Patient Group Direction (PGD) for

The Administration of Pneumococcal conjugate vaccine (PCV, Prevenar 13®▼) to children aged 2 months to five years, by Registered Nurses employed or commissioned by NHS Rotherham who have been certified after completing an agreed training plan.	
PGD Number:	VI 20
Author:	Lisa Murray and Kathy Wakefield
Date Recommended at Non Prescribing Procedure Advisory Group:	5.7.12
Date Sent to Medicines Management Committee:	25.7.12
Date of Next Review:	25.7.14
Dissemination:	General Practices
Implementation:	Relevant Clinical Lead
File Location:	Prescribing & Medicines Management with link to policies and procedures
Key Words:	PCV, Prevenar 13▼®, Patient Group Directions, Vaccinations
Date Uploaded & By Whom:	

This Patient Group Direction is operational from 25.7.12 and will be reviewed every two years or in the light of new national guidance

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1. Clinical Condition or situation to which the direction applies

Drug: Pneumococcal conjugate vaccine (PCV) (*Prevenar* 13 ®▼)

Clinical Indications	For active immunisation against invasive disease (including sepsis, meningitis, bacteraemic pneumonia, bacteraemia) caused by Streptococcus pneumonia serotype 1,3,4,5,6A, 6B,7F 9V, 14, 18C,19B, 19F and 23F. Immunisation against pneumococcal disease in children under 2 years of age as part of national child immunisation programme. Effective protection for children under 5 years of age in a clinical risk group.

Criteria for inclusion	• Parent/guardian valid, legal consent has been given to receive the vaccine.
	• Any previously unvaccinated child aged from 2 months to under 2 years of age, in line with Department of Health childhood vaccination schedule.
	• Children over the age of 2 months and under the age of 5 years who are considered at risk including those with:
	  ○ Asplenia or splenic dysfunction (including conditions such as homozygous sickle cell disease, coeliac syndrome that may lead to splenic dysfunction).
	  ○ Chronic respiratory disease (including cystic fibrosis, children with respiratory conditions caused by aspiration, a neuromuscular disease eg. cerebral palsy with a risk of aspiration, and severe asthma requiring continuous or frequently repeated use of systemic steroids leading to immunosuppression.
	  ○ Chronic heart disease
	  ○ Chronic kidney disease
	  ○ Chronic liver disease
	  ○ Diabetes (not including diabetes controlled by diet)
	• Iatrogenic or endogenous immunosuppression (including HIV)
	• Individuals with cochlear implants
	• Individuals with cerebrospinal fluid leaks

Criteria for exclusion	• Consent not given by patient/parent/guardian There are very few individuals who cannot receive pneumococcal vaccines. Where there is a clinical concern, seek advice from a suitably qualified clinician e.g. GP, Health Protection Agency. • Current acute febrile illness**.** Minor infections without fever or systemic upset are not reasons to postpone immunisation. • Children aged five years and over and adults. • Patients with Hodgkin's disease who have received extensive chemotherapy or nodal irradiation (as they are unlikely to mount an adequate immune response to the vaccine). • The vaccine should not be given to: those who have had a confirmed anaphylactic reaction to a previous dose of PCV those who have had a confirmed anaphylactic reaction to any component those who have had a confirmed anaphylactic reaction to diphtheria toxoid.

Action if excluded	• If excluded because of valid legal consent, obtain legal consent • Record in patient record • Arrange for further appointment if needed. • Notify Child Health. • Inform the relevant Health Visiting Team. • Referral to GP / seek specialist paediatric advice
Action if Parent/Legal Guardian 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 Doctors Drug Interactions	• Individuals with immunosuppression or with HIV infection (regardless of CD4 counts) should be considered for pneumococcal 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.

2. Description of treatment

Drug Name:

Name, strength and formulation of drug	• Prevenar 13®▼ • Adsorbed Polyvalent (13-valent) Pneumococcalpolysaccharide conjugated (single dose) (PCV) • Suspension for injection in 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 dose
Method /route	• Shake the vaccine well immediately before administration. • Intramuscular injection. • Bleeding disorders- subcutaneous route preferred. • Infants (under one year) - the anterolateral aspect of the thigh. • Children aged over one year - either the anterolateral aspect of the thigh or the deltoid muscle of the upper arm.
Frequency of administration	**Primary immunisation schedule**. • A primary immunisation scheduled course of three doses to be administered to infants at 2 months and 4 months of age with a booster dose between 12 and 13 months of age (ie within a month of the first birthday). • Vaccination of individuals with uncertain or incomplete immunisation status or late presentation and under the age of one year follow the routine immunisation schedule as above. • Children from 1 year to 2 years age should receive a single dose of PCV. If the primary course in children under one year was not completed, then a single booster dose of PCV should be given at least one month after the last dose to complete the course. **At-risk children-under 5 years old** Please refer to Appendix One at end of this PGD.

Total dose number	• Primary course - three or two dependent on age. • At-risk children- variable dependent upon age.
Identification and management of adverse reactions	• Any serious adverse reaction to the vaccine should be documented in a child's health records and on their medical records. • GP should also be informed. • 'Yellow card' must be filled in and sent to the MHRA. These can be found in the BNF or alternatively online at www.yellowcard.gov.uk
Patient/carer advice and follow-up treatment	• Inform individual about possible side effects and their management. • Temperature control-fevers over 37.5ºC are common in children and are usually mild. Advice on the use and appropriate dose of paracetamol or ibuprofen liquid should be given. However, whilst paracetamol and ibuprofen can lower the duration of fever and reduce distress, there is no evidence that they prevent febrile convulsions. *It is therefore recommended that these drugs not be used routinely to prevent fever following vaccination as there is some evidence that prophylactic use of antipyretics around the time of vaccination may lower the antibody response to some vaccines.* • Issue patient information leaflet. • Give advice regarding normal reaction to the injection e.g. sore arm. • Issue Prevenar 13 ▼®, manufacturer's Patient Information Leaflet (PIL). • Inform patient when subsequent doses are due when applicable. • Inform Child Health Department that vaccination has been given.
Reporting procedure of adverse reactions	• Any serious adverse reaction to the vaccine should be documented in their medical records and GP informed. • Any adverse events that may be attributable to PCV vaccination should be reported to the MHRA using the yellow card system. www.yellowcard.gov.uk and Wyeth, the pharmaceutical company that manufactures Prevenar 13▼®, on 01628 604377. • Local incident reporting procedures must be followed.

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

- 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

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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.

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 (63rd edition) section 3.4.3 page 205-208 (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 **Pneumococcal Conjugate Vaccine (PCV) ▼** (Brand **Prevenar13▼®**) 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 25: Pneumococcal www.dh.gov.uk/greenbook.
- www.immunisation.nhs.uk
- Current edition of BNF www.bnf.org.uk
- Summary Product Characteristics Prevenar13▼® 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 PPV vaccine

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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.

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*			
Health Protection and Infection Prevention Manager	*KATHY WAKEFIELD*		

The Administration of Pneumococcal conjugate vaccine (PCV, Prevenar13®▼) to children aged 2 months to five years, by Registered Nurses employed or commissioned by NHS Rotherham who have been certified after completing an agreed training plan.			
This Patient Group Direction for use in NHS Rotherham 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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This document expires on 25.7.14
Patient Group Direction Number VI 20

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 PCV vaccine ▼ (Brand Prevenar13®)
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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Appendix One: Vaccination schedule for those in a clinical risk group

Patient age at presentation	Vaccine given and when to immunise	
	13-valent PCV	23-valent PPV
At-risk children 2 months to under 12 months of age.	Vaccination according to routine immunisation schedule at 2, 4 and between 12 and 13 months of age (ie within a month of the first birthday).	One dose after the second birthday.
At-risk children 2 months to under 12 months who have asplenia, splenic dysfunction, complement deficiency or are immunosuppressed.	Vaccination according to routine immunisation schedule at 2, 4 and between 12 and 13 months of age (ie within a month of the first birthday).	One dose after the second birthday.
At-risk children 12 months to under 5 years.	One dose	One dose after second birthday and at least 2 months after final dose of PCV.
At-risk children 12 months to under 5 years of age who have asplenia, splenic dysfunction, complement deficiency or are immunosuppressed.	Two doses, with an interval of 2 months between doses.	One dose after second birthday and at least 2 months after final dose of PCV.
At-risk children over 5 years and at-risk adults.	PCV is not recommended.	One dose.