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Dear Colleague

## **EXTENDING THE HPV VACCINATION PROGRAMME**

- 1. We are writing to provide information on the forthcoming extension of the HPV vaccination programme. From the coming academic year (2019/20) the HPV vaccine will be offered to boys in S1, in addition to girls, as part of the routine school based programme.
- This follows the Scottish Government announcement in July 2018 to include HPV vaccination of boys in the national vaccination programme based on the advice of the Joint Committee of Vaccination and Immunisation (JCVI). The full JCVI statement setting out the recommendation to vaccinate boys against HPV is available at:
   <a href="https://assets.publishing.service.gov.uk/government/uploads/system/uploads/attachment\_data/file/726319/JCVI\_Statement\_on\_HPV\_vaccination\_2018.pdf">https://assets.publishing.service.gov.uk/government/uploads/system/uploads/attachment\_data/file/726319/JCVI\_Statement\_on\_HPV\_vaccination\_2018.pdf</a>
- 3. To date high vaccine uptake rates confirm that the existing girls HPV vaccination programme has been extremely successful. New findings show the levels of cancer-causing HPV in Scotland have dropped by 90% in young women, demonstrating the significant and continued benefits of the vaccination programme. The successful extension of the programme to include S1 boys will contribute further towards reducing the risk of HPV associated cancers and genital warts in the population.
- 4. This letter provides colleagues with the necessary information to introduce the programme. Annex A sets out the key changes to the programme. Annex B provides further guidance on the use of Gardasil®, including details of how to order the vaccine; data collection and funding arrangements. Annex C includes information on programme communications and workforce education materials.

#### Action

- 5. NHS Boards are asked to note and implement the arrangements outlined in this letter for the 2019/20 programme.
- We would like to take this opportunity to thank all of those who will be involved in delivering this programme for their efforts and continuing commitment to improving public health.

Yours sincerely,

Catherine Calderwood Diane Murray Rose Marie Parr

Chief Medical Acting Chief Chief Pharmaceutical Officer Nursing Officer Officer

From the Chief Medical Officer Acting Chief Nursing Officer Chief Pharmaceutical Officer Dr Catherine Calderwood Diane Murray Dr Rose Marie Parr

14 August 2019

SGHD/CMO(2019) 8

For action

Chief Executives, NHS Boards; Medical Directors, NHS Boards; Nurse Directors, NHS Boards Chairs, NHS Boards; Directors of Pharmacy, NHS Boards;

Directors of Public Health, NHS Boards;

Infectious Disease Consultants, NHS Boards; NHS Board Consultants in Public

Health Medicine; Immunisation Co-ordinators;

For information

Directors of Finance, NHS Boards; Health Protection Scotland; Chief Executive, Health Scotland NHS 24; Consultant Paediatricians;

Consultant Physicians; BBV Sexual Health Lead Clinicians; HIV Lead Clinicians; Sexual Health Lead Clinicians; NHS Board Executive Leads for Sexual Health; General Practitioners:

General Practitioners
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## CHANGES TO THE PROGRAMME - KEY POINTS

## **Vaccination for boys:**

- 7. The same vaccine that is currently used for the girls' vaccination programme (Gardasil®, which protects against HPV types 6,11,16 and 18) will be used for the extended programme.
- 8. Gardasil® should be routinely offered to all individuals in S1.
- 9. For practical reasons, any individual who is eligible to be in S1 should be offered HPV immunisation.
- 10. A 'catch up' programme for older boys will not be offered. The JCVI have not recommended a 'catch up' programme for boys as evidence suggests they are already benefitting greatly from the indirect protection built up over 10 years of the girls' HPV vaccination programme.
- 11. The HPV vaccine is offered to MSM ( men who have sex with men) up to and including the age of 45 attending sexual health or HIV clinics. This programme is in place to offer direct protection to those who benefit little from the herd protection afforded by the girls vaccination programme (https://www.sehd.scot.nhs.uk/cmo/CMO(2017)06.pdf)

# Eligible until 25th birthday:

- 12. Immunisation against Infectious Disease ('The Green Book') has been updated to reflect the change in eligibility for opportunistic HPV vaccination. The updated chapter is available at: <a href="https://www.gov.uk/government/publications/human-papillomavirus-hpv-the-green-book-chapter-18a">https://www.gov.uk/government/publications/human-papillomavirus-hpv-the-green-book-chapter-18a</a>
- 13. Those in eligible cohorts for vaccination in the national programme will remain eligible, and may be offered HPV vaccination opportunistically, up to their 25<sup>th</sup> birthday.
- 14. For clarity, this only applies to:
  - females under 25 who would have been eligible under routine, and catch up programmes, introduced in 2008 and;
  - those boys who become eligible from this coming academic year (2019/20).

## FURTHER GUIDANCE ON CHANGES TO THE HPV VACCINATION PROGRAMME

#### The Vaccine

15. The HPV vaccine to be used in the extended HPV vaccination programme is Gardasil®, which provides protection against HPV types 6, 11, 16 and 18.

# **Vaccine Supply**

- 16. Vaccine for the national programme will be centrally procured and should only be used for those eligible for the national vaccination programme.
- 17. Gardasil® should be ordered in the usual way from NHS Board vaccine holding centres.

## Vaccine schedule and timing

- 18. The first dose can be given at any time during the school year.
- 19. A two dose schedule is recommended for individuals under 15 years of age.
  - First dose of 0.5ml of HPV vaccine.
  - Second dose of 0.5ml six to 24 months after the first dose.
  - Any gap between doses of between 6 and 24 months is clinically acceptable.
  - As long as the first dose was received before the age of 15 years the two dose schedule can be followed.
  - If the second dose is not given within the recommended 24 month period then the course should be completed as soon as possible after that time.
- 20. Individuals in eligible cohorts who have not had their first dose of HPV vaccine by the time they are 15 years old should be offered a three dose schedule.
  - First dose of 0.5ml of HPV vaccine
  - Second dose of 0.5ml at least one month after the first dose
  - A third dose of 0.5ml at least three months after the second dose.

# Immunisation against Infectious Disease ('The Green Book')

- 21. The Human Papillomavirus chapter (chapter 18a) within Immunisation against Infectious Disease ('The Green Book') has been updated and is available at:

  <a href="https://www.gov.uk/government/publications/human-papillomavirus-hpv-the-green-book-chapter-18a">https://www.gov.uk/government/publications/human-papillomavirus-hpv-the-green-book-chapter-18a</a>
- 22. The chapter includes information about the presentation; dose and schedule; route of administration; contraindications and adverse reactions; and storage of the vaccine.

## **Patient Group Directions (PGD)**

- 23. The requirement for Patient Group Directions is described in HDL(2001)7 available from <a href="http://www.sehd.scot.nhs.uk/mels/HDL2001\_07.HTM">http://www.sehd.scot.nhs.uk/mels/HDL2001\_07.HTM</a>. Use of PGDs for administration of vaccines is described in the Green Book available at: <a href="http://media.dh.gov.uk/network/211/files/2012/07/Chapter-5.pdf">http://media.dh.gov.uk/network/211/files/2012/07/Chapter-5.pdf</a>.
- 24. A specimen PGD for use with the HPV vaccine, Gardasil®, for the universal HPV vaccination programme, has been produced by Health Protection Scotland (HPS) to assist NHS Boards. This is available on-line via the following link: <a href="https://www.hps.scot.nhs.uk/publications/patient-group-directions/">https://www.hps.scot.nhs.uk/publications/patient-group-directions/</a>

#### Consent

- 25. A consent pack, containing a letter, leaflet and consent form will be distributed to secondary schools to be sent home to parents/carers in school bags.
- 26. Information on consent for vaccination can be found in chapter two of the Green Book available at: <a href="https://www.gov.uk/government/publications/consent-the-green-book-chapter-2">https://www.gov.uk/government/publications/consent-the-green-book-chapter-2</a>.

# Reporting of adverse reactions

- 27. The most common adverse reactions observed are injection-site reactions. These include mild to moderate short lasting pain at the injection site, immediate localised stinging sensation, redness and swelling at the injection site. Other reactions commonly reported are headache, myalgia, fatigue and low grade fever. These adverse reactions are usually mild or moderate in intensity.
- 28. For a detailed list of adverse reactions observed after Gardasil® please refer to the manufacturer's Summary of Product Characteristics (SPC). Alternatively refer to the Patient Information Leaflet (PIL) supplied with each vaccine which is available at: <a href="https://www.medicines.org.uk/emc/medicine/19016">https://www.medicines.org.uk/emc/medicine/19016</a>
- 29. Suspected adverse drug reactions (ADRs) to vaccines should be reported via the Yellow Card Scheme available at: <a href="https://yellowcard.mhra.gov.uk/">https://yellowcard.mhra.gov.uk/</a>. Chapter 9 of the Green Book gives detailed guidance on which ADRs to report and how to do so. Additionally chapter 8 of the Green Book available at <a href="https://www.gov.uk/government/publications/vaccine-safety-and-adverse-events-following-immunisation-the-green-book-chapter-8">https://www.gov.uk/government/publications/vaccine-safety-and-adverse-events-following-immunisation-the-green-book-chapter-8</a> provides detailed advice on managing adverse events following vaccination.
- 30. Any reported adverse incidents, errors or events during or post vaccination must follow pre-determined procedures. In addition, teams must keep a local log of reports and discuss such events with the local Immunisation Co-ordinator. If you require contact details for your NHS Board Immunisation Coordinator please email <a href="mailto:immunisationprogrammes@gov.scot">immunisationprogrammes@gov.scot</a>

## Data collection

- 31. Maintenance of comprehensive and accurate data is a key factor in determining the effective delivery of all vaccination programmes.
- 32. 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 vaccinations given under the programme, whether administered in school or in GP practices or community clinics.
- 33. As with other national vaccination programmes, Information Services Division (ISD) using data held within CHSP-S (or SIRS) will calculate and publish HPV vaccination uptake rates for each NHS Board and nationally.

## **Funding arrangements**

34. 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.

# COMMUNICATIONS AND INFORMATION FOR PATIENTS AND REGISTERED HEALTHCARE PRACTITIONERS

## **Communication materials**

- 35. Consent packs containing a letter, leaflet and consent form will be distributed to secondary schools to be sent home to parents/carers in school bags from October 2019. The information provided in the letter and leaflet has been tested with 11-13 year old boys and girls and parents of 11-13 year olds in order to ensure adequate understanding of the vaccine and its benefits, to enable informed consent of the HPV vaccine.
- 36. The HPV leaflet will be made available in Polish, Mandarin, Arabic, easy read, audio and BSL format on <a href="www.nhsinform.scot/hpv">www.nhsinform.scot/hpv</a>. NHS Health Scotland is happy to consider requests for other languages. Please contact 0131 314 5300 or email <a href="mailto:nhs.healthscotland-alternativeformats@nhs.net">nhs.healthscotland-alternativeformats@nhs.net</a> to request other languages and formats.
- 37. To support the HPV vaccination programme in schools, NHS Health Scotland have produced an education pack that will contain a Head Teacher briefing with links to an online film aimed at young people, parents/carers and teachers; posters for displaying around the school; and a guide to an online vaccine learning resource called Kids Boost Immunity (KBI). KBI is a global World Health Organisation (WHO) accredited educational resource with lessons and quizzes about the HPV vaccine. KBI has been developed with Education Scotland to align with the Curriculum for Excellence, and schools taking part will earn vaccines for children across the world via UNICEF. The education pack will be available to download from Health Scotland's website at <a href="https://www.healthscotland.scot/hpveducationpack">www.healthscotland.scot/hpveducationpack</a> from 1 September 2019.
- 38. Posters will be distributed to community settings including GP practices and pharmacies. To order more copies of the posters, please email <a href="mailto:nhs.publications@nhs.net">nhs.publications@nhs.net</a>. The public should be signposted to the campaign page, <a href="www.hpv-vaccine.scot">www.hpv-vaccine.scot</a> for up to date information on the programme from September 2019.

# Workforce educational resources for registered healthcare practitioners

39. NHS Education for Scotland in partnership with Health Protection Scotland and the Scottish Health Protection Network has produced educational resources for registered healthcare practitioners. These include training slides with notes and a 'question and answer' resource. These can be found at: <a href="https://www.nes.scot.nhs.uk/education-and-training/by-theme-initiative/public-health/health-protection/immunisation/human-papillomavirus.aspx">https://www.nes.scot.nhs.uk/education-and-training/by-theme-initiative/public-health/health-protection/immunisation/human-papillomavirus.aspx</a>