



Bronllys Hospital, Bronllys, Brecon, Powys, LD3 0LU

This Patient Group Direction (PGD) must only be used by registered healthcare professionals who have been named and authorised by their organisation to practice under it. The most recent and in date final signed version of the PGD should be used. Healthcare professionals should always access the PGD via the PTHB internet to ensure that they are always working to the most up to date version

Patient Group Direction

for the administration of

human papillomavirus (HPV) vaccine

by registered healthcare professionals

to

individuals from 12 years of age or from school year 8 and aged less than 25 years

in accordance with the national immunisation programme

in Powys Teaching Health Board

Version number: PGD 0060 I

Change History

Version number	Change details	Date
PGD 0060	Initial issue- switch from Cervarix brand	01/09/2012
PGD 0060-A	Review issue and changed to two dose schedule	22/09/2014
PGD0060-B	Review issue	27/01/2017
PGD0060-C	<p>Review issue</p> <p>PHE HPV PGD amended to:</p> <ul style="list-style-type: none"> • include immunisation of transgender boys and transgender girls as appropriate • include registered nurses working in a Powys GP practice • provide additional information on capacity to consent with link to the DH 'Reference guide to consent for examination or treatment' • reference the protocol for ordering storage and handling of vaccines • add additional paragraphs to the off-label section on storage and consent • refer to vaccine incident guidelines • Moved pregnancy from cautions to exclusions with discussion in actions if patient is excluded <p>include rewording, layout and formatting changes for clarity and consistency with other PHE PGD templates</p>	20/05/2019
PGD0060-D	<p>PHE HPV PGD amended to:</p> <ul style="list-style-type: none"> • update inclusion criteria to include boys from September 2019 • include retention of eligibility until the individuals 25th birthday • update off-label section <p>include minor rewording, layout and formatting changes for clarity and consistency with other PHE and PTHB PGD templates</p>	21/10/2019
PGD0060-E	PGD updated to include additional healthcare professionals and to remove restriction for PGD to be used only by school nurses or in GP surgeries.	01/08/2020

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PGD0060F	<p>PHE template adopted - amendment includes:</p> <ul style="list-style-type: none"> • the nine valent vaccine (Gardasil® 9) • minor rewording • layout and formatting changes for clarity and consistency with other PGD templates 	1 st September 2021
PGD0060G	<p>UKHSA template adopted to:</p> <ul style="list-style-type: none"> • update dose and frequency section to reflect updated recommendations that, from 1 April 2022, those commencing vaccination from 15 years of age should commence a 2-dose schedule with a minimum 6-month interval • refer to Chapter 2 of the Green Book for further information on consent • update off-label section to reflect the revised schedule • reflect updated storage details for Gardasil 9 • update organisation from PHE to the UKHSA • include minor rewording, layout and formatting changes for clarity and consistency with other UKHSA PGDs 	01/04/2022
PGD0060H	<p>UKHSA template V6.00 adopted to:</p> <ul style="list-style-type: none"> • change to one-dose schedule for the routine HPV immunisation programme • update the eligible cohorts, clinical condition and criteria for inclusion • add use of Gardasil® 9 in pregnancy in off-label and special consideration sections and amend exclusion and actions to be taken sections accordingly • add one dose schedule in off-label section • add use of mixed schedule in off-label section • update criteria for exclusion • remove 2 doses schedule from dose and frequency • remove Gardasil® throughout the document as it has been discontinued and has not been used since July 2022 in the programme • include facilities for management for anaphylaxis statement in cautions section for consistency • add statement for separate order lines for gay, bisexual, and other men who have sex with men (GBMSM) and adolescent HPV programmes on ImmForm • add advice to be given if fainting occurs in patient advice 	01/09/2023

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	<ul style="list-style-type: none"> • add accessible information in written information section • update reference section • include minor rewording of standard text, layout and formatting changes for clarity and consistency with organisation change, gateway requirements and other UKHSA PGDs • amend NHS England and NHS Improvement (NHSEI) to NHSE following completion of merger on 1 July 2022 <p>Layout and formatting changes for clarity and consistency with other PGD templates.</p>	
PGD0060I	<p>Review issue in line with UKHSA HPV vaccine PGD template v7.0 to:</p> <ul style="list-style-type: none"> • update the schedule for routine immunisation in the dose and frequency of administration section • update qualifications and professional registration with reference to clinical scope • update expert panel • add pharmacy technicians in Section 1; qualifications and professional registration • update qualifications and professional registration section to include dietitians, podiatrists, and occupational therapists • add statement in dose and frequency section with reference to where vaccines have been given inadvertently • add statement in dose and frequency section with reference to using a mixed schedule for vaccination of individuals with unknown or incomplete vaccination status • delete the statement for post-marketing surveillance in the identification and management of adverse reactions section <p>Reviewed to include minor rewording of standard text, layout and formatting changes for clarity and consistency with other PTHB PGDs.</p>	01/09/2025

This Powys Teaching Health Board (PTHB) PGD is based on the UKHSA HPV vaccine PGD template v7.0 developed by the following health professionals on behalf of the UKHSA and peer reviewed by the UKHSA Immunisations PGD Expert Panel in accordance with the UKHSA PGD and Protocol Policy (also ratified by the UKHSA Medicines Governance Committee). The UKHSA template has been adapted for use in PTHB.

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Developed by the following health professionals on behalf of the UKHSA:

Developed By:	Name
Pharmacist (Lead Author)	Suki Hunjunt Lead Pharmacist Immunisation Programmes, UKHSA
Doctor	Sharif Ismail Consultant Epidemiologist, Public Health Infection Programmes, UKHSA
Registered Nurse (Chair of Expert Panel)	David Green Nurse Consultant for Immunisation Programmes, UKHSA

Expert Panel

Nicholas Aigbogun	Consultant in Communicable Disease Control, Yorkshire and Humber Health Protection Team, UKHSA
Gayatri Amrithalingham	Consultant Epidemiologist, Immunisation Programmes, UKHSA
Jessica Baldasera	Health Protection Practitioner, North East Health Protection Team Regions Directorate, UKHSA
Alison Campbell	Screening and Immunisation Coordinator, Public Health Commissioning NHS England (NHS England) Midlands
Jodie Crossman	Clinical Nurse Specialist GUM - Brighton SHAC, Co-Chair - STI Foundation
Jane Freeguard	Deputy Director of Vaccination – Medicines and Pharmacy NHS England
Rosie Furner	Advanced Specialist Pharmacist - Medicines Governance, Specialist Pharmacist Services (SPS)
Ed Gardner	Advanced Paramedic Practitioner/Emergency Care Practitioner, Medicines Manager, Proactive Care Lead
Shilan Ghafoor	Medicines Governance Lead Pharmacist, UKHSA
Greta Hayward	Consultant Midwife – Immunisation Programmes, UKHSA
Naveen Dosanjh	Senior Clinical Advisor - Vaccinations, NHS England
Elizabeth Lockett	Senior Screening and Immunisation Manager, NHS England South West
Briony Mason	Vaccination Manager, Professional Midwifery Advocate, Vaccination and Screening, NHS England, West Midlands
Vanessa MacGregor	Consultant in Communicable Disease Control, East Midlands Health Protection Team, UKHSA
Laura Craig	Lead Immunisation Nurse Specialist, Immunisation and Vaccine Preventable Diseases Division, UKHSA
Tushar Shah	Lead Pharmacy Advisor, NHSE London

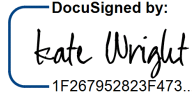


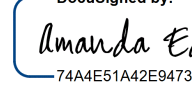
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PGD Authorisation

Name	Job title and organisation	Signature	Date
Senior doctor Dr Kate Wright	Lead doctor for PTHB	 DocuSigned by: <i>Kate Wright</i> 1F267952823F473...	8/18/2025
Chief Pharmacist Jonathan Boyd	Chief Pharmacist for PTHB	 Signed by: <i>Jon Boyd</i> 6D8ECFE8C9EB423...	8/19/2025
Senior representative of professional group using the PGD Claire Roche	Executive Director of Nursing and Midwifery for PTHB	 DocuSigned by: <i>Claire Roche</i> F07413E114E04B1...	8/19/2025
Clinical Governance Lead Amanda Edwards	Clinical Governance Lead for PTHB – Assistant Director for Innovation and Improvement	 DocuSigned by: <i>Amanda Edwards</i> 74A4E51A42E9473...	8/26/2025

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. [Appendix A](#) provides a staff accreditation sheet. Individual practitioners must be authorised by name to work to this PGD.

Those using this PGD must ensure that it is organisationally authorised and signed by an appropriate authorising person, relating to the class of person by whom the product is to be supplied, in accordance with Human Medicines Regulations 2012 (HMR2012)¹. **The PGD is not legal or valid without signed authorisation in accordance with [HMR2012 Schedule 16 Part 2](#).**

Operation of this PGD is the responsibility of commissioners and service providers. The final authorised copy of this PGD should be kept by PTHB for 25 years after the PGD expires. Provider organisations adopting authorised versions of this PGD should also retain copies for 25 years after the PGD expires.

¹ This includes any relevant amendments to legislation

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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. Enquiries relating to the availability of organisationally authorised PGDs and subsequent versions of this PGD should be directed to:

info.medicinesmanagement.powys@wales.nhs.uk

PGD adoption by the provider

Name	Job title and organisation	Signature	Date
Signatures to be determined locally, if relevant			

1. Characteristics of staff

<p>Qualifications and professional registration</p>	<p>All practitioners should only administer vaccination where it is within their clinical scope of practice to do so. Practitioners must also fulfil the additional requirements and continued training requirements to ensure their competency is up to date, as outlined in the section below: Practitioners working to this PGD must also be one of the following registered professionals who can legally supply and administer under a PGD:</p> <ul style="list-style-type: none"> • nurses and midwives currently registered with the Nursing and Midwifery Council (NMC) • pharmacists and pharmacy technicians currently registered with the General Pharmaceutical Council (GPhC) (Note: this PGD is not relevant to privately provided community pharmacy services) • paramedics, physiotherapists, dieticians, podiatrists, and occupational therapists currently registered with the Health and Care Professions Council (HCPC) <p>The practitioners above must also fulfil the Additional requirements detailed below.</p> <p>Check Appendix A – Staff Accredited to use the Patient Group Direction to confirm whether all practitioners listed above have organisational authorisation to work under this PGD.</p>
<p>Additional requirements</p>	<p>Additionally, practitioners:</p> <ul style="list-style-type: none"> • must be authorised by name as an approved practitioner under the current terms of this PGD before working to it • must have undertaken appropriate training for working under PGDs for supply/administration of medicines. Must have completed eLfh PGD eLearning Patient Group Directions training (available via learning@wales, PTHB staff to access via ESR). Evidence of ongoing PGD training to be submitted to Line Manager annually– this should include an annual completion certificate of PGD e-learning or a dated screenshot of the PGD e-learning assessment results as proof of completion. • must be competent in the use of PGDs (see NICE Competency framework for health professionals using PGDs). Individuals operating under this PGD must be assessed as competent (see Appendix A) • must be familiar with the vaccine product and alert to changes in the Summary of Product Characteristics (SPC), Immunisation Against Infectious Disease (the 'Green Book'), and national and local immunisation programmes

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	<ul style="list-style-type: none"> • must have undertaken training appropriate to this PGD as required by local policy and in line with the National Minimum Standards and Core Curriculum for Immunisation Training and online training. Please contact PTHB immunisation co-ordinator for further information. • must be competent to undertake immunisation and to discuss issues related to immunisation • must be competent in intramuscular injection techniques • must be competent in the handling and storage of vaccines, and management of the cold chain. Completion of cold chain training (also available via ESR) • must be familiar with All Wales Advisory document on Ordering Storage and Handling of Vaccines • must be competent in the recognition, management and reporting of recognised adverse drug reactions, including anaphylaxis. Must be competent in the administration of adrenaline 1 in 1000 and have up to date Basic Life Support (BLS) skills. • must have access to the PGD and associated online resources • should fulfil any additional requirements defined by local policy <p>The individual practitioner must be authorised by name, under the current version of this PGD before working according to it.</p>
<p>Continued training requirements</p>	<p>Updating at least every 2 years on the administration of human papillomavirus (HPV) vaccine.</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 must make a self-declaration of competency on PADR (if relevant). The personal development plan (yellow) section of the PADR booklet should be used to record completion of Statutory and Mandatory training, including annual PGD e-learning.</p> <p>Compliance with all mandatory NHS training (if relevant).</p> <p>Practitioners should be constantly alert to any subsequent recommendations from the Welsh Government and/or Public Health Wales and/or NHS Wales and/or the UKHSA</p>

	<p>and/or NHS England (NHSE) and other sources of medicines information.</p> <p>Note: The most current national recommendations should be followed but a Patient Specific Direction (PSD) or a prescription may be required to administer the vaccine in line with updated recommendations that are outside the criteria specified in this PGD.</p> <p>It is the responsibility of the healthcare professional to maintain their own competency to practice within this PGD.</p>
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2. Clinical condition or situation to which this PGD applies

Clinical condition or situation to which this PGD applies	<p>Indicated for the active immunisation of individuals from 12 years of age or from school year 8 and aged less than 25 years (see Criteria for Inclusion), for the prevention of human papillomavirus infection in accordance with the national immunisation programme and recommendations given in Chapter 18a of Immunisation Against Infectious Disease: The 'Green Book'.</p> <p>It is the responsibility of the administering healthcare professional to ensure that the individual is within the inclusion criteria, and that there are no reasons for exclusion before proceeding with the vaccination. If there is any reason for concern, seek medical advice.</p>
Criteria for inclusion	<p>Individuals who:</p> <ul style="list-style-type: none"> • are aged 12 to 13 years in the birth cohort for school year 8² • are females born on or after 1 September 1991 or males born on or after 1 September 2006 and are less than 25 years old • Transgender females and transgender males, in birth cohorts eligible for the girls' programme from 1 September 2008, may be vaccinated in accordance with this PGD as appropriate <p>Informed consent, from the individual (see note in special considerations below) or a person legally able to act on the individual's behalf), must be obtained prior to administration. NB. Refer to PTHB Consent to Treatment and Examination Policy.</p>

² Individuals in school year 8 who are aged outside the designated birth cohort for the school year may be immunised with their peers

	<p>Medical and drug history taken, no reason for exclusion.</p> <p>Any vulnerable adult or child protection concerns should be referred to Safeguarding and PTHB safeguarding policies followed. Where there are safeguarding concerns (Child Protection or Protection of Vulnerable Adults, POVA) advice from the local Safeguarding team should be sought (see below).</p>
<p>Criteria for exclusion (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>	<p>Individuals for whom no valid consent has been received (or for whom a best-interests decision in accordance with the Mental Capacity Act 2005, has not been obtained). For further information on consent, see Chapter 2 of the Green Book. Several resources are available to inform consent (see written information to be given to individual or carer section). If consent is not received, please refer to section Action to be taken if the individual or carer declines treatment.</p> <p>Individuals who:</p> <ul style="list-style-type: none"> • are less than 12 years of age and in school year 7 or lower • are less than 9 years of age • are aged 25 years and over, except those who have received a partial course of HPV immunisation (It is clinically appropriate to complete the course but vaccination of individuals who have attained 25 years of age will not attract a payment) • have had a confirmed anaphylactic reaction to a previous dose of HPV vaccine or to any components of the vaccine • have completed a course of HPV vaccine • are suffering from acute severe febrile illness (the presence of a minor infection is not a contraindication for immunisation) <p>Refer to section action to be taken if the individual is excluded.</p>
<p>Cautions including any relevant action to be taken</p>	<p>Facilities for management of anaphylaxis should be available at all vaccination sites (see Chapter 8 of the Green Book) and advice issued by the Resuscitation Council UK.</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</p>

	<p>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 (see Green Book Chapter 7). Seek medical advice as appropriate.</p> <p>Check for any other medications that the individual is taking, including topical or inhaled products, food supplements and herbal or homeopathic products. (Refer to BNF/SPC for full list)</p> <p>Under Section 128 and 130 of the Social Services and Wellbeing (Wales) Act 2014, staff have a duty to inform the Local Authority if they have reasonable cause to suspect that an adult or child is at risk. Any vulnerable adult or child protection concerns should be referred to Safeguarding and the PTHB safeguarding policies followed. Consider discussing with GP. Any safeguarding concerns need to be directed to Safeguarding Hub:</p> <ul style="list-style-type: none"> • to generic email address: PowysTHB.Safeguarding@wales.nhs.uk <p>and</p> <ul style="list-style-type: none"> • Central Safeguarding number: 01686 252806 • Out of hours: 0345 0544847 <p>Advice can also be sought from local Safeguarding Leads</p>
<p>Action to be taken if the individual is excluded</p>	<p>If aged less than 12 years and in a school year below year 8, advise the individual when the 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 or a prescription would be required.</p> <p>If aged 25 years and over advise that vaccination against HPV is not provided under the routine NHS HPV immunisation programme.</p> <p>GBMSM and are 25 years and over can be advised that HPV vaccination may be accessed through specialist sexual health services (see Chapter 18A).</p> <p>If a confirmed anaphylactic reaction has been experienced after a previous dose of HPV vaccine, or any of its components, specialist advice should be sought. If</p>

	<p>immunisation is recommended do not administer under this PGD; a PSD or a prescription will 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>Explain reason to individual/carer. Document the reason for exclusion and any action taken in the individual’s clinical records.</p> <p>Inform or refer to the GP or a prescriber as appropriate.</p>
<p>Action to be taken if the individual or carer declines treatment</p>	<p>Informed consent, from the individual or a person legally able to act on the individual’s behalf, must be obtained for each administration (see Additional Information).</p> <p>The patient information leaflet should be available to inform consent.</p> <p>Advise the individual/parent/carer about the protective effects of the vaccine, the risks of infection and potential complications.</p> <p>Document the advice given and the decision reached.</p> <p>Inform or refer to the GP or a prescriber as appropriate.</p> <p>Inform the Child Health department if appropriate – if any vaccination is declined for a child under 19 years, Child Health must be informed and appropriate form completed. Where appropriate, inform the GP using the local agreed system.</p>
<p>Arrangements for referral for medical advice</p>	<p>Refer to GP, paediatrician or consultant in communicable disease control (CCDC) for clinical advice as necessary.</p> <p>Document any advice given.</p>

3. Description of treatment

Name, strength and formulation of drug	Human papillomavirus 9-valent vaccine [types 6, 11, 16, 18, 31, 33, 45, 52, 58] (recombinant, adsorbed): <ul style="list-style-type: none"> • Gardasil® 9, suspension for injection in a pre-filled syringe or vial
Legal category	Prescription Only Medicine (POM)
Black triangle▼	No
Off-label use	<p>The use of a one-dose schedule of Gardasil® 9 is off-label, however, it is in accordance with national recommendations by JCVI and Chapter 18a of the 'Green Book'.</p> <p>The SPC does not recommend the use of Gardasil® 9 during pregnancy and advises to postpone the vaccination until completion of pregnancy. However, vaccination in pregnancy can be given in accordance with the Green Book, Chapter 18A (see Special considerations).</p> <p>Completion of a HPV vaccine course using Gardasil® 9 when it was not commenced with the same HPV vaccine product is off-label but is in accordance with official recommendations and Chapter 18a of the Green Book.</p> <p>The HPV vaccine SPC states that 'vaccinees should be observed for approximately 15 minutes after vaccine administration'. In line with advice in Chapter 4 of the 'Green Book', recipients of any vaccine should be observed for immediate adverse drug reactions. There is no evidence to support the practice of keeping individuals under longer observation.</p> <p>Vaccine should be stored according to the conditions detailed in the Storage section below. However, in the event of an inadvertent or unavoidable deviation of these conditions refer to the All Wales Advisory document on Ordering Storage and Handling of Vaccines and Vaccine Incident Guidance. Where vaccine is assessed in accordance with these guidelines as appropriate for continued use this would constitute off-label administration under this PGD.</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</p>

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	<p>accordance with national guidance but that this is outside the product licence.</p>
<p>Route and method of administration</p>	<p>Administer by intramuscular injection. The preferred site is the deltoid region of the upper arm (see The Green Book Chapter 4).</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>Individuals with bleeding disorders may be vaccinated intramuscularly if, in the opinion of a doctor familiar with the individual's bleeding risk, vaccines or similar small volume intramuscular injections can be administered with reasonable safety by this route. If the individual receives medication/treatment to reduce bleeding, for example treatment for haemophilia, intramuscular vaccination can be scheduled shortly after such medication/treatment is administered. Individuals on stable anticoagulation therapy, including individuals on warfarin who are up to date with their scheduled INR testing and whose latest INR was below the upper threshold of their therapeutic range, can receive intramuscular vaccination. A fine needle (equal to 23 gauge or finer calibre such as 25 gauge) should be used for the vaccination, followed by firm pressure applied to the site (without rubbing) for at least 2 minutes. If in any doubt, consult with the clinician responsible for prescribing or monitoring the individual’s anticoagulant therapy.</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: www.medicines.org.uk</p>

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<p>Dose and frequency of administration</p>	<p>Single 0.5ml dose per administration</p> <p>HPV vaccination should be routinely offered in school year 8 (see Additional information).</p> <p>Doses for routine and universal programme Individuals from 12 years of age or from school year 8 and aged less than 25 years:</p> <ul style="list-style-type: none"> • One dose of 0.5ml of HPV vaccine. <p>Individuals with immunosuppression and those living with HIV Individuals who are known to be immunosuppressed at the time of vaccination and those who are living with HIV, including those on antiretroviral therapy, should continue to be offered a 3 dose schedule in accordance with the Green Book, Chapter 18A.</p> <p>Administer a course of three doses on a 0, 1 and 4-6-month schedule, for instance:</p> <ul style="list-style-type: none"> • first dose of 0.5ml of HPV vaccine, then • second dose of 0.5ml at least one month after the first dose, then • a third dose of 0.5ml at least three months after the second dose <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 3-dose schedule should follow the recommended 0, 1, 4-6 month schedule. There is no clinical data on whether the interval between doses two and three can be reduced below three months. Where the second dose is given late and there is a high likelihood that the individual will not return for a third dose after three months or if, for practical reasons, it is not possible to schedule a third dose within this timeframe, then a third dose can be given at least one month after the second dose.</p> <p>If applicable, where vaccines have inadvertently been given at less than the recommended interval, the dose given early should be discounted and should be repeated at least 4 weeks from the dose given early in error.</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 and should be vaccinated in accordance with the schedules above.</p> <p>For individuals who are immunosuppressed and HIV positive and have started but not completed an HPV immunisation schedule at an eligible age, it is reasonable to complete their vaccination course, with Gardasil® 9, in accordance with the schedules above.³</p> <p>For individuals who are immunocompetent and are not HIV positive, and present with an inadequate vaccination history, every effort should be made to clarify what doses they have had and when they received them. Individuals who have received one HPV vaccine dose before reaching the age of 25 years, do not require any further doses.</p> <p>Individuals who started their schedule with a product not available in the UK, and require additional doses to complete their course, (see Chapter 18a) will follow a mixed schedule.</p>
<p>Duration of treatment</p>	<p>A one or three dose course (see Dose and frequency section above)</p>
<p>Quantity to be administered</p>	<p>Single 0.5 ml dose per administration.</p>
<p>Supplies</p>	<p>Centrally purchased vaccines for the national immunisation programme can only be ordered via ImmForm. Vaccines for use for the national immunisation programme are provided free of charge.</p> <p>There are separate order lines for the GBMSM and adolescent HPV programmes on ImmForm. The correct one must be used to order vaccine for each programme, even where an ImmForm account holder is ordering for both.</p> <p>Protocols for the ordering, storage and handling of vaccines should be followed to prevent vaccine wastage (see the 'Green Book' Chapter 3).</p>

³ It is clinically appropriate to complete the course but vaccination of individuals who have attained 25 years of age will not attract a payment.

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	<p>Also refer to All Wales Advisory document on Ordering Storage and Handling of Vaccines.</p>
<p>Storage</p>	<p>Store at +2°C to +8°C. Store in original packaging in order to protect from light. Do not freeze.</p> <p>Gardasil®9 should be administered as soon as possible after being removed from the refrigerator.</p> <p>Protocols for the storage and handling of vaccines should be followed to prevent vaccine wastage.</p> <p>Data from stability studies demonstrate that the Gardasil® 9 vaccine components are stable for 96 hours when stored at temperatures from +8°C to +40°C or for 72 hours when stored at temperatures from 0°C to +2°C. These data are intended to guide healthcare professionals in case of temporary temperature excursion only. This PGD may be used to administer vaccine that has not exceeded these stability data parameters.</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 on a case-by-case for suitability of continued off-label use or appropriate disposal. Refer to All Wales Advisory document on Ordering Storage and Handling of Vaccines and Vaccine Incident Guidance.</p> <p>See 'MMP 427 Safe and Secure Management of Refrigerated Medicines and Vaccines SOP' for details of actions required in the event of a fridge temperature excursion.</p> <p>Any loss of vaccines due to expiry date or fridge failure/breaches in cold chain must be reported on ImmForm, to PTHB Immunisation co-ordinator (Powys.Immunisations@wales.nhs.uk), and via PTHB Datix reporting system Once for Wales Reporting System.</p>
<p>Disposal</p>	<p>Equipment used for immunisation, including used vials, ampoules, or discharged vaccines in a syringe or applicator, should be disposed of safely in a UN-approved puncture-resistant 'sharps' box, according to local waste disposal arrangements and NHS England guidance in the technical memorandum 07-01: Safe management of healthcare waste (NHS England) and guidance in the</p>

	<p>Welsh Health Technical Memorandum 07-01 Safer management of healthcare waste.</p>
<p>Drug interactions</p>	<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>Gardasil® 9 may be administered concomitantly with dTaP, dT/IPV or dTaP/IPV with no significant interference with antibody response to any of the components of either vaccine. See the Green Book Chapter 18a for full details of vaccines that can be given at the same time as Gardasil®9.</p> <p>A detailed list of drug interactions is available in the SPC, which is available from the electronic Medicines Compendium website: www.medicines.org.uk</p>
<p>Identification and management of adverse reactions</p>	<p>Local reactions following vaccination are very common, such as pain, swelling or redness at the injection site and headache.</p> <p>Mild side effects such as nausea, dizziness, fatigue, fever, injection-site haematoma and injection-site pruritus are reported as common.</p> <p>Hypersensitivity reactions and anaphylaxis can occur but are very rare.</p> <p>In case of an acute anaphylactic reaction occurring, adequate treatment provision must be available for immediate use: Anaphylaxis and resuscitation equipment including adrenaline (1 in 1000) injection and a working telephone.</p> <p>In case of anaphylaxis:</p> <ul style="list-style-type: none"> • Refer to adrenaline (epinephrine) PGD0017 and anaphylaxis procedure • Request medical assistance urgently. If the GP is not immediately available dial 999 to transfer to A&E • Ensure reaction is fully documented in patient notes • Ensure all patient records are marked ALLERGIC TO HPV vaccine Gardasil® 9. • The patient may be advised to wear a MedicAlert or similar device to alert other healthcare providers • Report via Datix Once for Wales Reporting system

	<p>This list is not exhaustive. A detailed list of adverse reactions is available in the SPC which is available from the electronic Medicines Compendium website.</p>
<p>Reporting procedure of adverse reactions</p>	<p>Healthcare professionals and individuals/parents/carers are encouraged to report suspected adverse reactions to the Medicines and Healthcare products Regulatory Agency (MHRA) using the Yellow Card reporting scheme or search for MHRA Yellow Card in the Google Play or Apple App Store.</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> <p>All significant adverse drug reactions and any administration errors must be recorded via the Once for Wales Reporting System.</p>
<p>Written information to be given to individual or carer</p>	<p>Offer the marketing authorisation holder’s patient information leaflet (PIL) provided with the vaccine. For resources in accessible formats and alternative languages, please visit Home - Health Publications.</p> <p>Where applicable, inform the individual/parent/carer that the PIL with large print, Braille or audio CD can be ordered from the manufacturer (see electronic medicines compendium).</p> <p>Give appropriate advice if medication is used off-label.</p> <p>Immunisation promotional material may be provided as appropriate:</p> <ul style="list-style-type: none"> • Immunisations for teenagers and young people • HPV universal vaccination: leaflet - GOV.UK (www.gov.uk) • Human papillomavirus (HPV): vaccination record card - GOV.UK (www.gov.uk) <p>Available via the UKHSA Immunisation Collection webpage.</p> <p>Also see resources on Public Health Wales HPV vaccine.</p> <p>Further information for printing and website links suitable for the public can be found on the Public Health Wales intranet site Public Health Wales Immunisation and</p>

	<p>Vaccine Preventable Disease Programme, NHS 111 Wales and Health Information Resources.</p>
<p>Patient advice and follow up treatment</p>	<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>If relevant, advise the 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.</p> <p>Advise that HPV vaccination is not a replacement for the national cervical screening programme which should be accessed by individuals with a cervix at the appropriate age.</p> <p>As fainting can occur following vaccination, individuals, where appropriate, should be advised not to drive or use machinery until symptoms have cleared (see Cautions).</p> <p>When administration is postponed advise the individual/parent/carer when to return for vaccination.</p>
<p>Special considerations and additional information</p>	<p>Ensure there is immediate access to adrenaline (epinephrine) 1 in 1000 injection and access to a working telephone at the time of vaccination.</p> <p>Individuals who are not educated in a school year corresponding to their birth cohort may be immunised with their eligible peers as assessed as appropriate.</p> <p>For individuals with immunosuppression and those living with HIV who commenced but did not complete the vaccination course, it is reasonable to complete their HPV vaccination course with Gardasil® 9. Vaccination of individuals who have attained 25 years of age will not attract a payment.</p> <p>There is no data on fewer than 3 doses of HPV vaccine among HIV-positive or immunocompromised populations. Therefore, a 3-dose schedule should be offered to individuals who are known to be HIV positive, including those on antiretroviral therapy, or who are known to be immunocompromised at the time of immunisation.</p>

	<p>HPV vaccination is for prophylaxis against future HPV infection. It will not treat pre-existing HPV infection. It is also not intended to prevent progression of other established HPV-related lesions.</p> <p>Gardasil® 9 vaccine will protect against HPV types 6, 11, 16, 18, 31, 33, 45, 52 and 58. Appropriate precautions against sexually transmitted diseases should continue to be used.</p> <p>With regards to pregnancy, available data are very reassuring and do not indicate any safety concern or harm. Schoolgirls who are known to be sexually active, including those who are or who have been pregnant, may still be susceptible to high-risk HPV infection and could therefore benefit from vaccination according to the UK schedule. If a woman finds out she is pregnant after she has started a course of HPV vaccine, termination of pregnancy following inadvertent immunisation should not be recommended (see Chapter 18A).</p> <p>Routine questioning about last menstrual period and/or pregnancy testing is not required before offering HPV vaccine.</p> <p>For children under the age of 16 years being offered HPV vaccine, those assessed as Gillick competent can self-consent. For further information on consent see Chapter 2 of the Green Book.</p>
<p>Records</p>	<p>Record consultation details as required by local procedures. In addition, record:</p> <ul style="list-style-type: none"> • that valid informed consent was given or a decision to vaccinate made in the individual’s best interests in accordance with the Mental Capacity Act 2005. Record name of representative who gave consent if appropriate. • name of individual, address, date of birth, sex and GP with whom the individual is registered • medical and drug history taken, including any allergies and previous adverse events • printed name and signature of immuniser • name and brand of vaccine • date of administration • dose, form and route of administration of vaccine • quantity administered • batch number and expiry date • anatomical site of vaccination

- any reasons for exclusion or referral
- advice given, including advice given if excluded or declines immunisation
- details of any adverse drug reactions and actions taken
- administered via PGD, record PGD title and version number

Records should be signed and dated (or a password-controlled immuniser's record on e-records).

All records should be clear, legible and contemporaneous.

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.

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 (based in Llandrindod Hospital for school age).

Systems should be in place to ensure that the HPV vaccination record is uploaded onto the [Cervical Screening Management System](#) for NHS cervical screening programme call-recall purposes.

A record of all individuals receiving treatment under this PGD should also be kept for audit purposes in accordance with local policy.

4. Key references

<p>Key references</p>	<p>Human papillomavirus (HPV) vaccine</p> <ul style="list-style-type: none"> • Immunisation Against Infectious Disease: The Green Book Chapter 18a, last updated 20 June 2023. https://www.gov.uk/government/collections/immunisation-against-infectious-disease-the-green-book • Summary of Product Characteristic for Gardasil®9, MSD Ltd. Last updated 13 September 2024. https://www.medicines.org.uk/emc/product/7330 • HPV Vaccination Consent Form last updated 28 June 2023. www.gov.uk/government/publications/human-papillomavirus-hpv-vaccination-consent-form • JCVI statement on a one-dose schedule for the routine HPV immunisation programme 5 August 2022. www.gov.uk/government/publications/single-dose-of-hpv-vaccine-jcvi-concluding-advice/jcvi-statement-on-a-one-dose-schedule-for-the-routine-hpv-immunisation-programme • <u>HPV vaccination programme: changes from September 2023 bi-partite letter.</u> www.gov.uk/government/publications/hpv-vaccination-programme-changes-from-september-2023-letter • WHC/2023/016 Implementing the move to one dose of the HPV vaccine in Wales. 10 May 2023 <p>General</p> <ul style="list-style-type: none"> • Health Technical Memorandum 07-01: Safe Management of Healthcare Waste. NHS England, 2024. www.england.nhs.uk/publication/management-and-disposal-of-healthcare-waste-htm-07-01 • National Minimum Standards and Core Curriculum for Immunisation Training. Published June 2023. https://www.gov.uk/government/publications/national-minimum-standards-and-core-curriculum-for-immunisation-training-for-registered-healthcare-practitioners • NICE Medicines Practice Guideline 2 (MPG2): Patient Group Directions. Published March 2017. https://www.nice.org.uk/guidance/mpg2 • NICE MPG2 Patient group directions: competency framework for health professionals using patient group directions. Updated March 2017. https://www.nice.org.uk/guidance/mpg2/resources • UKHSA Immunisation Collection https://www.gov.uk/government/collections/immunisation
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	<ul style="list-style-type: none">• Vaccine Incident Guidance www.gov.uk/government/publications/vaccine-incident-guidance-responding-to-vaccine-errors• All Wales Advisory document on Ordering Storage and Handling of Vaccines 7th Edition, September 2017.• Welsh Health Technical Memorandum 07-01 Safer management of healthcare waste
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Appendix A – Staff Accredited to use the Patient Group Direction

Authorising Manager: I confirm that the practitioners named below have declared themselves suitably trained and competent to work under this PGD. I give authorisation on behalf of Powys Teaching Health Board or a Powys GP practice for the named healthcare professionals below who have signed the PGD to work under it. *The authorising manager must use the competency checklist (below).*

Practitioner: By signing this PGD you are indicating that you agree to its contents and that you will work within it. PGDs do not remove inherent professional obligations or accountability. It is the responsibility of each professional to practise only within the bounds of their own competence and professional code of conduct.

I confirm that I have read and understood the content of this Patient Group Direction and that I am willing and competent to work to it within my professional code of conduct.

Printed name of health professional	Signature of health professional	Printed name of senior representative authorising health professional (Authorising Manager)	Signature of senior representative authorising health professional (Authorising Manager)	Date

The authorising manager should retain a copy of the list, which will be requested for audit purposes. This list should be kept by PTHB (or the provider organisation adopting an authorised version of the PGD) for 25 years after the PGD expires.

The healthcare professional should retain a copy of the document after signing.

Competency check list for manager or senior team lead to use as part of the authorising process for health professionals to work to a Patient Group Direction (PGD). Review of authorisation will take place on each PGD update and at the individual’s annual PADR.

	Name: Role:	Sign / Initial	Further training identified (Y/N) Specify in comments	Comments
1	The PGD sign off is for the following PGD:(document the exact title and PGD number) _____			
2	We have discussed the expiry of the PGD and are using a version accessed electronically			
3	The member of staff has the appropriate qualifications and professional registration as outlined in the PGD			
4	The Patient Group Direction has been read in full by the staff member			
5	The identified training has been completed as specified in the PGD and is in date			
6	We have discussed some examples of inclusion criteria and exclusion criteria			
7	The staff member is confident in the administration method and doses			

Staff member print & sign name		Date
Manager or senior team lead to print & sign name		Date

Please send a copy of this completed form to individual’s line manager and to the staff member, in conjunction with the PGD Appendix A authorisation sheet. A copy of this form should also be kept by service lead in the training file.