Public Health England

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PATIENT GROUP DIRECTION (PGD)

Administration of human papillomavirus vaccine [Types 6, 11, 16, 18] (Recombinant, adsorbed) (HPV) to individuals aged 45 years and under who are men who have sex with men (MSM) and who attend Specialist Sexual Health Services (SSHS) and/or HIV clinics.

This PGD is for the administration of human papillomavirus vaccine [Types 6, 11, 16, 18] (Recombinant, adsorbed) (HPV) 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:	v01.00
Valid from:	1 April 2018
Review date:	30 September 2019
Expiry date:	31 March 2020

Public Health England has developed this PGD template to facilitate the delivery of publically 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.

Operation of this PGD is the responsibility of commissioners and service providers.

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

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

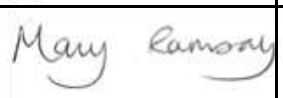
[1] This includes any relevant amendments to legislation (eg 2013 No.235, 2015 No.178 and 2015 No.323).

Change history

Version number	Change details	Date
V01.00	New PHE PGD template	16 March 2018

1. PGD template development

This PGD template 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 Services, PHE		23/03/2018
Doctor	Mary Ramsay Consultant Epidemiologist and Head of Immunisation, Hepatitis & Blood Safety Department, PHE		04/04/2018
Registered Nurse (Chair of Expert Panel)	David Green Nurse Consultant – Immunisations, PHE		16/03/2018

This PGD template 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
Michael Edelstein	Consultant Epidemiologist, Immunisation, Hepatitis & Blood Safety Department, Public Health England
Ed Gardner	Advanced Paramedic Practitioner/Emergency Care Practitioner, Medicines Manager, Proactive Care Lead
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 / NHS England South (South West)
Gill Marsh	Senior Screening and Immunisation Manager Public Health England / NHS England Lancashire and South Cumbria
Lesley McFarlane	Screening and Immunisation Co-ordinator (SIC) NHS England Leicestershire, Lincolnshire and Northamptonshire
Sally Millership	Consultant in Communicable Disease Control, Public Health England, East of England Health Protection Team
Tushar Shah	Pharmacy Advisor, NHS England London Region
Kelly Stoker	Senior Health Protection Nurse, North East Health Protection Team, Public Health England Centre North East
Sharon Webb	Programme Manager/Registered Midwife, NBHS Infectious Diseases in Pregnancy Screening Programme, Public Health England
Helen Wilkinson	Deputy Head of Medicines Management, NHS South Gloucestershire Clinical Commissioning Group

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 and Worcestershire + Birmingham, Solihull and the Black Country.
Limitations to authorisation
NHS England – West Midlands does not authorise the use of the PGD by healthcare assistants, student health professionals or registered health professionals not listed in PGD legislation.

Organisational approval (legal requirement)			
Role	**Name**	**Sign**	**Date**
Director of Commissioning Operations NHS England – West Midlands	Alison Tonge		**21/05/18**

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

Local enquiries regarding the use of this PGD may be directed to england.wmid-imms@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 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 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 aged 45 years and under who are MSM and who attend a SSHS and/or HIV clinic
Criteria for exclusion[2]	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 • 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 components 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 for girls if appropriate. Transgender individuals should be considered on a case by case basis and offered vaccination if their risk of HPV infection is similar to MSM eligible for the HPV-MSM vaccination programme. Immunisation in such instances is not covered by this PGD so a PSD would be required. If aged 46 years and over vaccination with HPV is not available under the NHS commissioned service. 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. Vaccination of men who are not MSM is not covered by this PGD. Vaccination of other individuals who have a similar risk profile to that

[2] Exclusion under this Patient Group Direction 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)	seen in the under 45 year old GUM attending MSM population would need to 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), eg: • 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 by deep subcutaneous injection to reduce the risk of bleeding (see "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. **MSM aged 15 years to 45 years 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 with a 6 month to 24 month interval between doses ie: • first dose of 0.5ml of HPV vaccine, then • second dose 6 to 24 months after 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. 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 protocol for ordering storage and handling of vaccines and 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 at the end of a session by sealing 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 ie 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	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 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. 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. When administration is postponed advise the individual when to return for vaccination.
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. Transgender individuals should be offered HPV vaccination on the basis of an individual risk assessment. The evidence base, regarding the level of risk from HPV for transgender individuals as a group, is limited. This PGD does not cover the vaccination of transgender individuals so a PSD may be required. 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.
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 • 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

Records (continued)	immunisation • details of any adverse drug reactions and actions taken • supplied via Patient Group Direction (PGD) Records should be signed and dated (or a password controlled immunisers 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 Papilloma Virus (HPV) vaccine** • Immunisation Against Infectious Disease: The Green Book Chapter 18a, last updated 5 June 2014. https://www.gov.uk/government/collections/immunisation-against-infectious-disease-the-green-book • Summary of Product Characteristic for Gardasil®, MSD Ltd. Last updated 25 April 2017. 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** • British National Formulary (BNF) www.BNF.org https://bnf.nice.org.uk/drug/human-papillomavirus-vaccines.html • 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 • Immunisation knowledge and skills competence assessment tool. Royal College of Nursing (RCN) 2015. https://www.rcn.org.uk/professional-development/publications/pub-005336 • 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. January 2014. 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 • Protocol for ordering storage and handling of vaccines. April 2014. https://www.gov.uk/government/publications/protocol-for-ordering-storing-and-handling-vaccines 1. 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 vaccine PGD v01.00 Valid from: 01/04/2018 Expiry: 31/03/2020

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 patient group direction you are indicating that you agree to its contents and that you will work within it.

Patient group directions 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 Patient Group Direction 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.