PATIENT GROUP DIRECTION FOR THE ADMINISTRATION OF HUMAN PAPILLOMA VIRUS (HPV) (GARDASIL) VACCINE

This Patient Group Direction (PGD) is a specific written instruction for the administration **Human Papilloma Virus (HPV) (Gardasil) Vaccine** to groups of patients who may not be individually identified before presentation for treatment.

This will enable the appropriate registered healthcare professional to supply/administer treatment in accordance with the following protocol, the recommendations of the Department of Health 1998, the codes and standards of conduct of their professional bodies and any guidelines issues by those bodies on the supply and administration of medicines.

The majority of clinical care should be provided on an individual, patient specific basis. The supply of medicines under Patient Group Directions should be reserved for those limited situations where this offers an advantage for patients care (without compromising patient safety) and where it is consistent with appropriate professional relationships and accountability.

Definition of clinical situation/condition	Active immunisation against disease caused by Human Papilloma Virus (HPV) types 6, 11, 16 and 18 in line with Scottish Government Health Directorate HPV immunisation programme.
Name of organisation(s) within which the PGD will operate	NHS Tayside, General Practices and community pharmacies contracted to supply services to NHS Tayside within NHS Tayside.
Name(s) of clinical areas and locations where the PGD will operate	All appropriately trained NHS Tayside staff. All clinics and wards within NHS Tayside. General Practices. Educational establishments. Community pharmacies. Primary Care Treatment and Care Hubs Community Clinics. Domiciliary environments.
Criteria for inclusion	• Females aged 11 to under 18 years. Although licensed for females aged 9 years, for the purposes of the Immunisation Programme, Gardasil® is routinely recommended in females from school year S1, aged around 11-12 years. • Females who do not commence HPV immunisation in S1 remain eligible until they reach 18 years of age. • Men who have sex with men, aged less than 46 years and have attended a sexual health clinic, in line with the Scottish

	Government Health Directorate HPV immunisation programme. • Valid consent has been given to receive the vaccine.
Precautions	**These are not exclusions but a risk assessment and care should be taken.** • **People with a Bleeding Disorder -** An individual risk assessment should be undertaken prior to vaccination. As with any intramuscular (IM) vaccination, the injection should be given with caution to patients with thrombocytopenia or any coagulation disorder as bleeding may occur following an intramuscular administration to these subjects. Therefore, patients with known bleeding disorders or on anticoagulant therapy should receive the vaccine by deep subcutaneous injection route to reduce the risk of bleeding. Individuals should be informed of the risk of developing haematoma and what to do if this occurs. • Minor illnesses without fever or systemic upset are not valid reasons to postpone immunisation. Patients, who are acutely unwell with fever, should have vaccination deferred until fully recovered in order to prevent confusion of the symptoms of the illness with any adverse effects of the vaccine. • The presence of a neurological condition is not a contraindication to immunisation but if there is evidence of current neurological deterioration, deferral of the vaccine 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.
Criteria for exclusion	• Females under 9 years of age. • Females over 18 years of age. • Men who do not have sex with men. • Any man over 46 years of age. • Confirmed anaphylactic reaction to a previous dose of HPV vaccine. • Confirmed anaphylactic reaction to any component of the vaccine. Practitioners must check the marketing authorisation holder's summary of product characteristics (SPC) for details of vaccine components. • Known pregnancy. • No valid consent.

	• Acute systemic or febrile illness –postpone immunisation until the individual has fully recovered. • Evolving neurological condition: immunisation should be deferred until diagnosed, resolved or stabilised.
Action if excluded	Advice should be sought in the first instance, from the patient's clinician or the Health Protection Team on the vaccine and circumstances under which it could be given. The risk to the individual of not being immunised must be taken into account. Discussion of the risk and benefits of vaccination should take place. Discussions and decisions taken should be document in clinical records. Inform the appropriate clinician, e.g. GP/Pediatrician/treating physician. Children who are excluded using the above criteria will be referred to their General Practitioner (GP). This will be documented in the child health records or/and on the computerised Child Health Surveillance Programme (CHSP) system. **Temporary Exclusion** In case of postponement due to acute febrile illness, arrange a future date for immunisation. Document in clinical records. In the case of postponement due to an unstable of developing neurological condition, vaccination should be promptly given once the diagnosis and/or the expected course of the condition becomes clear. The advice in the Green Book should also be followed.
Action if patient declines	Advise individual/parent/carer/guardian about the benefits and protective effects and possible side effects of the vaccine, the risks of infection and complications relating to infection. Ensure they have additional reading material (patient information leaflet) available to them. Document advice given and decision reached. Inform the appropriate clinician, e.g. GP/Pediatrician/treating physician. Child Health should be informed of any children and/or parent/carer/guardian not consenting.
Follow up of patient e.g. hospital admission/by GP/none required	Children will be called for repeat vaccination as appropriate, by the Scottish Immunisation Call and Recall System (SIRS) in line with national routine vaccination programme. For specific "at risk" patients follow the guidance set out in "Immunisation against Infectious Diseases – The Green Book". https://www.gov.uk/government/collections/immunisation-against-

	infectious-disease-the-green-book

CHARACTERISTICS OF STAFF AUTHORISED TO TAKE RESPONSIBILITY FOR THE SUPPLY OR ADMINISTRATION OF MEDICINES UNDER THIS PATIENT GROUP DIRECTION

Qualifications Required	A registered practitioner enabled under HDL (2001)7 to administer or supply medicines under a Patient Group Direction.
Additional Requirements	Approved by the organisation as competent: • To work within this patient group direction. • To undertake all aspects of immunisation and discussing issues related to benefits and risk of immunisation, contraindications, side effects and complications relating to the specific infections that the vaccine protects individuals from. • In intramuscular and subcutaneous injection techniques as appropriate. • In assessing the person's capacity to understand the nature and purpose of the immunisation in order to give or refuse consent. • In assessing the individual's fitness for immunisation. • In the recognition and immediate management of anaphylaxis in accordance NHS Tayside training e.g. Resuscitation Council (UK) http://www.resus.org.uk/pages/reaction.pdf • In basic life support and resuscitation techniques as per the published standard. The practitioner should have an understanding of and access to: • NHS Tayside Immunisation Policy. • This PGD • Summary of Product Characteristics for the vaccines being used https://www.medicines.org.uk/emc • Latest edition of the British National Formulary https://bnf.nice.org.uk/ • Latest edition of the Green Book https://www.gov.uk/government/collections/immunisation-against-infectious-disease-the-green-book

	• All relevant Scottish Government Health Directorate advice including the relevant CMO letter(s) http://www.sehd.scot.nhs.uk/index.asp?category=9 Risk assessment to be completed prior to each immunisation session. • Immediate access to adrenaline/epinephrine 1:1000 injection for Intramuscular (IM) use. The use of epinephrine in an emergency situation does not require a PGD or a prescription. • There must be easy access to a telephone in order to contact the emergency services if required.
Continuing Training Requirements	It is the responsibility of the individual to : • Keep up to date with all aspects of immunisation, including contraindications, side effects etc. • Attend annual training in the recognition and management of anaphylaxis. • Attend annual update on cardio-pulmonary resuscitation. • Training on use of PGD 3 yearly in line with PGD reviews or earlier if appropriate.

Profession	Registered Nurse or Midwife
Applicable professional codes and standards of conduct	The current NMC Code of Professional Conduct: Standards of Conduct, Performance and Ethics https://www.nmc.org.uk/standards/code/ All professionals should also take cognisance of the Royal Pharmaceutical Society guidance on handling medicines. https://www.rpharms.com/resources/professional-standards/safe-and-secure-handling-of-medicines
Applicable guidelines for supply and administration of medicines	Practitioners operating the PGD should be familiar with: • NHS Tayside Immunisation Policy • NHS Tayside PGD Policy http://staffnet.tayside.scot.nhs.uk/NHSTaysideDocs/groups/working_safely/documents/documents/prod_226903.pdf • NHS Tayside Safe and Secure Handling of Medicines Policy http://www.nhstaysideadtc.scot.nhs.uk/SSHM/MAIN/Front%20p

	age.htm • Immunisation against Infectious Disease [Green Book] https://www.gov.uk/government/collections/immunisation-against-infectious-disease-the-green-book • All relevant Scottish Government Health Directorate advice including the relevant CMO letter(s) http://www.sehd.scot.nhs.uk/index.asp?category=9 • UK Guidance on Best Practice in Vaccine Administration http://www.wales.nhs.uk/sitesplus/documents/861/UK%20best%20practice%20guidance%20vacc%20admin%202001.pdf • HPS Guidance on Vaccine Storage & Handling http://www.hps.scot.nhs.uk/immvax/resourcedetail.aspx?id=194

Profession	Pharmacist
Applicable professional codes and standards of conduct	The current GPhC Standards for Pharmacy Professionals and Standards for Registered Pharmacies. https://www.pharmacyregulation.org/standards
Applicable guidelines for supply and administration of medicines	None, but guiding principles laid out in the above documents.

DESCRIPTION OF TREATMENT AVAILABLE UNDER THIS PATIENT GROUP DIRECTION

Name of Medicine	Gardasil® ▼ Vaccine (Human Papilloma Virus Vaccine [Types 6, 11, 16, 18] (Recombinant, adsorbed)) During storage, a white precipitate may develop and the vaccine should be shaken before use to form a white cloudy liquid.
POM/P/GSL	POM
PGD Ref No	
Presentation	HPV vaccines are supplied as suspensions within pre-filled syringes. During storage, a white precipitate may develop and the vaccines should be shaken before use to form a white cloudy liquid.
Preparation	HPV vaccines are supplied as a per-filled syringe.
Dose/s	0.5ml
Route	**Preferred Route** Intramuscular injection **Bleeding Disorder** An individual risk assessment should be undertaken prior to vaccination of individuals with a known bleeding disorder. Vaccines should be given by deep subcutaneous injection to reduce the risk of bleeding. Injections should be given with the needle at a 45º angle to the skin and the skin should be bunched, not stretched. Pressure (no rubbing) should be applied to the injection site for at least 5 minutes following vaccination. **Site** In children over the age of one year and adults the deltoid region of the upper arm is the recommended site. The vaccine must **not** be administered via oral, intradermal or intravenous route.

Total dose number	The frequency depends on the age the individual receives their first dose and whether the individual is immunocompromised at the time of vaccination. **Individuals aged below 15 years when receiving the first dose:** 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. **Individuals aged 15 years or above receiving the first dose or individuals of any age who are known to be HIV positive (including those on antiretroviral therapy) or are immunocompromised at the time of vaccination** 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. 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. **Men who have sex with men (MSM) and have attended a sexual health clinic.** 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. 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.
Advice to be given to the patient	Supply the appropriate marketing authorisation holder's patient information leaflet (PIL) provided with vaccine. Advise individual to seek emergency medical advice in case of severe adverse reaction. The patient/parents/carers/guardians will be advised to contact GP if they experience severe symptoms, or if symptoms do not settle in a few days. The patient/parents/carers/guardians should be advised to contact GP/NHS24 is they have any concerns following vaccination. Inform patient/parents/carers/guardians of normal local and systemic reactions and how to minimise these including administration of paracetamol for reduction of pyrexia. Pain, swelling or redness at the injection site, low grade fever, malaise, shivering, fatigue, headache, myalgia and arthralgia are among the commonly reported symptoms of vaccination. For full details refer to the marketing authorisation holder's Summary of Product Characteristics. https://www.medicines.org.uk/emc The patient/parents/carers/guardians should be reassured that post-immunisation symptoms are not infectious. If appropriate, advise individual when subsequent doses are due and if any follow up is required. Further information is also available at https://www.nhsinform.scot/healthy-living/immunisation
Identification and management of possible adverse effects	For full details/information on possible adverse reactions, refer to the marketing authorisation holder's Summary of Product Characteristics. https://www.medicines.org.uk/emc Syncope (vasovagal reaction) or fainting can occur during any vaccination, most commonly amongst adolescents. Some individuals may also experience panic attacks before vaccination. The clinical features of fainting and panic attacks are described in Chapter 8 of the Green Book. Fainting and panic attacks before or very shortly after vaccination are not usually direct side effects (adverse reactions) of the vaccine but events associated with the injection process itself.

	Suspected and confirmed adverse reactions should be reported to the MHRA via the Yellow Card Scheme. Please visit www.mhra.gov.uk/yellowcard for further guidance. Any serious adverse reaction to the vaccine should be documented in an individual's health record. The relevant health professional should also be informed e.g. Health Visitor/Family Nurse/Midwife/Pediatrician/treating physician. Adverse events should also be reported through the NHS Tayside Datix system. **Anaphylaxis** Injections of IM adrenaline/epinephrine 1:1000 must be available to treat an anaphylactic reaction should this occur. The use of epinephrine in an emergency situation does not need a PGD or prescription. NHS Tayside guidance on resuscitation and the treatment of anaphylaxis should be followed. http://www.resus.org.uk/pages/reaction.pdf If a patient is thought to be experiencing an anaphylactic reaction in the community an ambulance should be called (999) immediately.
Referral for medical advice	Patients with a current febrile illness will be advised to attend once the illness has resolved. Other patients who are excluded using the exclusion criteria will be referred for a final medical decision on immunisation. Advise patient/parents/carers/guardians to seek emergency medical advice in case of severe adverse reaction. The patient/parents/carers/guardians should be advised to contact GP/NHS24 is they have any concerns following vaccination. The patient/parents/carers/guardians will be advised to contact GP if they experience severe symptoms, or if symptoms do not settle in a few days.
Facilities and supplies required	All practice dealing with medicines and vaccines should be in accordance with the NHS Tayside Safe and Secure Handling of Medicines policy http://www.nhstaysideadtc.scot.nhs.uk/SSHM/MAIN/Front%20page.htm and the NHS Tayside Immunisation Policy. Access to 'Immunisation against Infectious Disease' (Green Book) 2013 and the latest update available via the appropriate Green Book chapter on immunisation procedures and comply with its

	recommendations. https://www.gov.uk/government/collections/immunisation-against-infectious-disease-the-green-book Access to this PGD. **Storage and Transport** Vaccine should be stored in the original packaging and not exposed to light. Vaccine will be stored in a temperature controlled refrigerator between 2°C and 8°C and not frozen. Refrigerators should have maximum and minimum temperatures recorded daily. Temperatures should be maintained between 2°C and 8°C. If vaccine requires to be transported to a community setting, the cold chain must be maintained according to the criteria identified in NHS Tayside Immunisation Policy. Storage and transport in validated vaccine porters is acceptable. Any excursions out with the acceptable temperature range (2°C and 8°C) should be reported to Vaccine Services and the vaccines quarantined and not used until further guidance is sought. If the vaccine has been frozen, it should be discarded. **Resuscitation Equipment** Resuscitation equipment including epinephrine (adrenaline) injection (1 in 1,000) or pre-filled syringes such as Epipen and oxygen (if available) should be available in accordance with published standards for immunisation training e.g. Resuscitation Council (UK) http://www.resus.org.uk/pages/reaction.pdf. Practitioners must have immediate access to a telephone

Treatment Records	The approved practitioner must ensure maintenance of records for each supply and may be required to share information with appropriate parties in line with confidentiality protocols. All records must be clear and legible and, in an easily retrievable format. The information relating to immunisation of each individual must include as a minimum: • Patient's name and date of birth • Valid consent given • Name, brand, batch number and expiry date of vaccine • Dose • Route of injection (IM or SC) • Site of injection (L/R arm or L/R leg) • Date given and by whom. Depending on the clinical setting where immunisation is undertaken, the information should be recorded manually or electronically, in one (or more) of the following systems, as appropriate: • GP practice computer • Individuals GP records • Pharmacy PMR • Child Health Systems e.g. SIRS • EMIS • Clinical case notes • NASH (sexual health system) Patient records should be updated as soon as possible after immunisation and should be completed within two weeks of the date of the vaccination.
Patients on concurrent medication	HPV vaccines can be given at the same time as all other live or inactivated vaccines. If not given at the same time as other vaccines it can be can be given at any time interval before or after all other vaccines. Likewise other vaccines can be given at any time interval before or after HPV. If given at the same time as other vaccinations, care should be taken to ensure that the appropriate route of injection is used for all the vaccinations. The vaccines should be given at a separate site,

	preferably in a different limb. 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. For more information on concurrent administration of live vaccines see the Green book (https://www.gov.uk/government/collections/immunisation-against-infectious-disease-the-green-book) and the Recommendations for giving more than one live attenuated vaccine in current use in the UK https://www.gov.uk/government/publications/revised-recommendations-for-administering-more-than-1-live-vaccine
Patient Consent	Informed consent must be obtained from the patient/parent/carer/guardian prior to treatment. This will be recorded in the case notes and in the treatment record form as either signed consent or verbal consent. The NHS Tayside Informed Consent Policy and Immunisation Policy gives guidance on systems to be adopted.
Audit Trail	The use of a separate treatment record sheet or consent form will facilitate the audit process. An annual audit should be carried out. To facilitate the audit, information relating to immunisation of each individual must include as a minimum: • Patient's name and date of birth • Valid consent given • Name, brand, batch number and expiry date of vaccine • Dose • Route of injection (IM or SC) • Site of injection (L/R arm or L/R leg) • Date given and by whom.
Adverse Reactions and adverse incidents	It is NHS Tayside policy that all incidents and near misses are reported through the correct local electronic procedure (Datix). http://fernie.tnhs.tayside.scot.nhs.uk/datix/live/index.php All adverse reactions (actual and suspected) will be reported to the appropriate medical practitioner and recorded in the appropriate place (e.g. EMIS and the Minor Injury Record Sheet or the Allergies and Adverse Reactions section of the General Practice Record). Where appropriate a Yellow Card Report will be forwarded to the Committee on Safety of Medicines. A supply of these forms can be found at the rear of the British National Formulary. Online reporting is available at http://yellowcard.mhra.gov.uk/

AUDIT OF PATIENT GROUP DIRECTION

Annual audit of documentation and recording of information - **Who will carry this out and to whom will it be reported?**	Each clinical area/lead should undertake an annual audit of their service's documentation and information recording in associated with this PGD. The results of practitioner's documentation and information recording should be reported to their line manager /service lead. Areas where issues are identified an action plan to mitigate and address any risks should also be devised. This action plan and the audit results should be copied to the Immunisation Coordinator and Vaccine Programmes Manager so that areas of good practice and/or risks are escalated to the Tayside Immunisation Steering Group. Community Pharmacists should report the outcomes of their audit through the Consultant in Public Health Pharmacy.
Periodic audit of clinical outcome(s) - **Audit should be carried out at least annually; more often if required.** - **What are the audit questions?** - **Who will carry out the audit(s)** - **To whom will the audit be reported?**	Each practitioner should undertake an annual audit of their own clinical area associated with this PGD. A clinical audit tool that facilitates auditing of the environment, suitability of accommodation, quality and availability of equipment and resources is available as an appendix to the NHS Tayside Immunisation Policy. A review of adverse events and any yellow cards should be analysed. Issues of adequate consent should be examined. It is also good practice for each area to review any Datix events, including needle stick injuries reported in relation to immunisations. The results of practitioner's audits and reviews should be reported to their line manager /service lead. Areas where issues are identified an action plan to mitigate and address any risks should also be devised. This action plan and the audit results should be copied to the Immunisation Coordinator and Vaccine Programmes Manager so that areas of good practice and/or risks are escalated to the Tayside Immunisation Steering Group. Community Pharmacists should report the outcomes of their audit

	through the Consultant in Public Health Pharmacy.

MANAGEMENT & MONITORING OF PATIENT GROUP DIRECTION

Developed By:

[Note: development of any PGD for antimicrobial agents requires the involvement of and approval by the local Antimicrobial Management Group]

Medical Practitioner:	Dr Daniel Chandler	Signature:
Nurse:	Mrs Jane Forbes	Signature:
Pharmacist:	Mr Andrew Radley	Signature:
(Other):		Signature:

Approved By:

Lead Clinician

Name: Signature

Tayside Area Drug & Therapeutics Committee

Name: Professor Colin Fleming Signature:

Date Effective: **September 2018**

Review Date: **September 2021**

Plans must be made to ensure completion of a review on or by the date above. The revised PGD will then follow on immediately. If the review date is reached and no review has taken place, then the PGD will be null and void. Interim review will be required as and when new safety information comes to light

DECLARATION

This protocol is authorised for use within _____
(practice/hospital etc) by the individuals named below:

Clinical Lead _____ Date _____

I have read and understood this PGD and have received the specified local training to implement it effectively.

Name _____ Designation _____

Signed _____ Date _____

Name _____ Designation _____

Signed _____ Date _____

Name _____ Designation _____

Signed _____ Date _____

Name _____ Designation _____

Signed _____ Date _____

Name _____ Designation _____

Signed _____ Date _____

Name _____ Designation _____

Signed _____ Date _____

REGISTER OF NAMED INDIVIDUALS WHO MAY SUPPLY CARE UNDER THIS PATIENT GROUP DIRECTION

Date	Name	Qualifications

PATIENT GROUP DIRECTION HPV IMMUNISATION CONSENT SHEET

Patient Name …….…….. DOB/CHI ……..……

Address .....

Town ..... POSTCODE .....

Gender: (Please circle) Male / Female

CONSENT TO TREATMENT

I agree that I as the patient named above / or this person in my care (please delete as appropriate) can receive **Human Papilloma Vaccine (Gardasil) vaccine** under the appropriate Patient Group Direction.

Signed ……patient/parent//carer/guardian

IF SIGNED CONSENT IS NOT POSSIBLE, BUT VERBAL CONSENT HAS BEEN OBTAINED, THEN THE PRACTITIONER WILL SIGN BELOW.

Signed (practitioner) ……..…. Print Name ……..……

Recorded in case notes ☐

Recorded on computer system ☐

Patient Information Leaflet issued (from pack) ☐

PLEASE COMPLETE TREATMENT RECORD SHEET

PATIENT GROUP DIRECTION HPV IMMUNISATION
TREATMENT RECORD SHEET

PATIENT AND CONSULTATION DETAILS	
Patient Name	
Date of Birth/CHI	
Place of Issue	

CRITERIA FOR EXCLUSION		
The patient will be excluded from treatment under this PGD and referred immediately to a medical practitioner if any of the following criteria apply.		
Female patient ≤ 11 years or over 18 years?	**Yes**	**No**
Male patient over 46 years?	**Yes**	**No**
Known allergy or intolerance to the vaccine or any of its constituents?	**Yes**	**No**
Known to be pregnant?	**Yes**	**No**
Acute febrile illness?	**Yes**	**No**
No valid consent?	**Yes**	**No**

INFORMATION		
Does the patient have unanswered questions regarding this vaccine?	**Yes**	**No**
Advised on management of symptoms following immunisation?	**Yes**	**No**
Information leaflet issued?	**Yes**	**No**

DECLARATION
The above information is correct to the best of my knowledge. I have been informed about the use of this vaccine and understand the advice given to me by the practitioner. Patient's Signature: Date:
The patient is unable to give written consent. The patient/parent/carer/guardian has given verbal consent. Practitioner's Signature: Date:
The action specified was based on the information available to me and given to me by the patient/parent/carer/guardian and that to the best of my knowledge is correct. Practitioner's Signature: Date:

ACTION TAKEN					
HPV (Gardasil) vaccine given				**Yes**	**No**
Batch Number		Expiry Date			
Site	Left Arm		Right Arm		
Given by	Intramuscular Injection		Sub Cut Injection		