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## PATIENT GROUP DIRECTION (PGD)

Administration of human papillomavirus vaccine [Types 6, 11, 16, 18] (Recombinant, adsorbed) (HPV) to females from 12 years of age or from school year 8 in accordance with the national immunisation programme

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 PGD  
Version no: v02.00  
Valid from: 1 May 2018  
Review date: 31 October 2019  
Expiry date: 30 April 2020

**Public Health England has developed this PGD template to facilitate the delivery of publically funded immunisation 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)<sup>1</sup>. **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](mailto:immunisation@phe.gov.uk)




<sup>1</sup> This includes any relevant amendments to legislation (eg [2013 No.235](#), [2015 No.178](#) and [2015 No.323](#)).  
HPV PGD v02.00 Valid from: 01/05/2018 Expiry: 30/04/2020

## Change history

Version number	Change details	Date
V01.00	New PHE PGD template	06 April 2016
V02.00	PHE HPV PGD amended to: <ul style="list-style-type: none"> <li>• include immunisation of transgender boys and transgender girls as appropriate</li> <li>• provide additional information on capacity to consent with link to the DH 'Reference guide to consent for examination or treatment'</li> <li>• include additional healthcare practitioners (midwives, pharmacists, paramedics, physiotherapists) in Section 3</li> <li>• reference the protocol for ordering storage and handling of vaccines</li> <li>• add additional paragraphs to the off-label section on storage and consent</li> <li>• refer to vaccine incident guidelines</li> <li>• refer to upload of records onto National Health Application Infrastructure Services</li> <li>• include rewording, layout and formatting changes for clarity and consistency with other PHE PGD templates</li> </ul>	21 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
<b>Pharmacist</b> (Lead Author)	Elizabeth Graham Lead Pharmacist Immunisation Services, PHE		23/03/2018
<b>Doctor</b>	Mary Ramsay Consultant Epidemiologist and Head of Immunisation, Hepatitis & Blood Safety Department, PHE		04/04/2018
<b>Registered Nurse</b> (Chair of Expert Panel)	David Green Nurse Consultant – Immunisations, PHE		22/03/2018

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
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
Vanessa Saliba	Consultant Epidemiologist , Public Health England
Helen Wilkinson	Deputy Head of Medicines Management, NHS South Gloucestershire Clinical Commissioning Group
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


## 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 MIDLANDS AND EAST (CENTRAL MIDLANDS)** authorises this PGD for use by the services or providers listed below:

Authorised for use by the following organisations and/or services
<b>General medical practices from which NHS England Midlands and East (Central Midlands) commissions immunisation services</b>
Limitations to authorisation
<b>Practice staff are reminded that current contractual obligations may restrict administration of the vaccine covered by this PGD to a more limited cohort of patients than that legally permitted by the inclusion criteria.</b>

Organisational approval (legal requirement)			
Role	Name	Sign	Date
Medical Director, NHS England Midlands and East (Central Midlands)	Dr Aly Rashid		18.04.2018

Additional signatories according to locally agreed policy			
Role	Name	Sign	Date

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

**For Bedfordshire, Hertfordshire, Luton and Milton Keynes** - [england.immsqa@nhs.net](mailto:england.immsqa@nhs.net) - the (Central Midlands) South public health/screening and immunisation team

**For Leicestershire, Lincolnshire and Northamptonshire – [england.limms@nhs.net](mailto:england.limms@nhs.net) - the (Central Midlands) North and Central public health/screening and immunisation team**

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

<p><b>Qualifications and professional registration</b></p>	<p>Registered professional with one of the following bodies:</p> <ul style="list-style-type: none"> <li>• nurses and midwives currently registered with the Nursing and Midwifery Council (NMC)</li> <li>• pharmacists currently registered with the General Pharmaceutical Council (GPhC) (Note: This PGD is not relevant to privately provided community pharmacy services)</li> <li>• paramedics and physiotherapists currently registered with the Health and Care Professions Council (HCPC)</li> </ul> <p>The practitioners above must also fulfil the <a href="#">Additional requirements</a> detailed below.</p> <p>Check <a href="#">Section 2 Limitations to authorisation</a> to confirm whether all practitioners listed above have organisational authorisation to work under this PGD.</p>
<p><b>Additional requirements</b></p>	<p>Additionally practitioners:</p> <ul style="list-style-type: none"> <li>• must be authorised by name as an approved practitioner under the current terms of this PGD before working to it</li> <li>• must have undertaken appropriate training for working under PGDs for supply/administration of medicines</li> <li>• must be competent in the use of PGDs (see <a href="#">NICE Competency framework</a> for health professionals using PGDs)</li> <li>• must be familiar with the vaccine product and alert to changes in the Summary of Product Characteristics (SPC), Immunisation Against Infectious Disease (“<a href="#">The Green Book</a>”), and national and local immunisation programmes</li> <li>• must have undertaken training appropriate to this PGD as required by local policy and in line with the <a href="#">National Minimum Standards and Core Curriculum for Immunisation Training</a></li> <li>• must be competent to undertake immunisation and to discuss issues related to immunisation</li> <li>• must be competent in the handling and storage of vaccines, and management of the “cold chain”</li> <li>• must be competent in the recognition and management of anaphylaxis</li> <li>• must have access to the PGD and associated online resources</li> <li>• should fulfil any additional requirements defined by local policy</li> </ul> <p><b>THE INDIVIDUAL PRACTITIONER MUST BE AUTHORISED BY NAME, UNDER THE CURRENT VERSION OF THIS PGD BEFORE WORKING ACCORDING TO IT.</b></p>
<p><b>Continued training requirements</b></p>	<p>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).</p> <p>Practitioners should be constantly alert to any subsequent recommendations from Public Health England and/or NHS England and other sources of medicines information.</p> <p>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.</p>

#### 4. Clinical condition or situation to which this PGD applies

<b>Clinical condition or situation to which this PGD applies</b>	<p>Indicated for the active immunisation of females from 12 years of age or from school year 8 for the prevention of human papillomavirus (types 6, 11, 16, 18) infection in accordance with the national immunisation programme and recommendations given in <a href="#">Chapter 18a</a> of Immunisation Against Infectious Disease: “The Green Book”.</p>
<b>Criteria for inclusion</b>	<p>Individuals who:</p> <ul style="list-style-type: none"> <li>• are females<sup>2</sup> aged 12 years to under 18 years of age when starting a course of HPV immunisation</li> <li>• are females<sup>2</sup> aged less than 12 years of age who are in school year 8, 9, 10 or 11</li> <li>• are females<sup>2</sup> aged 18 years and over who have started but not completed a course of HPV immunisation before their 18<sup>th</sup> birthday</li> </ul>
<b>Criteria for exclusion<sup>3</sup></b>	<p>Individuals for whom no valid consent has been received (see <a href="#">DH Reference guide to consent for examination or treatment</a>).</p> <p>Individuals who:</p> <ul style="list-style-type: none"> <li>• are less than 12 years of age and in school year 7 or lower</li> <li>• are less than 9 years of age</li> <li>• are aged 18 years and over, except those who have received a partial course of HPV immunisation</li> <li>• are male<sup>2</sup></li> <li>• have had a confirmed anaphylactic reaction to a previous dose of HPV vaccine or to any components of the vaccine</li> <li>• have completed a course of HPV vaccine, with either HPV types 16, 18 (Cervarix<sup>®</sup>) or HPV types 6, 11,16, 18 (Gardasil<sup>®</sup>)</li> <li>• are known to be pregnant (Note: routine questioning about last menstrual period and/or pregnancy testing is not required before offering HPV 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>Cautions including any relevant action to be taken</b>	<p>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.</p> <p>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.</p>
<b>Action to be taken if the patient is excluded</b>  Continued over page	<p>If aged less than 12 years and in a school year below year 8, advise when national routine immunisation is indicated.</p> <p>If aged less than 9 years HPV vaccination is off-label. Immunisation is not indicated unless in school year 8 or above and a PSD would be required.</p>

<sup>2</sup> Transgender girls and transgender boys may be vaccinated in accordance with this PGD as appropriate.

<sup>3</sup> 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

<p><b>Action to be taken if the patient is excluded</b> (Continued)</p>	<p>If aged 18 years and over and previously unimmunised against HPV advise that vaccination against HPV is not covered by the national HPV vaccination programme.</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 known to be pregnant should complete immunisation after their pregnancy. If high-risk sexual activity continues during pregnancy, and the opportunity for vaccination after pregnancy is uncertain, the benefit of vaccination during pregnancy is likely to outweigh any potential risk. Vaccination during pregnancy is not covered by this PGD so in such instances the individual may need to be referred and/or a PSD may be required.</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 at the earliest opportunity.</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>In a GP practice setting, inform or refer to the GP or a prescriber as appropriate.</p>
<p><b>Action to be taken if the patient or carer declines treatment</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 (see <a href="#">Additional Information</a>).</p> <p>Advise the individual/parent/carer about the protective effects of the vaccine, the risks of infection and potential complications.</p> <p>Document advice given and the decision reached.</p> <p>In a GP practice setting, inform or refer to the GP as appropriate.</p>
<p><b>Arrangements for referral for medical advice</b></p>	<p>As per local policy</p>



## 5. Description of treatment

<b>Name, strength &amp; formulation of drug</b>	<p>Human papillomavirus vaccine [types 6, 11, 16, 18] (recombinant, adsorbed), eg:</p> <ul style="list-style-type: none"> <li>• Gardasil<sup>®</sup>, suspension for injection in a prefilled syringe or vial</li> </ul> <p>Note: This PGD does not cover the administration of the human papillomavirus 9-valent vaccine, Gardasil<sup>®</sup> 9.</p>
<b>Legal category</b>	<p>Prescription only medicine (POM)</p>
<b>Black triangle▼</b>	<p>No</p>
<b>Off-label use</b>	<p>Administration of a two-dose schedule to females aged from 14 years of age to under 15 years of age is off-label but is in accordance with PHE recommendations and <a href="#">Chapter 18a</a> of “The Green Book”.</p> <p>Completion of a vaccine course using Gardasil<sup>®</sup> where it was commenced with Cervarix<sup>®</sup> is off-label but is in accordance with PHE recommendations and <a href="#">Chapter 18a</a> of “The Green Book”.</p> <p>Administration of Gardasil<sup>®</sup> by deep subcutaneous injection to patients with a bleeding disorder is off-label administration but is in line with advice in <a href="#">Chapter 4</a> and <a href="#">Chapter 18a</a> of “The Green Book”.</p> <p>Vaccine should be stored according to the conditions detailed in the <a href="#">Storage section</a> below. However, in the event of an inadvertent or unavoidable deviation of these conditions refer to <a href="#">PHE Vaccine Incident Guidance</a>. Where vaccine is assessed in accordance with these guidelines as appropriate for continued use this would constitute off-label administration under this PGD.</p> <p>Where a vaccine is recommended off-label consider, as part of the consent process, informing the individual/parent/carer that the vaccine is being offered in accordance with national guidance but that this is outside the product licence.</p>
<b>Route / method of administration</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 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>

<p><b>Dose and frequency of administration</b></p>	<p>Single 0.5ml dose per administration</p> <p>HPV vaccination should be routinely offered to females in school year 8.</p> <p><b>Immunocompetent females aged under 15 years at time of first dose</b></p> <p>Administer a course of two doses with a 6 month to 24 month interval between doses ie:</p> <ul style="list-style-type: none"> <li>• first dose of 0.5ml of HPV vaccine, then</li> <li>• second dose at least 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> <p>For individuals infected with HIV refer to section below for dose schedule.</p> <p><b>Females aged 15 years to under 18 years at time of first dose and females under 18 years of age who are immunosuppressed or known to be HIV-infected (see “The Green Book” <a href="#">Chapter 18a</a>)</b></p> <p>Administer a course of three doses on a 0, 1 and 4-6 month schedule ie:</p> <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> <p>All three doses should ideally be given within a 12-month period. 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 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.</p> <p><b>Vaccination of females with unknown or incomplete vaccination status</b></p> <p>Unimmunised females aged 12 years to under 18 years of age should be vaccinated in accordance with the schedules above.</p> <p>A female who has started but not completed an HPV immunisation schedule should complete the vaccination course.</p> <p><b>Previous incomplete vaccination with Cervarix®</b></p> <p>For females who started the schedule with Cervarix®, but did not complete the vaccination course, the course can be completed with Gardasil®. The course should be completed according to the vaccination schedules above depending on the age of the girl when she received the first dose and whether 1 or 2 doses have already been given.</p>
<p><b>Duration of treatment</b></p>	<p>A two or three dose course (see <a href="#">Dose and Frequency</a> section above)</p>

<b>Quantity to be supplied / administered</b>	Single 0.5ml dose per administration.
<b>Supplies</b>	<p>Centrally purchased vaccines for the national immunisation programme for the NHS can only be ordered via ImmForm. Vaccines for use for the national immunisation programme are provided free of charge.</p> <p>Protocols for the ordering, storage and handling of vaccines should be followed to prevent vaccine wastage (see <a href="#">protocol for ordering storage and handling of vaccines</a> and Green Book <a href="#">Chapter 3</a>).</p>
<b>Storage</b>	<p>Store at between +2°C to +8°C. Store in original packaging in order to protect from light. Do not freeze.</p> <p>Gardasil<sup>®</sup> should be administered as soon as possible after being removed from the cold-chain.</p> <p>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.</p> <p>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 <a href="#">PHE Vaccine Incident Guidance</a>.</p>
<b>Disposal</b>	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 <a href="#">technical memorandum 07-01</a> : Safe management of healthcare waste (Department of Health, 2013).
<b>Drug interactions</b>	<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>
<b>Identification &amp; management of adverse reactions</b>	<p>Local reactions following vaccination are very common ie pain, swelling or redness at the injection site.</p> <p>Mild side effects such as headache, nausea, 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>

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<b>Identification &amp; management of adverse reactions</b> (continued)	<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>
<b>Reporting procedure of adverse reactions</b>	<p>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: <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 GP should be informed.</p>
<b>Written information to be given to patient or carer</b>	<p>Offer marketing authorisation holder's patient information leaflet (PIL) provided with the vaccine.</p> <p>Immunisation promotional material may be provided as appropriate:</p> <ul style="list-style-type: none"> <li>• <a href="#">Immunisations for young people</a></li> <li>• <a href="#">Your HPV vaccination guide</a></li> <li>• <a href="#">The HPV vaccine: beating cervical cancer – questions and answers</a></li> </ul> <p>Available from: <a href="http://www.gov.uk/government/collections/immunisation">www.gov.uk/government/collections/immunisation</a></p>
<b>Patient advice / follow up treatment</b>	<p>Inform the individual/parent/carer of possible side effects and their management. The individual/parent/carer should be advised to seek medical advice in the event of an adverse reaction.</p> <p>Advise individual/parent/carer when the next dose is due.</p> <p>Advise that individuals should continue to take appropriate precautions to protect themselves from sexually transmitted diseases and unwanted pregnancy. Advise that HPV vaccination is not a replacement for the national cervical screening programme which should be accessed at the appropriate age.</p> <p>When administration is postponed advise the individual/carer when to return for vaccination.</p>
<b>Special considerations / additional information</b>  Continued over page	<p>Ensure there is immediate access to adrenaline (epinephrine) 1 in 1000 injection and access to a telephone at the time of vaccination.</p> <p>Transgender boys and transgender girls may be vaccinated in accordance with this PGD as appropriate. Transgender boys should be offered vaccination to mitigate their risk of cervical cancer and transgender girls may be offered vaccination with their peers.</p> <p>There is no longer a national supply of Cervarix<sup>®</sup> available in the UK. For females who started the schedule with Cervarix<sup>®</sup>, but did not complete the vaccination course, the course can be completed with Gardasil<sup>®</sup>.</p> <p>For individuals who commenced but did not complete the vaccination course, it is reasonable to complete their HPV vaccination course after the age of 18 years. Vaccination of these individuals is outside the national programme and will not attract an enhanced service payment.</p> <p>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.</p> <p>HPV vaccination is for prophylaxis against future HPV infection. It will</p>

<p><b>Special considerations / additional information</b> (continued)</p>	<p>not treat pre-existing HPV infection.</p> <p>Gardasil® vaccine will protect against HPV types 6, 11, 16 and 18 with limited cross protection to other HPV types.</p> <p>For children under the age of 16 years being offered HPV vaccine, those assessed as Gillick competent can self-consent (see <a href="#">DH Reference guide to consent for examination or treatment</a>).</p>
<p><b>Records</b></p>	<p>Record:</p> <ul style="list-style-type: none"> <li>• that valid informed consent was given</li> <li>• name of individual, address, date of birth and GP with whom the individual is registered</li> <li>• name of immuniser</li> <li>• name and brand of vaccine</li> <li>• date of administration</li> <li>• dose, form and route of administration of vaccine</li> <li>• quantity administered</li> <li>• batch number and expiry date</li> <li>• anatomical site of vaccination</li> <li>• advice given, including advice given if excluded or declines immunisation</li> <li>• details of any adverse drug reactions and actions taken</li> <li>• supplied via Patient Group Direction (PGD)</li> </ul> <p>Records should be signed and dated (or a password controlled immunisers record on e-records).</p> <p>All records should be clear, legible and contemporaneous.</p> <p>This information should be recorded in the individual's GP record. Where vaccine is administered outside the GP setting appropriate health records should be kept and the individual's GP informed.</p> <p>When vaccine is administered to individuals under 19 years of age, notify the local Child Health Information Systems team (Child Health Records Department) using the appropriate documentation/pathway as required by any local or contractual arrangement.</p> <p>Systems should be in place to ensure that the HPV vaccination record is uploaded onto the National Health Application Infrastructure Services (NHAIS) system (also known as Open Exeter) for NHS cervical screening programme call-recall purposes.</p> <p>A record of all individuals receiving treatment under this PGD should also be kept for audit purposes in accordance with local policy.</p>

## 6. Key references

<b>Key references</b>	<b>Human Papilloma Virus (HPV) vaccine</b> <p>Immunisation Against Infectious Disease: The Green Book <a href="#">Chapter 18a</a>, 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></p> <ul style="list-style-type: none"><li>• Summary of Product Characteristic for Gardasil<sup>®</sup>, 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>• NHS public health functions agreement 2017-18, Service Specification No.11. Human Papillomavirus HPV Immunisation Programme. April 2017. <a href="https://www.england.nhs.uk/commissioning/pub-hlth-res/">https://www.england.nhs.uk/commissioning/pub-hlth-res/</a></li><li>• HPV Vaccination Consent Form, last updated 10 June 2014. <a href="https://www.gov.uk/government/publications/human-papillomavirus-hpv-vaccination-consent-form">https://www.gov.uk/government/publications/human-papillomavirus-hpv-vaccination-consent-form</a></li></ul> <b>General</b> <ul style="list-style-type: none"><li>• British National Formulary (BNF) and British National Formulary for Children (BNF-C) <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> <a href="https://bnfc.nice.org.uk/drug/human-papillomavirus-vaccines.html">https://bnfc.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-safe-management-of-healthcare-waste">https://www.gov.uk/government/publications/guidance-on-the-safe-management-of-healthcare-waste</a></li><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>• 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>
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## 7. Practitioner authorisation sheet

**HPV vaccine PGD v02.00 Valid from: 01/05/2018 Expiry: 30/04/2020**

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 I \_\_\_\_\_ **(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.