

**Patient Group Direction for the administration of HPV vaccination**

<b>Title of patient group direction</b>	Patient Group Direction for the administration of HPV vaccination
<b>Approved at</b>	NMP/PGD Group
<b>PGD approved / valid from</b>	March 2019
<b>Review date</b>	October 2021
<b>Expiry date</b>	March 2022
<b>Clinical area(s) where PGD applies</b>	York and North Yorkshire Sexual Health services
<b>Identified Lead for monitoring / review and contact details</b>	Alison Chorlton Lead Nurse ext. 5465
<b>CONSULTATION PROCESS ADOPTED IN DEVELOPING THE PATIENT GROUP DIRECTION (PGD)</b>	
<b>New Document</b>	Yes
<b>Reviewed Document</b>	No
<b>If the PGD is revised what revisions were required and for what reasons e.g. change in medical procedures or change in legislation</b>	
<b>List of persons involved in the consultation process.</b> (The group must include a sponsoring clinician, a pharmacist and a senior representative of the professional group. The job title and level of consultation should also be listed).	PHE document adapted Alison Chorlton, Lead nurse sexual health Dr Ian Fairley, Consultant

<b>CLINICAL CONDITION</b>	
<b>Condition</b>	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".
<b>Inclusion criteria</b>	<p>Individuals who:</p> <ul style="list-style-type: none"> <li>• Are aged 45 years and under who are MSM and who attend a SSHS and/or HIV clinic</li> <li>• Eligible patients that started but did not complete the immunisation schedule before reaching the age of 46 should complete the course</li> </ul>
<b>Exclusion criteria</b>	<p>Individuals for whom no valid consent has been received (see DH Reference guide to consent for examination or treatment <sup>1</sup>).</p> <p>Individuals who:</p> <ul style="list-style-type: none"> <li>• are females</li> <li>• are aged 46 years and over and not already had the vaccine</li> <li>• Children 12 years and under</li> <li>• Patients aged 13-15 who are not Fraser competent</li> <li>• are men who do not have sex with men</li> <li>• have had a confirmed anaphylactic reaction to a previous dose of HPV vaccine or to any components of the vaccine</li> <li>• are suffering from acute severe febrile illness (the presence of a minor infection is not a contraindication for immunisation)</li> </ul>
<b>Action if excluded</b>	<p>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.</p> <p>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</p>



	<p>the HPV-MSM vaccination programme. Immunisation in such instances is not covered by this PGD so a PSD would be required.</p> <p>If aged 46 years and over vaccination with HPV is not available under the NHS commissioned service.</p> <p>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 less than 9 years of age is off-label and is not covered by this PGD so a PSD would be required.</p> <p>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 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.</p> <p>If a confirmed anaphylactic reaction has been experienced after a previous dose of HPV vaccine specialist advice should be sought.</p> <p>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.</p> <p>Seek appropriate advice from the local Screening and Immunisation Team, local Health Protection Team or the individual's clinician as required.</p> <p>The risk to the individual of not being immunised must be taken into account.</p> <p>Document the reason for exclusion and any action taken in the individual's clinical records.</p> <p>Inform or refer to the patient's clinician as appropriate.</p>
<p><b>Action for patients not wishing to receive care under the PGD</b></p>	<p>Informed consent, from the individual or a person legally able to act on the person's behalf, must be obtained for each administration.</p>

	Advise the individual about the protective effects of the vaccine, the risks of infection and potential complications.
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	Document advice given and the decision reached.
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	Inform or refer to the patient's clinician as appropriate.
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DESCRIPTION OF TREATMENT			
Name of Medicine	Human papillomavirus vaccine [types 6, 11, 16, 18] (recombinant, adsorbed), e.g.: <ul style="list-style-type: none"> <li>• Gardasil®, suspension for injection in a prefilled syringe or vial</li> </ul> Note: This PGD does not cover the administration of the Human Papillomavirus 9-valent Vaccine, Gardasil® 9.		
Legal Classification	Licensed, Prescription only Medicine (POM)		
Licensing information	Administration of a two dose schedule to individuals aged from 9 to 13 is licensed. However, for individuals aged from 14 years to under 15 years this is 'off-label' Deep subcutaneous administration is 'off-label' use		
	Is the medicine licensed for the intended use?	YES	
	Does it have a black triangle status?		NO
	Does it have a Risk Minimisation Measures (RMM) recommendation		NO
Form	Suspension		
Strength	0.5 micrograms/mL		
Dose	Single 0.5ml dose per administration.		
Frequency	Vaccination should be aligned with other routine SSHS or HIV clinic re-attendance where possible to reduce additional visits for vaccination. <u><b>MSM aged 15 years to 45 years and MSM aged 45 years and under who are immunosuppressed or HIV positive</b></u> Administer a course of three doses: <ul style="list-style-type: none"> <li>• first dose of 0.5ml of HPV vaccine, then</li> <li>• second dose of 0.5ml at least one month after the first dose, then</li> <li>• a third dose of 0.5ml at least three months after the second dose</li> </ul> All three doses should ideally be given within a 12-month period. The programme will aim to deliver three doses within		



	<p>12 months where possible, using existing appointments where possible to limit additional appointments, and up to 24 months where this is not possible.</p> <p>If the course is interrupted, it should be resumed but not repeated, ideally allowing the appropriate interval between the remaining doses.</p> <p>Whenever possible, immunisations for all individuals on the three dose schedule should follow the recommended 0, 1, 4-6 months 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.</p> <p><b><u>Immunocompetent MSM aged under 15 years at time of first dose</u></b></p> <p>Administer a course of two doses to MSM aged under 15 years with a 6 month to 24 month interval between doses i.e.:</p> <ul style="list-style-type: none"> <li>• first dose of 0.5ml of HPV vaccine, then</li> <li>• second dose 6 to 24 months after the first dose</li> </ul> <p>If the course is interrupted it should be resumed but not repeated, even if more than 24 months have elapsed since the first dose.</p> <p>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.</p>
<b>Route</b>	<p>Administer by intramuscular injection. The preferred site is the deltoid region of the upper arm.</p> <p>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.</p> <p>For individuals with a bleeding disorder, vaccines normally given by an intramuscular route should be</p>



	<p>given by deep subcutaneous injection to reduce the risk of bleeding (see "The Green Book" <a href="#">Chapter 4</a>).</p> <p>The vaccine's normal appearance is a white cloudy liquid which may settle to a clear liquid and white precipitate. Shake well before use.</p> <p>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.</p> <p>The vaccine's SPC provides further guidance on administration and is available from the electronic Medicines Compendium website: <a href="http://www.medicines.org.uk">www.medicines.org.uk</a></p>	
<b>Total Treatment Quantity</b>	2 or 3 doses as per treatment schedule.	
<b>Interactions with other medicines</b> (This must include all potentially serious interactions listed in the BNF)	<p>Immunological response may be diminished in those receiving immunosuppressive treatment. Vaccination is recommended even if the antibody response may be limited.</p> <p>May be given at the same time as other vaccines.</p> <p>A trend of lower anti-HPV titres has been observed when Gardasil<sup>®</sup> is administered concomitantly with dTaP, dT/IPV and dTaP/IPV vaccines, though the clinical significance of this observation is unclear.</p> <p>A detailed list of drug interactions is available in the SPC, which is available from the electronic Medicines Compendium website: <a href="http://www.medicines.org.uk">www.medicines.org.uk</a></p> <p>See Appendix 1 in British National Formulary (BNF) under hepatitis vaccination. <b>If in doubt, contact Medicines Information for advice</b></p>	
<b>Adverse Reactions</b> (This should include all the common and potentially serious adverse reactions. It is acceptable to state that the BNF should be referred to for further information)	<p><b>Local reactions</b> following vaccination are very common i.e. pain, swelling or redness at the injection site.</p> <p>Mild side effects such as headache, nausea,</p>	<p><b>Treatment of adverse reactions</b></p> <p><b>Anaphylaxis:</b> Follow Trust anaphylaxis protocol.</p> <p>Healthcare professionals and patients/carers are encouraged to report suspected adverse reactions to the Medicines and</p>



	<p>pain in extremity, fever, injection-site haematoma and injection-site pruritus are reported as common.</p> <p>Other adverse events have been reported in post-marketing surveillance but the frequency of these is not known.</p> <p>Hypersensitivity reactions and anaphylaxis can occur but are very rare.</p> <p>A detailed list of adverse reactions is available in the SPC which is available from the electronic Medicines Compendium website:  <a href="http://www.medicines.org.uk">www.medicines.org.uk</a></p>	<p>Healthcare products Regulatory Agency (MHRA) using the Yellow Card reporting scheme on:  <a href="http://yellowcard.mhra.gov.uk">http://yellowcard.mhra.gov.uk</a></p> <p>Any adverse reaction to a vaccine should be documented in the individual's record and the individual's clinician should be informed.</p>
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<p><b>Advice to Patients:</b>  <b>Written and Oral advice</b>  (This should include the provision of a patient information leaflet)</p>	<p>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.</p> <p>Advise individual when the next dose is due.</p> <p>Advise that individuals should continue to take appropriate precautions to protect themselves from sexually transmitted diseases.</p> <p>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.</p> <p>When administration is postponed advise the individual when to return for vaccination.  Offer marketing authorisation holder's patient information leaflet (PIL) provided with the vaccine.</p> <p>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 is outside the product license</p>
<p><b>Follow up action</b></p>	<p>Arrange follow up appointments according to regimen prescribed.</p>
<p><b>Storage</b></p>	<ul style="list-style-type: none"> <li>• Store at between +2°C to +8°C.</li> <li>• Store in original packaging in order to protect from light.</li> <li>• Do not freeze.</li> <li>• Gardasil® should be administered as soon as possible after being removed from the cold chain.</li> <li>• 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.</li> </ul>



	<ul style="list-style-type: none"> <li>• 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.</li> </ul>
	<ul style="list-style-type: none"> <li>• Locked briefcase for outreach use</li> </ul>
<b>Records to be Kept</b>	<ul style="list-style-type: none"> <li>• Written/oral advice given.</li> <li>• Date</li> <li>• Drug name and strength</li> <li>• Batch number</li> <li>• Dose and form</li> <li>• Route of administration</li> <li>• Time of administration if appropriate</li> <li>• Advice given to patients</li> <li>• Signature of staff administering medicine</li> <li>• Details of any adverse drug reactions or side effects</li> <li>• Form of documentation (patient's records, letters etc.)</li> <li>• Any communication with other health care professionals</li> <li>• Follow up arrangements</li> <li>• HPV vaccination was administered under PGD</li> </ul>
<b>Audit Arrangements</b>	As per current Trust PGD Policy
<b>References</b>	<p><b>Human Papilloma Virus (HPV) vaccine</b></p> <ul style="list-style-type: none"> <li>• Immunisation Against Infectious Disease: The Green Book Chapter 18a, last updated 5 June 2014. <a href="https://www.gov.uk/government/collections/immunisation-against-infectious-disease-the-green-book">https://www.gov.uk/government/collections/immunisation-against-infectious-disease-the-green-book</a></li> <li>• Summary of Product Characteristic for Gardasil®, MSD Ltd. Last updated 25 April 2017. <a href="http://www.medicines.org.uk/emc/medicine/19016">http://www.medicines.org.uk/emc/medicine/19016</a></li> <li>• Service specification for human papillomavirus programme for men who have sex with men (HPV-MSM). <a href="https://www.england.nhs.uk/commissioning/pub-hlth-res/">https://www.england.nhs.uk/commissioning/pub-hlth-res/</a></li> </ul> <p><b>General</b></p> <ul style="list-style-type: none"> <li>• British National Formulary (BNF) <a href="http://www.bnf.org">www.BNF.org</a> <a href="https://bnf.nice.org.uk/drug/human-papillomavirus-vaccines.html">https://bnf.nice.org.uk/drug/human-papillomavirus-vaccines.html</a></li> <li>• Health Technical Memorandum 07-01: Safe Management of Healthcare Waste. Department of Health 20 March 2013 <a href="https://www.gov.uk/government/publications/guidance-on-the-">https://www.gov.uk/government/publications/guidance-on-the-</a></li> </ul>



	<p><u>safe-management-of-healthcare-waste</u></p> <ul style="list-style-type: none"> <li>• Immunisation knowledge and skills competence assessment tool. Royal College of Nursing (RCN) 2015. <a href="https://www.rcn.org.uk/professional-development/publications/pub-005336">https://www.rcn.org.uk/professional-development/publications/pub-005336</a></li> <li>• National Minimum Standards and Core Curriculum for Immunisation Training. Published February 2018 <a href="https://www.gov.uk/government/publications/national-minimum-standards-and-core-curriculum-for-immunisation-training-for-registered-healthcare-practitioners">https://www.gov.uk/government/publications/national-minimum-standards-and-core-curriculum-for-immunisation-training-for-registered-healthcare-practitioners</a></li> <li>• NICE Medicines Practice Guideline 2 (MPG2): Patient Group Directions. Published March 2017. <a href="https://www.nice.org.uk/guidance/mpg2">https://www.nice.org.uk/guidance/mpg2</a></li> <li>• NICE MPG2 Patient group directions: competency framework for health professionals using patient group directions. January 2014. <a href="https://www.nice.org.uk/guidance/mpg2/resources">https://www.nice.org.uk/guidance/mpg2/resources</a></li> <li>• PHE Immunisation Collection <a href="https://www.gov.uk/government/collections/immunisation">https://www.gov.uk/government/collections/immunisation</a></li> <li>• PHE Vaccine Incident Guidance <a href="https://www.gov.uk/government/publications/vaccine-incident-guidance-responding-to-vaccine-errors">https://www.gov.uk/government/publications/vaccine-incident-guidance-responding-to-vaccine-errors</a></li> <li>• Protocol for ordering storage and handling of vaccines. April 2014. <a href="https://www.gov.uk/government/publications/protocol-for-ordering-storing-and-handling-vaccines">https://www.gov.uk/government/publications/protocol-for-ordering-storing-and-handling-vaccines</a></li> <li>1. Reference guide to consent for examination or treatment, Department of Health, published 4 August 2009. <a href="https://www.gov.uk/government/publications/reference-guide-to-consent-for-examination-or-treatment-second-edition">https://www.gov.uk/government/publications/reference-guide-to-consent-for-examination-or-treatment-second-edition</a></li> </ul>
<p><b>Competency Requirements</b> (attach any competency frameworks / documents)</p>	<p><b>Registered Nurses</b></p> <p>Clinically competent to administer IM injections into the deltoid muscle.</p> <p>Knowledge base to enable full discussion regarding HPV and contra indications for the administration of HPV vaccination.</p> <p>Completion of a local sexual health training programme for the administration of HPV vaccination under PGD within sexual health services. This will require/include:</p> <p>Clinical competence in sexual history taking, the clinical assessment and screening required to enable the ability to identify patients who require HPV vaccination.</p> <p>Knowledge base of the interactions of HPV vaccination with other drugs, and other exclusions and contra-indications for administering HPV vaccination</p> <p>Competence in the above will be demonstrated by the undertaking of a local clinical competency based</p>

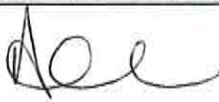




	<p>training and assessment programme, evidenced by completion of theoretical study including e-learning and clinical experience within sexual health.</p> <ul style="list-style-type: none"> <li>• Assessment will be undertaken by the Lead Sexual Health nurse or designated PGD assessor, who will both be fully competent and either practising as an independent prescriber themselves, or practicing in accordance with this PGD.</li> </ul>
	<ul style="list-style-type: none"> <li>• Receiving Clinical Supervision and/or audit of case notes on an ongoing basis</li> <li>• Commitment to continuing professional development identified through Clinical Supervision and appraisal</li> <li>• Evidence of continuing professional development in sexual health</li> <li>• Regular attendance and participation in the monthly educational clinical governance/</li> </ul> <p>Maintain professional accountability with the Nursing and Midwifery Council (NMC) and ensure continuing professional development.</p> <p>Attendance at Trust PGD awareness session or Trust HUB e-learning and vaccination and immunisation updates/training</p>





**AUTHORISATION OF THE PATIENT GROUP DIRECTION (PGD) FOR ADMINISTRATION  
OF: Hepatitis B vaccination**

**PGD Development / Review Team – responsible for PGD content**

Title	Name	Signature	Date
Lead Author	Alison Chorlton		04.06.18
Clinical Director Lead Approval	Ian Fairley		05-06-2018
Directorate Pharmacy Lead Approval	Paul Jackson		5/7/18

**PGD Approved by the NMP/PGD Group**

Title	Name	Signature	Date
NMP Lead / Lead Nurse Medicines Management	Jennie Booth		16.8.18
Chief Pharmacist / Deputy Chief Pharmacist	Stuart Parkes		16/8/18

**Authorisation to work within the PGD**

This patient group direction must be agreed to and signed by all health care professionals involved in its use.

The PGD must be easily accessible in the clinical setting.

**Notes to the NMP/PGD Authorising staff**

- Do not proceed unless this document carries the signatures of the development / review team (Lead Author, Lead Clinical Director and Directorate Lead Pharmacy)
- You are responsible for fulfilling the legal requirement that a senior person from the profession ensures that only fully competent, qualified and trained professionals operate under this PGD
- Using a PGD is not a form of prescribing



Staff authorised to work under this PGD	
Ward / Department	Sexual Health
Professionals to whom this Patient Group Direction applies	Qualified nurses who work within sexual health and have completed the agreed training programme

*I confirm that I have read and understood the content of this patient group direction and that I am willing and competent to work under it within my professional code of conduct when working for this Trust:*

Name (Capitals)	Sign	Job Title	Authorising Manager	Date