UK Health Security Agency

Publications gateway number: GOV-14792

Human papillomavirus (HPV) vaccine Patient Group Direction (PGD)

This PGD is for the administration of human papillomavirus (HPV) vaccine 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.

This PGD is for the administration of HPV vaccine by registered healthcare practitioners identified in Section 3, subject to any limitations to authorisation detailed in Section 2.

Reference no:	HPV Vaccine PGD
Version no:	v6.00
Valid from:	1 September 2023
Review date:	1 April 2025
Expiry date:	1 September 2025

The UK Health Security Agency (UKHSA) has developed this PGD to facilitate the delivery of publicly funded immunisation in England in line with national recommendations.

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

Authorising organisations must not alter, amend or add to the clinical content of this document (sections 4, 5 and 6); such action will invalidate the clinical sign-off with which it is provided. In addition, authorising organisations must not alter section 3 'Characteristics of staff'. Only sections 2 and 7 can be amended within the designated editable fields provided.

Operation of this PGD is the responsibility of commissioners and service providers. The final authorised copy of this PGD should be kept by the authorising organisation completing Section 2 for 8 years after the PGD expires if the PGD relates to adults only and for 25 years after the PGD expires if the PGD relates to children only, or adults and children. Provider organisations adopting authorised versions of this PGD should also retain copies for the periods specified above.

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 UKHSA PGD templates for authorisation can be found from: Immunisation patient group direction (PGD) templates

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

Enquiries relating to the availability of organisationally authorised PGDs and subsequent versions of this PGD should be directed to: england.londonimms@nhs.net

[1] This includes any relevant amendments to legislation

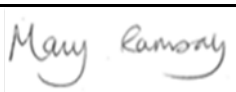
Change history

Version number	Change details	Date
V1.00	New PHE PGD template	6 April 2016
V2.00	PHE HPV PGD amended to: • include immunisation of transgender boys and transgender girls as appropriate • provide additional information on capacity to consent with link to the DH 'Reference guide to consent for examination or treatment' • include additional healthcare practitioners (midwives, pharmacists, paramedics, physiotherapists) in Section 3 • 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 • refer to upload of records onto National Health Application Infrastructure Services • include rewording, layout and formatting changes for clarity and consistency with other PHE PGD templates	21 March 2018
V3.00	PHE HPV PGD amended to: • update inclusion criteria to include boys from September 2019 • include retention of eligibility until the individuals 25th birthday • update off-label section • include minor rewording, layout and formatting changes for clarity and consistency with other PHE PGD templates	17 April 2019
V4.00	PHE HPV PGD amended to: • include the nine valent vaccine (Gardasil® 9) • include minor rewording, layout and formatting changes for clarity and consistency with other PHE PGD templates	21 July 2021
V5.00	HPV PGD amended to: • 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	4 March2022

V6.00	HPV PGD amended to: • change to one-dose schedule for the routine HPV immunisation programme • update the eligible cohorts on Page 1, 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 • 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	28 June 2023

1. PGD development

This PGD has been developed by the following health professionals on behalf of the UKHSA:

Developed by:	Name	Signature	Date
Pharmacist (Lead Author)	Suki Hunjunt Lead Pharmacist Immunisation Services, Immunisation and Vaccine Preventable Diseases Division, UKHSA		28 June 2023
Doctor	Mary Ramsay Consultant Epidemiologist, Immunisation and Vaccine Preventable Diseases Division, UKHSA		28 June 2023
Registered Nurse (Chair of Expert Panel)	David Green Nurse Consultant for Immunisation, Immunisation and Vaccine Preventable Diseases Division, UKHSA		28 June 2023

This PGD has been peer reviewed by the UKHSA Immunisations PGD Expert Panel in accordance with the UKHSA PGD Policy. It has been ratified by the UKHSA Medicines Governance Group.

Expert Panel

Nicholas Aigbogun	Consultant in Communicable Disease Control, Yorkshire and Humber Health Protection Team, UKHSA
Gayatri Amrithalingham	Consultant Epidemiologist, Immunisation and Vaccine Preventable Diseases Division, UKHSA
Alison Campbell	Screening and Immunisation Coordinator,Public Health Commissioning NHS England (NHSE) Midlands
Sarah Dermont	Clinical Project Coordinator and Registered Midwife, NHS Infectious Diseases in Pregnancy Screening Programme, NHSE
Rosie Furner	Pharmacist - Medicines Governance, Specialist Pharmacist Services (SPS)
Ed Gardner	Advanced Paramedic Practitioner/Emergency Care Practitioner, Medicines Manager, Proactive Care Lead
Jacqueline Lamberty	Lead Pharmacist, Medicines Governance, UKHSA
Michelle Jones	Principal Medicines Optimisation Pharmacist, Bristol North Somerset and South Gloucestershire Integrated Care Board
Shamez Ladhani	Paediatric Infectious Disease Consultant, UKHSA
Elizabeth Luckett	Senior Screening and Immunisation Manager NHSE South West
Vanessa MacGregor	Consultant in Communicable Disease Control, East Midlands Health Protection Team, UKHSA
Lesley McFarlane	Lead Immunisation Nurse Specialist Immunisation and Vaccine Preventable Diseases Division, UKHSA
Nicola Philbin	Screening and Immunisation Manager, Vaccination and screening programmes – Public Health Commissioning NHSE Midlands
Vanessa Saliba	CRF Consultant Epidemiologist, UKHSA
Tushar Shah	Lead Pharmacy Advisor, NHSE London

2. Organisational authorisations

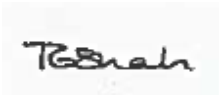
The PGD is not legally valid until it has had the relevant organisational authorisation.

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 – London authorises this PGD for use by the services or providers listed below:

Authorised for use by the following organisations and/or services
This PGD must only be used by specified registered healthcare professionals working for providers that are directly commissioned by NHS England - London, or who are administering vaccinations as part of a national immunisation programme, and who have been named and authorised to practice under it
Limitations to authorisation
None

Organisational approval (legal requirement)			
Role	**Name**	**Sign**	**Date**
Chief Nurse, NHS England - London	Jane Clegg		27/07/2023

Additional signatories according to locally agreed policy			
Role	**Name**	**Sign**	**Date**
Director of Nursing Leadership and Quality, NHS England – London	Gwen Kennedy		20/07/2023
Lead Pharmacy Adviser, NHS England - London	Tushar Shah		20/07/2023

Local enquiries regarding the use of this PGD may be directed to england.londonimms@nhs.net

Section 7 provides a practitioner authorisation sheet. Individual practitioners must be authorised by name to work to this PGD. Alternative practitioner authorisation sheets may be used where appropriate in accordance with local policy but this should be an individual agreement or a multiple practitioner authorisation sheet as included at the end of this PGD.

3. Characteristics of staff

Qualifications and professional registration	Registered professional with one of the following bodies: • nurses and midwives currently registered with the Nursing and Midwifery Council (NMC) • pharmacists currently registered with the General Pharmaceutical Council (GPhC) (Note: This PGD is not relevant to privately provided community pharmacy services) • paramedics and physiotherapists currently registered with the Health and Care Professions Council (HCPC) The practitioners above must also fulfil the Additional requirements detailed below. Check Section 2 Limitations to authorisation to confirm whether all practitioners listed above have organisational authorisation to work under this PGD.
Additional requirements	Additionally, practitioners: • must be authorised by name as an approved practitioner under the current terms of this PGD before working to it • must have undertaken appropriate training for working under PGDs for supply/administration of medicines • must be competent in the use of PGDs (see NICE Competency framework for health professionals using PGDs) • must be familiar with the vaccine product and alert to changes in the Summary of Product Characteristics (SPC), Immunisation Against Infectious Disease (the 'Green Book'), and national and local immunisation programmes • must have undertaken training appropriate to this PGD as required by local policy and in line with the National Minimum Standards and Core Curriculum for Immunisation Training • must be competent to undertake immunisation and to discuss issues related to immunisation • must be competent in the handling and storage of vaccines, and management of the cold chain • must be competent in the recognition and management of anaphylaxis • must have access to the PGD and associated online resources • should fulfil any additional requirements defined by local policy **The individual practitioner must be authorised by name, under the current version of this PGD before working according to it.**
Continued training requirements	Practitioners must ensure they are up to date with relevant issues and clinical skills relating to immunisation and management of anaphylaxis, with evidence of appropriate Continued Professional Development (CPD). Practitioners should be constantly alert to any subsequent recommendations from the UKHSA and/or NHSE and other sources of medicines information. Note: The most current national recommendations should be followed but a Patient Specific Direction (PSD) may be required to administer the vaccine in line with updated recommendations that are outside the criteria specified in this PGD.

4. Clinical condition or situation to which this PGD applies

Clinical condition or situation to which this PGD applies	Indicated for the active immunisation of individuals 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'.
Criteria for inclusion	Individuals who: • are aged 12 to 13 years in the birth cohort for school year 8[2]. • are females born on or after 1 September 1991 and 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
Criteria for exclusion[3]	Individuals for whom no valid consent has been received. For further information on consent see Chapter 2 of the Green Book. Individuals who: • 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[4] • 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)
Cautions including any relevant action to be taken	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. Syncope (fainting) can occur following, or even before, any vaccination especially in adolescents as a psychogenic response to the needle injection. This can be accompanied by several neurological signs such as transient visual disturbance, paraesthesia and tonic-clonic limb movements during recovery. It is important that procedures are in place to avoid injury from faints. The immunogenicity of the vaccine could be reduced in immunosuppressed subjects. Vaccination should proceed in accordance with the national recommendations. However, re-immunisation may need to be considered (see Green Book Chapter 7). Seek medical advice as appropriate.
Action to be taken if the patient is excluded Continued over page	If aged less than 12 years and in a school year below year 8, advise when national routine immunisation is indicated. 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.

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

[3] 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.

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

Action to be taken if the patient is excluded (continued)	If aged 25 years and over advise that vaccination against HPV is not provided under the routine NHS HPV immunisation programme. GBMSM and are 25 years and over can be advised that HPV vaccination may be accessed through specialist sexual health services (see Chapter 18A). 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 immunisation is recommended do not administer under this PGD; a PSD will be required. 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. Seek appropriate advice from the local Screening and Immunisation Team, local Health Protection Team or the individual's clinician as required. The risk to the individual of not being immunised must be taken into account. Document the reason for exclusion and any action taken in the individual's clinical records. Inform or refer to the GP or a prescriber as appropriate.
Action to be taken if the patient or carer declines treatment	Informed consent, from the individual or a person legally able to act on the individual's behalf, must be obtained for each administration (see Additional Information). Advise the individual/parent/carer about the protective effects of the vaccine, the risks of infection and potential complications. Document the advice given and the decision reached. Inform or refer to the GP or a prescriber as appropriate.
Arrangements for referral for medical advice	As per local policy

5. 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): • Gardasil® 9, suspension for injection in a pre-filled syringe or vial
Legal category	Prescription only medicine (POM)
Black triangle▼	No
Off-label use	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'. 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). 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. 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. 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 Vaccine Incident Guidance. Where vaccine is assessed in accordance with these guidelines as appropriate for continued use this would constitute off-label administration under this PGD. Where a vaccine is recommended off-label consider, as part of the consent process, informing the individual/parent/carer that the vaccine is being offered in accordance with national guidance but that this is outside the product licence.
Route and method of administration Continued over page	Administer by intramuscular injection. The preferred site is the deltoid region of the upper arm. When administering at the same time as other vaccines care should be taken to ensure that the appropriate route of injection is used for all the vaccinations. The vaccines should be given at separate sites, preferably in different limbs. If given in the same limb, they should be given at least 2.5cm apart. The site at which each vaccine was given should be noted in the individual's records. 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

Route and method of administration (continued)

rubbing) for at least 2 minutes. If in any doubt, consult with the clinician responsible for prescribing or monitoring the individual's anticoagulant therapy.

The vaccine's normal appearance is a white cloudy liquid which may settle to a clear liquid and white precipitate. Shake well before use.

The vaccine should be visually inspected for particulate matter and discoloration prior to administration. In the event of any foreign particulate matter and/or variation of physical aspect being observed, do not administer the vaccine.

The vaccine's SPC provides further guidance on administration and is available from the electronic Medicines Compendium website.

Dose and frequency of administration

Single 0.5ml dose per administration

HPV vaccination should be routinely offered in school year 8 (see Additional information).

Doses for routine and universal programme

Date of birth	Eligible from academic year	Schedule from 1 Sep 2023
1 Sep 2010 to 31 Aug 2011	2023 to 2024	One dose HPV schedule
1 Sep 2009 to 31 Aug 2010	2022 to 2023	Consider fully vaccinated if received one dose of the HPV vaccine
Born before 1 Sep 2009	various	One dose HPV schedule

Individuals who become eligible for the HPV vaccine from the academic year 2023/24 (date of birth between 1 September 2010 to 31 August 2011) onwards will only require one dose and this will continue to be routinely offered to individuals in school year 8 and those of an equivalent age who are not in mainstream education.

For those individuals who became eligible for the HPV vaccination programme in the 2022/23 academic year (date of birth between 1 September 2009 to 31 August 2010) the following applies:

- those who started their HPV vaccination schedule and have already received one dose of the vaccine will be considered fully vaccinated
- those who have not yet received any HPV vaccinations will be eligible to receive one dose of the HPV vaccine

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.

Administer a course of three doses on a 0, 1 and 4-6-month schedule, for instance:

- first dose of 0.5ml of HPV vaccine, then
- second dose of 0.5ml at least one month after the first dose, then
- a third dose of 0.5ml at least three months after the second dose

All three doses should ideally be given within a 12-month period. If the course is interrupted, it should be resumed but not repeated, ideally allowing the appropriate interval between the remaining doses.

Continued over page

Dose and frequency of administration (continued)	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. **Vaccination of individuals with unknown or incomplete vaccination status** 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. 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.[5] 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.
Duration of treatment	A one or three dose course (see Dose and Frequency section above)
Quantity to be supplied and administered	Single 0.5ml dose per administration.
Supplies	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. 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. Protocols for the ordering, storage and handling of vaccines should be followed to prevent vaccine wastage (see the 'Green Book' Chapter 3).
Storage Continued over page	Store at +2°C to +8°C. Store in original packaging in order to protect from light. Do not freeze. Gardasil® 9 should be administered as soon as possible after being removed from the refrigerator. 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. In the event of an inadvertent or unavoidable deviation of these conditions vaccine that has been stored outside the conditions stated above should be

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

Storage (continued)	quarantined and risk assessed for suitability of continued off-label use or appropriate disposal. Refer to Vaccine Incident Guidance.
Disposal	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 authority arrangements and guidance in the technical memorandum 07-01: Safe management of healthcare waste (NHSE, 2022).
Drug interactions	Immunological response may be diminished in those receiving immunosuppressive treatment. Vaccination is recommended even if the antibody response may be limited. May be given at the same time as other vaccines. 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. A detailed list of drug interactions is available in the SPC, which is available from the electronic Medicines Compendium website.
Identification and management of adverse reactions	Local reactions following vaccination are very common, such as pain, swelling or redness at the injection site. Mild side effects such as headache, nausea, dizziness, fatigue, fever, injection-site haematoma and injection-site pruritus are reported as common. Other adverse events have been reported in post-marketing surveillance but the frequency of these is not known. Hypersensitivity reactions and anaphylaxis can occur but are very rare. A detailed list of adverse reactions is available in the SPC which is available from the electronic Medicines Compendium website.
Reporting procedure of adverse reactions	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. Any adverse reaction to a vaccine should be documented in the individual's record and the individual's GP should be informed.
Written information to be given to patient or carer Continued over page	Offer the marketing authorisation holder's patient information leaflet (PIL) provided with the vaccine. If applicable, inform the individual/parent/carer that PIL with large print, Braille or audio CD can be ordered from the manufacturer (see electronic medicines compendium). Immunisation promotional material may be provided as appropriate: • Immunisations for young people • Your HPV vaccination guide • HPV universal vaccination: leaflet - GOV.UK (www.gov.uk) • Human papillomavirus (HPV): vaccination record card - GOV.UK (www.gov.uk)

Written information to be given to patient or carer (continued)	Available via the UKHSA Immunisation Collection webpage.
Patient advice and follow up treatment	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. If relevant, advise the individual/parent/carer when the next dose is due. 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 by individuals with a cervix at the appropriate age. As fainting can occur following vaccination, individuals, where appropriate, should be advised not to drive or use machinery until symptoms have cleared (see Cautions). When administration is postponed advise the individual/parent/carer when to return for vaccination.
Special considerations and additional information	Ensure there is immediate access to adrenaline (epinephrine) 1 in 1000 injection and access to a telephone at the time of vaccination. 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. For individuals 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. 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. HPV vaccination is for prophylaxis against future HPV infection. It will not treat pre-existing HPV infection. 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. 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). Routine questioning about last menstrual period and/or pregnancy testing is not required before offering HPV vaccine 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.

Records	Record: • that valid informed consent was given • name of individual, address, date of birth, sex and GP with whom the individual is registered • name of immuniser • name and brand of vaccine • date of administration • dose, form and route of administration of vaccine • quantity administered • batch number and expiry date • anatomical site of vaccination • advice given, including advice given if excluded or declines immunisation • details of any adverse drug reactions and actions taken • supplied via PGD 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. 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. A record of all individuals receiving treatment under this PGD should also be kept for audit purposes in accordance with local policy.

6. Key references

Key references	**Human papillomavirus (HPV) vaccine** • Immunisation Against Infectious Disease: The Green Book Chapter 18a, last updated 20 June 2023. www.gov.uk/government/collections/immunisation-against-infectious-disease-the-green-book • Summary of Product Characteristic for Gardasil®9, MSD Ltd. Last updated 13 March 2023. www.medicines.org.uk/emc/product/7330 • HPV Vaccination Consent Form last updated 9 November 2021. 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 • HPV vaccination programme: changes from September 2023 bi-partite letter. www.gov.uk/government/publications/hpv-vaccination-programme-changes-from-september-2023-letter **General** • Health Technical Memorandum 07-01: Safe Management of Healthcare Waste. NHSE, 2022. www.england.nhs.uk/publication/management-and-disposal-of-healthcare-waste-htm-07-01/ • National Minimum Standards and Core Curriculum for Immunisation Training. Published February 2018. 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. www.nice.org.uk/guidance/mpg2 • NICE MPG2 Patient group directions: competency framework for health professionals using patient group directions. Updated March 2017. www.nice.org.uk/guidance/mpg2/resources • UKHSA Immunisation Collection. www.gov.uk/government/collections/immunisation • Vaccine Incident Guidance. www.gov.uk/government/publications/vaccine-incident-guidance-responding-to-vaccine-errors

7. Practitioner authorisation sheet

HPV vaccine PGD v06.00 Valid from: 1 September 2023 Expiry: 1 September 2025

Before signing this patient group direction (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 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 PGD 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 the following named organisation …….. for the above named healthcare 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.