

Dear Colleague

## **HUMAN PAPILLOMAVIRUS (HPV) VACCINATION PROGRAMME: CHANGES TO THE VACCINE**

1. This letter provides information on forthcoming changes to the HPV vaccination programme.
2. The vaccine supplied for the programme will change from Gardasil® to Gardasil® 9 once current stocks of Gardasil® have depleted.
3. This change will affect both aspects of the HPV programme (adolescents in S1, including those who remain eligible until their 25th birthday, and men who have sex with men (MSM) up to 45 years of age).
4. The introduction of Gardasil® 9 follows advice from the Joint Committee on Vaccination and Immunisation (JCVI) that the 9-valent vaccine was the preferred vaccine for the HPV vaccination programme due to the additional health benefits it provided in protecting against the five additional cancer causing HPV types.

### **Background**

5. The quadrivalent vaccine Gardasil® was introduced in September 2012 and offers protection against HPV types 6, 11, 16 and 18. This replaced the bivalent vaccine Cervarix® which offered protection against HPV types 16 and 18. Infection by high-risk HPV types 16 and 18 has been found to be the most important causal factor for the development of cervical pre-cancerous and cancerous lesions. Whereas, infection by low-risk HPV types 6 and 11 has been found to cause approximately 90% of all genital warts, which is the most common virally sexually transmitted infection in the UK.
6. The 9-valent vaccine Gardasil® 9 offers protection against HPV types 6, 11, 16, 18, 31, 33, 45, 52 and 58, increasing the coverage of protection against HPV-induced cancers, through the inclusion of the extra five HPV types 31, 33, 45, 52 and 58.
7. To date, high vaccine uptake rates confirm that the teenage HPV vaccination programme has been extremely successful. New findings show the levels of cancer-causing HPV in Scotland have

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Chief Nursing Officer  
Chief Pharmaceutical Officer**  
Professor Sir Gregor Smith  
Professor Alex McMahon  
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#### **For action**

Directors of Pharmacy  
NHS Board Immunisation  
Coordinators  
NHS Board Medical Directors  
Nurse Directors, NHS Boards  
Directors of Public Health  
Infectious Disease Consultants  
CPHMs  
Sexual Health Services

#### **For information**

NHS Board Chief Executives  
Consultant Physicians  
Public Health Scotland  
Chief Executive, NHS Health  
Scotland  
NHS 24  
Scottish General Practitioners  
Committee  
General Practitioners  
Practice Nurses  
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#### **Further Enquiries**

**Policy Issues**  
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dropped by 90% in young women, demonstrating the significant and continued benefits of the vaccination programme.

**Eligibility**

8. Gardasil® 9 can be used for all those who were eligible to receive Gardasil®: adolescents aged S1, including those who remain eligible until they turn 25 years of age, and MSM up to 45 years of age. Further information is included in the Annexes set out below.

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Yours sincerely,

*Gregor Smith*

*Alex McMahon*

*Alison Strath*

Professor Sir Gregor Smith  
**Chief Medical Officer**

Professor Alex McMahon  
**Chief Nursing Officer**

Professor Alison Strath  
**Chief Pharmaceutical Officer**

## CHANGES TO THE PROGRAMME – KEY POINTS

### Change of vaccine

1. The 9-valent vaccine Gardasil® 9 (manufactured by MSD) received licensing approval for use in the UK for a two dose schedule in adolescent girls in April 2016 and is licensed for individuals from aged 9 (SPC, Gardasil9).
2. Gardasil® 9 can be used for all those eligible: adolescents aged in S1, including those who remain eligible until they turn 25 years of age, and MSM up to 45 years.
3. In June 2016, the JCVI summarised that the 9-valent vaccine was the preferred vaccine for the HPV programme because of the additional health benefits that it provided in protecting against the five additional cancer causing HPV types. The JCVI has not made any statements or published any advice about the vaccine of choice for a gender-neutral programme.
4. As the programme transitions to Gardasil®9, some individuals may receive a mixed schedule during the switch. The two vaccines are considered interchangeable by the JCVI and vaccination should not be delayed due to preference for either vaccine. For those individuals who started the schedule with Gardasil®, the course can be completed with Gardasil® 9.

### Eligibility

5. The Immunisation against Infectious Disease Book (i.e. 'The Green Book') has been updated to reflect the change in eligibility for opportunistic HPV vaccination. The updated chapter is available at: <https://www.gov.uk/government/publications/human-papillomavirus-hpv-the-green-book-chapter-18a>
6. HPV vaccination may be offered to MSM up to, and including, 45 years of age who are attending sexual health/ HIV clinics regardless of risk, sexual behaviour or disease status.
7. 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.
8. For clarity, this only applies to:
  - those currently eligible;
  - boys who became eligible from academic year (2019/20);
  - girls under 25 who would have been eligible under routine, and catch up programmes, introduced in 2008.

## FURTHER GUIDANCE ON CHANGES TO THE HPV IMMUNISATION PROGRAMME

### The Vaccine

1. The HPV vaccine to be supplied for the HPV vaccination programme is Gardasil® 9, which provides protection against HPV types 6, 11, 16, 18, 31, 33, 45, 52 and 58.

### Vaccine Supply

2. Vaccine for the national programme will be centrally procured and should only be used for those eligible for the national vaccination programme.
3. Gardasil® and Gardasil® 9 should be ordered in the usual way from NHS Board vaccine holding centres. Gardasil® will be available to order until current stocks run out, Gardasil® 9 will then become the sole vaccine available to order for the HPV vaccination programme.

### Timing of two dose schedule for men who have sex with men (MSM)

4. **Please Note:** The change in schedule from 3 to 2 doses for those eligible MSM starting the schedule was introduced from 1 April 2022.
5. The first dose may be offered opportunistically to MSM attending sexual health / HIV clinics.
6. The JCVI recommends a schedule of 0, 6-24 months for all HPV vaccines. The **minimum** time between the first and second dose of Gardasil® should be six months. For Gardasil®9 the **minimum** interval between the two doses can be 5 months.
7. Any gap between doses of between six and 24 months is clinically acceptable. For operational purposes, around a 12 month gap between the two doses is recommended which would reduce the number of HPV vaccination sessions. However, local needs should be considered when planning.
8. If the course is interrupted, it should be resumed but not repeated, even if more than 24 months have elapsed since the first dose.
9. For those individuals who started the schedule with Gardasil® the course can be completed with Gardasil® 9.

### Timing of doses for school based adolescent programme

10. **Please note:** From 01 August 2022, a 2 dose schedule is being recommended for the school based adolescent programme for those ages 15 years and older, and details of this change will be outlined in a separate CMO letter.
11. The first dose can be given to pupils at any time during the academic year.
12. The JCVI recommends a schedule of 0, 6-24 months for all HPV vaccines. The **minimum** time between the first and second dose of Gardasil® should be six months. For Gardasil®9 the **minimum** interval between the two doses can be 5 months.
13. Any gap between doses of between six and 24 months is clinically acceptable. For operational purposes, around a 12 month gap between the two doses is recommended which would reduce the number of HPV vaccination sessions. However, local needs

should be considered when planning. Again, for Gardasil® 9 the minimum interval between the two doses can be 5 months.

14. If the course is interrupted, it should be resumed but not repeated, even if more than 24 months have elapsed since the first dose.
15. **Please note:** Individuals who commences a 3 dose schedule prior to 01 August 2022, whose schedule is interrupted/delayed resulting in an interval of 6 months or more between their first and second dose, only require a 2 dose schedule (do not require a third dose). Further details can be found on this in chapter 18a of the Green Book.
16. Consent provided for the HPV vaccination programme reflects consent to the course of vaccination regardless of the vaccine used. Consent will continue, even if the course of vaccination spans more than one academic year.

#### **Timing of doses among HIV-infected or immunocompromised populations**

17. There are no data on schedules of fewer than 3 doses among HIV-infected or immunocompromised populations. Therefore, a 3 dose schedule should continue to 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.

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

18. The Human Papillomavirus chapter (chapter 18a) within the Immunisation against Infectious Disease Book ('The Green Book') has been updated and is available at: <https://www.gov.uk/government/publications/human-papillomavirus-hpv-the-green-book-chapter-18a>
19. 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)**

20. A national specimen Patient Group Direction (PGD) for administration of HPV vaccine is available on the Public Health Scotland website at: [https://publichealthscotland.scot/publications/?q=&fq=phs\\_publication\\_type%3APatient+Group+Direction%23](https://publichealthscotland.scot/publications/?q=&fq=phs_publication_type%3APatient+Group+Direction%23)

#### **Consent**

21. Information on informed consent for vaccination can be found in chapter two of the Green Book available at: <https://www.gov.uk/government/publications/consent-the-green-book-chapter-2>
22. There is also information on informed consent for young people at: [www.nhsinform.scot/campaigns/vaccines-for-young-people](http://www.nhsinform.scot/campaigns/vaccines-for-young-people)

#### **Reporting of adverse reactions**

23. For a detailed list of ADRs associated with Gardasil® 9 please refer to the manufacturer's SPC or the Patient Information Leaflet (PIL) supplied with each vaccine: <https://www.medicines.org.uk/emc/product/7330>
24. Suspected adverse reactions (ADRs) to vaccines should be reported via the Yellow Card Scheme available at: <https://yellowcard.mhra.gov.uk/>. 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 provides detailed advice on managing ADRs following vaccination.

25. Any serious or unusual suspected 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

### **Data collection**

26. Maintenance of comprehensive and accurate data is a key factor in determining the effective delivery of all vaccination programmes.
27. NHS Boards (working in partnership with their local education departments and independent schools) should continue to use Child Health Systems Programme School (CHSP-S) (or Scottish Immunisations and recall system (SIRS) to record all HPV immunisations given under the programme, whether administered in school or in GP practices or community clinics.
28. As with other national immunisation programmes, PHS using data held within CHSP-S (or SIRS) will calculate and publish HPV immunisation uptake rates for each NHS Board and nationally.
29. Vaccination records for each eligible MSM attending a sexual health clinic should be recorded on the National Sexual Health IT System (NaSH). Vaccination records for each eligible MSM attending for HIV related care should be recorded on NaSH where appropriate or an alternative system which has been arranged locally and which collects the equivalent data to allow monitoring of uptake.
30. Vaccination prescribing and administration, including vaccination site and batch number should be recorded using the NaSH prescription page. Clinicians should ensure that vaccine batch numbers are entered into the NaSH system to enable rapid identification of specific individuals who have been given a particular batch of vaccine.
31. Vaccine uptake will be monitored primarily via the NaSH IT System in sexual health clinics, in some HIV clinics, and in some prison settings. In clinics and settings where NaSH is not available, local arrangements will be in place to record equivalent information to allow national monitoring of vaccine uptake.

### **Funding arrangements**

32. The Scottish Government will continue to fund the full costs of the HPV vaccine for this programme.

## COMMUNICATIONS AND INFORMATION FOR PATIENTS AND HEALTHCARE Practitioners

### Communications materials

1. When pupils become eligible, consent packs containing a letter, leaflet and consent form will be distributed to secondary schools to be sent home to pupils to discuss and sign with their parents/carers. The leaflet is also available online: [www.nhsinform.scot/hpv](http://www.nhsinform.scot/hpv). There is also further information on informed consent for vaccines for young people at: [www.nhsinform.scot/campaigns/vaccines-for-young-people](http://www.nhsinform.scot/campaigns/vaccines-for-young-people)
2. The HPV leaflets will be made available in English, Polish, Mandarin, Arabic, Russian, Ukrainian, Kurdish Sorani, Tigrinya, Easy Read, Audio and BSL format on [www.nhsinform.scot/hpv](http://www.nhsinform.scot/hpv). Public Health Scotland is happy to consider requests for other languages. Please email [phs.otherformats@phs.scot](mailto:phs.otherformats@phs.scot) to request other languages and formats.
3. To support the HPV programme in schools, Public Health Scotland have produced an education pack which contains a Head Teacher briefing; a link to an animation aimed at young people, parents/carers and teachers; posters for displaying around the school and social media assets. . The education pack will be available to download from Public Health Scotland's website at <https://publichealthscotland.scot/publications/hpv-education-pack>

### Educational resources for registered healthcare practitioners

4. NHS Education for Scotland in partnership with Public Health Scotland and the Scottish Health Protection Network has produced educational resources for healthcare practitioners. These include training slides with notes and an accompanying information resource. These will be made available at: [Immunisation | Turas | Learn \(nhs.scot\)](#)