NHS
Greater Glasgow and Clyde

Patient Group Direction (PGD)

Administration of Gardasil® Vaccine Human Papillomavirus Vaccine [Types 6, 11, 16, 18] (Recombinant, adsorbed)

PGD No: 2022/2378

Date approved: 27 APRIL 2022

Review date: November 2023

Expiry date: 31 April 2024

Most recent changes

Version	Date	Summary of changes
6.0	01/04/22	Version 6.0 produced • frequency section updated to reflect updated recommendations that those commencing vaccination from 15 years of age should commence a 2-dose schedule with a minimum 6-month interval. • use out with SPC section updated. • minor rewording, layout, formatting changes for clarity and consistency with other PHS national specimen PGDs.

Contents

Authorisation

This Patient Group Direction (PGD) has been produced by Public Health Scotland to assist NHS boards. NHS boards should ensure that the final PGD is considered and approved in line with local clinical governance arrangements for PGDs.

The qualified health professionals who may administer HPV vaccine under this PGD can only do so as named individuals. It is the responsibility of each professional to practice within the bounds of their own competence and in accordance with their own Code of Professional Conduct and to ensure familiarity with the manufacturer's product information/summary of product characteristics (SPC) for all vaccines administered in accordance with this PGD.

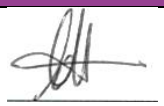
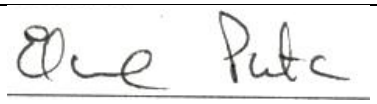
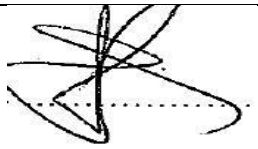
NHS board governance arrangements will indicate how records of staff authorised to operate this PGD will be maintained. Under PGD legislation there can be no delegation. Administration of the vaccine has to be by the same practitioner who has assessed the patient under the PGD.

This PGD has been produced for NHS Greater Glasgow and Clyde by:

Doctor	Dr Gillian Penrice, Consultant in Public Health	
Pharmacist	Val Reilly, Public Health Pharmacist	
Nurse	Hilda Crookshanks (Health Protection Nurse Specialist)	

Date 27th April 2022

Approved on behalf of NHS Greater Glasgow and Clyde by ADTC Patient Group Direction Sub Committee representatives:

Chair	Dr Craig Harrow	
Senior Pharmacist	Elaine Paton, Senior Prescribing Adviser	
Nurse Director Representative	John Carson, Lead Nurse North Sector	

Date approved: 27th April 2022

Effective from: 27/04/2022 **Review date:** 01/11/2023

PGD Gardasil® Vaccine (Human Papillomavirus Vaccine [Types 6, 11, 16, 18] (Recombinant, adsorbed))

Clinical situation

Category	Description
Indication	Active immunisation against disease caused by Human Papillomavirus (HPV) types 6, 11, 16 and 18 in line with Scottish Government Health Directorate HPV immunisation programme.
Inclusion criteria	• Individuals aged 11 to under 25 years. • Gardasil® is recommended in males and females from school year S1, aged around 11-13 years, including those not in school. • Individuals who do not commence HPV immunisation in S1 remain eligible until they reach 25 years of age. • Men who have sex with men (MSM) aged up to and including 45 years of age attending sexual health or HIV clinic. • Prisoners up to and including 45 years of age who identify as MSM. • Valid consent has been given to receive the vaccine.
Exclusion criteria	• Confirmed anaphylactic reaction to a previous dose of HPV vaccine. • Confirmed anaphylactic reaction to any component of the vaccine. • Individuals less than 9 years of age • Practitioners must check the marketing authorisation holder's summary of product characteristics (SPC) for details of vaccine components. • History of severe (i.e. anaphylactic reaction) to latex where the vaccine is not latex free. • Known pregnancy. • No valid consent. • Acute systemic or febrile illness –postpone immunisation until the individual has fully recovered.

Category	Description
Cautions/need for further advice/ circumstances when further advice should be sought from a doctor	Chapter 18a of the Green Book advises that there are very few individuals who cannot receive HPV vaccine. Where there is doubt, rather than withholding vaccination, appropriate advice should be sought from the relevant specialist, or from the local immunisation or health protection team. The presence of a neurological condition is not a contraindication to immunisation but if there is evidence of current neurological deterioration, deferral of vaccination may be considered, to avoid incorrect attribution of any change in the underlying condition. The risk of such deferral should be balanced against the risk of the preventable infection, and vaccination should be promptly given once the diagnosis and/or the expected course of the condition becomes clear. 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.
Action if excluded	Specialist advice must be sought on the vaccine and circumstances under which it could be given. Immunisation using a patient specific direction may be indicated. The risk to the individual of not being immunised must be taken into account. Document the reason for exclusion and any action taken in accordance with local procedures. Inform or refer to the clinician in charge at the clinic or GP as appropriate. In case of postponement due to acute severe febrile illness, advise when the individual can be vaccinated and ensure another appointment is arranged.
Action if patient declines	Advise the individual about the protective effects of the vaccine, the risks of infection and potential complications of disease. Advise how future immunisation may be accessed if they subsequently decide to receive the vaccine Document advice given and decision reached. In NHS clinic setting, inform or refer to the clinician in charge. In GP practice setting, inform or refer to GP.

Description of treatment

Category	Description
Name of medicine	Gardasil® Vaccine (Human Papillomavirus Vaccine [Types 6, 11, 16, 18] (Recombinant, adsorbed))
Form/strength	Suspension for injection in a prefilled syringe or vial
Route of administration	Administer by intramuscular or subcutaneous injection. The preferred site is the deltoid region of the upper arm. It can also be administered in the anterolateral area of the thigh. The intramuscular route is routinely used because localised reactions are more common when vaccines are given subcutaneously. However, for individuals with a bleeding disorder, vaccines may alternatively be given by subcutaneous injection to reduce the risk of bleeding. During storage, a white precipitate may develop and the vaccine should be shaken before use to form a white cloudy liquid. 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. During storage, a white precipitate may develop and the vaccine should be shaken before use to form a white cloudy liquid.
Dosage	0.5ml
Frequency	**Immunocompetent individuals who are not known to be HIV positive** The course consists of two doses: • first dose • second dose at least six months after the first dose Both doses should ideally be given with a 24-month period. If the course is interrupted, it should be resumed but not repeated even if more than 24 months have elapsed since the first dose. **Individuals who are immunosuppressed or known to be HIV positive** The course consists of three doses: • first dose • second dose at least one month after the first dose • third dose at least three months after the second dose

Category	Description
	All three doses should be ideally given within a 12-month period. If the course is interrupted, it should be resumed but not repeated, ideally allowing the appropriate interval between the remaining doses. There are no clinical data on whether the interval between doses two and three can be reduced below three months. Where the second dose is given late and there is a high likelihood that the individual will not return for a third dose after three months or if, for practical reasons, it is not possible to schedule a third dose within this time-frame, then a third dose of HPV vaccine can be given at least one month after the second dose. Individuals who started their course prior to April 2022 should continue on the planned three dose schedule. Those individuals who commenced vaccination prior to April 2022 whose schedule is interrupted/delayed such that they had an interval of six months or more between their first and second dose only need a two dose schedule (do not require a third dose).
Duration of treatment	See Frequency section.
Maximum or minimum treatment period	See Frequency section.
Quantity to supply/administer	Maximum 2 to 3 doses – see frequency section.
▼ black triangle medicines	No
Legal category	Prescription Only Medicine (POM)
Is the use out with the SPC?	Yes. Administration of a two-dose schedule of Gardasil® to individuals aged from 14 years of age but is in accordance with **official recommendations** and **Chapter 18a** of the 'Green Book'. Administration of a two-dose course with a 0, 6-24 month schedule and administration of a 3 dose course on a 0, 1, 4-6 month schedule differs slightly from the 0, 6 months and 0, 2, 6 month schedules in the SPC but is in accordance with official recommendations in Chapter 18a of 'The Green Book'. Administration of Gardasil® by deep subcutaneous injection to patients with a bleeding disorder is off label administration but is in line with advice in Chapter 4 and Chapter 18a of the Green Book. The HPV vaccine SPCs state that 'vaccinees should be observed for approximately 15 minutes after vaccine administration'. In line with advice in

Category	Description
	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 below. However, in the event of an inadvertent or unavoidable deviation of these conditions refer to NHS board guidance on storage and handling of vaccines or national vaccine incident guidance. Where vaccine is assessed in accordance with these guidelines as appropriate for continued use, administration under this PGD is allowed.
Storage requirements	Vaccine should be stored at a temperature of +2° to +8°C. Store in the original packaging to protect from light. Do not freeze. NHS GG&C Vaccine Ordering, Storage and Handling Guidelines should be observed. http://www.staffnet.ggc.scot.nhs.uk/Info%20Centre/PoliciesProcedures/GGCClinicalGuidelines/GGC%20Clinical%20Guidelines%20Electronic%20Resource%20Direct/Vaccine%20Ordering%20Storage%20and%20Handling.pdf Vaccine storage history e.g. temperature charts must be checked and deemed satisfactory before administration to patient. 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.
Additional information	Minor illnesses without fever or systemic upset are not valid reasons to postpone immunisation. If an individual is acutely unwell, immunisation may be postponed until they have fully recovered. HPV vaccine can be given at the same time as other vaccines such as DTaP/IPV/Hib/HepB, 4CMenB, MMR, MenACWY, Hib/MenC, Rotavirus and influenza. When administering at the same time as other vaccines care should be taken to ensure that the appropriate route of injection is used for all the vaccinations. The vaccines should be given 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.

Adverse reactions

Category	Description
Warnings including possible adverse reactions and management of these	The most common adverse reaction observed after HPV vaccine administration is mild to moderate short-lasting pain at the injection site. An immediate localised stinging sensation has also been reported. Redness has also been reported at the injection site. Other reactions commonly reported are headache, myalgia, fatigue and low grade fever. For full details/information on possible side effects, refer to the marketing authorisation holder's SPC. As with all vaccines there is a very small possibility of anaphylaxis and facilities for its management must be available. In the event of severe adverse reaction individual should be advised to seek medical advice.
Reporting procedure for adverse reactions	Healthcare professionals and individuals/carers should report suspected adverse reactions to the Medicines and Healthcare products Regulatory Agency (MHRA) using the Yellow Card reporting scheme on **http://yellowcard.mhra.gov.uk/** Any adverse reaction to a vaccine should be documented in accordance with locally agreed procedures in the individual's record and the individual's GP should be informed.
Advice to patient or carer including written information	Written information to be given to individual • Provide manufacturer's consumer information leaflet/patient information leaflet (PIL) provided with the vaccine. • Supply immunisation promotional material as appropriate. Individual advice / follow up treatment • Inform the individual/carer of possible side effects and their management. • Give advice regarding normal reaction to the injection e.g. sore arm is possible. • Give advice on the management if individual becomes feverish. • Advise individual when subsequent doses are due when applicable. • The individual should be advised to seek medical advice in the event of a severe adverse reaction. • Inform the individual that they can report suspected adverse reactions to the MHRA using the Yellow Card reporting scheme on: **http://yellowcard.mhra.gov.uk**

Category	Description
Monitoring	Following immunisation individual to remain under observation in line with NHS board policy.
Follow up	Advise individual when subsequent doses are due when applicable.
Additional facilities	A protocol for the management of anaphylaxis and an anaphylaxis pack must always be available whenever vaccines are given. Immediate treatment should include early treatment with intramuscular adrenaline, with an early call for help and further IM adrenaline every 5 minutes. The health professionals overseeing the immunisation service must be trained to recognise an anaphylactic reaction and be familiar with techniques for resuscitation of a patient with anaphylaxis.

Characteristics of staff authorised under the PGD

Category	Description
Professional qualifications	The following classes of registered healthcare practitioners are permitted to administer this vaccine: • nurses and midwives currently registered with the Nursing and Midwifery Council (NMC) • pharmacists currently registered with the General Pharmaceutical Council (GPhC) • chiropodists/podiatrists, dieticians, occupational therapists, orthoptists, orthotists/prosthetists, paramedics, physiotherapists, radiographers and speech and language therapists currently registered with the Health and Care Professions Council (HCPC) • dental hygienists and dental therapists registered with the General Dental Council • optometrists registered with the General Optical Council.
Specialist competencies or qualifications	Persons must only work under this PGD where they are competent to do so. All persons operating this PGD: • must be authorised by name by their employer as an approved person under the current terms of this PGD before working to it • must be familiar with the vaccine product and alert to changes in the manufacturers product information/summary of product information,

Category	Description
	• must be competent to undertake immunisation and to discuss issues related to immunisation to assess patients for vaccination and obtain consent • must be competent in the correct storage of vaccines and management of the cold chain if receiving, responsible for, or handling the vaccine • must be competent in the recognition and management of anaphylaxis or under the supervision of persons able to respond appropriately to immediate adverse reactions • must have access to the PGD and associated online resources • should fulfil any additional requirements defined by local policy Employer The employer is responsible for ensuring that persons have the required knowledge and skills to safely deliver the activity they are employed to provide under this PGD As a minimum, competence requirements stipulated in the PGD must be adhered to.
Continuing education and training	All practitioners operating under the PGD are responsible for ensuring they remain up to date with the use of vaccines included. If any training needs are identified these should be discussed with the individuals in the organisation responsible for authorising individuals to act under this PGD.

Audit trail

Name	Description
Record/ audit trail	Record: • that valid informed consent was given • name of individual, address, date of birth and GP with whom the individual is registered if possible • name of person that undertook assessment of individual's clinical suitability for vaccine • name of person that administered the vaccine • name and brand of vaccine • date of administration • dose, form and route of administration of vaccine • batch number • where possible 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 • administered under PGD Records should be kept line with local procedures. Local policy should be followed to encourage information sharing with the individual's General Practice. All records should be clear, legible and contemporaneous and in an easily retrievable format.

Additional references

Name	Description
Additional references	Practitioners operating the PGD must be familiar with: • **Immunisation against Infectious Disease [Green Book]** • **Immunisation against Infectious Disease [Green Book] chapter 18a** • all relevant Scottish Government Health Directorate advice including the relevant CMO letter(s) • current edition of British National Formulary • marketing authorisation holder’ s Summary of Product Characteristics • Professional Guidance on the Administration of Medicines in Healthcare Settings 2019 **https://www.rpharms.com/Portals/0/RPS document library/Open access/Professional standards/SSHM Admin/Admin Meds prof guidance.pdf/ver=2019-01-23-145026-567** • Professional Guidance on the Safe and Secure Handling of Medicines **https://www.rpharms.com/recognition/setting-professional-standards/safe-and-secure-handling-of-medicines/professional-guidance-on-the-safe-and-secure-handling-of-medicines**

PGD for administration of Gardasil® vaccine – authorisation

Practitioner

This PGD does not remove professional obligations and accountability. It is the responsibility of each professional to practice within the bounds of their own competence and in accordance with their Code of Professional Conduct and to ensure familiarity with the marketing authorisation holder's summary of product characteristics for all vaccines administered in accordance with this PGD.

By signing this Patient Group Direction you are indicating that you agree to its contents and that you will work within it. I agree to administer Gardasil® vaccine only in accordance with this PGD.

Name of professional	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 **[insert name of organisation]** for the above named health care professionals who have signed the PGD to work under it.

Lead clinician for the service area

Name ……..

Signature ……..

Date ……

Authorised staff should be provided with an individual copy of the clinical content of the PGD and a photocopy of the document showing their authorisation. This authorisation sheet should be retained to serve as a record of those practitioners authorised to work under this PGD.

Version history

Version	Date	Summary of changes
4.0	Jul 2019	• Inclusion criteria updated to reflect inclusion of males in immunisation programme in schools. • Inclusion criteria updated to reflect the policy change to include individuals up to age 25 years. • Inclusion criteria updated to include MSM in same PGD as individuals at school. • Quantity section wording updated. • Use out with SPC section updated to highlight at administration by deep subcutaneous injection is off label but in line with Green Book advice. • Use out with SPC section updated to recommend assessment following inadvertent of unavoidable deviation from recommended storage conditions. • Storage section updated to include additional information on data from stability studies and action required following inadvertent of unavoidable deviation from recommended storage conditions. • Record/audit trail section updated to add NaSH as record of vaccination in MSM.
5.0	01/09/21	Version 5.0 produced This PGD has undergone minor rewording, layout, formatting changes for clarity and consistency with other PHS national specimen PGDs
6.0	01/04/22	Version 6.0 produced • frequency section updated to reflect updated recommendations that those commencing vaccination from 15 years of age should commence a 2-dose schedule with a minimum 6-month interval. • use out with SPC section updated.

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		• minor rewording, layout, formatting changes for clarity and consistency with other PHS national specimen PGDs.