Chief Medical Officer Directorate

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The Scottish Government

Dear Colleague

**INTRODUCTION OF HPV VACCINATION PROGRAMME FOR MEN WHO HAVE SEX WITH MEN (MSM)**

1. We are writing to inform you that from 1 July 2017 MSM aged up to, and including 45 years of age, who attend sexual health / HIV clinics will be eligible to receive the HPV vaccine as part of a national HPV vaccination programme. Prisoners who identify as MSM will also be able to access the HPV vaccine through prison health services.

2. The introduction of this programme is based on the advice of the Joint Committee on Vaccination and Immunisation (JCVI). The JCVI recognises that MSM are a group at high risk of HPV infection and associated disease who receive little indirect health benefit from the existing HPV vaccination programme for girls. Since the girls' programme was introduced in 2008 evidence has emerged that HPV vaccination is likely to provide protection against a wider range of HPV related diseases such as penile, anal and a subset of orophyaryngeal (head and neck) cancers. The full JCVI statement setting out the recommendation to vaccinate MSM against HPV is available at: https://www.gov.uk/government/uploads/system/uploads/attachment_data/file/477954/JCVI_HPV.pdf

3. This letter provides colleagues with the necessary information to introduce the programme. It provides guidance on those eligible for vaccination **(Annex A)**; clinical advice on the use of Gardasil®, including details of how to order the vaccine; data collection arrangements and funding arrangements **(Annex B)**. Information on programme communications and workforce education materials can be found in **Annex C**.

4. The successful introduction of this new vaccination programme will contribute towards reducing the risk of HPV associated cancers and genital warts in this population. We would like to take this opportunity to thank all who will be involved in delivering this programme for their efforts and continuing commitment to improving public health.

Yours sincerely

| *Catherine Calderwood* | *Fiona McQueen* | *Rose Marie Parr* |
|---|---|---|
| **Chief Medical Officer** | **Chief Nursing Officer** | **Chief Pharmaceutical Officer** |

**From the Chief Medical Officer**
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For action
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NHS Board Consultants in Public Health Medicine;
BBV Sexual Health Lead Clinicians;
HIV Lead Clinicians;
Sexual Health Lead Clinicians;
General Practitioners;
Practice Nurses;
Immunisation Co-ordinators;
Scottish Prison Service

For information
Chairs, NHS Boards;
Consultant Paediatricians;
Consultant Physicians;
Health Protection Scotland;
Chief Executive, Health Scotland
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Directors of Finance, NHS Boards;
Infectious Disease Consultants, NHS Boards;
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**ANNEX A**

## ELIGIBILITY FOR THE HPV VACCINATION PROGRAMME FOR MSM

### National Programme

5. 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.

6. Prisoners who identify as MSM and are aged up to, and including, 45 years may also be offered the HPV vaccine through prison health services.

7. Any eligible individual who starts the vaccination schedule should complete the course. Course dosage depends on the age of the individual and is set out in **Annex B**.

8. Clinics are not required to proactively identify and contact individuals who have previously attended services.

9. Clinics are not required to arrange separate HPV vaccination appointments for eligible individuals who do not routinely access services for sexual health care.

### Outwith the national programme - clinical discretion on a case by case basis

10. In discussing the extension of the HPV vaccination programme to MSM, the JCVI also decided that there may be considerable benefit in offering the HPV vaccine to other individuals who have a similar risk profile to that seen in the 45 year-old-and-under MSM population attending sexual health / HIV clinics.

11. The JCVI concluded that clinicians, using their clinical judgement and on a case by case basis, can offer HPV vaccination to individuals outwith the national programme including some:

    - MSM over the age of 45
    - sex workers
    - HIV+ve women
    - HIV+ve men
    - transgender women; and
    - transgender men.

12. **However, these individuals are not eligible as part of the national programme and vaccine centrally procured for the HPV MSM programme should not be used for this purpose. In these instances, HPV vaccine should be purchased by the NHS Board directly.**

**ANNEX B**

## INTRODUCTION OF HPV VACCINATION PROGRAMME FOR MSM

### Background

13. HPV is a virus transmitted through sexual contact. There are over 200 different types of HPV, 13 of which are known to be associated with cervical cancer, with 2 types (HPV16 and HPV18) responsible for about 80% of all cervical cancers in the UK. HPV types 6 and 11 can also cause genital warts, whilst HPV types 16 and 18 can cause cancers of the anus, penis, mouth and throat, vagina and vulva.

14. In 2008, on the advice of the JCVI, a HPV vaccination programme was introduced across the UK to routinely offer a course of HPV vaccine to all girls aged 12-13. A catch-up programme offered HPV vaccine to girls aged 13-17 year old. The girls' HPV vaccination programme has proved highly successful, with coverage exceeding 80% in the routine cohort.

15. While the girls' programme confers indirect protection to heterosexual males, MSM receive little benefit from it. The JCVI considered modelling studies to assess the cost-effectiveness of targeted HPV vaccination of MSM in sexual health and HIV clinics, looking at the impact of vaccination against penile, anal and a subset of oropharyngeal (head and neck) cancers, and genital warts. Evidence suggests that 80-85% of anal cancers, 30-70% of oropharyngeal, and 50% of penile cancers are linked to HPV infection.

16. In November 2015, the JCVI advised that a targeted HPV vaccination programme with a course of three doses for MSM aged up to, and including, 45 years who usually attend sexual health and HIV clinics should be undertaken, subject to procurement of the vaccine and delivery of the programme at a cost-effective price.

### The Vaccine

17. The HPV vaccine to be used in the HPV MSM vaccination programme is Gardasil®, supplied by Merck Sharp & Dohme Limited.

18. The quadrivalent vaccine, Gardasil®, provides protection against HPV types 16, 18, 6, and 11.

### Vaccine Supply

19. Vaccine for the national programme will be centrally procured and should only be used for those eligible for the national HPV MSM vaccination programme as described in **Annex A**.

20. Gardasil® should be ordered in the usual way from NHS Board vaccine holding centres.

21. NHS Board vaccine holding centres should be aware that separate order lines have been established for the girls' HPV programme and the HPV programme for MSM. It is important that vaccine holding centres use the appropriate drop down box – ***MSM-Gardasil*** – when ordering Gardasil ® for the MSM programme as this will help with monitoring of supply requirements for the programme.

22. **Centrally procured vaccine should not be used to vaccinate individuals outwith the national programme** (i.e. those who may be offered the vaccine based on clinical judgement as described in **Annex A**). In these instances, vaccine should be purchased directly by NHS Boards from the routine pharmaceutical supply chain (wholesalers or direct from manufacturer).

**Vaccine Storage**

23. Vaccines should be stored in the original packaging between +2˚C and +8˚C (ideally aim for 5°C) and protected from light. Gardasil® should not be frozen. 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.

**Vaccine Stock Management**

24. Please ensure sufficient fridge space is available for the HPV vaccine. A review of available fridge space will be necessary to ensure adequate storage capacity at the start of the programme.

25. Effective management of vaccines throughout the supply chain is essential to reduce vaccine wastage. Local protocols should be in place to reduce vaccine wastage to a minimum. Even small percentage reductions in vaccine wastage will have a major impact on the financing of vaccine supplies.

26. Any cold chain failures or other stock incidents must be documented and reported to the local NHS Board using local reporting arrangements.

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

27. The Human Papillomavirus chapter (chapter 18a) within the Immunisation against Infectious Disease Book ('The Green Book') is available at: https://www.gov.uk/government/publications/human-papillomavirus-hpv-the-green-book-chapter-18a

28. The chapter has not been updated as the HPV MSM vaccination programme is not yet available across the whole of the UK. The chapter does, however, include information about the presentation, administration, storage etc of the vaccine.

**Patient Group Directions (PGD)**

29. The requirement for Patient Group Directions is described in HDL(2001)7 available from http://www.sehd.scot.nhs.uk/mels/HDL2001_07.HTM. Use of PGDs for administration of vaccines is described in the Green Book available at: http://media.dh.gov.uk/network/211/files/2012/07/Chapter-5.pdf.

30. A specimen PGD for use with the HPV vaccine, Gardasil®, for the HPV vaccination programme for MSM, has been produced by Health Protection Scotland (HPS) to assist NHS Boards. This is available on-line via the following link: http://www.hps.scot.nhs.uk/immvax/pgd.aspx.

**Contraindications**

31. There are very few individuals who cannot receive Gardasil®. When in doubt, appropriate advice should be sought from an immunisation co-ordinator rather than withhold immunisation.

32. Gardasil® should **not** be given to those who have had:
    - a confirmed anaphylactic reaction to a previous dose of the vaccine, OR
    - a confirmed anaphylactic reaction to any component of the vaccine.

33. For the composition and full list of excipients of the vaccine, please refer to the vaccine manufacturer's Summary of Product Characteristics (SPC) at: https://www.medicines.org.uk/emc/medicine/19016

**Consent**

34. See chapter two of the Green Book available at: https://www.gov.uk/government/publications/consent-the-green-book-chapter-2.

**Vaccine Administration**

35. Gardasil® is administered by a single intramuscular injection into the upper arm (deltoid region).

36. Healthcare professionals are encouraged to read the SPC for Gardasil® to ensure accurate preparation and administration the vaccine.

37. Full guidance on administration of the vaccine is also included in chapter 18a of the Green available at: https://www.gov.uk/government/publications/human-papillomavirus-hpv-the-green-book-chapter-18a.

38. Any unused medicinal product or waste material should be disposed of in accordance with local requirements.

**Vaccination Dosage and Schedule**

39. Due to the flexibility in the Gardasil® summary of product characteristics (SPC), variable spacing options for the doses are possible. This will enable the administration of subsequent doses to be aligned with recommended clinic re-attendance.

40. **A <u>three</u> dose schedule is recommended for individuals 15 years of age or older:** three doses of 0.5ml.
    - First dose of 0.5ml of Gardasil® HPV vaccine.
    - Second dose of 0.5ml at least one month after the first dose.
    - Third dose of 0.5ml at least three months after the second dose.
    - There is no clinical data on whether the interval between the second and third doses can be reduced to less than below three months, however, where the second dose is given late, and there is a high likelihood that the individual will not return for a third dose after three months, or if, for practical reasons, it is not possible to schedule a third dose within this timeframe, then a third dose can be given at least one month after the second dose.

- All three doses should ideally be given within one year; however, a 24 month period is clinically acceptable.

41. **A <u>two</u> dose schedule is recommended for individuals <u>under</u> 15 years of age:** two doses of 0.5ml given at least six months apart.
    - First dose of 0.5ml of Gardasil® 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. However, 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.

42. If the course is interrupted it should be resumed (using the same vaccine) but not repeated, ideally allowing the appropriate interval between the remaining doses.

**Reporting of adverse reactions**

43. The most common adverse reactions (ADRs) observed are injection-site reactions. These include mild to moderate short lasting pain at the injection side, 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.

44. 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/medicine/19016

45. 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.

46. 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

**Immunosuppression and HIV Infection**

47. Individuals with immunosuppression and human immunodeficiency virus (HIV) infection who are eligible to receive the vaccine (regardless of CD4 count) should be given the vaccine in accordance with the routine three dose schedule.

48. As part of the national programme a three dose schedule should be offered to MSM aged up to and including 45 years who are known to be HIV infected.

**Concomitant Administration with other vaccines**

49. Gardasil® is an inactivated vaccine and will not be affected by, nor interfere with, other inactivated or live vaccines given at the same time as, or at any interval from, each other.

50. Hepatitis B and Hepatitis A vaccination may be administered at the same time as HPV vaccine.

51. Where two or more injections need to be administered at the same visit, they should be given at separate sites, preferably in separate limbs. If given in the same limb, they should be given at least 2.5cm apart. The site at which each vaccine was given should be noted in the individual's health records.

**Hepatitis B vaccination check**

52. When vaccinating eligible patients healthcare professionals should take the opportunity to check patients' hepatitis B virus (HBV) vaccination status. The risk based vaccination policy for HBV includes MSM. Maintaining high vaccine coverage in MSM is important to avoid outbreaks of infection.

53. Guidelines for HBV vaccination are detailed in chapter 18 of the Green Book available at: https://www.gov.uk/government/publications/hepatitis-b-the-green-book-chapter-18

**Data collection**

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

55. Vaccination records for each eligible MSM attending a sexual health clinic should be recorded on 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.

56. The National Sexual Health IT System (NaSH) routinely records age, gender, lifetime partner gender and prescribing.

57. 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

58. The vaccination recording page on NaSH has been upgraded to establish vaccination status at baseline (for eligibility). A change has been implemented which will mean that HPV vaccination status is added to the BBV page which is renamed BBV/HPV issues. This will provide the facility to record:

- Date of commencement of vaccination
- Date of completion of vaccination
- HPV vaccination status prior to attendance:
    a) Never immunised
    b) Immunisation complete
    c) Immunisation in progress
    d) Immunisation lapsed
    e) Immunisation declined
    f) Other
    g) Not known

**Vaccine uptake**

59. 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.

60. Recording of patient age, clinic attended, vaccine start and completion dates are important to allow monitoring of HPV vaccine uptake. Additional data from NaSH will be extracted to monitor eligibility and define the denominator for measuring uptake.

61. As with other national immunisation programmes, HPS will collate the data from NaSH and other recording systems for other settings where vaccine is being delivered. The data will be used to determine HPV MSM vaccination uptake rates by NHS Board and nationally.

**Surveillance**

62. The HPV MSM vaccination programme will be carefully monitored by Health Protection Scotland (HPS) and the Medicines and Healthcare Products Regulatory Agency (MHRA). HPS aims to assess the impact of the HPV vaccine programme by linking HPV vaccine status to prescription genital wart treatments within the sexual health setting.

63. Health Protection Scotland has collected data on rectal HPV prevalence from a cohort of men who attend sexual health services, prior to implementation of the selective vaccination programme for MSM. HPV prevalence in this population was high: 782/1064 (73%) were HPV positive and 531/1064 (50%) were positive for at least one of the types within the quadrivalent vaccine. Once the vaccine programme has been implemented, a further collection will occur within several years to ascertain impact of the vaccination programme.

**Funding arrangements**

64. The Scottish Government will fund the cost of the HPV vaccine required for the national MSM vaccination programme, i.e. MSM up to, and including, 45 years of age who attend sexual health / HIV clinics and prisoners up to, and including, 45 years of age who identify as MSM.

65. Invoices for HPV vaccine used in the national HPV MSM programme will be paid directly by the Scottish Government.

66. The Scottish Government <u>will not</u> fund HPV vaccine required for those in the clinical discretion groups. As with other vaccination programmes, NHS Boards should procure vaccine required for clinical discretion categories directly and the associated costs should be met by the NHS Board.

**ANNEX C**

## COMMUNICATIONS AND INFORMATION FOR PATIENTS AND HEALTH PROFESSIONALS

### Communications

67. NHS Health Scotland has produced a public information leaflet, *The HPV Vaccine for men who have sex with men (MSM)*, to support the programme. This can be accessed at: www.immunisationscotland.org.uk/vaccines-and-diseases/hpvmsm.aspx once the programme starts.

68. A supply of these public information leaflets will be distributed to all sexual health and HIV clinics in Scotland with details of where to order further copies, if required. A supply of leaflets will also be made available to prison health services. Each leaflet will include a vaccination record card.

69. The public information leaflet will also be made available in Polish, Chinese, Urdu and easy read format on the immunisation website above. 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 to request other languages and formats.

70. Further information about the full range of immunisations and vaccines in Scotland is available on the public information website: www.immunisationscotland.org.uk.

### Educational resources for registered healthcare practitioners

71. 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: http://www.nes.scot.nhs.uk/education-and-training/by-theme-initiative/public-health/health-protection/immunisation/human-papillomavirus-msm.aspx