

NHS NHS NHS NHS NHS NHS

Grampian

Highland

Orkney

Shetland

Tayside

Eileanan Siar
Western Isles

**Patient Group Direction For The Administration Of Human
Papillomavirus (HPV) Vaccine By Approved Healthcare Professionals
Working Within NHS Grampian, Highland, Orkney, Shetland, Tayside
And Western Isles**

Lead Author:

PGD adapted from PHS
template by Medicines
Management Specialist
Nurse NHSG

Consultation Group:

See relevant page in the
PGD

Approver:

NoS PGD Group

Authorisation:

NHS Grampian

Signature:

Signature:

NoS Identifier:

NoS/PGD/HPV/MGPG1293

Review Date:

August 2024

Date Approved:

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Expiry Date:

August 2025

NHS Grampian, Highland, Orkney, Shetland, Tayside and Western Isles have authorised this Patient Group Direction to help individuals by providing them with more convenient access to an efficient and clearly defined service within the NHS Boards. This Patient Group Direction cannot be used until Appendix 1 and 2 are completed.

Uncontrolled when printed

Version 3.1 (Amended December 2022)

Revision History:

Reference and approval date of PGD that has been adapted and/or superseded		PGD adapted from PHS national PGD template and supersedes NoS/PGD/Gardasil/MGPG1293 v3
Date of change	Summary of Changes	Section heading
August 2022	PGD adapted from PHS national PGD and on new NoS PGD template.	
August 2022	PGD filename changed from Gardasil to HPV	Throughout
August 2022	Additional sentence added regarding MSM and ongoing eligibility.	Frequency of dose/Duration of treatment
August 2022	NHST specific inclusion for children requiring booster following chemotherapy added.	Inclusion criteria and Frequency of dose/Duration of treatment
December 2022	Use out with SmPC updated to align with JCVI advice on one dose schedule.	Is the use out with the SmPC?
December 2022	Frequency section updated to align with JCVI advice on one dose schedule.	Frequency of dose/Duration of treatment
December 2022	References updated to include JCVI advice on one dose schedule.	References

NoS Identifier: NoS/PGD/HPV/MGPG1293 Version 3.1**Keyword(s):** PGD Patient Group Direction nurses HPV human papillomavirus Gardasil® vaccine 6 11 16 18 recombinant men sex Gardasil ®9

Policy Statement: It is the responsibility of the individual healthcare professional and their line managers to ensure that they work within the terms laid down in this PGD and to ensure that staff are working to the most up to date PGD. By doing so, the quality of the services offered will be maintained, and the chances of staff making erroneous decisions which may affect individual, staff or visitor safety and comfort will be reduced. Supervisory staff at all levels must ensure that staff using this PGD act within their own level of competence.

The lead author is responsible for the review of this PGD and for ensuring the PGD is updated in line with any changes in clinical practice, relevant guidelines, or new research evidence.



Review date: The review date for a PGD needs to be decided on a case-by-case basis in the interest of safety. The expiry date should not be more than 3 years, unless a change in national policy or update is required.

Document:	Drafted:	July 2022
	Completed:	August 2022
	Approved:	August 2022 (Published – September 2022)
	Amended and re- authorised:	December 2022


Organisational Authorisations

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


PGD Developed/Reviewed by;

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Approved for use within NoS Boards by;

North of Scotland (NoS) PGD Group Chair	Signature	Date Signed
Lesley Coyle		14/12/2022

Authorised and executively signed for use within NoS Boards by;

NHS Grampian Chief Executive	Signature	Date Signed
Professor Caroline Hiscox		05/01/2023

Management and Monitoring of Patient Group Direction

PGD Consultative Group

The consultative group is legally required to include a medical practitioner, a pharmacist and a representative of the professional group who will provide care under the direction.

Frances Adamson
Dr Maggie Watts
Alison Jane Smith
Fiona Browning
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Patient Group Direction For The Administration Of Human Papillomavirus (HPV) Vaccine By Approved Healthcare Professionals Working Within NHS Grampian, Highland, Orkney, Shetland, Tayside And Western Isles

Clinical indication to which this PGD applies

<p>Definition of situation/Condition</p>	<p>This Patient Group Direction (PGD) will authorise approved healthcare professionals as detailed in the characteristics of staff authorised to work under this PGD to administer Human Papillomavirus (HPV) Vaccine in line with the Scottish Government Health Directorate HPV immunisation programmes.</p> <p>This PGD should be used in conjunction with the recommendations in the current British National Formulary (BNF), British National Formulary for Children (BNFC), The Green Book Chapter 18a and the individual Summary of Product Characteristics (SmPC).</p>
<p>Inclusion criteria</p>	<p>Individuals who:</p> <ul style="list-style-type: none"> • Are between 11 and 25 years of age Note: Boys born before 01/09/2006 are not eligible for vaccination unless also in MSM cohort. • Are from school year S1, aged around 11-13 years, including those not in school. • Are up to 25 years of age with uncertain or incomplete immunisation status in accordance with the vaccination of individuals with uncertain or incomplete immunisation status flow chart. • Are Men who have Sex with other Men (MSM) aged up to and including 45 years of age attending sexual health or HIV clinics. • Are prisoners up to and including 45 years of age who identify as MSM. <p>The following inclusion is relevant to NHS Tayside only and does not apply in any other NoS Board - Children requiring booster doses 6 months after completing chemotherapy as per NHST local guidance.</p> <p>For all Boards, prior to the administration of the vaccine, valid consent to receiving treatment under this PGD must be obtained. Consent must be in line with current individual NHS Boards consent policy.</p>
<p>Exclusion criteria</p>	<p>Individuals who:</p> <ul style="list-style-type: none"> • Have a current acute systemic or febrile illness. • Have had an anaphylactic reaction to previous dose of the vaccine or to any of its excipients.

	<ul style="list-style-type: none"> • Are aged less than 9 years of age. • Are pregnant. • Have a history of severe (i.e. anaphylactic reaction) to latex where the vaccine is not latex free. <p>Individuals for whom no valid consent has been received.</p>
Precautions and special warnings	<p>Minor illness without fever or systemic upset is not a valid reason to postpone immunisation. If an individual is acutely unwell, immunisation may be postponed until they have fully recovered.</p> <p>Chapter 18a of The Green Book advises that there are very few individuals who cannot receive HPV vaccine. Where there is doubt, rather than withholding vaccination, appropriate advice should be sought from the relevant specialist, or from the local immunisation or health protection team.</p> <p>The presence of a neurological condition is not a contraindication to immunisation but if there is evidence of current neurological deterioration, deferral of vaccination may be considered, to avoid incorrect attribution of any change in the underlying condition. The risk of such deferral should be balanced against the risk of the preventable infection, and vaccination should be promptly given once the diagnosis and/or the expected course of the condition becomes clear.</p>
Action if excluded from treatment	<p>Medical advice must be sought – refer to relevant medical practitioner for advice on the vaccine and circumstances under which it could be given using a patient specific direction.</p> <p>The risk to the individual of not being immunised must be taken into account. Discussion of the risk and benefits of vaccination should take place. Discussions and decisions taken should be documented in clinical records.</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>In case of postponement due to acute severe febrile illness, advise when the individual can be vaccinated at a later date and ensure another appointment is arranged.</p>

	Document the reason for exclusion under the PGD and any action taken in the individual's appropriate clinical records.
Action if treatment is declined	<p>Advise about the protective effects of the vaccine and the risk of infection and disease complications. Ensure they have additional reading material, e.g. the Patient Information Leaflet (PIL) available to print here. Document advice given and decision reached.</p> <p>Advise how future immunisation may be accessed if they subsequently decide to receive the vaccine.</p> <p>Inform/refer to the relevant medical practitioner if individual/parent/carer treatment.</p> <p>Document that the administration of the vaccine was declined, the reason and advice given in appropriate clinical records.</p>

Description of vaccine available under the PGD

Name form and strength of vaccine	<p>Gardasil® Vaccine (Human papillomavirus Vaccine [Types 6, 11, 16, 18] (Recombinant, adsorbed))</p> <p>Or</p> <p>Gardasil® 9 Vaccine (Human papillomavirus 9 valent Vaccine [Types 6, 11, 16, 18, 31, 33, 45, 52, 58] (Recombinant, adsorbed))</p> <p>Suspension for injection in a prefilled syringe or vial.</p>
Legal status	Gardasil® and Gardasil® 9 Vaccines are Prescription-only Medicines (POM).
Is the use out with the SmPC?	<p>Administration of a one dose schedule for all those eligible in the programme up to their 25th birthday is off-label but is in accordance with the JCVI statement on a one-dose schedule for the routine HPV immunisation programme.</p> <p>Additionally in those from the age of 25 years in the MSM programme administration of a two-dose schedule of Gardasil® or Gardasil® 9 is off-label but is in accordance with the JCVI statement on a one-dose schedule for the routine HPV immunisation programme.</p> <p>Administration of a two-dose course with a 0, 6-24 month schedule differs slightly from the schedules in the SmPC but is in accordance with official recommendations in Chapter 18a of The Green Book.</p>

	<p>Completion of a HPV vaccine course using Gardasil® or 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.</p> <p>Administration of Gardasil® and Gardasil® 9 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.</p> <p>The HPV vaccine SmPCs state 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.</p> <p>The individual/parent/carer should be informed prior to the administration that the use is off-label, however the vaccine is being offered in accordance with national guidance.</p> <p>Vaccine should be stored according to the conditions detailed below. However, in the event of an inadvertent or unavoidable deviation of these conditions refer to NHS Board guidance on storage and handling of vaccines guidance. Where vaccine is assessed in accordance with these guidelines as appropriate for continued use, administration under this PGD is allowed.</p>
Dosage/Maximum total dose	<p>Single dose of 0.5mL per administration. Maximum 2-3 doses dependent on age – see Frequency of dose/Duration of treatment section below.</p>
Frequency of dose/Duration of treatment	<p>As the HPV vaccination programme transitions to Gardasil® 9, some individuals may receive a mixed schedule during the switch. Gardasil® and Gardasil® 9 vaccines are considered interchangeable and vaccination should not be delayed due to preference for either vaccine.</p> <p>Immunocompetent individuals in routine adolescent programme and MSM programme before their 25th birthday who are not known to be HIV positive.</p> <p>The vaccination schedule is one dose.</p> <p>If an eligible individual has started a three or two-dose course under 25 years of age before January 2023, their vaccination schedule should now be regarded as complete regardless of whether Gardasil® or Gardasil® 9 was used.</p>

	<p>Immunocompetent individuals from age of 25 years in the MSM programme who are not known to be HIV positive.</p> <p>The course consists of two doses:</p> <ul style="list-style-type: none"> • First dose. • Second dose at least six months after the first dose. <p>Both doses should ideally be given with a 24-month period. 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 of Gardasil® Vaccine have been administered less than 6 months apart a third dose should be given at least 3 months after the second dose.</p> <p>Where two doses of Gardasil® 9 Vaccine have been administered less than 5 months apart a third dose should be given at least 3 months after the second dose.</p> <p>Individuals who started their course prior to August 2022 when a two dose schedule was introduced should continue on the planned three dose schedule.</p> <p>Those individuals who commenced vaccination prior to August 2022 whose schedule is interrupted/delayed such that they had an interval of six months or more between their first and second dose only need a two dose schedule (do not require a third dose).</p> <p>Individuals who are immunosuppressed or known to be HIV positive</p> <p>The course consists of three doses:</p> <ul style="list-style-type: none"> • First dose. • Second dose at least one month after the first dose. • Third dose at least three months after the second dose. <p>All three doses should be ideally 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>There are 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 of HPV vaccine can be given at least one month after the second dose.</p>
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	<p>Vaccination of individuals with unknown or incomplete vaccination status</p> <p>Unimmunised individuals who enter an eligible cohort for HPV vaccination (see Criteria for inclusion) will retain their eligibility until their 25th birthday or in case of MSM aged up to and including 45 years of age attending sexual health or HIV clinic and should be vaccinated in accordance with the schedules above. For an individual who has started but not completed an HPV immunisation schedule at an eligible age, it is reasonable to complete their vaccination course, with Gardasil® or Gardasil® 9, in accordance with the schedules above.</p> <p>NHS Tayside ONLY:</p> <p>Revaccination of children aged up to 16 years who have received chemotherapy within the last 6 months</p> <p>In accordance with the schedule recommended in the Vaccinations For Paediatric Patients Treated With Standard-Dose Chemotherapy And Haemopoietic Stem Cell Transplantation (HSCT) Recipients</p>
Maximum or minimum treatment period	See Frequency of dose/Duration of treatment section above.
Route/Method of administration	<p>Administer by intramuscular or deep subcutaneous injection.</p> <p>The preferred site is the deltoid region of the upper arm. It can also be administered in the anterolateral area of the thigh.</p> <p>The intramuscular route is routinely used because localised reactions are more common when vaccines are given subcutaneously. However, for individuals with a bleeding disorder, vaccines may alternatively be given by deep subcutaneous injection to reduce the risk of bleeding.</p> <p>During storage, a white precipitate may develop and the vaccine should be shaken before use to form a white cloudy liquid.</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>HPV vaccine can be given at the same time as other vaccines such as DTaP/IPV/Hib/Hip, 4CMenB, MMR, MenACWY, Hib/MenC, Rotavirus and influenza. 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 when possible in different limbs to allow monitoring of local reactions to Gardasil® or Gardasil® 9. If given in the same limb they should be given at different sites at least 2.5cm apart (American Academy of Paediatrics 2003). The site at which each vaccine was administered should be noted in the individual's records.</p>
Quantity to be administered	0.5mL per dose for a maximum of three doses according to vaccination schedule. See Frequency of dose/Duration of treatment section above.
Storage requirements	<p>Vaccine will be stored in a temperature controlled refrigerator between +2°C and +8°C. Refrigerators should have maximum and minimum temperatures recorded daily. Do not freeze.</p> <p>Store in original packaging in order to protect from light.</p> <p>Data from stability studies demonstrate that the Gardasil® vaccine components are stable for 72 hours when stored at temperatures from +8°C to +42°C and 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 a vaccine that has not exceeded these stability data parameters.</p> <p>Individual NHS Board guidance on the storage, handling and cold chain in relation to vaccines must be observed. Likewise, individual NHS Board guidance in relation to waste management and the disposal of all spent, partially spent or unused vaccines must also be observed.</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.</p>
Follow-up (if applicable)	The individual should not leave if they have any concerns that the vaccine recipient is unwell without speaking to the healthcare professional who administered the vaccine first. If necessary a doctor or the individuals GP should be contacted for advice.

<p>Advice (Verbal)</p>	<ul style="list-style-type: none"> • Advise individual/parent/carer what to expect and of the possible side effects and their management • Give advice regarding normal reaction to the injection e.g. sore arm is possible • Give advice on the management if individual becomes feverish • The individual should be advised to seek medical advice in the event of a severe adverse reaction • Individual/parent/carer should be advised to report suspected adverse reactions to the Medicines and Healthcare products Regulatory Agency (MHRA) using the Yellow Card reporting scheme. <p>When administration is postponed advise the individual/parent/carer when to return for vaccination.</p> <p>Advise when subsequent doses are due and if any follow up is required.</p>
<p>Advice (Written)</p>	<p>The PIL contained in the medicine(s) should be made available to the individual/parent/carer. Where this is unavailable, or unsuitable, sufficient information should be given in a language that they can understand.</p> <p>Supply immunisation promotional material as appropriate. More information regarding this vaccine can be found at: https://www.nhsinform.scot/healthy-living/immunisation</p>
<p>Identifying and managing possible adverse reactions</p>	<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 most commonly seen reactions are minor local injection site reactions such as hardening of the skin, oedema, pain and redness. A small painless nodule may form at the injection site.</p> <p>Other reactions commonly reported are headache, myalgia, fatigue and low grade fever.</p> <p>As with all vaccines there is a very small possibility of anaphylaxis and facilities for its management must be available.</p>

	<p>This list is not exhaustive. Please also refer to current BNF/BNFC and manufacturers SmPC for details of all potential adverse reactions.</p> <p>BNF/BNFC: BNF British National Formulary - NICE BNF for Children British National Formulary - NICE</p> <p>SmPC/PIL/Risk Minimisation Material: Home - electronic medicines compendium (emc) MHRA Products Home RMM Directory - (emc)</p> <p>If an adverse reaction does occur give immediate treatment and inform relevant medical practitioner as soon as possible.</p> <p>Document in accordance with locally agreed procedures in the individual's record.</p> <p>Report any suspected adverse reactions using the Yellow Card System. Yellow Card Scheme - MHRA.</p>
Facilities and supplies required	<p>The following are to be available at sites where the vaccine is to be administered:</p> <ul style="list-style-type: none"> • Pharmaceutical refrigerator (or a validated cool box for storing vaccine if mobile unit) • An acceptable level of privacy to respect individual's right to confidentiality and safety • Basic airway resuscitation equipment (e.g. bag valve mask) • Immediate access to Epinephrine (Adrenaline) 1 in 1000 injection • Access to a working telephone • Another competent adult, who can summon urgent emergency support if required should ideally be present • Access to medical support (this may be via the telephone) • Approved equipment for the disposal of used materials • Clean and tidy work areas, including access to hand washing facilities or alcohol hand gel • A copy of this PGD in print or electronically.

Characteristics of staff authorised to administer vaccine under PGD

Professional qualifications	<p>The following classes of registered healthcare professionals are permitted to administer vaccines as identified and included in individual Board immunisation delivery plans:</p> <ul style="list-style-type: none"> • Nurses and midwives currently registered with the Nursing and Midwifery Council (NMC)
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	<ul style="list-style-type: none"> • Pharmacists currently registered with the General Pharmaceutical Council (GPhC) • Chiropodists/podiatrists, dieticians, occupational therapists, orthoptists, orthotists/prosthetists, paramedics, physiotherapists, radiographers and speech and language therapists currently registered with the Health and Care Professions Council (HCPC) • Dental hygienists and dental therapists registered with the General Dental Council • Optometrists registered with the General Optical Council.
Specialist competencies	<p>Approved by the organisation as:</p> <ul style="list-style-type: none"> • Competent to assess the individual's/parent's/carer's capacity to understand the nature and purpose of vaccination in order to give or refuse consent • Familiar with the vaccine product and alert to changes in the product information • Competent to undertake administration of the vaccine and discuss issues related to vaccination • Competent in the recognition and management of anaphylaxis or under the supervision of persons able to respond appropriately to immediate adverse reactions • Competent in the handling and storage of vaccines, and management of the "cold chain" • Competent to work under this PGD and authorised by name as an approved person to work under the terms of the PGD.
Ongoing training and competency	<p>All professionals working under this PGD must:</p> <ul style="list-style-type: none"> • Have undertaken NoS PGD module training on TURAS Learn • Have attended basic life support training either face to face or online and updated in-line with individual Board requirements • Have undertaken immunisation training • Have undertaken NHS e-anaphylaxis training or equivalent which covers all aspects of the identification and management of anaphylaxis updated in-line with individual Board requirements • Maintain their skills, knowledge and their own professional level of competence in this area according to their individual Code of Professional Conduct. Note: All practitioners operating under the PGD are responsible for ensuring they remain up to date with the use of the vaccine. If any training needs are identified these should be discussed with those responsible for authorisation to act under the PGD • Have knowledge and familiarity of the following; <ul style="list-style-type: none"> ○ Current edition of the Green Book

	<ul style="list-style-type: none"> ○ SmPC for the vaccine to be administered in accordance with this PGD ○ Relevant policy relating to vaccine storage and immunisation procedures for use within their Health Board ○ Relevant Scottish Government Health Directorate advice including the relevant CMO letter(s).
Responsibilities of professional manager(s)	<p>Professional manager(s) will be responsible for;</p> <p>Ensuring that the current PGD is available to all staff providing care under this direction.</p> <p>Ensuring that staff have received adequate training in all areas relevant to this PGD and meet the requirements above.</p> <p>Maintain up to date record of all staff authorised to administer the vaccine specified in this direction.</p>

Documentation

Authorisation of administration	<p>Qualified registered healthcare professionals working within NHS Grampian, Highland, Orkney, Shetland, Tayside and Western Isles listed and approved in legislation as able to operate under PGD can be authorised to administer the vaccine specified in this PGD in accordance with local delivery plans and by agreement at individual Board level as per the following:</p> <p>Nurses, midwives and health visitors can be authorised by their line manager.</p> <p>Pharmacists working within NHS Grampian, Highland, Orkney, Shetland, Tayside and Western Isles can be authorised to administer the medicine(s) specified in this PGD when they have completed local Board requirements for service registration.</p> <p>The following list of healthcare professionals can be authorised by their Line Manager, Head of Service or Vaccine Coordinator: Chiropodists, dental hygienists, dental therapists, dieticians, occupational therapists, optometrists, orthoptists, orthotist/prosthetists, paramedics, physiotherapists, podiatrists, radiographers and speech and language therapists.</p> <p>All authorised staff are required to read the PGD and sign the Agreement to Administer Medicines Under PGD (Appendix 1).</p>
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	<p>A Certificate of Authorisation (Appendix 2) signed by the authorising professional/manager should be supplied. This should be held in the individual health professional's records, or as agreed within the individual Health Board.</p>
Record of administration	<p>An electronic or paper record must be completed to allow audit of practice.</p> <p>An electronic/Hospital Electronic Prescribing and Medicines Administration (HEPMA) record of the screening and subsequent administration, or not of the medicine(s) specified in this PGD should be made in accordance with individual Health Board electronic/HEPMA recording processes.</p> <p>If a paper record is used for recording the screening of individuals and the subsequent administration, or not of the medicine(s) specified in this PGD, it should include as a minimum:</p> <ul style="list-style-type: none"> • Date and time of vaccine administration • Individuals name, address and CHI • GP with whom the individual is registered • Exclusion criteria, record why the vaccine was not administered (if applicable) • Record that valid consent to treatment under this PGD was obtained • The name, brand, dose, form, batch number, expiry date, route/and anatomical site of the vaccination administered • Advice given, including advice given if excluded or declined vaccination under this PGD • Signature and name in capital letters of the healthcare professional who administered the vaccine, and who undertook the assessment of the individual's clinical suitability for the vaccine • Record of any adverse effects and the actions taken (advise individuals' GP/relevant medical practitioner). <p>Depending on the clinical setting where administration is undertaken, the information should be recorded manually or electronically on the individual service specific system, as appropriate.</p> <ul style="list-style-type: none"> • Individual's GP records if appropriate • HEPMA • Individual service specific systems. <p>Local policy should be followed with respect to sharing information with the individual's General Practitioner.</p> <p>All records should be clear, legible and contemporaneous and in an easily retrievable format.</p>

Audit	<p>All records of the vaccine specified in this PGD will be filed with the normal records of medicines in each practice/service. A designated person within each practice/service where the PGD will be used will be responsible for annual audit to ensure a system of recording medicines administered under a PGD.</p>
References	<p>Electronic Medicines Compendium http://www.medicines.org.uk</p> <p>Gardasil® suspension for injection in a pre-filled syringe – Date of revision of text 01/01/21, accessed 02/08/2022.</p> <p>Gardasil® 9 suspension for injection in a pre-filled syringe – Date of revision of text 29/04/22, accessed 02/08/2022.</p> <p>British National Formulary for Children and the British National Formulary accessed 02/08/2022.</p> <p>Department of Health (2006): Immunisation against Infectious Disease [Green Book]</p> <p>Human papillomavirus (HPV): the green book, chapter 18a - GOV.UK (www.gov.uk)</p> <p>JCVI statement on a one-dose schedule for the routine HPV immunisation programme - GOV.UK (www.gov.uk)</p> <p>Vaccinations For Paediatric Patients Treated With Standard-Dose Chemotherapy And Haemopoietic Stem Cell Transplantation (HSCT) Recipients (2020)</p> <p>American Academy of Pediatrics (2003) Active immunisation. In: Pickering LK (ed.) Red Book: 2003 Report of the Committee on Infectious Diseases, 26th edition. Elk Grove Village, IL: American Academy of Pediatrics, p 33.</p>

Appendix 1

Healthcare Professional Agreement to Administer Vaccine Under Patient Group Direction

I: _____ (Insert name)

Working within: _____ e.g. Area, Practice

Agree to administer the vaccine contained within the following Patient Group Direction:

Patient Group Direction For The Administration Of Human Papillomavirus (HPV) Vaccine By Approved Healthcare Professionals Working Within NHS Grampian, Highland, Orkney, Shetland, Tayside And Western Isles

I have completed the appropriate training to my professional standards enabling me to administer the vaccine under the above direction. I agree not to act beyond my professional competence, nor out with the recommendations of the direction.

Signed: _____

Print Name: _____

Date: _____

Profession: _____

Professional Registration number/PIN _____

Appendix 2

Healthcare Professionals Authorisation to Administer Vaccine Under Patient Group Direction

The Lead manager/Professional of each clinical area is responsible for maintaining records of all clinical areas where this PGD is in use, and to whom it has been disseminated.

The Senior Nurse/Professional who approves a healthcare professional to administer the vaccine under this PGD is responsible for ensuring that he or she is competent, qualified and trained to do so, and for maintaining an up-to-date record of such approved persons.

The Healthcare Professional that is approved to administer the vaccine under this PGD is responsible for ensuring that he or she understands and is qualified, trained and competent to undertake the duties required. The approved person is also responsible for ensuring that administration is carried out within the terms of the direction, and according to his or her individual code of professional practice and conduct.

Patient Group Direction For The Administration Of Human Papillomavirus (HPV) Vaccine By Approved Healthcare Professionals Working Within NHS Grampian, Highland, Orkney, Shetland, Tayside And Western Isles

Local clinical area(s) where the listed healthcare professionals will operate under this PGD:

Name of Healthcare Professional	Signature	Date	Name of Manager	Signature	Date

Patient Group Direction For The Administration Of Human Papillomavirus (HPV) Vaccine By Approved Healthcare Professionals Working Within NHS Grampian, Highland, Orkney, Shetland, Tayside And Western Isles

Name of Healthcare Professional	Signature	Date	Name of Manager	Signature	Date