

This patient group direction (PGD) must only be used by registered health 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.

Patient Group Direction (PGD)

For the administration of

Human Papillomavirus Vaccine (HPV)

By registered health care professionals for

**Individuals from 12 years of age or from school year 8 in accordance
with the national immunisation programme**

**Throughout the Manx Care and those contracted by the Manx Care where appropriate within
practice**

PGD NUMBER 03

1. Change History

Version number	Change Details	Date
V01.00	New PHE PGD template	06/04/2016

V02.00	<p>PHE HPV PGD amended to:</p> <ul style="list-style-type: none"> 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 	21/03/2018
V03.00	<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 include minor rewording, layout and formatting changes for clarity and consistency with other PHE PGD templates 	17/04/2019
V04.00	<p>PHE HPV PGD V03.00 amended to:</p> <ul style="list-style-type: none"> include the nine valent vaccine (Gardasil® 9) include minor rewording, layout and formatting changes for clarity and consistency with other PHE PGD templates 	21/07/2021
V04.1	<p>PHE HPV PGD V04.00 amended to:</p> <ul style="list-style-type: none"> Following the Green book update guidance dated 24 February 2022 (NHS Publishing Approval Reference: PAR1322 UKHSA Gateway Number: GOV-10957) the 'Dose & Frequency' was updated regarding Immunocompetent individuals aged under 15 years at time of first dose and individuals aged 15 years to under 25 years at time of first dose 	22/04/2022
V05.00	<p>HPV PGD amended 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 	04/03/2022

V6.00	<p>HPV PGD amended to:</p> <ul style="list-style-type: none"> • include additional information for clinicians regarding ongoing training and competency in line with other Manx Care PGDs • 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 • 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 other Manx Care PGDs • amend NHS England and NHS Improvement (NHSEI) to NHSE following completion of merger on 1 July 2022 	28/06/23
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2. Medicines practice guideline 2: *Patient group directions*

Refer to the relevant sections of NICE medicines practice guideline 2: *Patient group directions* as stated in the blank template notes. For further information about PGD signatories, see the NHS and Manx Care [PGD website FAQs](#)

3. PGD development

Refer to the NICE PGD competency framework for people developing PGDs

Job Title & organisation	Name	Signature	Date
Author of the PGD			
Member of the PGD working group			

4. PGD authorisation

Refer to the NICE PGD competency framework for people authorising PGDs

Job Title	Name	Signature	Date
Medical Director			
Chief Pharmacist/ Pharmaceutical Adviser			
Deputy to Senior Paramedic			
Director of Nursing			
GP Adviser			
Senior Microbiologist (if PGD contains antimicrobials)	N/A	N/A	N/A

5. PGD adoption by the provider

Refer to the NICE PGD competency framework for people authorising PGDs

Job title and organisation	Signature	Date	Applicable or not applicable to area

6. Training and competency of registered healthcare professionals, employed or contracted by the Manx Care, GP practice or Hospice

Refer to the NICE PGD competency framework for health professionals using PGDs

	Requirements of registered Healthcare professionals working under the PGD
Qualifications and professional registration	<p>Registered healthcare professionals, working within or contracted by the Manx Care, GP practice or Hospice who are permitted staff groups outlined within the current PGD policy</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 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 <p>The individual practitioner must be authorised by name, under the current version of this PGD before working according to it.</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>Check Section 2 Limitations to authorisation to confirm whether all practitioners listed above have organisational authorisation to work under this PGD.</p>
Initial training	<ul style="list-style-type: none"> • Knowledge of current guidelines and the administration of the drug specified in this PGD/BNF and of the inclusion and exclusion criteria • Training which enables the practitioner to make a clinical assessment to establish the need for the medication covered by this PGD • Local training in the use of PGDs
Competency assessment	Staff will be assessed on their knowledge of drugs and clinical assessment as part the competency framework for registered health professionals using PGDs
Ongoing training and competency	<ul style="list-style-type: none"> • The registered health care professionals should make sure they are aware of any changes to the recommendations for this medication; it is the responsibility of the registered health care professionals to keep up to date with continuing professional development. PGD updates will be held every two years • 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.

7. Clinical Conditions

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>
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Inclusion criteria	<p>Individuals who:</p> <ul style="list-style-type: none"> • are aged 12 to 13 years in the birth cohort for school year 8¹. • 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 exclusion²	<p>Individuals for whom no valid consent has been received. For further information on consent see Chapter 2 of the Green Book.</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 aged 25 years and over, except those who have received a partial course of HPV immunisation³ • 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)	<ul style="list-style-type: none"> • 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
Arrangements for referral for medical advice	<p>Patient should be referred to a more experienced clinical practitioner for further assessment</p>

¹ Individuals in school year 8 who are aged outside the designated birth cohort for the school year may be immunised with their peers

² 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.

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.

Action to be taken if patient excluded	<ul style="list-style-type: none"> • Patient should be referred to a more experienced clinical practitioner for further assessment • If aged less than 12 years and in a school year below year 8, advise when national routine immunisation is indicated. • 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 of the 'Green Book') • 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 patient declines treatment	<ul style="list-style-type: none"> • 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 advice given and the decision reached. • Inform or refer to the GP or a prescriber as appropriate.

8. Details of the medicine

Name, form and strength of medicine	<ul style="list-style-type: none"> • 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

<p>Indicate any <u>off-label use</u> (if relevant)</p>	<ul style="list-style-type: none"> • 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 'vaccines 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
<p>Route/method of administration</p>	<ul style="list-style-type: none"> • 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

	<p>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> <ul style="list-style-type: none">• The vaccine’s SPC provides further guidance on administration and is available from the electronic Medicines Compendium website.												
Dose and frequency	<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</p> <table><tr><th>Date of birth</th><th>Eligible from academic year</th><th>Schedule from 1 Sep 2023</th></tr><tr><td>1 Sep 2010 to 31 Aug 2011</td><td>2023 to 2024</td><td>One dose HPV schedule</td></tr><tr><td>1 Sep 2009 to 31 Aug 2010</td><td>2022 to 2023</td><td>Consider fully vaccinated if received one dose of the HPV vaccine</td></tr><tr><td>Born before 1 Sep 2009</td><td>various</td><td>One dose HPV schedule</td></tr></table> <p>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.</p> <p>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:</p> <ul style="list-style-type: none">• 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 <p>Individuals with immunosuppression and those living with HIV</p> <p>Individuals who are known to be immunosuppressed at the time of vaccination and those who are living with HIV, including those on</p>	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
Date of birth	Eligible from academic year	Schedule from 1 Sep 2023											
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Born before 1 Sep 2009	various	One dose HPV schedule											

	<p>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:</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>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.⁴</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>
Quantity to be administered	Single 0.5ml dose per administration.
Maximum or minimum	A one or three dose course (see Dose and Frequency section above)

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.

treatment period	
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Storage	<ul style="list-style-type: none"> • 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 quarantined and risk assessed for suitability of continued off-label use or appropriate disposal. Refer to UKHSA Vaccine Incident Guidance
Identification and management of adverse reactions	<ul style="list-style-type: none"> • 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. <p>Reporting procedures of adverse reactions:</p> <ul style="list-style-type: none"> • 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.
Records to be kept	<p>The administration of any medication given under a PGD must be recorded within the patients' medical records</p> <p>Please see Appendix C for more details.</p>

9. Patient information

Verbal/Written information to be given to patient or carer	<p>Offer the patient information leaflet (PIL) provided with the vaccine.</p> <p>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).</p> <p>Immunisation promotional material may be provided as appropriate:</p> <ul style="list-style-type: none"> • 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) • Available via the UKHSA Immunisation Collection webpage.
Follow-up advice to be given to patient or carer	<ul style="list-style-type: none"> • 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

10. Appendix A

References

1. British National Formulary (BNF) available online: <https://bnf.nice.org.uk>
2. Nursing and Midwifery “The code” available online: <https://www.nmc.org.uk>
3. Current Health Care Professions Council standards of practice
4. General Pharmaceutical Council standards
5. Electronic medicines compendium available online: <https://www.medicines.org.uk>

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

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- Health Technical Memorandum 07-01: Safe Management of Healthcare Waste. NHSE, 2022. www.england.nhs.uk/publication/management-and-disposal-of-healthcare-waste-hm-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

11. Appendix B

Health professionals agreed to practice

- Each registered healthcare professional will hold their own Competency framework which will be signed and agreed by their mentor
- A mentor is defined within the Manx Care policy as any ward/area managers, sisters, senior nurses, GPs, pharmacists or senior paramedics who has completed the PGD training themselves

12. Appendix C

Special considerations/ 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 the 'Green Book'](#)).
- 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.

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	<ul style="list-style-type: none"> 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.
Supplies	<ul style="list-style-type: none"> 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).
Records (continued)	<p>Record:</p> <ul style="list-style-type: none"> that valid informed consent was given name of individual, address, date of birth 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 <ul style="list-style-type: none"> 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

Records <i>(continued)</i>	<p>health records should be kept and the individual's GP informed</p> <ul style="list-style-type: none"> • 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
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