



CLINICAL AND OPERATIONAL GUIDANCE FOR THE HPV FOR MSM VACCINATION PILOT

1. This guidance is based on advice from the Joint Committee on Vaccination and Immunisation (JCVI)¹, the UK's independent committee of immunisation experts. The *Immunisation against infectious disease* ('the Green Book') chapter on HPV has not been updated to reflect the MSM pilot, but includes information about the presentation, administration, storage, etc. of the vaccine. This is available at: [Green Book chapter on HPV](#). The chapter will be updated should a full national HPV programme be introduced for MSM.

Aims

2. The aims of the HPV-MSM immunisation pilot are to evaluate:
 - the cost-effectiveness of the delivery of the vaccination through GUM and HIV clinics; evaluate vaccine uptake, evaluate the impact on clinic attendance, and to identify and address any unforeseen issues that may arise during the pilot.
 - the offer of a full course of the quadrivalent HPV vaccine (Gardasil®) opportunistically to all MSM up to and including the age of 45 years attending participating GUM and HIV clinics.

Objectives

3. The aim will be achieved by delivering a targeted, evidence-based immunisation pilot that:
 - identifies the eligible population and ensures effective, timely delivery with high completion and uptake rates;
 - is safe, effective, of a high quality and is externally and independently monitored;
 - is delivered and supported by suitably trained, competent and qualified clinical and non-clinical staff who participate in recognised ongoing training and development;

¹ The JCVI statement: [JCVI statement on HPV for MSM](#)

- avoids increased attendance and costs by delivering the full vaccination course opportunistically alongside existing appointments for other sexual health care/treatment, recommended GUM re-attendance, routine investigations for HIV+ve MSM, or other care;
- delivers, manages and stores vaccine in accordance with national guidance²;
- provides relevant information and advice to the identified cohort;
- is supported by regular and accurate data collection using the appropriate returns and formal evaluation of the program by PHE.

Background to the introduction of HPV vaccination for MSM

4. HPV is a virus transmitted through sexual contact. There are over 100 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 strain types 6 and 11 can also cause genital warts, whilst HPV strain types 16 and 18 can cause cancers of the anus, penis, mouth and throat, vagina and vulva.
5. In 2008, on the advice of the JCVI, a HPV immunisation programme was introduced across the UK to routinely offer a course of vaccine to all girls aged 12-13. A catch-up programme offered vaccine to girls aged 13-17 year old. The girls' HPV vaccine programme has proved highly successful, with coverage exceeding 85% in the routine cohort. In addition to direct protection to females, it induces herd protection, which provides substantial protection to boys as long as there is high vaccine coverage in girls. Since September 2012 the quadrivalent vaccine Gardasil® has been used for the national programme, which provides protection against HPV types 16, 18, 6, and 11. HPV types 6 and 11 are responsible for the majority of cases of genital warts in the UK.
6. While the girls' programme confers indirect protection to heterosexual males, MSM receive little benefit from it. JCVI considered modelling studies to assess the cost-effectiveness of a targeted HPV vaccination of MSM in GUM and HIV clinics, looking at the impact of vaccination against penile, anal and oropharyngeal (head and neck) cancers, and genital warts. Evidence suggests that 80-85% of anal cancers, 36% of oropharyngeal, and 50% of penile cancer are linked to HPV infection.
7. 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 attend GUM and HIV clinics should be undertaken, subject to procurement of the vaccine and delivery of the programme at a cost-effective price.

² Public Health England's Protocol for ordering, storing and handling of vaccines:

https://www.gov.uk/government/uploads/system/uploads/attachment_data/file/300304/Protocol_for_ordering_storing_and_handling_vaccines_March_2014.pdf

8. GUMCAD data reports there are approximately 110,000 eligible MSM who would benefit in the first year from an HPV for MSM immunisation programme. However, once implemented, it is estimated that the proportion of eligible MSM (i.e. less those already vaccinated) will reduce each year.

Recommendations for the use of the quadrivalent HPV vaccine (Gardasil®) in MSM

Eligibility

9. A full course of vaccination should systematically be offered to every MSM up to and including 45 years attending the clinic regardless of risk, sexual behaviour or disease status; until the number of vaccine courses allocated to the clinic has been met. Clinics are responsible for managing their own stock locally and should work within the volume of vaccine they have been allocated to ensure a full course is available for each vaccinee.
10. Any eligible individual that starts the vaccination schedule should complete the course.
11. The JCVI considered that there may be considerable benefit in offering the HPV vaccine to other individuals who have a similar risk profile to the GUM attending MSM population. Clinicians are able to offer vaccinations using individual clinical judgement, and HPV vaccination could therefore be considered for such individuals on a case-by-case basis. **However, these individuals are not eligible as part of this pilot and vaccine centrally procured for the HPV MSM pilot should not be used for this purpose. In these instances, vaccine should be purchased directly from the manufacturer.**

Administration

12. Gardasil® is administered by a single intramuscular injection into the upper arm (deltoid region). One dose has a volume of 0.5ml and the vaccine is provided in a pre-filled syringe.
13. Prior to use, the pre-filled syringe should be shaken well to obtain a white, cloudy suspension. Two needles of different lengths are provided in the pack. Healthcare professionals should choose the appropriate needle to ensure an intramuscular (IM) administration depending on the vaccinee's size and weight.
14. A small air bubble may be visible in the prefilled syringe. This is not harmful and should not be removed prior to administration. This small bolus of air injected following

administration of medication clears the needle and prevents a localised reaction from the vaccination. To try to expel it risks accidentally expelling some of the vaccine and therefore not giving the patient the full dose.

15. Any unused medicinal product or waste material should be disposed of in accordance with local requirements.
16. Healthcare professionals are encouraged to read the manufacturer's Summary of Product Characteristics (SPC)³ for Gardasil® to ensure accurate reconstitution and delivery of the product.
17. The Green Book chapter on HPV is not being updated to reflect the MSM pilot, but includes information on the presentation, administration, storage etc of the vaccine. This is available at: [Green Book chapter on HPV](#).

Dosage and schedule

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 GUM re-attendance, routine investigations for HIV+ve MSM, or other care, in order to reduce introducing additional visits for vaccination only.

18. **Two dose schedule for individuals under 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.
19. **Three dose schedule 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.
 - All three doses should ideally be given within one year, however a 24 month period is clinically acceptable.

³ Gardasil Summary of Product Characteristics. Available at the electronic Medicines Compendium (eMC) <https://www.medicines.org.uk/emc/medicine/19016>

20. 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.

Contraindications

21. There are very few individuals who cannot receive Gardasil®. When in doubt, appropriate advice should be sought from a consultant with immunisation expertise, a member of the screening and immunisation team or from the local health protection team, rather than withholding immunisation.
22. 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 constituent or excipient of the vaccine.
23. For the composition and full list of excipients of the vaccine, please refer to the manufacturer's Summary of Product Characteristics (SPC).

Immunosuppression and HIV infection

24. Individuals with immunosuppression and human immunodeficiency virus (HIV) infection (regardless of CD4 count) **should** be given the vaccine in accordance with the routine three dose schedule above.
25. Only a three dose schedule should be offered to individuals in the eligible cohort who are known to be HIV infected.

Concomitant administration with other vaccines

26. 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.
27. 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.

Consent

28. See Chapter Two of *Immunisation against infectious disease* ('the Green Book'): **The Green Book - consent: chapter two**

Pharmacy issues

Vaccine brand name

29. Gardasil® - supplied by Sanofi Pasteur MSD.

Presentation

- 30. Gardasil® will be supplied in single dose packs.
- 31. Gardasil® is supplied as a 0.5ml liquid suspension for injection in a pre-filled syringe. The entire 0.5ml dose should be administered.
- 32. Prior to agitation, Gardasil® may appear as a clear liquid with a white precipitate. After thorough agitation, it is a white, cloudy liquid.

Vaccine supply (including ImmForm registration)

- 33. Gardasil® for this pilot should be ordered via the [ImmForm website](#)⁴ and will be distributed by Movianto UK (Tel: 01234 248631) as part of the national immunisation programme. Vaccines for private prescriptions, occupational health use or travel are NOT provided free of charge and should be ordered from the manufacturers. Further information about ImmForm, including registration, is available at [ImmForm Helpsheet](#) or from the ImmForm helpdesk at helpdesk@immform.org.uk or Tel: 0844 376 0040.

Storage

- 34. 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.
- 35. Effectiveness cannot be guaranteed for vaccines unless they have been stored at the correct temperature. To ensure vaccines are ordered, stored and monitored as per national recommendations, healthcare professionals should familiarise themselves with Public Health England's Protocol for ordering, storing and handling of vaccines: https://www.gov.uk/government/uploads/system/uploads/attachment_data/file/300304/Protocol_for_ordering_storing_and_handling_vaccines_March_2014.pdf

Vaccine stock management

- 36. Please ensure sufficient fridge space is available for the vaccines. A maximum of two weeks of stock is recommended at any one time. A review of available fridge space will be necessary to ensure adequate storage capacity at the start of the pilot.
- 37. 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.
- 38. Any cold chain failures or other stock incidents must be documented and reported as part of the evaluation and recorded through the ImmForm website on the Stock

⁴ ImmForm website: www.immform.dh.gov.uk

Incident page found in the Vaccine Supply section. A new category to record disposal of 'HPV vaccine unused as part of the pilot programme for MSM' has been added to monitor wastage of vaccine.

Reporting of adverse reactions (ADRs)

39. 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.
40. Other reactions commonly reported are headache, myalgia, fatigue, and low grade fever. These adverse reactions are usually mild or moderate in intensity.
41. For a detailed list of ADRs associated with Gardasil® please refer to the manufacturer's Summary of Product Characteristics (SPC) or the Patient Information Leaflet (PIL) that comes with each vaccine.
42. Any suspected ADRs to vaccines should be reported via the Yellow Card Scheme⁵ (<https://yellowcard.mhra.gov.uk/>). Chapter Nine⁶ of the Green Book gives detailed guidance which ADRs to report and how to do so. Additionally, Chapter Eight⁷ of the Green Book provides detailed advice on managing ADRs following immunisation.
43. Any reported adverse incidents, errors or events during or post vaccination must follow determined procedures.

Patient Specific Directions (PSDs)

44. PHE will not be providing a national Patient Group Direction (PGD) template for the pilot. Providers may choose to source their own PGDs locally; or prescribe the vaccination on an individual patient level using a Patient Specific Direction (PSD).

Vaccine coverage data collection

45. Accurate recording of all vaccine doses given and reasons for not offering/giving the vaccine to eligible MSM (via the codes available in surveillance and reporting systems) is essential.

⁵ Yellow Card Scheme: <https://yellowcard.mhra.gov.uk/>

⁶ Green Book chapter nine - surveillance and monitoring for vaccine safety:
<https://www.gov.uk/government/publications/surveillance-and-monitoring-for-vaccine-safety-the-green-book-chapter-9>

⁷ Green Book chapter eight - vaccine safety and adverse events following immunisation:
<https://www.gov.uk/government/publications/vaccine-safety-and-adverse-events-following-immunisation-the-green-book-chapter-8>

46. Vaccine uptake will be monitored primarily via two existing surveillance and reporting systems, namely the Genitourinary medicine clinic activity dataset (GUMCADv2) and the HIV and AIDS reporting system (HARS).

47. GUMCADv2 collection will use three existing SHHAPT codes:

- W1Q: HPV vaccination: 1st dose
- W2Q: HPV vaccination: 2nd dose
- W3Q: HPV vaccination: 3rd dose, and two new SHHAPT codes:
- W4: HPV vaccine offered and declined
- W5: HPV vaccine not offered: previously received in full.

48. HARS collection will include two new items:

AN2: Human papillomavirus (HPV) vaccine activity offer status code:

- 01: Offered and Undecided
- 02: Offered and Declined
- 03: Offered and Accepted
- 05 Not Offered: HPV vaccination previously received in full
- 06: Not offered: Other reason
- 09: Not known (Not recorded)

AN1: HPV Vaccination Dose Number Given:

- 1: 1st dose
- 2: 2nd dose
- 3: 3rd dose.

49. Vaccination records for each eligible MSM attending a GUM clinic should be coded on GUMCADv2. Vaccination records for each eligible MSM attending for HIV related care should be coded on HARS (in addition, if your clinic would usually also enter an attendance for HIV related care on GUMCADv2 (i.e. SHHAPT code H2) then the HPV vaccination records should be entered on both GUMCADv2 and HARS).

Funding arrangements

50. PHE will pay providers an administration fee of £10 per dose (inc VAT) given to eligible MSM payable upon annual invoicing by the provider clinic to PHE. Invoices should be sent to: immunisation@phe.gov.uk

Communications and information for the public and health professionals

51. An integrated communications strategy has been produced by PHE for the HPV-MSM pilot. The strategy provides communications colleagues in partner organisations with information and resources to assist with the delivery of the pilot. Partners include the

Department of Health (DH), NHS England and national HPV, LGBT and cancer charities and organisations.

52. An NHS branded information leaflet has being produced by PHE to support the pilot programme. This should only be used by clinics involved in the pilot. The leaflet can be downloaded from this site: <https://www.gov.uk/government/publications/hpv-vaccination-pilot-for-men-who-have-sex-with-men-msm>. Alternatively, hard copies are available to order from the DH/ PHE Publications Orderline⁸(product code 3204636). Clinics are encouraged to supply this leaflet to patients when they are opportunistically offered vaccination at existing clinic appointments.
53. A vaccination record card for the pilot can be found here: <https://www.gov.uk/government/publications/hpv-vaccination-pilot-for-men-who-have-sex-with-men-msm>. Credit card sized hard copies will soon be available to order (in packs of 30) from the DH/ PHE Publications Orderline⁸
54. Materials for health care professionals will be made available here: <https://www.gov.uk/government/publications/hpv-vaccination-pilot-for-men-who-have-sex-with-men-msm>

Training resources

55. Information for healthcare professional in the form of a Q&A and a standard training slide set will be made available here: <https://www.gov.uk/government/publications/hpv-vaccination-pilot-for-men-who-have-sex-with-men-msm>

Questionnaires

Patient questionnaire

56. As part of the evaluation of the pilot programme, we would like clinics to ask vaccinees to complete a voluntary, anonymous questionnaire (**Annex A**) while they are in the clinics. A clinic identifier should be inserted in the top right hand box on the form. We suggest a post box is provided in reception/waiting area where patients can deposit their completed paper questionnaires.
57. Clinics should post completed questionnaires **monthly** to the following address:

PHE Immunisation,
HPV-MSM pilot,
5th Floor North,
Wellington House,
133-155 Waterloo Road,
London. SE1 8UG

⁸ DH/PHE publications orderline: https://www.orderline.dh.gov.uk/ecom_dh/public/home.jsf

Provider questionnaire

58. We would also value the feedback of healthcare workers involved in delivering the pilot programme for the evaluation. A provider questionnaire will be emailed to clinic contacts in due course.

Hepatitis B (HBV) vaccination check

59. Please take the opportunity to check (and correctly code) patients' HBV vaccination status. The UK's risk-based vaccination policy for HBV includes MSM (<http://antibiotic-action.com/wp-content/uploads/2011/07/DH-National-strategy-for-sexual-health-and-HIV.pdf>). However, HBV vaccination uptake amongst MSM attending GUM clinics is below national targets, both for first dose uptake and for completion of three doses of vaccine (<https://www.collectlane.com/#/post-event/41/posters/20300>). Recording of both HBV immunity and HBV vaccine delivery by clinician coding is also suboptimal. Maintaining high vaccine coverage in MSM is important to avoid outbreaks of infection. Guidelines for HBV vaccination are detailed elsewhere (<http://www.bashh.org/documents/New%20Viral%20Hepatitides%20FINAL%20DRAFT%20MAY15.pdf> , https://www.gov.uk/government/uploads/system/uploads/attachment_data/file/503768/2905115_Green_Book_Chapter_18_v3_0V.PDF). (See points 27 and 28 in this guidance regarding concomitant administration).

Withdrawn April 2018

Annex A

PATIENT QUESTIONNAIRE

Enter clinic identifier:

Human papillomavirus (HPV) vaccination pilot for men who have sex with men Patient Questionnaire

Public Health England (PHE) is piloting this new HPV vaccination programme in selected clinics across England. This clinic is one of the first to offer the vaccine as part of the pilot.

Your feedback is important to us. We would be really grateful if you could take the time to answer this short questionnaire to help us determine how we can roll out this programme successfully across the country. Your participation in this questionnaire is completely voluntary, and your decision to participate or not will have no impact on your future care.

This information is being collected by PHE exclusively for the evaluation of the pilot programme. The answers provided will be stored and used securely, and will not be shared with other organisations. No attempt will be made to identify or contact individuals in the future.

Q1 - Have you ever attended a GUM/HIV clinic before?

- ☐ Yes I have attended a clinic before
- ☐ No I have never attended a clinic before

Q2 – Is this your local/usual clinic?

- ☐ Yes
- ☐ No

Q3 - Did you know that HPV vaccination is recommended for men who have sex with men before your appointment today?

- ☐ Yes
- ☐ No – if no, please go to Question 6

Q4 - Was getting the HPV vaccine the main reason that you attended the clinic today?

- ☐ Yes
- ☐ Yes, but wanted a check-up or had other reasons to attend as well
- ☐ No – if no, please go to Question 6

Q5 – How did you know the HPV vaccine was available at this particular clinic? (please select all that apply)

- ☐ Someone told me
- ☐ I read a leaflet about it
- ☐ A charity
- ☐ A newspaper / magazine
- ☐ Another clinic told me
- ☐ The internet (please specify website)

- ☐ I did not know that I could get the vaccine at this particular clinic, but knew that it was available at GUM/sexual health clinics
- ☐ Other (please specify)

Q6 - Did you access any other health services as part of attendance today (e.g. HIV and/or STI testing, health advice, condoms, HIV care and treatment monitoring, etc.)?

- ☐ Yes
- ☐ No

Q7 - Why did you choose to attend this particular clinic? (please select all that apply)

- ☐ This is the clinic I usually attend
- ☐ This is my local clinic
- ☐ This is the most convenient clinic for me
- ☐ I wanted the HPV vaccine but my local/usual clinic does not have it.
- ☐ I wanted the HPV vaccine and knew this clinic provided it
- ☐ Other reason (please specify)

The next two questions will help us to plan for possible wider availability of the vaccine

Q8 – To ensure maximum protection from HPV infection you will need two more doses of vaccine over the next 12 months to complete this course. If we were to send reminders about your next dose, how would you like us to do this? (please select all that apply)

- ☐ Text message/SMS
- ☐ Email

- Phone call
- Other (please specify)

- All of the above
- I would not want a reminder

Note: some clinics may offer a reminder service already – clinic staff will advise you about this.

Q9 – If you had the choice, where would you like to have your next HPV vaccine doses?
(please select all that apply)

- At this clinic
- A clinic closer to where I live
- A clinic closer to where I work
- A high street pharmacy
- My GP practice
- Other (please specify)

Thank you for taking the time to complete this questionnaire.

If you have any comments or queries about the HPV vaccination programme you can contact the PHE Immunisation team at

immunisation@phe.gov.uk or by phone on 0207 654 8121

Withdrawn April 2018

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First published: July 2016

Gateway 2016245

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