Patient Group Direction (PGD) for

The Administration of Pneumococcal Polysaccharide Vaccine (PPV, Pneumovax II ®) to adults over 65 years and at risk groups aged 2 years and over, 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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Date Uploaded & By Whom:	

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1. Clinical Condition or situation to which the direction applies

PPV vaccine (Brand Pneumovax II®)

Clinical Indications	To provide effective protection for adults and at risk children over two years of age against disease caused by the pneumococcal serotypes included in the vaccine in accordance with the current Department of Health's Immunisation Programme.
Criteria for inclusion	▪ Consent given to receive vaccine ▪ Adults aged 65 years and over ▪ All patients aged two years or over in whom pneumococcal infection is likely to be more common or dangerous.- seek current national guidance in the Green Book ▪ Splenectomised individuals/those with splenic dysfunction/chronic kidney disease who have not received a dose of PPV within the previous 5 years
Criteria for exclusion	▪ Consent not given by patient/parent/guardian ▪ Current acute febrile illness ▪ Hypersensitivity to any component of vaccine ▪ Children under 2 years ▪ Children over 2 years and adults under 65 years not in an 'at-risk' group (seek current national guidance in the Green Book) ▪ Children under 5 years who have previously had invasive pneumococcal disease ▪ Splenectomised individuals/those with splenic dysfunction/chronic kidney disease who have received a dose of PPV within the previous 5 years ▪ Individuals (not with splenic dysfunction/splenectomised/chronic kidney disease) who have previously been vaccinated with PPV ▪ Patients who are receiving immunosuppressive therapy or have done so in the last 6 months or 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) At risk children presenting late for immunisation (refer to DOH – changes to childhood immunisation programme 12/07/2006)

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Action if excluded	▪ If excluded because of valid legal consent, obtain legal consent. ▪ For acute or febrile illness advise when the vaccine may be given. ▪ Arrange for further appointment if needed. ▪ Refer other exclusions to medical practitioner. ▪ Document in patient's clinical record. ▪ Notify child health if under 19 years of age ▪ Notify health-visitor if under 5 years of age.
Action if patient declines treatment	▪ Advise about protective effects of the vaccine and the risks of infection and disease complications (if vaccine not given). ▪ Inform or refer to GP as appropriate. ▪ Document action and advice given in patient's clinical records. ▪ Record in patient record ▪ Notify child health if under 19 years of age.
Notes for Doctors Drug Interactions	Individuals with immunosuppression or with HIV infection (regardless of CD4 counts) should be considered for PPV 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. Pneumococcal vaccine can be given at the same as other childhood and influenza vaccines but should be given in separate sites. Pneumococcal vaccines can be given in pregnancy where there is an urgent need for protection

2. Description of treatment

Drug Name PPV vaccine (Brand Pneumovax® II)

Name, strength and formulation of drug	Polyvalent (23-valent) unconjugated Pneumococcal polysaccharide (Pneumovax II)
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/dose range	0.5ml
Method /route	Prior to administration the vaccine should be inspected to make sure it is clear and colourless. **Adults and children**-IM injection into deltoid region. **Bleeding disorders-** subcutaneous injection.
Frequency of administration	Single dose. (For children in pneumococcal clinical risk groups - at least two months after final dose of Pneumococcal conjugated vaccine- *Prevenar*®▼ - see Appendix One at end of PGD. Revaccination is not recommended except after 5 years, in individuals in whom antibody concentration is likely to decline more rapidly (e.g. asplenia, splenic dysfunction and nephrotic syndrome). For patients undergoing planned splenectomy or immunosuppressive treatment pneumococcal vaccine should ideally be given 4-6 weeks prior to surgery/commencement of treatment. NB if vaccination cannot take place at least two weeks prior to splenectomy, it should be postponed until at least two weeks after surgery. SEEK MEDICAL ADVICE BEFORE REVACCINATION – discuss with Haematologist, Immunologist or Microbiologist.
Total dose number	One
Identification and management of adverse reactions	Management of local reactions. If more severe reactions are experienced, e.g. breathlessness, swelling, rash they must contact GP. Advise to seek medical advice should unexpected symptoms develop. 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.**

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. • Give advice regarding normal reaction to the injection e.g. sore arm. • Issue *Pneumovax II*® manufacturer's Patient Information Leaflet (PIL). • Inform patient when subsequent doses are due when applicable.
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 HPV vaccination should be reported to the MHRA using the yellow card system. www.yellowcard.gov.uk and Sanofi Pasteur, the pharmaceutical company that manufactures *Pneumovax*® II, on 01628 785291. • Local incident reporting procedures must be followed.

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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 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

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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 child 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 (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 PPV vaccine (Brand Pneumovax® II) 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 Pneumovax® II 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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This document expires on 25.7.14

Patient Group Direction Number VI 19

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*		

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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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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 PPV vaccine (Pneumovax II®)
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.