

PATIENT GROUP DIRECTION

For the Administration of Pneumococcal Polysaccharide Vaccine (PPV) for Adults over 65 years and At-Risk Groups Aged 24 Months or Over
by registered nurses to patients registered with General Practitioners
within NHS Cambridgeshire

Issue date: 1st February 2012

Supersedes: PGD Administration of Pneumococcal Polysaccharide Vaccine (PPV) to Adults over 65 years and At-risk Groups Aged 24 Months or Over (issued 1st December 2011)

Expiry date: 31st January 2014, or earlier in the light of local or national changes

Developed & produced by:

Name	Designation/Title	Signature	Date
Dr Lincoln Sargeant	Consultant in Public Health NHSC	Signed on	11.01.2012
Janet Watkinson	Public Health Pharmacist NHSC	Signed on	12.01.2012
Penny Miller	Immunisation Coordinator NHSC	Signed on	12.01.2012
June Grainger	Practice Nurse	Signed on	11.01.2012
Roisin Wright	Medicines Management Nurse Specialist NHSC	Signed on	25.01.2012

This patient group direction has been approved on behalf of NHS Cambridgeshire by:

Name	Designation/Title	Signature	Date
Sati Ubhi	Deputy Chief Pharmacist	Signed on	25.01.2012
Dr Christine Macleod	Medical Director	Signed on	24.01.2012

Authorisation of Employer (if not employed by NHS Cambridgeshire):

Name	Designation/Title	Signature	Date

Action required before proceeding with administration and/or supply of a vaccine /medication under this Patient Group Direction

Each registered practitioner authorised to administer medication under this PGD must have read, understood and signed this version of the PGD and completed the agreement to practice form before attempting to work to it.

By signing this PGD you are indicating that you agree to its contents and that you will work within it.

PGDs do not remove inherent professional obligations or accountability. It is the responsibility of each professional to practice only within the bounds of their own competence.

It is the responsibility of each individual practitioner to confirm before each administration that the information within this PGD is 'up-to-date'.

In the event that the information links no longer work, or the PGD has expired, please notify NHS Cambridgeshire's Medicines Management Team. In such circumstances a Patient Specific Direction (PSD) is indicated.

In order for administration and/or supply of the vaccine/medication under this PGD to be valid, practitioners should have electronic access to, or a hard copy of, the most recent information relating to the named vaccine:

- **Childhood Immunisation Schedule** (Department of Health, 2010), available at http://www.dh.gov.uk/prod_consum_dh/groups/dh_digitalassets/documents/digitalasset/dh_122401.pdf
- **Relevant chapter(s) of 'The Green Book' – Immunisation against infectious disease** (Department of Health, 2006), available via http://www.dh.gov.uk/en/Publicationsandstatistics/Publications/PublicationsPolicyAndGuidance/DH_079917
- **Summary of Product Characteristics from the electronic Medicines Compendium (eMC)**, available via <http://www.medicines.org.uk/EMC/default.aspx>
- **British National Formulary**, available online at <http://bnf.org/bnf/bnf/current/> (Athens login required)
- **Patient information leaflets from the electronic Medicines Compendium (eMC)**, available via <http://www.medicines.org.uk/EMC/default.aspx>

Vaccination information for members of the public (NHS Choices, 2011), is available at <http://www.nhs.uk/Planners/vaccinations/Pages/Landing.aspx>

Further immunisation information for health care professionals (Department of Health, 2011), is available at <http://www.dh.gov.uk/en/Publichealth/Immunisation/index.htm>

Further information relating to Healthcare professional reporting adverse reactions (MHRA, 2011), is available at <http://www.mhra.gov.uk/Safetyinformation/Reportingsafetyproblems/Reportingsuspectedadversedrugreactions/Healthcareprofessionalreporting/Adversedrugreactions/index.htm>

The original copy, signed by all those concerned, should be kept in a designated safe place within the practice, and readily accessible to all registered nurses for reference.

Patient Group Direction for Administration of Pneumococcal Polysaccharide Vaccine (PPV) to Adults over 65 years and At-risk Groups Aged 24 Months or Over

1. Characteristics of Staff	
1.1 Professional qualification	This PGD is agreed for use by Registered Nurses undertaking immunisation/vaccination
1.2 Additional requirements	<ul style="list-style-type: none"> • Resuscitation skills & anaphylaxis training • Competent to undertake immunisations <p>All authorised staff must demonstrate an appropriate level of understanding and knowledge with regards to:</p> <ul style="list-style-type: none"> • Assessment of patient • The medication, therapeutic use, contraindications, side-effects, interactions and storage and handling requirements • Be familiar with relevant NHSC medicines policies • Have access to local and national guidance as outlined on page 2
1.3 Continued training requirements	<ul style="list-style-type: none"> • Annual attendance at the PCT 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)
2. Clinical condition or situation to which the direction applies	
2.1 Indication	For active immunisation against invasive disease caused by <i>Streptococcus pneumoniae</i> of the 23 pneumococcal serotypes included in the vaccine
2.2 Criteria for inclusion	<ul style="list-style-type: none"> • All adults aged 65 years or over who have not been previously immunised • Adults and children aged 24 months and over in the clinical risk groups in whom there is increased risk of morbidity or mortality from pneumococcal disease as listed in Table 25.1 Chapter 25 of the Green Book: <ul style="list-style-type: none"> – Asplenia or dysfunction of the spleen – Chronic respiratory disease – Chronic Heart Disease – Chronic Kidney Disease – Chronic Liver Disease – Diabetes (requiring insulin or other antihyperglycaemic drugs, does not include diet controlled) – Immunosuppression – Individuals with cochlear implants – Individuals with cerebrospinal fluid leaks • Close contacts of invasive pneumococcal disease and in local outbreaks, following advice from the Health Protection Agency
2.3 Criteria for exclusion	<ul style="list-style-type: none"> • No valid consent • Confirmed history of true anaphylaxis to a previous dose of this vaccine • Confirmed history of true anaphylaxis to any

Patient Group Direction for Administration of Pneumococcal Polysaccharide Vaccine (PPV) to Adults over 65 years and At-risk Groups Aged 24 Months or Over

	<p>component/constituent of this vaccine, including the active substances, or to any of the excipients</p> <ul style="list-style-type: none"> • Current acute febrile illness (postpone and reschedule). <i>Minor illnesses or infections without fever or systemic upset are not a contraindication to vaccination and not a valid reason to delay immunisation</i> • Children under 2 years of age – there is no evidence of effectiveness of PPV in children under 2 years of age • Healthy adults and children under 65 years • Persons who have previously received 23-valent pneumococcal polysaccharide vaccine PPV • Individuals who have received a dose of PCV within the last 2 months • Pregnant or lactating women • People who have had pneumococcal pneumonia or other pneumococcal infection • Elective splenectomy – not to be administered later than 2 weeks prior to elective splenectomy, and not to be administered until at least 2 weeks after the operation • Chemotherapy/radiotherapy treatment – not to be administered later than 2 weeks before initiation of treatment, nor before three months after completion of treatment – see ‘Frequency’ section <p>NB Patients may be excluded by cautions or interactions</p> <p><i>Where there is doubt, appropriate advice should be sought from a consultant paediatrician, immunisation coordinator or consultant in communicable disease control, rather than withhold immunisation. Specialist advice must be sought on the vaccines and circumstances in which they could be given</i></p> <p>The risk to the individual of not being immunised must be taken into account</p> <p>For further details please refer to the Green Book and the SPC and/or contact the manufacturer</p>
<p>2.4 Action if excluded</p>	<ul style="list-style-type: none"> • Offer advice on when individuals may have the vaccine • Discuss with the patient/client/guardian and document the reasons for exclusion from treatment under the PGD • Reschedule or refer/transfer to the appropriate prescriber/service as soon as clinically appropriate • Specialist advice must be sought on the vaccine/medication and circumstances under which they could be given • The risk to the individual of not being immunised must be taken into account • Advise the patient/parent/guardian regarding the risks of pneumococcal disease, disease transmission, signs and symptoms
<p>2.5 Action if patient declines treatment</p>	<ul style="list-style-type: none"> • Advise patient/parent/guardian about protective effects of the vaccine, the risks of pneumococcal disease, disease transmission, signs and symptoms

	<ul style="list-style-type: none"> Advise patient/parent/guardian of possible consequences of refusing treatment and of alternative sources of treatment Document refusal and advice given in the patient record Inform or refer to GP as appropriate
2.6 Reasons for referral or seeking medical advice	<ul style="list-style-type: none"> Exclusions or patient/guardian preference Emergency treatment of anaphylactic reactions – Guidelines for Healthcare Providers – Resuscitation Council UK available online at http://www.resus.org.uk/pages/reaction.pdf with the following algorithm http://www.resus.org.uk/pages/anaalgo.pdf In the event of an adverse reaction refer for medical advice If there are any concerns or cautions/interactions relating to the medicine to be given, practitioners should seek medical advice or refer/transfer to the appropriate prescriber/service if necessary
3. Description of Treatment	
3.1 Name, strength & formulation of drug	Pneumococcal polysaccharide vaccine (23-valent) (PPV) Brand name covered by this PGD Pneumovax II ®
3.2 Legal status	POM (Prescription Only Medicine)
3.3 ▼ Black triangle?	No
3.4 PGD covering use outside terms of Summary of Product Characteristics?	<p>Yes – regarding recommendation to re-immunise individuals with asplenia after 5 years as per BNF and ‘Green Book’. SPC advises ‘revaccination after 3 years can be considered’ – ‘Green Book’ advice overrides the manufacturer’s recommendations</p> <p><i>Please explain to patient/client/guardian/carer that advice differs from the patient information leaflet and the reason for this</i></p>
3.5 Route/method of administration	<ul style="list-style-type: none"> Pneumovax II® vaccine should be administered via the intramuscular route preferably into the deltoid muscle Intradermal and intravascular administration must be avoided May be administered by the deep subcutaneous route in individuals with bleeding disorders Pneumococcal polysaccharide vaccine (PPV) may be administered simultaneously with influenza vaccines and routine childhood immunisations The vaccines must not be mixed in the same syringe and be given with different needles The vaccines must be given at separate sites, preferably in a different limb. If administered in the same limbs sites must be at least 2.5cms apart
3.6 Dose	0.5ml
3.7 Frequency of	See Green Book Chapter 25 Table 25.2 for the vaccination

Patient Group Direction for Administration of Pneumococcal Polysaccharide Vaccine (PPV) to Adults over 65 years and At-risk Groups Aged 24 Months or Over

<p>administration</p>	<p>schedule for those in the clinical risk groups (refer to the schedule in the Pneumovax II ® PPV column)</p> <p>For at risk children aged 2-5 years</p> <ul style="list-style-type: none"> • A single dose of 23-valent polysaccharide vaccine (PPV Pneumovax II ®) should be given after the second birthday and at least 2 months after the pneumococcal conjugate vaccine (PCV Prevenar 13 ®) according to schedule • Children aged under 5 who have been fully immunised with PCV as part of the routine programme (see PCV PGD), and who then develop splenic dysfunction more than one year after completing immunisation, should be offered an additional dose of PCV. The PPV vaccine should not be given until at least 2 months after that PCV dose <p>For children aged over 5 years and adults</p> <ul style="list-style-type: none"> • A single dose of PPV should be given <p>Children and adults requiring splenectomy or commencing immunosuppressive treatment</p> <ul style="list-style-type: none"> • Previously unvaccinated children and adults requiring splenectomy or commencing immunosuppressive treatment may be at an increased risk of pneumococcal disease and should be vaccinated according to the schedule for this specific risk group • Ideally the vaccine should be given 4-6 weeks before elective splenectomy or initiation of treatment such as chemotherapy or radiotherapy • Where this is not possible, it can be given up to 2 weeks before • If it is not possible to vaccinate beforehand, splenectomy, chemotherapy or radiotherapy should never be delayed • Splenectomy – if it is not practical to vaccinate 2 weeks before splenectomy, immunisation should be delayed until at least 2 weeks after the operation as functional antibody responses may be better after this time • Immunosuppressive treatment – if it is not practicable to vaccinate 2 weeks before initiation of chemotherapy or radiotherapy, immunisation can be delayed until at least 3 months after completion of therapy in order to maximise the response to the vaccine. Immunisation should not be delayed if this is likely to result in a failure to vaccinate. Also a longer delay may be appropriate for patients who have received intensive or prolonged treatment. Seek advice as to the appropriate time to administer, and obtain a Patient Specific Direction if appropriate • Individuals scheduled to receive Cochlear implants – it is important that immunisation does not delay the cochlear implantation. Where possible vaccination should be completed at least 2 weeks prior to surgery to
------------------------------	--

Patient Group Direction for Administration of Pneumococcal Polysaccharide Vaccine (PPV) to Adults over 65 years and At-risk Groups Aged 24 Months or Over

	allow a protective immune response to develop
3.8 Cautions	<ul style="list-style-type: none"> • Minor illnesses without fever or systemic upset are not valid reasons to postpone immunisation. If an individual is acutely unwell, immunisation should 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. • Children and adults requiring splenectomy or commencing immunosuppressive treatment – see ‘frequency’ section for the recommended time to give the vaccine • The occurrence of apnoea following vaccination is especially increased in infants who were born prematurely • Further guidance is provided by the Royal College of Paediatrics and Child Health http://www.rcpch.ac.uk/, the British HIV Association (BHIVA) Immunisation Guidelines for HIV-infected adults (BHIVA, 2006) and the Children’s HIV Association of UK and Ireland (CHIVA) immunization guidelines http://www.chiva.org.uk/ • The vaccine is relatively ineffective in patients with multiple myeloma, Hodgkins and Non-Hodgkins lymphoma, especially during treatment, and in chronic alcoholism • See current SPC, the BNF and/or contact the manufacturer
3.9 Interaction	<ul style="list-style-type: none"> • Pneumococcal vaccine can be administered simultaneously with influenza vaccine as long as different needles and injection sites are used • Pneumovax II ® and Zostavax ® should not be given concurrently (see SPC)
3.10 Special Considerations / Additional Information	<ul style="list-style-type: none"> • Re-immunisation is not normally advised except in the following circumstances: <ul style="list-style-type: none"> – Patients with no spleen, splenic dysfunction or chronic renal disease should be re-immunised every 5 years – For children aged 2-10 years at high risk of pneumococcal infection (e.g. nephritic syndrome, asplenia or sickle cell disease) revaccination after 3 years should be considered as antibody concentration may decline more rapidly • At least 2 weeks should elapse between immunisation and initiation of chemotherapy/radiotherapy or immunosuppressive treatment to allow development of adequate antibody response – Pregnancy and breastfeeding – there is no evidence of risk from vaccinating pregnant or breast-feeding women with inactivated or bacterial vaccines or toxoids. Although the safety of pneumococcal vaccines during pregnancy has not been assessed the vaccine may be given if clinically indicated i.e. the need for protection is required without delay (Green Book recommendation) – refer to Independent Prescriber – Patient Specific Direction required in this instance

Patient Group Direction for Administration of Pneumococcal Polysaccharide Vaccine (PPV) to Adults over 65 years and At-risk Groups Aged 24 Months or Over

3.11 Potential adverse reactions/ side effects	<ul style="list-style-type: none"> • Very common– injection site reactions consisting of pain, soreness, erythema, warmth, swelling and local induration. Fever
3.12 Reporting procedure of Adverse Drug Reactions	<ul style="list-style-type: none"> • Report any suspected ADR to a medical practitioner as soon as possible • Patients with unusual or persistent side effects should be reviewed by the GP • Any serious adverse reaction to the vaccine/medication should be documented and on their medical records. GP should also be informed. • For established medicines, report all serious suspected reactions in adults, and all serious AND minor reactions in children (under 18 years) via the Yellow Card reporting scheme • For medicines showing the black triangle ▼ symbol ALL suspected ADRs should be reported via the Yellow Card reporting scheme
3.13 Patient advice	<ul style="list-style-type: none"> • Explain treatment and course of action • Inform possible side effects and their management • Give advice on temperature control • Always provide the manufacturers Patient Information Leaflet and any specific local/national leaflets to patient/parent/guardian as appropriate. • Document in the patient's records • Explain treatment and any further instructions to aid compliance/concordance • Advise the patient/patient/guardian to seek medical advice in case of severe or unexpected adverse events • Reassurance, if required, that the vaccine contains no thiomersal • Advise that the vaccine only protects against 23 serotypes of <i>Streptococcus pneumoniae</i> and so will not provide protection from disease caused by any other serotypes or other micro-organisms • Refer to the Green Book and SPC for further details
3.14 Follow up treatment	<ul style="list-style-type: none"> • Next vaccination date is advised if appropriate • Advice and information on follow-up will be discussed and provided to the patient/parent/guardian • If the patient is not eligible for treatment under this PGD refer to GP or other service as appropriate
3.15 Storage and Handling	<ul style="list-style-type: none"> • Vaccine should be maintained at a temperature of +2° to +8°C. If the vaccine has been frozen, the vaccine should be discarded • Store in the original package in order to protect from light • Disposal should be by incineration at a suitably authorised facility • Before use, nurses should satisfy themselves that the vaccine has been properly stored and that the cold chain has not been broken • Not for intravascular use • The vial must be inspected visually for any foreign particulate matter and/or any abnormal physical appearance. In the event of either being observed

Patient Group Direction for Administration of Pneumococcal Polysaccharide Vaccine (PPV) to Adults over 65 years and At-risk Groups Aged 24 Months or Over

	discard the vaccine
--	---------------------

Please note:

Listed above are the interactions with commonly used medicines and the main side effects. If the patient/client is taking a medicine not listed above or reports side effects refer to the current BNF, Patient information Leaflet or electronic Medicines Compendium <http://www.medicines.org.uk/emc/default.aspx> or seek advice from pharmacist or medicines information department

4. Facilities and supplies that must be available	
4.1 Medicine to be stocked	Pneumovax II ®
4.2 Storage	<ul style="list-style-type: none"> • Lockable monitored medicines refrigerator maintained between +2°C and +8°C
4.3 Reporting incidents	<ul style="list-style-type: none"> • Incidents and near misses must be reported using the NHS Cambridgeshire Incident Reporting form (DATIX), which should be forwarded to the Risk Manager as soon as possible AND/OR • Via employer's critical incident reporting system
4.4 Other requirements	<ul style="list-style-type: none"> • Working telephone and/or access to emergency assistance • Anaphylaxis policy • Immediate access to Epinephrine (Adrenaline) 1in 1000 injection • Current BNF • Access to National Guidance – eg Green Book • Access to SPC • Supplies of Patient Information Leaflets
5. Records to be kept for audit purposes	
5.1 Patient details	<ul style="list-style-type: none"> • Patient identifiers • Allergies • Any reason for exclusion and action taken • Document patient consent or refusal • Advice sought from medical/specialist service • Details of any adverse reactions experienced by the patient and action taken • Verbal and written advice given to patient • Follow up and referral details
5.2 Records of administration	<ul style="list-style-type: none"> • In all cases manual records and computer records should include : <ul style="list-style-type: none"> ○ Patient's name and date of birth ○ Dose, site and route of injection/medication ○ Brand, batch number and expiry date of vaccine ○ Date given and by whom ○ Consent given and if a child by whom <p>Where vaccination is given to a child, this should also be recorded in the Child Health Record (PCHR red book)</p>
5.3 Audit	<ul style="list-style-type: none"> • Annual audit must be carried out by the clinical lead or nominated deputy within each practice • A computer or manual record of all individuals receiving immunisation under this Patient Group Direction should

Patient Group Direction for Administration of Pneumococcal Polysaccharide Vaccine (PPV) to Adults over 65 years and At-risk Groups Aged 24 Months or Over

- also be kept for audit purposes within each practice
- Regulations require that there is a secure system for recording and monitoring medicines use from which it should be possible to reconcile incoming stock and out-goings on a patient-by-patient basis
- Audit may include evidence of authorised practitioner signatures, appropriate supply, standards of documentation, follow-up arrangements, advice and information given to patients, reporting of adverse effects and incidents

6. References

Department of Health (2006) **The Green Book – Immunisation against infectious disease**, available online at

http://www.dh.gov.uk/en/Publicationsandstatistics/Publications/PublicationsPolicyAndGuidance/DH_079917 (accessed 16.11.2011).

Department of Health (2010) **Childhood Immunisation Schedule**, available online at

http://www.dh.gov.uk/prod_consum_dh/groups/dh_digitalassets/documents/digitalasset/dh_122401.pdf (accessed 26.11.2011).

Department of Health (2011) **Immunisation information for health care professionals**,

available online at <http://www.dh.gov.uk/en/PublicHealth/Immunisation/index.htm> (accessed 26.11.2011).

Electronic Medicines Compendium (2011) **Summary of Product Characteristics for**

Pneumovax II® (Sanofi Pasteur MSD Limited) last updated on the eMC website 22.06.2011, available online at <http://www.medicines.org.uk/EMC/medicine/15259/SPC/REVAXIS/> (accessed 16.11.2011).

Health Protection Agency (HPA) (2011) **Vaccination Immunisation**, available online at

http://www.hpa.org.uk/infections/topics_az/vaccination/vac_guidelines.htm (accessed 26.11.2011).

Medicines and Healthcare products Regulatory Agency (MHRA) (2011) **Healthcare professional reporting: Adverse drug reactions**, available online at

<http://www.mhra.gov.uk/Safetyinformation/Reportingsafetyproblems/Reportingsuspectedadversedrugreactions/Healthcareprofessionalreporting/Adversedrugreactions/index.htm> (accessed 26.11.2011).

NHS Choices (2011) **Vaccinations: Your NHS guide to vaccinations for you and your family**,

available online at <http://www.nhs.uk/Planners/vaccinations/Pages/Landing.aspx> (accessed 26.11.2011).

Resuscitation Council (UK) (2008) **Emergency treatment of anaphylactic reactions:**

Guidelines for healthcare providers, available online at

<http://www.resus.org.uk/pages/reaction.pdf> (accessed 26.11.2011).

AGREEMENT BY HEALTH PROFESSIONAL TO ACT UNDER THE PATIENT GROUP DIRECTION

I have read and fully understand the following:

Patient Group Direction for Administration of Pneumococcal Polysaccharide Vaccine (PPV) to Adults over 65 years and At-risk Groups Aged 24 Months or Over

Issue date: 1st February 2012 **Expiry date:** 31st January 2014

BNF and SPC monographs (and for Immunisation & Vaccination, the appropriate chapters of the Green Book) for all drugs included in this PGD.

NHS Cambridgeshire Patient Group Direction Policy

- I agree to act within the terms of the Patient Group Direction and administer and/or supply medicines in accordance with the documents listed above.
- I understand that my employer e.g. GP practice or NHS Cambridgeshire, is vicariously liable for acts and omissions by me during my employment with them.
- I understand that failure to comply with the terms and conditions of the PGD, including the expiry date and limitations on practitioners, patients, drugs and indications may render me liable to disciplinary action by my employer e.g. GP practice or NHSC under their performance and conduct arrangements.

BY SIGNING THIS PATIENT GROUP DIRECTION YOU ARE INDICATING THAT YOU AGREE TO ITS CONTENTS AND THAT YOU WILL WORK WITHIN IT

PGDs DO NOT REMOVE INHERENT PROFESSIONAL OBLIGATIONS OR ACCOUNTABILITY

IT IS THE RESPONSIBILITY OF EACH PROFESSIONAL TO PRACTICE ONLY WITHIN THE BOUNDS OF THEIR OWN COMPETENCE

Name: *(block capitals)* (Health Professional)

Signature: (Health Professional)

Position:

GP Lead:

Site/Practice:

Date signed:

The original must be filed in the health professional's personal file and a copy held by their manager or employer for the purposes of ensuring practice occurs only in accordance with the PGD and is only undertaken by approved practitioners.

Patient Group Direction for Administration of Pneumococcal Polysaccharide Vaccine (PPV) to Adults over 65 years and At-risk Groups Aged 24 Months or Over

