

Dear Colleague

**HUMAN PAPILLOMAVIRUS (HPV) VACCINATION PROGRAMME:
CHANGE IN SCHEDULE FROM 2 TO 1 DOSES FOR ELIGIBLE MEN
WHO HAVE SEX WITH MEN (MSM) UP TO AGE 25 YEARS**

1. This letter provides information on forthcoming changes to the HPV vaccination programme.
2. The HPV vaccination programme in Scotland was introduced for girls on 1 September 2008. From 2017, the HPV vaccination has been available to men who have sex with men (MSM) up to, and including 45 years of age who attend sexual health and HIV clinics. The MSM programme was introduced to offer direct protection to those older males who are at particularly high risk from HPV infection and disease and who benefit very little from the indirect protection afforded by the adolescent girls' programme. In 2019, a gender neutral HPV vaccination programme was introduced, which extended the existing girls' programme to include teenage boys, helping to further protect against high risk HPV types which may develop into cancer later in life, via routine immunisation in early secondary school, from S1, through the school-based programme.
3. In May 2020, the JCVI reviewed the latest evidence, and concluded that there was no compelling reason to continue with a three dose schedule for those starting the schedule aged 15 years and above and that the programme should move to a two-dose schedule for young people and adults, including MSM, at a suitable time.
4. In December 2021, the JCVI undertook a further review of the latest evidence on one-dose schedules. Subsequently, the Committee agreed that there was now sufficient evidence to advise of a change in the schedule from two doses to one dose of HPV vaccine in the routine adolescent programme for children and young people aged up to (and including) 14 years of age. This advice was interim, pending a stakeholder consultation, which ran for 6 weeks. No interim advice was published for HPV MSM programme at this time.
5. The JCVI HPV Sub Committee met on 17 May 2022 to review the stakeholders' responses and receive an update on the latest evidence supporting a one-dose schedule. These

**From the Chief Medical
Officer
Chief Nursing Officer
Chief Pharmaceutical Officer**
Professor Sir Gregor Smith
Professor Alex McMahon
Professor Alison Strath

4 October 2022

SGHD/CMO(2022)34

For action

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

For information

NHS Board Chief Executives
Directors of Pharmacy
Consultant Physicians
Public Health Scotland
Chief Executive, NHS Health
Scotland
NHS 24
General Practitioners

Further Enquiries to:

Policy Issues
Vaccination Policy Team
immunisationpolicy@gov.scot

Medical Issues
Dr Lorna Willocks
St Andrew's House
lorna.willocks@gov.scot

Pharmaceutical and Vaccine
Supply
William Malcolm
NHS National Services Scotland
william.malcolm@nhs.scot

findings were reported at the June 2022 JCVI meeting, thus finalising the advice on one dose. On 5 August 2022, the JCVI published their recommendation of a one-dose schedule for the routine adolescent programme and MSM programme.

6. JCVI have recommended the following schedules for the HPV programme:
 - a one-dose schedule for the routine adolescent programme and MSM programme before the 25th birthday
 - a two-dose schedule from the age of 25 years in the MSM programme
 - a three-dose schedule for individuals who are immunosuppressed and those known to be HIV-positive.
7. Currently, there are no data on fewer than three doses among HIV-infected or immunocompromised populations. Therefore, a three-dose schedule should still be offered to individuals who are known to be HIV-infected, including those on antiretroviral therapy, or are known to be immunocompromised at the time of immunisation.
8. The JCVI statement on a one-dose schedule published on 5 August 2022 is available here: [JCVI statement on a one-dose schedule for the routine HPV immunisation programme - GOV.UK \(www.gov.uk\)](https://www.gov.uk/government/news/jcvi-statement-on-a-one-dose-schedule-for-the-routine-hpv-immunisation-programme)
9. The change from two-dose to a one-dose dose schedule for all those eligible up to the age of 25 will take place from 1 January 2023.
10. Further information is included in the Annexes set out below.

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

Scheduling Vaccinations

1. The one dose schedule is recommended for all those eligible in the programme up to their 25th birthday (excluding those HIV-infected or immunocompromised populations as they should remain on a three-dose schedule) and may be offered opportunistically to MSM attending sexual health / HIV clinics. Those over the age of 25 years should remain on a two-dose schedule.
2. More information on the two-dose schedule can be found in a previously published CMO letter here: [Change in Schedule from 3 to 2 Doses for Eligible MSM \(scot.nhs.uk\)](https://www.scot.nhs.uk/cmo/letters/change-in-schedule-from-3-to-2-doses-for-eligible-msm). **Please Note:** This information will now only apply to those eligible MSM over the age of 25 years.
3. The programme has now transitioned to Gardasil®9. Therefore, some individuals may have started the course with Gardasil®. The two vaccines are considered interchangeable by the JCVI and are both suitable for the one-dose schedule.
4. If an eligible individual under 25 years of age has started a three or two-dose course before January 2023, their vaccination schedule should now be regarded as complete regardless of the vaccine product used.
5. There are no data on schedules of fewer than three doses among HIV-infected or immunocompromised populations. Therefore, a three-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.

Eligibility

6. The Immunisation against Infectious Disease Book ('The Green Book') will be updated to reflect the change in eligibility for HPV vaccination. The chapter will be updated in due course to reflect the change in eligibility for HPV vaccination and made available online at: <https://www.gov.uk/government/publications/human-papillomavirus-hpv-the-green-book-chapter-18a>
7. **Please note:** The HPV chapter of the Green Book may not be available until after January 2023. Therefore, the latest JCVI statement recommending the change to a one dose schedule and CMO letter should be followed pending the publication of an updated HPV Green Book chapter. The JCVI statement on a one-dose schedule published on 5 August 2022 is available here: [JCVI statement on a one-dose schedule for the routine HPV immunisation programme - GOV.UK \(www.gov.uk\)](https://www.gov.uk/government/statements/jcvi-statement-on-a-one-dose-schedule-for-the-routine-hpv-immunisation-programme)
8. 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.
9. For clarity:
 - a one-dose schedule for the MSM programme before the 25th birthday
 - a two-dose schedule from the age of 25 years in the MSM programme
 - a three-dose schedule for individuals who are immunosuppressed and those known to be HIV-positive.

FURTHER GUIDANCE ON CHANGES TO THE HPV IMMUNISATION PROGRAMME

Vaccine Dosage and Supply

1. **Please Note:** As of June 2022, the programme has now transitioned to Gardasil®9 as the sole vaccine in use and available to order for HPV immunisation.
2. Gardasil®9 and Gardasil® have been recommended by JCVI for use in a one-dose schedule. The patient information leaflet (PIL) included in the packaging may refer to a 3-dose schedule, or give a different recommended timing between doses. 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/publications/immunisation-procedures-the-green-book-chapter-4>

3. **Please note:** Again, the HPV chapter of the Green Book may not be available until after January 2023. Therefore, the latest JCVI statement recommending the change to a one dose schedule and CMO letter should be followed pending the publication of an updated HPV Green Book chapter. The JCVI statement on a one-dose schedule published on 5 August 2022 is available here: [JCVI statement on a one-dose schedule for the routine HPV immunisation programme - GOV.UK \(www.gov.uk\)](https://www.gov.uk/government/publications/jcvi-statement-on-a-one-dose-schedule-for-the-routine-hpv-immunisation-programme).
4. For individuals not affected by this change to a one-dose schedule (i.e. HIV-positive or immunocompromised populations), the guidance in the HPV chapter of the Green Book should be followed. Further details of the vaccine schedule and dosage for these individuals can be found in the Green Book, chapter 18a on Human Papillomavirus (HPV): <https://www.gov.uk/government/publications/human-papillomavirus-hpv-the-green-book-chapter-18a>
5. Gardasil®9 should be ordered in the usual way from NHS Board vaccine holding centres.

Patient Group Directions (PGD)

6. A national specimen Patient Group Direction (PGD) for administration of HPV vaccine will be produced and issued to NHS boards. This will be made available on the Public Health Scotland website at: https://publichealthscotland.scot/publications/?q=&fq=phs_publication_type%3APatient+Group+Direction%23

Consent

7. 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>

Reporting of adverse reactions

8. The most common adverse reactions (ADRs) observed are injection-site reactions. These include mild to moderate short lasting pain at the injection site, immediate localised stinging sensation and 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.
9. 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>
10. Suspected adverse reactions (ADRs) to vaccines should be reported via the Yellow Card Scheme available at: www.mhra.gov.uk/yellowcard. 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.
11. 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.

Data collection

12. Maintenance of comprehensive and accurate data is a key factor in determining the effective delivery of all vaccination programmes.
13. 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.
14. 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.
15. 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

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

COMMUNICATIONS AND INFORMATION FOR PATIENTS AND HEALTH PROFESSIONALS

Communications materials

1. The HPV leaflet for men who have sex with men is available online in English, Polish, Chinese, Arabic, BSL, Easy Read and audio format at www.nhsinform.scot/hpvmmsm. Hard copies of the English leaflet can be ordered through the Web2Print service at <http://print.healthscotland.com/home>. Public Health Scotland is happy to consider requests for other languages and formats. Please email phs.otherformats@phs.scot to request other languages and formats.

Workforce education for healthcare practitioners

2. NHS Education for Scotland (NES), in partnership with Public Health Scotland and the Scottish Health Protection Network will produce educational resources for healthcare practitioners. These will be made available at: [Human papillomavirus MSM | Turas | Learn \(nhs.scot\)](#)