Public Health England

Protecting and improving the nation's health

HPV vaccination programme for men who have sex with men (MSM)

Clinical and operational guidance

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Published April 2018
PHE publications
gateway number: 2017892

PHE supports the UN
Sustainable Development Goals

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Background

In June 2012, the Joint Committee on Immunisation and Vaccination (JCVI) asked the Health Protection Agency (now Public Health England), to undertake modelling studies to assess the impact and cost effectiveness of HPV vaccination for men who have sex with men (MSM), acknowledging this group are expected to benefit far less from indirect herd protection from the current HPV vaccination programme in which the vaccine is offered to adolescent females.

Since 2012, the JCVI has regularly reviewed all the available evidence on the disease epidemiology, vaccine efficacy and cost effectiveness of an HPV MSM immunisation programme in the UK.

In November 2015, the JCVI published its advice on the extension of HPV vaccination to MSM[1]. It advised that a programme should be undertaken to vaccinate all MSM up to and including 45 years of age who attend sexual health services and HIV treatment services, subject to procurement of the vaccine and delivery of the programme at a cost-effective price

In June 2016, a PHE-led pilot commenced in which the HPV vaccine was offered opportunistically to men who have sex with men (MSM) up to and including the age of 45, attending selected local sexual health services. The purpose of the pilot was to evaluate the feasibility, acceptability, uptake, impact and equity of a potential national HPV vaccination programme for MSM. The pilot demonstrated that such a programme can be delivered opportunistically in an acceptable and equitable manner through GUM and HIV clinics and consequently, the decision was made to roll out a national programme to all clinics across the country from April 2018.

This document contains both clinical and operational guidance to facilitate the safe and effective delivery of this programme.

Human papillomavirus (HPV)

HPV infects the surface of the skin and mucosae of the upper respiratory and anogenital tracts. There are over 100 types of HPV viruses of which about 40 infect the genital tract[2]

[1] Joint Committee on Vaccination and Immunisation. Statement on HPV vaccination of men who have sex with men. November 2015. Available at: https://www.gov.uk/government/publications/jcvi-statement-on-hpv-vaccination-of-men-who-have-sex-with-men

[2] McCance DJ (2004) Papillomaviruses. In: Zuckerman AJ, Banatvala JE, Pattison JR, Griffiths P and Schoub B (eds) Principles and practice of clinical virology. 5th edition. Wiley & Sons Ltd.

The majority of HPV infections do not cause any symptoms and infection is usually cleared by the body's immune system without the need for treatment. However persistent infection with high risk HPV types such as types16 and 18 can lead to cancer – most notably cancer of the anus, throat and penis, as well as cervical cancer in women. Other types of HPV such as 6 and 11 cause genital warts. Strains of HPV that cause genital warts do not cause cancer and strains that cause cancer do not cause genital warts. The presence or absence of genital warts is not therefore an indication of the presence or absence of cancer causing strains of HPV.

HPV is one of the most common sexually transmitted infections in the UK. HPV infections are acquired primarily by sexual contact with an infected partner, particularly through sexual intercourse but also by non-penetrative genital contact, including oral sex. Anyone who is sexually active can contract HPV. The risk of acquiring infection increases with the number of previous sexual partners, the introduction of a new sexual partner, and the sexual history of partners.

HPV vaccination programme for men who have sex with men (MSM)

The aim of the programme

The aim of the programme is to extend protection against HPV infection, HPV associated cancers and genital warts to the MSM population up to and including the age of 45 years through opportunistic vaccination at Specialist Sexual Health Services* (SSHS) and HIV clinics.

In all men 80-85% of anal cancers, 36% of oro-pharyngeal cancer and 50% of penile cancers are associated with HPV infection[3,4]. MSM bear a significantly increased burden of HPV-related disease and adverse outcomes compared to heterosexual men. HPV-associated anal cancers in particular are far more common in MSM compared to heterosexual men[5,6].

*Specialist sexual health services (SHSS) refers to genitourinary medicine (GUM) and integrated GUM/sexual and reproductive health (SRH) services

[3] Giuliano AR, Nyitray AG et al. EUROGIN 2014 roadmap: Differences in human papillomavirus infection natural history, transmission and human papillomavirus-related cancer incidence by gender and anatomic site of infection. Int J Cancer 2014; Jul 17. doi: 10.1002/ijc.29082
[4] Kreimer AR, Clifford GM et al. Human Papillomavirus Types in Head and Neck Squamous Cell Carcinomas Worldwide: A Systematic Review. Cancer Epidemiol Biomarkers Prev 2005; 14:467-75
[5] Chin-Hong PV, Vittinghoff E et al. Age-Specific prevalence of anal human papillomavirus infection in HIV-negative sexually active men who have sex with men: the EXPLORE study. J Infect Dis 2004; 190:2070-6
[6] Daling JR, Weiss NS et al. Sexual practices, sexually transmitted diseases, and the incidence of anal cancer. N Engl J Med 1987; 317:973-7

Since September 2008, a national HPV immunisation programme for girls has been delivered throughout the UK to help prevent cervical cancer. The programme offers vaccination to school year 8 females (age 12-13 years) with a catch up for girls under 18 years of age. The implementation of the girls' HPV vaccine programme has been highly successful, with coverage exceeding 85% in the routine cohort. In addition to direct protection to females, the current HPV programme induces herd protection, which provides substantial protection to heterosexual boys and men. However, men who have sex with men will benefit less from this protection. Offering the HPV vaccine to MSM in SSHS and HIV services will offer protection against HPV related disease in this high risk group.

Eligibility

The HPV vaccine is recommended for all MSM up to and including 45 years of age, attending participating SSHS or HIV clinics, regardless of risk, sexual behaviour or disease status.

MSM older than 45 years are not eligible for HPV vaccination under this NHS England procured service.

JCVI considers 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 SHSS-attending MSM population, including some MSM over 45, sex workers, HIV+ve women, and HIV+ve men. Clinicians may exercise their clinical judgement to offer vaccinations outside of the national programme and so HPV vaccination can therefore be considered for such individuals on a case-by-case basis. Vaccine centrally procured for the HPV MSM programme should not be used for this purpose. In these instances, vaccine should be purchased directly from the manufacturer or pharmaceutical wholesaler and providers will not be paid for administering the vaccine.

Transgender individuals

The eligibility of transgender women (i.e.women who were assigned male at birth) should be a case-by-case clinical decision based on a risk assessment that includes the woman's sexual behaviour and the sexual behaviour of her partners. Transgender women are eligible if their risk of acquiring HPV is equivalent to the risk of MSM eligible for the HPV vaccine.

Transgender men (i.e. men who were assigned female at birth) are eligible if they have sex with other men, attend specialist sexual health or HIV services and are aged 45 and under. If they have previously completed a course of HPV vaccination as part of the girls' school year 8 HPV vaccine programme, no further doses need be given.

Clinical guidance

The HPV vaccine

Gardasil® is the recommended vaccine for the MSM vaccination programme and is the only market authorised quadrivalent HPV vaccine in the UK.

Gardasil® provides protection against four HPV strains: HPV16 and HPV18, the two high risk HPV types that can lead to cancer; and HPV6 and HPV11, the two HPV types that cause approximately 90% of all anogenital warts in males and females.

The vaccine is approved for use in females and males from 9 years of age.

How the vaccine works

The vaccine is made from the proteins that make up the outer coat of the virus types. These proteins assemble into small spheres that are called virus-like particles (VLPs). VLPs are not infectious and cannot cause HPV-associated cancers or genital warts as they do not contain the virus's DNA. VLPs are however very immunogenic, which means that they induce high levels of antibody production by the body.

As with many other immunisations, when a person is vaccinated, their immune system mounts a response against these VLPs. When a person is then exposed to the naturally occurring virus, the body's immune system reacts quickly to stop the infection.

Gardasil® has been shown to be highly effective in preventing the types of HPV infection for which it is indicated.

Prior infection with one HPV type does not diminish the efficacy of the vaccine against other HPV types included in the vaccine. To get the best protection, it is important the full course of vaccination is received.

In clinical trials in young women with no previous history of HPV infection, vaccine was 99% effective at preventing pre-cancerous lesions associated with HPV types 16 and 18[7,8,9].

[7] Ault KA and Future II Study Group. Effect of prophylactic human papillomavirus L1 virus-like-particle vaccine on risk of cervical intraepithelial neoplasia grade 2, grade 3, and adenocarcinoma in situ: a combined analysis of four randomised clinical trials. Lancet 2007: 369(9576): 1861-8

[8] Lu B, Kumar A et al. Efficacy and safety of prophylactic vaccines against cervical HPV infection and diseases among women: a systematic review and meta-analysis. BMC Infectious Diseases 2011: 11:13

[9] Harper DM, Franco EL et al. Sustained efficacy up to 4.5 years of a bivalent L1 virus-like particle vaccine against human papillomavirus types 16 and 18: follow-up from a randomised control trial. Lancet 2006: 367(9518):1247-55.

Gardasil® is also 99% effective at preventing genital warts associated with vaccine types in young women[10].

A clinical trial of Gardasil® in men indicated that it can prevent anal cell changes caused by persistent HPV infection, and genital warts[11].

HPV vaccines have not been shown to have an impact on an existing infection or any of the outcomes of an existing HPV infection, such as anogenital warts, but may boost immunity and prevent re-infection or reduce recurrences in people with established disease[12,13].

Vaccine safety

The safety of Gardasil® vaccine has been established through rigorous testing in clinical trials, followed by use of many millions of doses across the world over the past few years. As with any vaccine, some people may experience a side effect, but these are generally of short duration and are far outweighed by the expected benefits of the vaccine.

The UK Medicines and Healthcare products Regulatory Agency (MHRA) have published extensive reviews of HPV vaccine safety[14]. The US Centres for Disease Prevention and Control (CDC) have also posted very clear advice on their website supporting the safety of HPV vaccine (www.cdc.gov/vaccinesafety/Vaccines/HPV/index.html).

Recently, concerns regarding the safety of the HPV vaccine have been raised in the UK and other European countries, with some parents and pressure groups linking the vaccination to postural orthostatic tachycardia syndrome (POTS) and complex regional pain syndrome (CRPS). In June 2015, the JCVI reviewed the available evidence and concluded that it had no concerns about the safety of the HPV vaccine[15]. The European Medicines Agency has also conducted an independent review[16] and, in line

[10] Barr E and Tamms G. Quadrivalent human papillomavirus vaccine. Clin Infect Dis 2007; 45(5): 609-17.
[11] Giuliano AR, Palefsky JM, Goldstone S, et al. Efficacy of quadrivalent HPV vaccine against HPV Infection and disease in males. New England Journal of Medicine 2011; 364(5):401-411
[12] Swedish KA, Factor SH, Goldstone SE. Prevention of recurrent high-grade anal neoplasia with quadrivalent human papillomavirus vaccination of men who have sex with men: a nonconcurrent cohort study. Clin Infect Dis. 2012;54:891-8.
[13] Miltz A, Price H et al. Systematic review and meta-analysis of L1-VLP-based human papillomavirus vaccine efficacy against anogenital pre-cancer in women with evidence of prior HPV exposure. PLoS One. 2014;9:e90348
[14] Medicines and Healthcare products Regulatory Agency Cervarix HPV vaccine: safety update at end of 4 years routine use in HPV immunisation programme. December 2012. Available at: http://www.mhra.gov.uk/safety-public-assessment-reports/CON221607
[15] Joint Committee on Vaccination and Immunisation HPV Sub-committee minutes of meeting held on June 8 2015. Available at: https://app.box.com/s/600veu6zr6s3gjvx8mkt/file/74115214198
[16] European Medicines Agency. Assessment report. Human papillomavirus (HPV) vaccines. November 2015. Available at: http://www.ema.europa.eu/docs/en_GB/document_library/Referrals_document/HPV_vaccines_20/Opinion_provided_by_Committee_for_Medicinal_Products_for_Human_Use/WC500197129.pdf

with findings from the UK's Medicine and Healthcare Regulatory Agency (MHRA), concluded that available evidence does not support a causal link between the vaccine and either of these two conditions.

Vaccine storage

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

Effectiveness cannot be guaranteed for vaccines if they have not 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, available at: https://www.gov.uk/government/publications/protocol-for-ordering-storing-and-handling-vaccines

Vaccine administration

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.

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 patient's size and weight. For individuals who have a bleeding disorder, the vaccine should be given by deep subcutaneous injection to reduce the risk of bleeding.

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 accidently expelling some of the vaccine and therefore not giving the patient the full dose.

Healthcare professionals are encouraged to read the Summary of Product Characteristics (SPC) to ensure accurate reconstitution and delivery of the product.

Vaccine schedule

Individuals 15 years of age and older

Gardasil® should be administered as a 3 dose schedule of 0.5 ml.

Due to the flexibility in the Gardasil® Summary of Product Characteristics (SPC), variable spacing options for the three doses are possible. This should enable the administration of subsequent doses to be aligned with recommended SSHS re-attendance in order to avoid the need for additional visits for vaccination only.

In a 3 dose schedule, the second dose should be administered at least 1 month after the first dose and the third dose should be administered at least 3 months after the second dose. All three doses should ideally be given within one year; however a 24 month period is clinically acceptable.

Whenever possible, immunisations for all individuals should follow the recommended 0, 1, 4-6 month schedule. There is no clinical data on whether the interval between doses two and three can be reduced below three months. 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 time-frame, then a third dose can be given at least one month after the second dose.

Any eligible patient that started, but did not complete the schedule before reaching the age of 46 years, should complete the vaccination course

Individuals under 15 years of age

Gardasil® can be administered as a 2 dose schedule of 0.5ml with the second dose being given at least six to 24 months after the first dose.

As long as the first dose was received before the age of 15 years the two dose schedule can be followed. If the course is interrupted, it should be resumed but not repeated, even if more than 24 months have elapsed since the first dose. For example, if first dose given aged 14 years but patient does not re-present in clinic until aged 17 years, only one further dose need be given.

Gardasil® received licensing approval from the European Medicines Agency (EMA) for a two-dose schedule in adolescents in 2014. The two-dose schedule for Gardasil® is licensed for individuals aged nine up to and including 13 years of age. JCVI has

agreed, however, to recommend a two-dose schedule up to, and including, 14 years of age for Gardasil®. The WHO's Strategic Advisory Group of Experts (SAGE) on immunisation also recently reviewed the evidence on HPV immunisation schedules. Following their review, SAGE also recommended a two-dose schedule before the age of 15 years.

Booster doses

Current studies suggest that protection is maintained for at least 10 years although protection is expected to last longer. Long term follow up studies are currently in place to evaluate this and will determine the need for any subsequent boosters.

Contraindications

There are very few individuals who cannot receive the HPV vaccine. Where there is doubt, instead of withholding immunisation, 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.

Gardasil® should not be administered to those who have had:

1. a confirmed anaphylactic reaction to a previous dose of the vaccine OR
2. a confirmed anaphylactic reaction to any constituent or excipient of the vaccine

For the composition and full list of excipients of the vaccine, please refer to the manufacturer's Summary of Product Characteristics (SPC).

Minor illnesses without fever or systemic upset are not valid reasons to postpone immunisation. If an individual is acutely unwell, immunisation may be postponed until they have fully recovered. This is to avoid confusing the differential diagnosis of any acute illness by wrongly attributing any signs or symptoms to any possible adverse effects of the vaccine.

Reporting of adverse reactions

The most common adverse reactions observed are injection-site reactions. These include mild to moderate short-lasting pain at the injection site, immediate localised stinging sensation and redness 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.

For a detailed list of adverse reactions 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.

Any suspected side effects following administration should be reported to the Yellow Card Scheme https://yellowcard.mhra.gov.uk/. Chapter Nine of the Green Book gives detailed guidance on reporting reactions to vaccines. Additionally, Chapter Eight of the Green Book provides detailed advice on managing adverse reactions following immunisation.

Immunosuppression and HIV infection

Eligible MSM with human immunodeficiency virus (HIV) infection should be given HPV vaccine regardless of CD4 count, antiretroviral therapy use or viral load. Evidence suggests individuals with HIV infection are at increased risk of acquiring HPV and persistent infection, as well as frequent carriage of multiple HPV types and increased risk of HPV-related rapidly progressive malignancies[17].

There are limited data on 3 dose schedules in HIV infected populations; however HPV vaccines are known to be safe and immunogenic when given to individuals infected with HIV with no adverse impact on CD4 cell counts or viral load observed.

There is no data to support giving fewer than 3 doses among HIV-infected individuals, therefore only a 3-dose schedule should be offered to individuals in the eligible cohort who are known to be HIV-infected. The immune response to this vaccination and its effectiveness may be less than that observed among those who are not infected with HIV.

Gardasil® and individuals with a yeast allergy

Yeast allergy is not a contraindication to the HPV vaccine. Although Gardasil® is grown in yeast cells, the final vaccine product does not contain any yeast.

Gardasil® vaccine composition

Gardasil® does not contain the preservative thiomersal or porcine gelatine which is used in some live vaccines as a stabiliser. For a full list of excipients (other substances

[17] British HIV Association (BHIVA) guidelines on the use of vaccines in HIV-positive adults 2015, Chapter 9 HUMAN PAPILLOMA VIRUS Available at: http://www.bhiva.org/documents/Guidelines/Vaccination/2015-Vaccination-Guidelines.pdf

contained in the vaccine besides the HPV antigens), healthcare professionals should consult the manufacturer's Summary of Product Characteristics (SPC).

Concomitant administration with other vaccines

Gardasil® is an inactivated vaccine and will not be affected by, or interfere with other inactivated or live vaccines given at the same time as or at any interval from each other.

Where two or more injections need to be administered at the same time, they should be given at separate sites, preferably in a different limb. If more than one injection is to be given in the same limb, they should be administered at least 2.5cm apart. The site at which each vaccine was given should be noted in the individual's health records.

Clinics/clinicians should take the opportunity to check (and correctly code) patients' hepatitis B virus (HBV) vaccination status. 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[18]. Recording of both HBV immunity and HBV vaccine delivery by clinician coding is also suboptimal. The UK's risk-based vaccination policy for HBV includes MSM and maintaining high vaccine coverage in MSM is important to avoid outbreaks of HBV infection.

For more information on hepatitis B immunisation, please see;
Public Health England. Immunisation against infectious diseases: Hepatitis B. Chapter 18. Available at: https://www.gov.uk/government/publications/hepatitis-b-the-green-book-chapter-18

British Association for Sexual Health and HIV (BASHH). National Guidelines for the Management of the Viral Hepatitides 2017 interim update. Available at: https://www.bashhguidelines.org/current-guidelines/viral-hepatitis/download-the-full-guideline/?show=1257

What to do if the vaccine course is interrupted or an individual misses a scheduled dose

If the vaccine course is interrupted, it should be resumed but not repeated, ideally allowing the appropriate interval between the remaining doses. Individuals should be advised that although they will ultimately be protected if they receive the vaccine over a

[18] National Institute for Health and Care Excellence. Baseline real-time monitoring report for uptake of Hepatitis B screening and vaccination in at-risk groups attending the sexual health service. March 2016 Available at: https://www.nice.org.uk/sharedlearning/improving-the-uptake-of-hepatitis-b-screening-and-vaccination-in-at-risk-groups-attending-the-sexual-health-service

longer period of time, they may remain susceptible to HPV infection prior to completing the course.

What to do if an individual following the 3 dose schedule has received their vaccine doses at less than the recommended interval

Where vaccines have been given at less than the recommended interval, the dose should be repeated once the recommended time period has elapsed and at least four weeks from the last dose given. Patients should be advised this may lead to an increased risk of local reaction.

What to do if an individual following the 2 dose schedule has received their vaccine doses at less than the recommended six month interval

Two doses of Gardasil® given less than six months apart should not be considered adequate to provide long-term protection and a third dose should be given according to the guidance on the 3 dose schedule above.

What to do if less than the recommended dose of vaccine is inadvertently administered

In the event that Gardasil® vaccine is administered at less than the recommended 0.5 ml dose, the vaccination will need to be repeated because the dose that the individual received may not be sufficient to evoke a full immune response. Where possible, the dose should be repeated on the same day or as soon as possible after.

Useful Links

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

JCVI statement on HPV vaccination of men who have sex with men https://www.gov.uk/government/publications/jcvi-statement-on-hpv-vaccination-of-men-who-have-sex-with-men

Public Health England. Immunisation against infectious diseases: Human papillomavirus (HPV) 18a. https://www.gov.uk/government/publications/human-papillomavirus-hpv-the-green-book-chapter-18a

Operational guidance

Vaccine supply and ordering

Gardasil® for the HPV MSM programme should be ordered via the ImmForm website (www.immform.dh.gov.uk). It is then distributed by Movianto UK (Tel: 01234 248631).

There are separate order lines for the MSM and girls HPV programmes on Immform. The correct one must be used to order vaccine volumes for each programme, even where an ImmForm account holder is ordering for both.

Vaccines for use outside of the national programme recommendations (see page 6 Eligibility section) should be ordered from the manufacturers or pharmaceutical wholesaler.

Further information about ImmForm, including registration, is available from the ImmForm helpdesk at helpdesk@immform.org.uk or Tel: 0844 376 0040.

Vaccine stock management

Please ensure sufficient fridge space is available for the vaccines. A maximum of two to four weeks of stock is recommended at any one time. A review of available fridge space is recommended to ensure adequate storage capacity before commencing this HPV vaccine programme.

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.

Any cold chain failures or other stock incidents must be documented and recorded through the ImmForm website on the Stock Incident page found in the Vaccine Supply section.

Patient Group Direction (PGD)

PHE have provided a national Patient Group Direction (PGD) template for the HPV MSM programme. It is available at www.gov.uk/government/collections/immunisation-patient-group-direction-pgd.

PHE immunisation PGD templates require further authorisation in Section 2 of the PGD document before they can be used. This should be by an appropriate authorising person, relating to the class of person by whom product is to be supplied, in accordance with the Human Medicines Regulations 2012 (HMR). This may be a clinical governance or patient safety lead, who has designated responsibility for signing PGDs on behalf of the authorising body. The PGD is not legal or valid without signed authorisation in accordance with HMR 2012 schedule 16 part 2.

Adoption and governance of the use of PHE PGD is the responsibility of the authorising organisation and provider.

Provider organisations, health professionals and immunisation practitioners should check they are working to the current PGD version and only work to documents authorised in accordance with HMR 2012 schedule 16 part 2.

The PGD should be used with reference to the Green Book and Summary of Product Characteristics for the vaccine.

Vaccine coverage data collection

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.

Vaccine uptake will be monitored primarily via two existing surveillance and reporting systems, namely the GUMCAD STI Surveillance System and the HIV and AIDS reporting system (HARS).

1. GUMCAD collection will use three existing SHHAPT codes:

- W1: HPV vaccination: 1st dose
- W2: HPV vaccination: 2nd dose
- W3: HPV vaccination: 3rd dose

and two new SHHAPT codes*:

- W4: HPV vaccine offered and declined
- W5: HPV vaccine not offered, previously received in full.

* codes W4 and W5 are pending approval from NHS Digital in 2018/19

2. 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.

Vaccination records for each eligible MSM attending a GUM clinic should be coded on GUMCAD. 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 GUMCAD (i.e. SHHAPT code H2) then the HPV vaccination records should be entered on both GUMCAD and HARS).

Communications and information for the public and health professionals

An integrated communications strategy has been produced by PHE for the HPV MSM programme. The strategy provides communications colleagues in partner organisations with information and resources to assist with the delivery of the programme. Partners include the Department of Health and Social Care (DHSC), NHS England and national HPV, LGBT and cancer charities and organisations.

Recommended training resources

A training slide set for health care professionals is available at: https://publichealthengland-immunisati.box.com/s/1icndho89hf81qfucjvsuw1jji1s0c84g (link available on PHE HPV for MSM programme page). This provides a detailed overview of HPV infection, the HPV MSM programme and information about the HPV vaccination. Trainers can adapt the slide set according to the needs of their audience, the time available and level of detail required. It is recommended that training be offered not only to those administering the vaccine but also to those advising on it and those booking appointments.

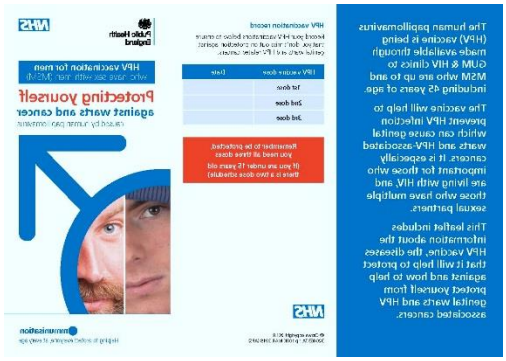
Free posters, leaflets and record cards

An NHS branded information leaflet, poster and record card have been produced by PHE to support the programme. These can be viewed and downloaded at: https://www.gov.uk/government/publications/hpv-vaccination-for-msm-posters-and-leaflets

However it is <u>not</u> recommended that you print them yourself: hard copies are available to order free of charge from the DH/ PHE Publications Orderline Telephone number 0300 123 1002

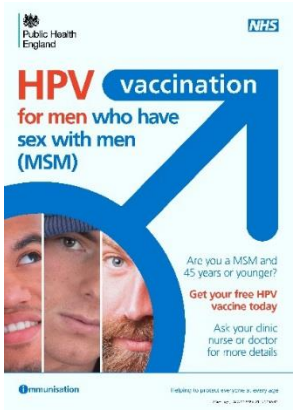
Orders are also dispatched free of charge and usually arrive within 3-5 working days. Register your clinic at the order line website and then you can use the product code to find the publication you need.

HPV for MSM leaflet - Product code 3204637A



Clinics are encouraged to supply this leaflet to patients when they are opportunistically offered vaccination at existing clinic appointments.

HPV for MSM programme poster - Product code: 3204637B



Clinics are encouraged to order this poster and display it in communal waiting areas, windows and treatment or consultation rooms to show to patients when visiting the clinic or department for existing clinic appointments.

HPV for MSM programme record card - Product code: 3202636B

The vaccination record card can be found and viewed here: https://www.gov.uk/government/publications/hpv-vaccination-pilot-for-men-who-have-sex-with-men-msm

Credit card sized hard copies are available to order (in packs of 30) from the DH/ PHE Publications Orderline https://www.orderline.dh.gov.uk/ecom_dh/public/home.jsf