NHS Rotherham

Patient Group Direction (PGD) for

Patient Group Direction for the Administration of Combined Diphtheria, Tetanus, acellular Pertussis, Inactivated Polio Vaccine and Hib (DTaP/IPV/Hib - Pediacel®) to Children Aged from 2 months up to 10 years of age by Registered Nurses employed or commissioned by NHS Rotherham who have been certified after completing an agreed training plan.

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Author:	Kathy Wakefield and Lisa Murray.
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Key Words:	Combined Diphtheria, Tetanus, acellular Pertussis, Inactivated Polio Vaccine and Hib (DTaP/IPV/Hib - Pediacel®), PGD
Date Uploaded & By Whom:	

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1. Clinical Condition

Drug Name: Combined Diphtheria, Tetanus, acellular Pertussis, Inactivated Polio Vaccine and Hib (DTaP/IPV/Hib-Pediacel®).

Clinical Indications	For active immunisation against diphtheria, tetanus, pertussis, poliomyelitis and Hib in children aged from 2 months and up to 10 years of age: • As a primary course in previously unimmunised children or where there is an unreliable or no history of previous immunisation against diphtheria, tetanus, pertussis, poliomyelitis and Hib • To complete a primary course of immunisation against diphtheria, tetanus, pertussis, poliomyelitis and Hib
Criteria for inclusion	Any child aged from 2 months and up to 10 years of age where:- • parent/guardian has given valid, legal consent to receive the vaccine • as a primary course of diphtheria, tetanus, pertussis, poliomyelitis and Hib • to complete a primary course of diphtheria, tetanus, pertussis, Hib and polio (DTP-Hib and IPV vaccines).
Criteria for exclusion	• No valid, legal consent • Any individual who has had a true anaphylactic reaction to a previous dose of diphtheria, tetanus, pertussis, inactivated polio and Hib • A true anaphylactic reaction to neomycin, streptomycin or polymixin B (which may be present in trace amounts). • Infants below 2 months of age • Children aged over 10 years of age • Adults
Action if excluded	• If excluded because of lack of valid legal consent, obtain valid, legal consent. • Specialist advice must be sought on the vaccines and circumstances under which they could be given. The risk to the individual of not being immunised must be taken into account • Information given about when patient may have vaccine if appropriate. • Document advice given in patients notes. • Inform or refer to GP as appropriate. • Notify Child Health. • Inform the relevant Health Visiting Team.

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Action if Parent/Legal Guardian declines Treatment	• Advice about protective effects of the vaccine and the risks of infection and disease complications. • Document advice given in patients notes • Inform or refer to GP as appropriate. • Notify Child Health.
Notes for doctors / drug interactions	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. This is to avoid confusing the differential diagnosis of any acute illness by wrongly attributing any signs or symptoms to the adverse effects of the vaccine. Individuals with immunosuppression or with HIV infection (regardless of CD4 counts) should be considered for diphtheria-containing vaccines in accordance with the recommendations above. However, these individuals may not develop a full antibody response if they are immunosuppressed, and vaccine protective efficacy has not been studied. Re-immunisation should be considered after treatment is finished and recovery has occurred. Specialist advice may be required. DTaP/IPV/Hib vaccine can be given at the same time as other vaccines including MenC vaccine but at a different injection site – either in different limbs or at least 2.5cms from the concomitant immunisation. DTaP/IPV/Hib vaccine is compatible with previously administered DTwP-Hib and oral polio vaccines. DTaP/IPVHib vaccine should only be used as a primary course or to complete a primary course in children aged from 2 months and under 10 years of age.

2. Description of treatment

Drug Name: Combined Diphtheria, Tetanus, acellular Pertussis, Inactivated Polio Vaccine and Hib (DTaP/IPV/Hib -Pediacel®)

Name, strength & formulation of drug	Adsorbed diphtheria, tetanus, acellular pertussis, Inactivated Polio Viruses and Hib vaccine (DTaP/IPV/Hib - Pediacel®) is in the form of a sterile liquid suspension supplied in a single dose (0.5 ml) vial with an elastomer (latex free) stopper.
Legal status	POM (Prescription Only Medicine)
Storage	Vaccines must be stored, transported and disposed according to manufacturers and the Department of Health guidelines and current legislation.
Dose	0.5ml
Route/ method	Children over one year-IM injection into the deltoid. Infants under one year-IM injection into the anterolateral thigh. Bleeding disorders-deep subcutaneous injection. The site at which the vaccine was given should be noted in the individual's records.

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	N.B. Shake the vaccine well immediately before use
Frequency	• Routine childhood immunisation programme: A primary course of three-doses at 2, 3 & 4 months. • For children aged between 2 months and under 10 years of age: A primary course of three doses at one-month intervals • To complete a primary course at one month intervals
Total dose number	Three
Advice and Follow up	• Inform individual about possible side effects and their management. • Give advice on temperature control if they become feverish. • 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 Package Leaflet is a legal requirement). • Local reactions (pain, erythema, induration and oedema) within 48 hours after vaccination, and persisting for 1-2 days. • Inform Child Health Department that vaccination has been given. 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 Personal Child Health Record (PCHR-red book), 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 immunisation under this Patient Group Direction should also be kept for audit purposes

Vaccine Audit Trail Data Collection

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- 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 RESUSCITATION COUNCIL GUIDELINES.

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 adolescent 12-18 years	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 (64th edition) section 3.4.3 page 202-205(Updated Jan 2008)

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 **Combined Diphtheria, Tetanus, acellular Pertussis, Inactivated Polio Vaccine and Hib (DTaP/IPV/Hib - Pediacel®)**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' www.dh.gov.uk/greenbook.
- www.immunisation.nhs.uk
- Current edition of BNF www.bnf.org.uk
- Summary Product Characteristics Pediacel® 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.

6. Management of patient group direction

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.

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Adapted from DH template

Developed by:-	Name & Title	*Signature*	*Date*
Prepared and approved by: *Name and title in block capitals*			
Advice sought from	Suzanna Mathews		
Lead pharmacist	Lisa Murray		
Lead health professional from group who will administer/supply medicine			
Health Protection and Infection Prevention Manager	Kathy Wakefield		

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This Patient Group Direction for use in NHS Rotherham is authorised by us			
Job Title	**Name**	**Signed**	**Date**
NHS Rotherham Director of Public Health	Dr John Radford		
NHS Rotherham Medical Director	Dr David Plews		
Head of medicines management	Stuart Lakin		
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 Combined Diphtheria, Tetanus, acellular Pertussis, Inactivated Polio Vaccine and Hib (DTaP/IPV/Hib - Pediacel®) 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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