Public Health England

PHE publications gateway number: GW-1139

Human papillomavirus vaccine for men who have sex with men Patient Group Direction (PGD)

This PGD is for the administration of human papillomavirus (HPV) vaccine [Types 6, 11, 16, 18] (recombinant, adsorbed) to men who have sex with men (MSM), who attend Specialist Sexual Health Services (SSHS) and/or HIV clinics.

This PGD is for the administration of HPV vaccine by registered healthcare practitioners identified in Section 3, subject to any limitations to authorisation detailed in Section 2.

Reference no:	HPV (MSM) PGD
Version no:	v02.00
Valid from:	1 April 2020
Review date:	30 September 2021
Expiry date:	31 March 2022

Public Health England has developed this PGD to facilitate the delivery of publicly-funded immunisations in line with national recommendations.

Those using this PGD must ensure that it is organisationally authorised and signed in Section 2 by an appropriate authorising person, relating to the class of person by whom the product is to be supplied, in accordance with Human Medicines Regulations 2012 (HMR2012)[1]. **The PGD is not legal or valid without signed authorisation in accordance with HMR2012 Schedule 16 Part 2.**

Authorising organisations must not alter, amend or add to the clinical content of this document (sections 4, 5 and 6); such action will invalidate the clinical sign-off with which it is provided. In addition authorising organisations must not alter section 3 'Characteristics of staff'. Only sections 2 and 7 can be amended within the designated editable fields provided.

Operation of this PGD is the responsibility of commissioners and service providers. The final authorised copy of this PGD should be kept by the authorising organisation completing Section 2 for 8 years after the PGD expires if the PGD relates to adults only and for 25 years after the PGD expires if the PGD relates to children only, or adults and children. Provider organisations adopting authorised versions of this PGD should also retain copies for the periods specified above.

Individual practitioners must be authorised by name, under the current version of this PGD before working according to it.

Practitioners and organisations must check that they are using the current version of the PGD. Amendments may become necessary prior to the published expiry date. Current versions of PHE PGD templates for authorisation can be found from: https://www.gov.uk/government/collections/immunisation-patient-group-direction-pgd

Any concerns regarding the content of this PGD should be addressed to: immunisation@phe.gov.uk

[1] This includes any relevant amendments to legislation (such as 2013 No.235, 2015 No.178 and 2015 No.323).

Change history

Version number	Change details	Date
V01.00	New PHE PGD template	16 March 2018
V02.00	PHE HPV (MSM) PGD amended to: • allow completion of an HPV vaccine course after the 46th birthday • mention those who may have a similar risk profile for HPV infection as MSM, who should be considered for HPV vaccination on a case by case basis and not under this PGD • include rewording, layout and formatting changes for clarity and consistency with other PHE PGDs	6 February 2020

1. PGD development

This PGD has been developed by the following health professionals on behalf of Public Health England:

Developed by:	Name	Signature	Date
Pharmacist (Lead Author)	Elizabeth Graham Lead Pharmacist Immunisation and Countermeasures, PHE		07/02/2020
Doctor	Michael Edelstein Consultant Epidemiologist, Immunisation and Countermeasures, PHE		27/2/2020
Registered Nurse (Chair of Expert Panel)	David Green Nurse Consultant Immunisation and Countermeasures, PHE		11/02/2020

This PGD has been peer reviewed by the PHE Immunisations PGD Expert Panel in accordance with PHE PGD Policy. It has been ratified by the PHE Medicines Management Group and the PHE Quality and Clinical Governance Delivery Board.

Expert Panel

Name	Designation
Nicholas Aigbogun	Consultant in Communicable Disease Control, Public Health England,
Ed Gardner	Advanced Paramedic Practitioner/Emergency Care Practitioner, Medicines Manager, Proactive Care Lead
Michelle Jones	Senior Medicines Optimisation Pharmacist, NHS Bristol North Somerset & South Gloucestershire CCG
Jacqueline Lamberty	Lead Pharmacist Medicines Management Services, Public Health England
Vanessa MacGregor	Consultant in Communicable Disease Control, Public Health England, East Midlands Health Protection Team
Alison Mackenzie	Consultant in Public Health Medicine, Screening and Immunisation Lead, Public Health England (South West) / NHS England and NHS Improvement South (South West)
Gill Marsh	Senior Screening and Immunisation Manager, Public Health England / NHS England and NHS Improvement (North West)
Lesley McFarlane	Screening and Immunisation Co-ordinator, Public Health England / NHS England and NHS Improvement (Central Midlands)
Tushar Shah	Pharmacy Advisor, NHS England and NHS Improvement (London Region)
Sharon Webb	Programme Manager / Registered Midwife, NHS Infectious Diseases in Pregnancy Screening Programme, Public Health England

2. Organisational authorisations

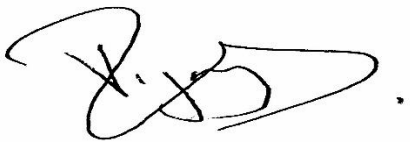
The PGD is not legally valid until it has had the relevant organisational authorisation.

It is the responsibility of the organisation that has legal authority to authorise the PGD, to ensure that all legal and governance requirements are met. The authorising body accepts governance responsibility for the appropriate use of the PGD.

NHS England – West Midlands authorises this PGD for use by the services or providers listed below:

Authorised for use by the following organisations and/or services
NHS England – West Midlands commissioned immunisation services provided by GP Practices within Arden, Herefordshire, Worcestershire, Birmingham, Solihull and the Black Country
Limitations to authorisation

Organisational approval (legal requirement)			
Role	**Name**	**Sign**	**Date**
Director of Nursing Leadership and Quality, NHS England and Improvement	**Manjit Darby**		**12.03.2020**

Additional signatories according to locally agreed policy			
Role	**Name**	**Sign**	**Date**
Deputy Medical Director Commissioning (Primary Care Strategy and Public Health) NHS England and NHS Improvement- Midlands	**Vijay Rawal**		**12.03.2020**

Local enquiries regarding the use of this PGD may be directed to…….

Section 7 provides a practitioner authorisation sheet. Individual practitioners must be authorised by name to work to this PGD. Alternative practitioner authorisation sheets may be

used where appropriate in accordance with local policy but this should be an individual agreement or a multiple practitioner authorisation sheet as included at the end of this PGD.

3. Characteristics of staff

Qualifications and professional registration	Registered professional with one of the following bodies: • nurses and midwives currently registered with the Nursing and Midwifery Council (NMC) • pharmacists currently registered with the General Pharmaceutical Council (GPhC) (Note: This PGD is not relevant to privately provided community pharmacy services) • paramedics and physiotherapists currently registered with the Health and Care Professions Council (HCPC) The practitioners above must also fulfil the Additional requirements detailed below. Check Section 2 Limitations to authorisation to confirm whether all practitioners listed above have organisational authorisation to work under this PGD.
Additional requirements	Additionally practitioners: • must be authorised by name as an approved practitioner under the current terms of this PGD before working to it • must have undertaken appropriate training for working under PGDs for supply/administration of medicines • must be competent in the use of PGDs (see NICE Competency framework for health professionals using PGDs) • must be familiar with the vaccine product and alert to changes in the Summary of Product Characteristics (SPC), Immunisation Against Infectious Disease (the 'Green Book'), and national and local immunisation programmes • must have undertaken training appropriate to this PGD as required by local policy and in line with the National Minimum Standards and Core Curriculum for Immunisation Training • must be competent to undertake immunisation and to discuss issues related to immunisation • must be competent in the handling and storage of vaccines, and management of the cold chain • must be competent in the recognition and management of anaphylaxis • must have access to the PGD and associated online resources • should fulfil any additional requirements defined by local policy **The individual practitioner must be authorised by name, under the current version of this PGD before working according to it.**
Continued training requirements	Practitioners must ensure they are up to date with relevant issues and clinical skills relating to immunisation and management of anaphylaxis, with evidence of appropriate Continued Professional Development (CPD). Practitioners should be constantly alert to any subsequent recommendations from Public Health England and/or NHS England and other sources of medicines information. Note: The most current national recommendations should be followed but a Patient Specific Direction (PSD) may be required to administer the vaccine in line with updated recommendations that are outside the criteria specified in this PGD.

4. Clinical condition or situation to which this PGD applies

Clinical condition or situation to which this PGD applies	Indicated for the active immunisation of individuals aged 45 years and under[2] who are MSM and who attend SSHS and/or HIV clinics, for the prevention of human papillomavirus (types 6, 11, 16, 18) infection in accordance with the recommendations given in Chapter 18a of Immunisation Against Infectious Disease: the 'Green Book'.
Criteria for inclusion	Individuals who: • are MSM aged 45 years and under[2] who attend a SSHS and/or HIV clinic and have not previously completed a course of HPV vaccination
Criteria for exclusion[3]	Individuals for whom no valid consent has been received (see DH Reference guide to consent for examination or treatment). Individuals who: • are females • are aged 46 years and over, except those who have received a partial course of HPV vaccination[2] • are under 9 years of age • are men who do not have sex with men • have had a confirmed anaphylactic reaction to a previous dose of HPV vaccine or to any component of the vaccine • are suffering from acute severe febrile illness (the presence of a minor infection is not a contraindication for immunisation)
Cautions including any relevant action to be taken	Syncope (fainting) can occur following, or even before, any vaccination especially in adolescents as a psychogenic response to the needle injection. This can be accompanied by several neurological signs such as transient visual disturbance, paraesthesia and tonic-clonic limb movements during recovery. It is important that procedures are in place to avoid injury from faints. The immunogenicity of the vaccine could be reduced in immunosuppressed subjects. Vaccination should proceed in accordance with the national recommendations. However, re-immunisation may need to be considered. Seek medical advice as appropriate.
Action to be taken if the patient is excluded Continued over page	If female, this PGD does not apply. Refer to the PHE HPV PGD for vaccination in accordance with the national HPV programme if appropriate. Individuals aged 46 years and over are not eligible to commence a course of HPV vaccination under the NHS commissioned service. However, courses commenced before 46 years of age as part of the pilot or national programme can be completed under this PGD. JCVI has advised that there should no longer be a lower age limit for the HPV immunisation of MSM. However HPV vaccine administration to those under 9 years of age is off-label and is not covered by this PGD so a PSD would be required.

[2] Anyone eligible for the HPV vaccination programme for MSM that started, but did not complete the schedule before reaching the age of 46 years, should complete the vaccination course, providing the first dose was given as part of the pilot or national programme

[3] Exclusion under this PGD does not necessarily mean the medication is contraindicated, but it would be outside its remit and another form of authorisation will be required

Action to be taken if the patient is excluded (continued)	Vaccination of individuals who are not MSM is not covered by this PGD. Vaccination should be offered to individuals attending SSHS or HIV clinics who have a similar risk profile to that seen in the MSM population. This includes some transgender individuals, sex workers, and those living with HIV infection. These individuals should be assessed on a case-by-case basis and a PSD would be required. Vaccine centrally procured for the HPV MSM programme should not be used for this purpose. If HPV vaccine is indicated but use is outside of the HPV MSM programme, vaccines should be purchased directly from the manufacturer or pharmaceutical wholesaler. If a confirmed anaphylactic reaction has been experienced after a previous dose of HPV vaccine specialist advice should be sought. Individuals suffering acute severe febrile illness should postpone immunisation until they have recovered; immunisers should advise when the individual can be vaccinated and ensure another appointment is arranged. Seek appropriate advice from the local Screening and Immunisation Team, local Health Protection Team or the individual's clinician as required. The risk to the individual of not being immunised must be taken into account. Document the reason for exclusion and any action taken in the individual's clinical records. Inform or refer to the patient's clinician as appropriate.
Action to be taken if the patient or carer declines treatment	Informed consent, from the individual or a person legally able to act on the person's behalf, must be obtained for each administration. Advise the individual about the protective effects of the vaccine, the risks of infection and potential complications. Document advice given and the decision reached. Inform or refer to the patient's clinician as appropriate.
Arrangements for referral for medical advice	As per local policy

5. Description of treatment

Name, strength & formulation of drug	Human papillomavirus vaccine [types 6, 11, 16, 18] (recombinant, adsorbed): • Gardasil®, suspension for injection in a prefilled syringe or vial Note: This PGD does not cover the administration of the Human Papillomavirus 9-valent Vaccine, Gardasil® 9.
Legal category	Prescription only medicine (POM)
Black triangle▼	No
Off-label use	Administration of a two-dose schedule to individuals aged from 14 years of age to under 15 years of age is off-label but is in accordance with PHE recommendations and Chapter 18a of the 'Green Book'. Administration of Gardasil® by deep subcutaneous injection to patients with a bleeding disorder is off-label administration but is in line with advice in Chapter 4 and Chapter 18a of the 'Green Book'. Vaccine should be stored according to the conditions detailed in the Storage section below. However, in the event of an inadvertent or unavoidable deviation of these conditions refer to PHE Vaccine Incident Guidance. Where vaccine is assessed in accordance with these guidelines as appropriate for continued use this would constitute off-label administration under this PGD. Where a vaccine is recommended off-label consider, as part of the consent process, informing the individual that the vaccine is being offered in accordance with national guidance but that this is outside the product licence.
Route / method of administration	Administer by intramuscular injection. The preferred site is the deltoid region of the upper arm. When administering at the same time as other vaccines care should be taken to ensure that the appropriate route of injection is used for all the vaccinations. The vaccines should be given at separate sites, preferably in different 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 records. For individuals with a bleeding disorder, vaccines normally given by an intramuscular route should be given in accordance with the recommendations in the 'Green Book' Chapter 4). The vaccine's normal appearance is a white cloudy liquid which may settle to a clear liquid and white precipitate. Shake well before use. The vaccine should be visually inspected for particulate matter and discoloration prior to administration. In the event of any foreign particulate matter and/or variation of physical aspect being observed, do not administer the vaccine. The vaccine's SPC provides further guidance on administration and is available from the electronic Medicines Compendium website: www.medicines.org.uk

Dose and frequency of administration	Single 0.5ml dose per administration. Vaccination should be aligned with other routine SSHS or HIV clinic re-attendance where possible to reduce additional visits for vaccination. The vaccine schedule is determined by the age of the individual when they receive their first dose of HPV vaccine. **MSM aged 15 years to 45 years at time of first dose and MSM aged 45 years and under who are immunosuppressed or HIV positive** Administer a course of three doses: • first dose of 0.5ml of HPV vaccine, then • second dose of 0.5ml at least one month after the first dose, then • a third dose of 0.5ml at least three months after the second dose All three doses should ideally be given within a 12-month period. The programme will aim to deliver three doses within 12 months where possible, using existing appointments where possible to limit additional appointments, and up to 24 months where this is not possible. If the course is interrupted, it should be resumed but not repeated, ideally allowing the appropriate interval between the remaining doses. Whenever possible, immunisations for all individuals on the three dose schedule 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. **Immunocompetent MSM aged under 15 years at time of first dose** Administer a course of two doses to MSM aged under 15 years at the time of the first dose, with a 6-month to 24-month interval between doses. If the course is interrupted it should be resumed but not repeated, even if more than 24 months have elapsed since the first dose. Where two doses have been administered less than 6 months apart a third dose should be given at least 3 months after the second dose.
Duration of treatment	A two or three dose course (see Dose and Frequency section above)
Quantity to be supplied / administered	Single 0.5ml dose per administration.
Supplies	Centrally purchased vaccines for the HPV MSM programme can only be ordered via ImmForm. Vaccines for use for the HPV MSM programme are provided free of charge. Protocols for the ordering, storage and handling of vaccines should be followed to prevent vaccine wastage (see Green Book Chapter 3).

Storage	Store at between +2°C to +8°C. Store in original packaging in order to protect from light. Do not freeze. Gardasil® should be administered as soon as possible after being removed from the cold chain. Data from stability studies demonstrate that the vaccine components are stable for 72 hours when stored at temperatures from +8°C to +42°C. These data are intended to guide healthcare professionals in case of temporary temperature excursion only. This PGD may be used to administer vaccine that has not exceeded these stability data parameters. In the event of an inadvertent or unavoidable deviation of these conditions vaccine that has been stored outside the conditions stated above should be quarantined and risk assessed for suitability of continued off-label use or appropriate disposal, refer to PHE Vaccine Incident Guidance.
Disposal	Equipment used for immunisation, including used vials, ampoules, or discharged vaccines in a syringe or applicator, should be disposed of safely in a UN-approved puncture-resistant 'sharps' box, according to local authority regulations and guidance in the technical memorandum 07-01: Safe management of healthcare waste (Department of Health, 2013).
Drug interactions	Immunological response may be diminished in those receiving immunosuppressive treatment. Vaccination is recommended even if the antibody response may be limited. May be given at the same time as other vaccines. A trend of lower anti-HPV titres has been observed when Gardasil® is administered concomitantly with dTaP, dT/IPV and dTaP/IPV vaccines, though the clinical significance of this observation is unclear. A detailed list of drug interactions is available in the SPC, which is available from the electronic Medicines Compendium website: www.medicines.org.uk
Identification & management of adverse reactions	Local reactions following vaccination are very common such as pain, swelling or redness at the injection site. Mild side effects such as headache, nausea, pain in extremity, fever, injection-site haematoma and injection-site pruritus are reported as common. Other adverse events have been reported in post-marketing surveillance but the frequency of these is not known. Hypersensitivity reactions and anaphylaxis can occur but are very rare. A detailed list of adverse reactions is available in the SPC which is available from the electronic Medicines Compendium website: www.medicines.org.uk
Reporting procedure of adverse reactions Continued over page	Healthcare professionals and patients/carers are encouraged to report suspected adverse reactions to the Medicines and Healthcare products Regulatory Agency (MHRA) using the Yellow Card reporting scheme on: http://yellowcard.mhra.gov.uk

Reporting procedure of adverse reactions (continued)	Any adverse reaction to a vaccine should be documented in the individual's record and the individual's clinician should be informed.
Written information to be given to patient or carer	Offer marketing authorisation holder's patient information leaflet (PIL) provided with the vaccine.
Patient advice / follow up treatment	Inform the individual of possible side effects and their management. The individual should be advised to seek medical advice in the event of an adverse reaction. Advise individual when the next dose is due. If administration is postponed advise the individual when to return for vaccination. Advise that individuals should continue to take appropriate precautions to protect themselves from sexually transmitted diseases. Advise individuals that using a condom during sex can help to prevent an HPV infection. However, condoms don't offer complete protection. HPV can be present all over the area around the genitals and anus, and is spread through skin-to-skin contact of the genital area.
Special considerations / additional information	Ensure there is immediate access to adrenaline (epinephrine) 1 in 1000 injection and access to a telephone at the time of vaccination. HPV vaccination is for prophylaxis against future HPV infection. It will not treat pre-existing HPV infection. Gardasil® vaccine will protect against HPV types 6, 11, 16 and 18 with limited cross protection to other HPV types. There may be considerable benefit in offering the HPV vaccine to individuals attending SSHS or HIV clinics who were not eligible for the routine HPV programme and are deemed to have a similar risk profile to that seen in the MSM population. This includes some transgender individuals, sex workers, and men and women living with HIV infection. Those whose risk of acquiring HPV is considered equivalent to the risk of MSM eligible for the HPV vaccine, should be offered vaccination. However, this PGD does not cover the vaccination of these individuals so a PSD may be required. For those who have previously completed a course of HPV vaccination as part of the school HPV programme, no further doses need be given. There is no data on fewer than 3 doses of HPV vaccine 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. For individuals who started but did not complete an HPV vaccine schedule with an HPV vaccine other than Gardasil®, the course can be completed with Gardasil®, the vaccine currently in use in the UK HPV programme for MSM.
Records continued over page	Record: • that valid informed consent was given • name of individual, address and date of birth • name of immuniser • name and brand of vaccine • date of administration

Records (continued)	• dose, form and route of administration of vaccine • quantity administered • batch number and expiry date • anatomical site of vaccination • advice given, including advice given if excluded or declines immunisation • details of any adverse drug reactions and actions taken • supplied via PGD Records should be signed and dated (or a password-controlled immuniser's record on e-records). All records should be clear, legible and contemporaneous. Vaccination records for each eligible MSM should be coded on GUMCADv2 and/or HARS in accordance with the service specification. A record of all individuals receiving treatment under this PGD should also be kept for audit purposes in accordance with local policy.

6. Key references

Key references	**Human papillomavirus (HPV) vaccine** • Immunisation Against Infectious Disease: The Green Book Chapter 18a, 12 July 2019. https://www.gov.uk/government/collections/immunisation-against-infectious-disease-the-green-book • Summary of Product Characteristic for Gardasil®, MSD Ltd. 7 May 2019. http://www.medicines.org.uk/emc/medicine/19016 • Service specification for human papillomavirus programme for men who have sex with men (HPV-MSM). https://www.england.nhs.uk/commissioning/pub-hlth-res/ **General** • Health Technical Memorandum 07-01: Safe Management of Healthcare Waste. Department of Health 20 March 2013. https://www.gov.uk/government/publications/guidance-on-the-safe-management-of-healthcare-waste • National Minimum Standards and Core Curriculum for Immunisation Training. Published February 2018. https://www.gov.uk/government/publications/national-minimum-standards-and-core-curriculum-for-immunisation-training-for-registered-healthcare-practitioners • NICE Medicines Practice Guideline 2 (MPG2): Patient Group Directions. Published March 2017. https://www.nice.org.uk/guidance/mpg2 • NICE MPG2 Patient group directions: competency framework for health professionals using patient group directions. Updated March 2017. https://www.nice.org.uk/guidance/mpg2/resources • PHE Immunisation Collection https://www.gov.uk/government/collections/immunisation • PHE Vaccine Incident Guidance https://www.gov.uk/government/publications/vaccine-incident-guidance-responding-to-vaccine-errors • Reference guide to consent for examination or treatment, Department of Health, published 4 August 2009. https://www.gov.uk/government/publications/reference-guide-to-consent-for-examination-or-treatment-second-edition

7. Practitioner authorisation sheet

HPV (MSM) PGD v02.00 Valid from: 01/04/2020 Expiry: 31/03/2022

Before signing this PGD, check that the document has had the necessary authorisations in section two. Without these, this PGD is not lawfully valid.

Practitioner

By signing this PGD you are indicating that you agree to its contents and that you will work within it.

PGDs do not remove inherent professional obligations or accountability.

It is the responsibility of each professional to practise only within the bounds of their own competence and professional code of conduct.

I confirm that I have read and understood the content of this PGD and that I am willing and competent to work to it within my professional code of conduct.			
Name	Designation	Signature	Date

Authorising manager

I confirm that the practitioners named above have declared themselves suitably trained and competent to work under this PGD. I give authorisation on behalf of **insert name of organisation** for the above named health care professionals who have signed the PGD to work under it.			
Name	Designation	Signature	Date

Note to authorising manager

Score through unused rows in the list of practitioners to prevent practitioner additions post managerial authorisation.

This authorisation sheet should be retained to serve as a record of those practitioners authorised to work under this PGD.