

Dear Colleague

**HUMAN PAPILLOMAVIRUS (HPV) VACCINATION PROGRAMME:
CHANGE IN SCHEDULE FROM 3 TO 2 DOSES FOR ELIGIBLE
ADOLESCENTS AND ADULTS STARTING THE COURSE AFTER
THEY TURN 15 YEARS**

1. This letter provides information on forthcoming changes to the HPV vaccination programme.
2. The HPV vaccination programme in Scotland was introduced to girls on 1 September 2008. From 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 Joint Committee on Vaccination and Immunisation (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 therefore move to a 2 dose schedule for children and adults, including Men Who Have Sex With Men (MSM), at a suitable time.
4. **Please note:** A CMO letter titled "*Human Papillomavirus (HPV) Vaccination Programme: Change in schedule from 3 to 2 doses for eligible MSM*" was published 31 March 2022, detailing the change for this cohort.
5. Currently, there is no data on fewer than 3 doses among HIV-infected or immunocompromised populations. Therefore, a 3-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.
6. 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.

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

23 June 2022

SGHD/CMO(2022)25

For action

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

For information

General Practitioners
Practice Nurses
Primary Care Leads, NHS Boards
NHS Board Chief Executives
Directors of Pharmacy
Consultant Physicians
Public Health Scotland
Chief Executive, NHS Health Scotland
NHS 24
Scottish General Practitioners'
Committee

Further Enquiries

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

7. This change in schedule from 3 to 2 doses for those starting the schedule aged 15 years and above will take place from 1 August 2022.

8. Further information is included in the Annexes set out below.

Yours sincerely,

Gregor Smith

Professor Sir Gregor Smith
Chief Medical Officer

Alex McMahon

Professor Alex McMahon
Chief Nursing Officer

Alison Strath

Professor Alison Strath
Chief Pharmaceutical Officer

CHANGES TO THE PROGRAMME – KEY POINTS

Scheduling Vaccinations

1. The 2 dose schedule is recommended by JCVI for all eligible ages in the programme (excluding those HIV-infected or immunocompromised populations as they should remain on a 3 dose schedule). JCVI recommends a schedule of 0, 6-24 months for all HPV vaccines. 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. For Gardasil® 9 the minimum interval between the two doses can be 5 months.
2. If the course is interrupted, it should be resumed with the available Gardasil vaccine but not repeated, even if more than 24 months has 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: [Human papillomavirus \(HPV\): the green book, chapter 18a - GOV.UK \(www.gov.uk\)](https://www.gov.uk/government/publications/human-papillomavirus-hpv-the-green-book-chapter-18a)
3. If an individual has started a 3 dose course before August 2022, this course should be, wherever 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.
4. **Please note:** Individuals who commence a 3 dose schedule prior to 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.
5. 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.
6. The programme will transition to Gardasil® 9 once current stocks of Gardasil® have depleted. Therefore, 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.
7. 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.

Eligibility

8. The Immunisation against Infectious Disease Book ('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>
9. Those in eligible cohorts for vaccination in the national programme will remain eligible, and may be offered HPV vaccination opportunistically, up to their 25th birthday.

10. 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

Vaccine Dosage and Supply

1. The vaccines used for the current 3 dose programme are Gardasil® and Gardasil® 9, and both are suitable for the new 2 dose schedule.
2. Gardasil® 9, Gardasil® and Cervarix® have been recommended by JCVI for use in a 2 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 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.

[Immunisation procedures: the green book, chapter 4 - GOV.UK \(www.gov.uk\)](http://www.gov.uk/government/publications/immunisation-procedures-the-green-book-chapter-4)

3. Further 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: [Human papillomavirus \(HPV\): the green book, chapter 18a - GOV.UK \(www.gov.uk\)](http://www.gov.uk/government/publications/human-papillomavirus-hpv-the-green-book-chapter-18a)
4. Gardasil® and Gardasil® 9 should be ordered in the usual way from NHS Board vaccine holding centres.

Immunisation against Infectious Disease ('The Green Book')

5. 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>
6. 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)

7. 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

Consent

8. 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>
9. There is also information on informed consent for young people at: www.nhsinform.scot/campaigns/vaccines-for-young-people

Reporting of adverse reactions

10. 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>
11. For a detailed list of ADRs associated with Gardasil® please refer to the manufacturer's SPC or the Patient Information Leaflet (PIL) supplied with each vaccine:
<https://www.medicines.org.uk/emc/product/261/smpc>
12. 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.
13. 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

14. Maintenance of comprehensive and accurate data is a key factor in determining the effective delivery of all vaccination programmes.
15. 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.
16. 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.

Funding arrangements

17. 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. There is also further information on informed consent for vaccines for young people at: 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. Public Health Scotland is happy to consider requests for other languages. Please email 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 \(nhs.scot\)](#)