibody response to 2 doses of the vaccine in adolescent girls is as good as a 3 dose course.
5. Emerging evidence from evaluation of HPV vaccination programmes around the world has shown that the number of young people with pre-cancerous lesions is falling and protection is expected to be long lasting.
6. This change in schedule from 3 to 2 doses will take place from **September 2014**.

From the Acting Chief Medical Officer
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For action

Chief Executives, NHS Boards
Medical Directors, NHS Boards
Directors of Public Health, NHS Boards
Directors of Pharmacy, NHS Boards
General Practitioners
Practice Nurses
Immunisation Co-ordinators
CPHMs

For information

Chairs, NHS Boards
Infectious Disease Consultants
Consultant Paediatricians
Consultant Physicians
Health Protection Scotland
Chief Executive, Health Scotland
NHS 24
Directors of Finance, NHS Boards

Enquiries to:

Policy Issues

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Pharmaceutical and vaccine supply issues

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Scheduling vaccinations

7. The 2 dose schedule is only recommended if the first vaccination is given at less than 15 years of age. In this instance, the **minimum** recommended time between the first and second doses should be 6 months. The second dose should be given within 24 months of the first dose. Any gap between the first and second doses of between 6 months and 24 months is clinically acceptable. Local needs should be considered when planning the programme.

8. As long as the first dose was received before the age of 15 years the 2 dose schedule can be followed. If the course is interrupted, it should be resumed (using the same vaccine) but not repeated, even if more than 24 months have elapsed since the first dose. Further details can be found on this in the Green Book, Immunisation against Infectious Disease, chapter 18a on Human Papillomavirus (HPV) available online at:

https://www.gov.uk/government/uploads/system/uploads/attachment_data/file/317821/Green_Book_Chapter_18a.pdf

9. **Girls who have not had their first dose of HPV vaccine by the time they are 15 years old should be offered the 3 dose schedule.** This is because the antibody response in older girls may be less good than that of younger girls.

10. If an individual has started a 3 dose course before 1 September 2014 then this course should be, where possible, completed according to the vaccination schedule of 0, 1, 4-6 months. If the course is interrupted it should be resumed (using the same vaccine) but not repeated, ideally allowing the appropriate interval between remaining doses. Further details can be found on this in chapter 18a of the Green Book.

11. There are no data on schedules of fewer than 3 doses among HIV-infected or immunocompromised populations. Therefore a 3 dose schedule should be offered to individuals who are known to be HIV-infected, including those on antiretroviral therapy, or who are known to be immunocompromised at the time of immunisation. Further details can be found on this in chapter 18a of the Green Book.

12. Consent forms signed for HPV vaccination reflect consent to the course of vaccination. That consent form continues to apply even if the course of vaccination spans more than one academic year.

Eligibility for routine HPV immunisation programme

13. The first dose of HPV vaccine can be given to girls from S1. This allows more opportunities for girls to start the programme before they are 15 years old.

14. Girls who are under 18 remain eligible for the HPV vaccination through the programme, regardless of school year. Those who have not yet taken up the offer or who have not completed their course should continue to have the opportunity to do so.

15. Vaccination for females over the age of 18 years is not covered by the national HPV vaccination programme. However, for girls who commenced, but did not complete vaccination, it is reasonable to complete their HPV vaccination course after the age of 18 years.

16. NHS Boards should put arrangements in place to offer the vaccine to any girls who are eligible and who either did not receive the vaccine when scheduled or have not completed the course up to the age of 18.

17. For anyone not covered by the national programme GPs continue to be able to prescribe the vaccine if it is clinically indicated, and according to the marketing authorisation under the NHS via GP10.

Vaccine dosage and supply

18. The vaccine used for the current 3 dose programme is Gardasil® and is suitable for the new 2 dose schedule.

19. Both Gardasil® and Cervarix® have been approved for use in a 2 dose schedule. The patient information leaflet (PIL) included in the packaging may still refer to a 3 dose schedule, or give a different recommended timing between doses. The PIL will be updated by the vaccine manufacturers as soon as possible. In the meantime, the guidance in the updated HPV chapter of the Green Book and in this letter should be followed. The Green Book states:

*Recommendations on immunisation procedures are based on currently available evidence and experience of best practice. **In some circumstances, this advice may differ from that in vaccine manufacturers' Summaries of Product Characteristics (SPCs).** When this occurs, the recommendations in this book (which are based on current expert advice received from the Joint Committee on Vaccination and Immunisation (JCVI)) should be followed.*
https://www.gov.uk/government/uploads/system/uploads/attachment_data/file/147915/Green-Book-Chapter-4.pdf

20. Full details of the vaccine schedule and dosage can be found in the Green Book, chapter 18a on Human Papillomavirus (HPV). This is available online at: https://www.gov.uk/government/uploads/system/uploads/attachment_data/file/317821/Green_Book_Chapter_18a.pdf

21. NHS Board Vaccine Holding Centres should use the existing ordering arrangements to place orders for Gardasil®.

Vaccine storage

22. 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.

23. NHS Board Vaccine Holding Centres should ensure sufficient fridge space is available for Gardasil® vaccines.

Patient group directions

24. The requirement for Patient Group Directions (PGD) 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', www.dh.gov.uk/greenbook

25. An updated specimen PGD for use with HPV vaccine Gardasil® has been produced by Health Protection Scotland (HPS) to assist NHS Boards. This will be available at: <http://www.hps.scot.nhs.uk/immvax/pgd.aspx>

Data collection and monitoring vaccine uptake

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

27. As with other national immunisation programmes, ISD using data held within CHSP-S (or SIRS) will calculate and publish HPV immunisation uptake rates for each NHS Board and nationally.

Funding arrangements

28. The Scottish Government will continue to fund the full costs of the HPV vaccine for this programme. As with previous years, invoices for HPV vaccine will be paid directly by the Scottish Government. NHS Boards should continue to ensure that records of vaccine deliveries are sent to Janet Sneddon in the Health Protection Team of the Scottish Government each time a delivery is received to enable invoices to be paid. Any delay in these confirmation of deliveries being sent will result in a delay in invoices being paid. Delivery confirmations (see Annex A) should be emailed to janet.sneddon@scotland.gsi.gov.uk or telephone 0131 244 2681.

Communications and information for young people and health professionals

29. Communication is key this year to ensure a smooth transition to a 2 dose schedule.

30. Information leaflets have been refreshed to include details of the reduced dose schedule. A HPV leaflet for girls will be distributed to school health teams, alongside the main Teenage Immunisation Leaflet during August 2014.

31. All public information materials relating to the HPV vaccination programme will be available for download from the Immunisation Scotland website at: <http://www.immunisationscotland.org.uk/vaccines-and-diseases/hpv.aspx>

32. The leaflet is available in Urdu, Chinese and Polish and an Easy Read format. NHS Health Scotland is happy to consider requests for other languages and formats. Please contact 0131 314 5300 or email nhs.healthscotland-alternativeformats@nhs.net

33. Any questions in relation to the public information materials should be directed to the Publications Team at NHS Health Scotland on 0131 314 5300 or nhs.healthscotland-publications@nhs.net.

Educational resources for registered healthcare practitioners

34. NHS Education for Scotland in partnership with HPS are revising their existing educational resources for registered healthcare practitioners. These include updated training slides and notes and a 'question and answer' resource. These resources will be available at: <http://www.nes.scot.nhs.uk/education-and-training/by-theme-initiative/public-health/resources/health-protection-publications/hpv-training-slides.aspx>

Conclusion

35. We would like to take this opportunity to thank you for your contributions in delivering this successful programme. We are very grateful for the efforts of all professionals involved in the first six years of this vaccination programme. As at 24 September 2013 82.0% of girls in S2 in school year 2012/13 had completed the 3 dose course of HPV vaccination by the end of the school year; 91.8% had received 2 doses and 93.5% had received one dose. This success is a direct result of the efforts of NHS Boards and staff should be commended for their continued hard work in delivering this service.

Yours sincerely

Aileen Keel

Ros Moore

Bill Scott

DR AILEEN KEEL CBE

ROS MOORE

PROFESSOR BILL SCOTT

HPV – GARDASIL VACCINE DELIVERY RECORD

Vaccine Holding Centre:
NHS Board:
Post Code:
Account Number:
Contact Name & Telephone Number:

Product	GARDASIL
Date Received:	
NHS Order Number:	
Batch Number of Vaccine:	
Movianto Dispatch Number:	
Number of Doses Ordered:	
Number of Doses Received:	

Comments – Please give details of discrepancies/ returned stock:

Please return within 2 working days of receipt of vaccine, by email to – janet.sneddon@scotland.gsi.gov.uk

Please direct any inquiries to:

Janet Sneddon
Scottish Government
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Public Health Division
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Tel: 0131 244 6281
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