UK Health Security Agency

Publications gateway number: GOV-14793

Human papillomavirus vaccine for gay, bisexual, and men who have sex with men (GBMSM) Patient Group Direction (PGD)

This PGD is for the administration of human papillomavirus (HPV) vaccine to GBMSM, 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 (GBMSM) PGD
Version no:	v4.00a
Valid from:	1 September 2023
Review date:	1 April 2025
Expiry date:	1 September 2025

The UK Health Security Agency (UKHSA) has developed this PGD to facilitate the delivery of publicly funded immunisation in England 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 UKHSA PGD templates for authorisation can be found from: Immunisation patient group direction (PGD) templates

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

Enquiries relating to the availability of organisationally authorised PGDs and subsequent versions of this PGD should be directed to: england.swvast@nhs.net

[1] This includes any relevant amendments to legislation.

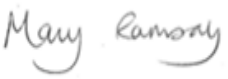
Change history

Version number	Change details	Date
V1.00	New PHE PGD template	16 March 2018
V2.00	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
V3.00	HPV (MSM) PGD amended to: • include the nine valent vaccine (Gardasil® 9) • update dose and frequency section to reflect updated recommendations that, from 1 April 2022, those commencing vaccination from 15 years of age should commence a 2-dose schedule with a minimum 6-month interval • refer to Chapter 2 of the Green Book for further information on consent • update organisation from PHE to the UKHSA • include minor rewording, layout and formatting changes for clarity and consistency with other UKHSA PGDs	4 March 2022

V4.00	HPV (GBMSM) PGD amended to: • update MSM to GBMSM throughout the document as per updated Green Book, Chapter 18A • update off-label and dose and frequency sections with one dose schedule • add one dose schedule for under 25 years who are immunocompetent and are not HIV positive in dose and frequency • add to exclusion section individuals who are immunocompetent and are not HIV positive under 25 years and have received a dose of HPV • update the dose and frequency for 2 dose as per JCVI recommendations • add use of variable spacing of doses option for 2 or 3 dose schedules and recommendations for individuals reaching age of 46 years in dose and frequency section • remove Gardasil® throughout the document as it has been discontinued and has not been used since July 2022 in the programme • include facilities for management for anaphylaxis statement in cautions section for consistency • add statement for separate order lines for GBMSM and adolescent HPV programmes on ImmForm and ordering supplies for outside programme in the supplies section • add information for HPV vaccination link in written information given to patient or carer • add accessible information in written information section • add advice to be given if fainting occurs in patient advice • update reference section • include minor rewording of standard text, layout and formatting changes for clarity and consistency with organisation change, gateway requirements and other UKHSA PGDs • amend NHS England and NHS Improvement (NHSEI) to NHSE following completion of merger on 1 July 2022	28 June 2023
V4.00a	HPV (GBMSM) PGD amended to: • correct the date on page 4	16 August 2023

1. PGD development

This PGD has been developed by the following health professionals on behalf of the UKHSA:

Developed by:	Name	Signature	Date
Pharmacist (Lead Author)	Suki Hunjunt Lead Pharmacist Immunisation Services, Immunisation and Vaccine Preventable Diseases Division, UKHSA		28 June 2023
Doctor	Mary Ramsay Consultant Epidemiologist, Immunisation and Vaccine Preventable Diseases Division, UKHSA		28 June 2023
Registered Nurse (Chair of Expert Panel)	David Green Nurse Consultant for Immunisation, Immunisation and Vaccine Preventable Diseases Division, UKHSA		28 June 2023

This PGD has been peer reviewed by the UKHSA Immunisations PGD Expert Panel in accordance with the UKHSA PGD Policy. It has been ratified by the UKHSA Medicines Governance Group.

Expert Panel

Nicholas Aigbogun	Consultant in Communicable Disease Control, Yorkshire and Humber Health Protection Team, UKHSA
Gayatri Amrithalingham	Consultant Epidemiologist, Immunisation and Vaccine Preventable Diseases Division, UKHSA
Alison Campbell	Screening and Immunisation Coordinator, Public Health Commissioning NHS England (NHSE) Midlands
Sarah Dermont	Clinical Project Coordinator and Registered Midwife, NHS Infectious Diseases in Pregnancy Screening Programme, NHSE
Rosie Furner	Pharmacist - Medicines Governance, Specialist Pharmacist Services (SPS)
Ed Gardner	Advanced Paramedic Practitioner/Emergency Care Practitioner, Medicines Manager, Proactive Care Lead
Jacqueline Lamberty	Lead Pharmacist, Medicines Governance, UKHSA
Michelle Jones	Principal Medicines Optimisation Pharmacist, Bristol North Somerset and South Gloucestershire Integrated Care Board
Shamez Ladhani	Paediatric Infectious Disease Consultant, UKHSA
Elizabeth Luckett	Senior Screening & Immunisation Manager, NHSE South West
Vanessa MacGregor	Consultant in Communicable Disease Control, East Midlands Health Protection Team, UKHSA
Lesley McFarlane	Lead Immunisation Nurse Specialist Immunisation and Vaccine Preventable Diseases Division, UKHSA
Nicola Philbin	Screening and Immunisation Manager, Vaccination and screening programmes – Public Health Commissioning NHSE Midlands
Vanessa Saliba	CRF Consultant Epidemiologist, UKHSA
Tushar Shah	Lead Pharmacy Advisor, NHSE London

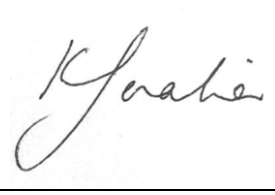
2. Organisational authorisations

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 (South West) authorises this PGD for use by the services or providers listed below:

Authorised for use by the following organisations and/or services
All NHS England commissioned immunisation services within • Bath & North East Somerset, Swindon, and Wiltshire • Bristol, North Somerset, and South Gloucestershire • Cornwall and the Isles of Scilly • Devon • Dorset • Gloucestershire • Somerset
Limitations to authorisation
This patient group direction (PGD) must only be used by the registered healthcare practitioners identified in Section 3 who have been named by their organisation to practice under it. The most recent in-date final version authorised by NHS England (South West) must be used. This PGD includes vaccination of individuals across the national immunisation programme. Users of this PGD should note that where they are commissioned to immunise certain groups this PGD does not constitute permission to offer immunisation beyond the groups they are commissioned to immunise.

Organisational approval (legal requirement)			
Role	**Name**	**Sign**	**Date**
Medical Director, System Improvement and Professional Standards, NHS England (South West)	Dr Kheelna Bavalia MRCGP MSc		**25/08/2023**

Additional signatories according to locally agreed policy			
Role	**Name**	**Sign**	**Date**

Local enquiries regarding the use of this PGD may be directed to england.swvast@nhs.net

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 the UKHSA and/or NHSE 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 GBMSM and who attend SSHS and/or HIV clinics, for the prevention of human papillomavirus infection in accordance with the recommendations given in Chapter 18a of Immunisation Against Infectious Disease: The 'Green Book'.
Criteria for inclusion	Individuals who: • are GBMSM aged 45 years and under[2] who attend a SSHS and/or HIV clinic
Criteria for exclusion[3]	Individuals for whom no valid consent has been received. For further information on consent see Chapter 2 of the Green Book. Individuals who: • are females • are aged less than 25 years who are immunocompetent and are not HIV positive, and have received one dose of HPV vaccine • 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	Facilities for management of anaphylaxis should be available at all vaccination sites (see Chapter 8 of the Green Book) and advice issued by the Resuscitation Council UK. 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 (see Green Book Chapter 7). Seek medical advice as appropriate.
Action to be taken if the patient is excluded Continued over page **Action to be taken if the patient is excluded**	If female, this PGD does not apply. Refer to the UKHSA 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 GBMSM. However, HPV vaccine administration to

[2] Anyone eligible for the HPV vaccination programme for GBMSM 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

(continued)	those under 9 years of age is off-label and is not covered by this PGD so a PSD would be required. Vaccination of individuals who are not GBMSM 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 GBMSM 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 GBMSM programme should not be used for this purpose. If HPV vaccine is indicated but use is outside of the HPV GBMSM 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 or any of its components, specialist advice should be sought. If immunisation is recommended do not administer under this PGD; a PSD will be required. 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 at the earliest opportunity. 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 individual'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 individual'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 the advice given and the decision reached. Inform or refer to the individual's clinician as appropriate.
Arrangements for referral for medical advice	As per local policy

5. Description of treatment

Name, strength and formulation of drug	Human papillomavirus 9-valent vaccine [types 6, 11, 16, 18, 31, 33, 45, 52, 58] (recombinant, adsorbed): • Gardasil® 9, suspension for injection in a pre-filled syringe or vial
Legal category	Prescription only medicine (POM)
Black triangle▼	No
Off-label use	The use of a one-dose schedule of Gardasil® 9 is off-label, however it is in accordance with national recommendations by JCVI and Chapter 18a of the Green Book. Administration of a two-dose course with a 0, 6-24 month schedule differs slightly from the schedules in the SPC, but is in accordance with official recommendations and Chapter 18a of the Green Book. Completion of a HPV vaccine course using Gardasil® 9 when it was not commenced with the same HPV vaccine product is off-label but is in accordance with official recommendations and Chapter 18a of the Green Book. The HPV vaccine SPC states that 'vaccinees should be observed for approximately 15 minutes after vaccine administration'. In line with advice in Chapter 4 of the Green Book, recipients of any vaccine should be observed for immediate adverse drug reactions. There is no evidence to support the practice of keeping individuals under longer observation. 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 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 and method of administration Continued over page **Route and 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. Individuals with bleeding disorders may be vaccinated intramuscularly if, in the opinion of a doctor familiar with the individual's bleeding risk, vaccines or similar small volume intramuscular injections can be administered with reasonable safety by this route. If the individual receives medication/treatment to reduce bleeding, for example treatment for haemophilia, intramuscular vaccination can be scheduled shortly after such medication/treatment is administered. Individuals on stable anticoagulation therapy, including individuals on warfarin who are up to date with their scheduled INR testing and whose latest INR was below the upper threshold of their therapeutic range, can receive intramuscular vaccination. A fine needle (equal to 23 gauge or finer calibre such as 25 gauge) should be used for the vaccination, followed by firm pressure applied to the site (without rubbing) for at least 2 minutes. If in any doubt, consult with the clinician

continued	responsible for prescribing or monitoring the individual's anticoagulant therapy. 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.
Dose and frequency of administration Continued over page **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. **One dose HPV schedule for individuals aged less than 25 years from 1 September 2023** Immunocompetent GBMSM who are not known to be HIV positive, are aged less than 25 years and have not yet received any HPV vaccinations: • one dose (0.5ml) HPV vaccine Individuals who have already received at least one dose of the HPV vaccine before their 25th birthday should be considered to have completed their vaccination course and do not require further doses. **Two dose HPV schedule for individuals aged 25 years and up to and including 45 years** Immunocompetent GBMSM, who are not known to be HIV positive, aged 25 years and up to and including 45 years: Administer a course of two doses with at least a 6-month interval between doses, for instance: • first dose of 0.5ml of HPV vaccine, then • second dose at least 6 months after and ideally within 24 months of the first dose If the course is interrupted it should be resumed but not repeated, even if more than 24 months have elapsed since the first dose. Whenever possible, immunisations for all individuals should follow the recommended 0, 6-24 months schedule, but there is some clinical data that suggests the interval between the two doses can be reduced to five months for Gardasil®9. **Note:** Anyone eligible for the GBMSM HPV vaccination programme who started but did not complete the required schedule before reaching the age of 46 years, should complete the vaccination course, providing the first dose was given as part of the national programme. **Three dose HPV schedule for individuals who are HIV-positive and/or immunosuppressed** GBMSM who are immunosuppressed and/or known to be HIV-positive aged 45 years and under (see the Green Book Chapter 18a and Chapter 7) 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.

continued	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 3-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 timeframe, then a third dose can be given at least one month after the second dose. For the GBMSM programme, variable spacing options for the two or three dose courses are possible. Owing to the opportunistic nature of delivery, a 24-month period for completion of the course is clinically acceptable, providing the minimum interval between doses is respected where 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.
Duration of treatment	A one, two or three dose course (see Dose and Frequency section above)
Quantity to be supplied and administered	Single 0.5ml dose per administration.
Supplies	Centrally purchased vaccines for the HPV GBMSM programme can only be ordered via ImmForm. Vaccines for use for the HPV GBMSM programme are provided free of charge. There are separate order lines for the GBMSM and adolescent HPV programmes on Immform. The correct one must be used to order vaccine for each programme, even where an ImmForm account holder is ordering for both. Vaccines for use outside of the national programme recommendations should be ordered from the manufacturers or pharmaceutical wholesaler. Protocols for the ordering, storage and handling of vaccines should be followed to prevent vaccine wastage (see the Green Book Chapter 3).
Storage Continued over page **Storage** (continued)	Store at +2°C to +8°C. Store in original packaging in order to protect from light. Do not freeze. Gardasil® 9 should be administered as soon as possible after being removed from the refrigerator. Data from stability studies demonstrate that the Gardasil® 9 vaccine components are stable for 96 hours when stored at temperatures from +8°C to +40°C or for 72 hours when stored at temperatures from 0°C to +2°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 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 arrangements and guidance in the technical memorandum 07-01: Safe management of healthcare waste (NHSE, 2022).
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. Gardasil® 9 may be administered concomitantly with dTaP, dT/IPV or dTaP/IPV with no significant interference with antibody response to any of the components of either vaccine. See the Green Book Chapter 18a for full details of the vaccines that can be given at the same time as Gardasil®9. A detailed list of drug interactions is available in the SPC, which is available from the electronic Medicines Compendium website.
Identification and management of adverse reactions	Local reactions following vaccination are very common i.e., pain, swelling or redness at the injection site. Mild side effects such as headache, nausea, dizziness, fatigue, 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.
Reporting procedure of adverse reactions	Healthcare professionals and individuals are encouraged to report suspected adverse reactions to the Medicines and Healthcare products Regulatory Agency (MHRA) using the Yellow Card reporting scheme or search for MHRA Yellow Card in the Google Play or Apple App Store. 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 the marketing authorisation holder's patient information leaflet (PIL) provided with the vaccine. If applicable, inform the individual/parent/carer that PIL with large print, Braille or audio CD can be ordered from the manufacturer (see electronic medicines compendium). Immunisation promotional material may be provided as appropriate: • HPV for MSM: Information leaflet • Information on HPV vaccination Available via the UKHSA Immunisation Collection webpage.
Patient advice and follow up treatment Continued over page **Patient advice and follow up treatment** (continued)	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. As fainting can occur following vaccination, individuals, where appropriate, should be advised not to drive or use machinery until symptoms have cleared (see Cautions).
Special considerations and 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® 9 vaccine will protect against HPV types 6, 11, 16, 18, 31, 33, 45, 52 and 58. Appropriate precautions against sexually transmitted diseases should continue to be used. 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 GBMSM population. This includes some transgender individuals, sex workers, and men and women living with HIV. Those whose risk of acquiring HPV is considered equivalent to the risk of GBMSM 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-positive or immunocompromised populations. Therefore, a 3-dose schedule should be offered to individuals who are known to be HIV positive, 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, the course can be completed with Gardasil® 9, the vaccine currently in use in the UK HPV programme for GBMSM.
Records Continued over page **Records** (continued)	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 • 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 GBMSM 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: Chapter 18a, last updated 20 June 2023. www.gov.uk/government/collections/immunisation-against-infectious-disease-the-green-book • Summary of Product Characteristic for Gardasil®9, MSD Ltd. Last updated 13 March 2023. www.medicines.org.uk/emc/product/7330 • Collection: HPV vaccination programme for men who have sex with men (MSM). www.gov.uk/government/collections/hpv-vaccination-for-men-who-have-sex-with-men-msm-programme • JCVI statement on a one-dose schedule for the routine HPV immunisation programme 5 August 2022. www.gov.uk/government/publications/single-dose-of-hpv-vaccine-jcvi-concluding-advice/jcvi-statement-on-a-one-dose-schedule-for-the-routine-hpv-immunisation-programme • HPV vaccination programme: changes from September 2023 bi-partite letter. www.gov.uk/government/publications/hpv-vaccination-programme-changes-from-september-2023-letter **General** • Health Technical Memorandum 07-01: Safe Management of Healthcare Waste. NHSE, 2022. www.england.nhs.uk/publication/management-and-disposal-of-healthcare-waste-htm-07-01/ • National Minimum Standards and Core Curriculum for Immunisation Training. Published February 2018. 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. www.nice.org.uk/guidance/mpg2 • NICE MPG2 Patient group directions: competency framework for health professionals using patient group directions. Updated March 2017. www.nice.org.uk/guidance/mpg2/resources • UKHSA Immunisation Collection. www.gov.uk/government/collections/immunisation • Vaccine Incident Guidance. www.gov.uk/government/publications/vaccine-incident-guidance-responding-to-vaccine-errors

7. Practitioner authorisation sheet

HPV (MSM) PGD v4.00a Valid from: 1 September 2023 Expiry: 1 September 2025

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 healthcare 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.