Patient Group Direction (PGD) for

The Administration of Human Papilloma Virus (Brand 'Gardasil' ®▼) to females aged from 12 years up to 18 years, by Registered Nurses employed or contracted by Rotherham Community Health Services or working within GP Practices in Rotherham who have been certified after completing an agreed training plan.

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Author:	Kathy Wakefield, Lisa Murray.
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Date Uploaded & By Whom:	

This Patient Group Direction is operational from 2.5.12
and will be reviewed every two years or in the light of new national guidance

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The Administration of Human Papilloma Virus (Brand 'Gardasil' ®▼) to females aged 12 to 18 years, by Registered Nurses employed or contracted by Rotherham Community Health Services or working within GP Practices in Rotherham who have been certified after completing an agreed training plan.

1. Clinical Condition or situation to which the direction applies

Human Papillomavirus vaccine (Brand Gardasil® ▼)

Clinical Indications	Active immunisation against invasive cervical cancer caused by human papillomavirus (HPV) as part of the UK National Immunisation Programme.
Criteria for inclusion	• Any female aged from 12 years up to the age of 18 years (ie up to the day before their 18th birthday), as a primary course of immunisation against human papillomavirus strains 6, 11, 16 and 18. • Valid, legal consent obtained - verbal informed consent can be given by patient on the day of vaccination. **Under 16's follow Fraser guideline**

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Criteria for exclusion	• If excluded because of valid legal consent, obtain legal consent. • Any female who has had an anaphylactic reaction to a previous dose of the vaccine. • Confirmed anaphylactic reaction to any component of the vaccine. • Individuals with a severe latex allergy (e.g. anaphylaxis). • Girls under 12 years of age • Girls 18 years and over. • Current acute or febrile illness. • Pregnancy.(NB The DH has advised that there is no need to screen for pregnancy – see also Reporting procedure of adverse reactions)
Action if excluded	• For acute or febrile illness advise when the vaccine may be given. • If excluded due to pregnancy, vaccination should be postponed until pregnancy completed. • Arrange for further appointment if needed. • Notify Child Health. • Record in patient's record
Action if patient declines treatment	• Advise about protective effects of the vaccine and the risks of infection and disease complications if vaccination not given. • Inform or refer to GP as appropriate. • Document action and advice given in patient's clinical records.
Notes for GP/Clinician Drug Interactions	Individuals with immunosuppression or with HIV infection (regardless of CD4 counts) should be considered for HPV vaccines in accordance with the recommendations in the Green Book. However, individuals who are immunosuppressed may not develop a full antibody response. Re-immunisation should be considered after treatment is finished or recovery has occurred. Specialist advice may be required. Notify Child Health within 2 days.

2. Description of treatment

Drug Name: Human Papillomavirus vaccine (Brand Gardasil▼®)

Name, strength and formulation of drug	Human papillomavirus vaccine suspension for injection Gardasil®▼ human papillomavirus vaccine types 6, 11, 16 and 18 (recombinant, adsorbed). 0.5ml pre-filled syringe.
Legal status	POM - Prescription only medicine. Black triangle ▼-intensively monitored by CHM and MHRA.
Storage	Vaccines must be stored, transported and disposed according to manufacturers and the Department of Health guidelines and current legislation.
Dose/dose range	• 0.5ml
Method /route	• Gardasil▼® should be agitated well before use. • Intramuscular injection given into the upper arm (deltoid muscle) • Gardasil▼® should under no circumstances be given intravascularly or intradermally. • Bleeding disorders- subcutaneous route preferred. • **Do not mix Gardasil▼® with any other vaccines.** • The Gardasil▼® vaccine can be given at the same time as other vaccines. It should be given at a separate site, preferably in a different limb. If given in the same limb, sites should be at least 2.5cm apart. The site where each vaccine was given should be noted in the individual's records.
Frequency of administration	Primary course consists of three doses: • first dose of 0.5ml of Gardasil▼® HPV vaccine • second dose of 0.5ml, at least one month after the first dose • third dose of 0.5ml at least three months after the second dose. All three doses should be given within a 12-month period. For planning purposes, a vaccination schedule of 0, 1-2, 6 months is appropriate. If the course is interrupted, it should be resumed but not repeated, ideally allowing the appropriate interval between the remaining doses. Rarely, if a vaccination course of Gardasil▼® was started but has been unable to be completed using Gardasil▼®, then the course may be finished with Cervarix® to a total of three HPV doses. The course should follow the vaccination schedule of 0, 1-2 and 6 months.

Total dose number	Three
Patient/carer advice and follow-up treatment	• Inform individual about possible side effects and their management. • Give advice on temperature control *only* if patient become feverish. Whilst paracetamol and ibuprofen can lower the duration of fever and reduce distress, there is no evidence that they prevent febrile convulsions. It is not therefore recommended that these drugs are used routinely to prevent fever following vaccination as there is some evidence that prophylactic administration of antipyretic drugs around the time of vaccination may lower antibody responses to some vaccines. • Give advice regarding normal reaction to the injection. • Inform patient when subsequent doses are due when applicable. • Please include a copy of any patient information to be given with this medicine. (Provision of the Patient Information Leaflet is a legal requirement). • Local reactions (pain, erythema, induration and oedema) within 48 hours after vaccination, and persisting for 1-2 days. **Following immunisation/vaccination:** The patient should be observed for an immediate adverse reaction, usually 5-10 minutes and should remain under observation until they have been seen to be in good health and not to be experiencing an immediate adverse reaction.

3. Records

In all cases manual records including the Parent held Personal Child Health Record (PCHR-red book), Patient held record, computerised records and data collection for Child Health Information Services (CHIS) should include:

- Complete Record of Attendance documentation and if appropriate enter on record 'Protocol fulfilled'
- Patient's name, address, date of birth and consent given
- Diagnosis
- Name of medication
- Dose given.
- Brand, Batch Number and Expiry Date (if supplied)
- Signature & name of staff who administered or supplied the medication, and also, if relevant, signature & name of staff who removed/discontinued the treatment
- Route and site of administration (record all sites of administration to allow any reactions to be related to the site of the injection
- Contact details of GP (if registered)
- Information & advice given to patient (including side effects)
- Details of any adverse drug reaction and actions taken, including documentation in the patient's medical record. Any adverse reaction must be notified to GP.
- Referral arrangements (including self care)
- Date administered / supplied
- Any serious adverse events that may be attributable to black triangled drugs ▼ should be reported via SUI trust procedure and then to the MHRA using the yellow card system.
- Any serious adverse event should be reported through local incident procedures

A computer or manual record of all individuals receiving immunization under this Patient Group Direction should also be kept for audit purposes

Vaccine Audit Trail Data Collection

- A record of all individuals receiving treatment under this Patient Group Direction should also be kept for audit purposes within each practice/service.
- Vaccines must be stored and transported according to manufacturer guidelines and trust procedures/guidelines (including cold chain policy)

Reconciliation: Stock balances should be reconcilable with Receipts, Administration, Records and Disposals on a patient by patient basis

Storage: Standards must be consistent with the Summary of Product Characteristics. All medication must be stored in a secure locked environment away from the direct patient care area

4. Anaphylaxis - Emergency Treatment

Before administering any medication the possibility of anaphylaxis must be discussed and documented with the patient/carer prior to administration of any medication, which may produce an anaphylactic reaction.
When giving any medication the following should always be readily available:

- Access to the patients notes
- Adrenaline (Epinephrine) 1 in 1000 for intramuscular (i.m.) injection for use in emergency (NB: **check expiry dates** regularly)
- Syringes and needles of **suitable size** and capacity for dose.
- Patient Group Direction for the Administration of Adrenaline (Epinephrine) 1 in 1000.
- Access to a telephone

PLEASE BE AWARE OF CURRENT RESUSCITATION COUNCIL GUIDELINES – Jan 2008.

Adrenaline (Epinephrine) 1 in1000 (1mg/ml)	**For intramuscular injection**	
Age	Dose	Volume
Children under 6 years	150 micrograms	0.15ml
Children 6 – 12 years	300 micrograms	0.3ml
Adults and adolescents	500 micrograms	0.5ml
These doses may be repeated if necessary at 5-minute intervals according to blood pressure, pulse and respiratory function.		
Special cautions: see BNF 3.4.3	Epinephrine/ Adrenaline	

BNF (62nd edition) section 3.4.3 page 199-202 (Updated Jan 2008)

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5. Professional Responsibility - All practitioners

- The practitioner will ensure he/she has the relevant training and is competent, including contra-indications. He/she will attend training updates as appropriate. Details of the competency programme developed for use with this PGD must be attached (see PGD process above).
- The practitioner will have due regard for their Professional Conduct and Guidelines for the Administration of Medicines
- It is the responsibility of the individual practitioner to ensure that he/she has appropriate knowledge of the product prior to proceeding. Refer to the Summary of Product Characteristics (SPC) or current BNF for further details on the product.
- Must have access to a current copy of the BNF and *Immunisation against infectious disease* ('Green book') and comply with its recommendations (available on DH website – www.dh.gov.uk/greenbook)
- Each individual must have received a personal copy of the PGD and signed on the list of individual professionals who may work within this PGD (kept with master copy of this PGD)
- Must be competent in the recognition and management of anaphylaxis.
- Must have access to all relevant DH advice, including the relevant CMO letters or training and competent in all aspects of immunisation including contraindications and recognition and treatment of anaphylaxis.
- Annual attendance at NHS Rotherham's or workplace update on resuscitation skills and the management of anaphylaxis within the community.
- Maintenance of own level of updating with evidence of continued professional development (PREP requirements)
- Regular updates in immunisation, vaccination, anaphylaxis and cardiopulmonary resuscitation
- To reinforce and update knowledge and skills in this area of practice, including basic resuscitation and anaphylaxis training, with particular reference to changes and national directives.
- Such practitioners that meet the above criteria for training have NHS Rotherham approval to administer Human Papillomavirus vaccine (Brand Gardasil®▼) in accordance with this PGD without a doctor's prescription, and with the patient's informed consent.

Sources:

- HSC 200/026 Patient Group Directions;
- Refer to NHS Rotherham Procedure N1 Procedure for Emergency Treatment of Anaphylactic Reactions in the Community (link http://websrv.rotherhampct.nhs.uk/?FileID=9575)
- Department of Health (2006-web version only): Immunisation against infectious disease. The 'Green book' chapter 18a - Human papillomavirus www.dh.gov.uk/greenbook.
- www.immunisation.nhs.uk
- Current edition of BNF www.bnf.org.uk
- Summary Product Characteristics Cervarix® available http://www.medicines.org.uk.
- NMC 2007 Standards for Medicine Management.
- NMC Code of Professional Conduct (2008).
- Resuscitation Council (UK) Emergency Medical Treatment of anaphylactic reaction by first medical responders and community nurses www.resus.org.uk/siteindx.htm.
- Patient Group Direction' National Prescribing Centre 2004 www.npc.co.uk/publications/pgd.pdf.
- MHRA Advice on Human Papillomavirus vaccine http://www.mhra.gov.uk/Safetyinformation/Generalsafetyinformationandadvice/Product-specificinformationandadvice/HumanpapillomavirusHPVvaccine/index.htm

6. Management of Patient Group Direction

This Patient Group Direction is operational from 2.5.12
and will be reviewed every two years or in the light of new national guidance

NHS Rotherham

This document expires on 31.3.2014
Patient Group Direction Number VI 14a

This patient group direction is to be read, agreed to and signed by all health professionals to whom it applies. One copy should be given to each nurse with the original signed with a copy being kept by the nominated doctor with responsibility for PGDs within the organisation.

Adapted from DH template

Developed by:-	**Name & Title** *in block capitals*	**Signature**	**Date**
Advice sought from	*SUZANNA MATHEWS*		
Lead pharmacist	Lisa Murray		
Lead health professional from group who will administer/supply medicine *e.g. Sister XXXX Diabetic Nurse Specialist*	*MARGARET MURPHY*		
Health Protection and Infection Prevention Manager	Kathy Wakefield		

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This Patient Group Direction for use in Rotherham Primary Care Trust is authorised by us			
Job Title	**Name**	**Signed**	**Date**
Director of Public Health	*Dr. John Radford*		
Medical Director	*Dr. David Plews*		
Head of Medicines Management	*Stuart Lakin*		
TRFT Chief of Community Service	*Andy Irvine*		
Senior Partner (or delegate) - for GP employed nurses only			

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The registered nurses named below, being employees of

NHS Rotherham based at…….*Clinic

OR GP Employer Name* ……..……..
***delete/complete as appropriate**

are authorised to administer Human Papillomavirus vaccine (Brand Gardasil®▼)
as specified under this Patient Group Direction

Register of Staff trained and assessed to administer this vaccine: (additional sheets may be attached)

"I confirm that I have read and understood the content of this patient group direction and that I am willing and competent to work under it within my professional code of conduct".

Name of authorised practitioner	Signature of authorised practitioner	Clinical manager or GP	Signature of clinical manager or GP	Date

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