Public Health England

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PATIENT GROUP DIRECTION (PGD)

Administration of pneumococcal polysaccharide conjugate vaccine (13-valent, adsorbed) (PCV)

Individuals from 8 weeks to under 2 years of age in accordance with the national immunisation programme

For the administration of pneumococcal polysaccharide conjugate vaccine (13-valent, adsorbed) (PCV) by currently registered nurses to individuals from 8 weeks to under 2 years of age in accordance with the national immunisation programme for active immunisation against pneumococcal disease.

Reference no:	*PCV PGD*
Version no:	*v01.00*
Valid from:	*1 February 2016*
Review date:	*1 August 2017*
Expiry date:	*31 January 2018*

Public Health England has developed this PGD for local authorisation by NHS England to facilitate delivery of the national immunisation programme.

Those using this PGD must ensure that it is formally authorised and signed by a clinical governance or patient safety lead, who has designated responsibility for signing PGDs on behalf of NHS England for their geographical area, so that this document meets legal requirements for a PGD. **THE PGD IS NOT LEGAL OR VALID WITHOUT THIS LOCAL, FORMAL AUTHORISATION.**

Authorising organisations must not alter or amend the *clinical* content of this document (sections 4, 5 and 6); such action will invalidate the *clinical sign-off* with which it is provided. In addition authorising organisations must not alter section 3 'Characteristics of staff'. Only sections 2 and 7 can be amended.

Operation of this PGD is the responsibility of commissioners and service providers.

THE PRACTITIONER MUST BE AUTHORISED BY NAME, UNDER THE CURRENT VERSION OF THIS PGD BEFORE WORKING ACCORDING TO IT.

Practitioners and organisations must check that they are using the current version of the PGD. Amendments may become necessary prior to the published expiry date. Current versions of PHE PGD templates for local authorisation can be found from: https://www.gov.uk/government/collections/immunisation

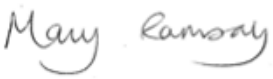
Any concerns regarding the content of this PGD should be addressed to: Immunisation@phe.gov.uk

Change history

Version number	Change details	Date
V01.00	New PHE PGD template	19/01/2016

1. PGD template development

This PGD template has been developed by the following on behalf of Public Health England:

Developed by:	Name	Signature	Date
Pharmacist (Lead Author)	Elizabeth Graham Lead Pharmacist Immunisation Services, PHE		21/01/2016
Doctor	Mary Ramsay Consultant Epidemiologist and Head of Immunisation, Hepatitis & Blood Safety Department, PHE		21/01/2016
Registered Nurse	David Green Nurse Consultant – Immunisations, PHE		21/01/2016

This PGD template has been peer reviewed by the PHE Immunisations PGD Expert Panel in accordance with PHE Policy for PGD Templates. It has been ratified by PHE Medicines Management Group and PHE Clinical Governance Group.

Acknowledgements

Name	Designation
Shamez Ladhani	Paediatric Infectious Disease Consultant, Public Health England
Jacqueline Lamberty	Medicines Management Adviser – Public Health England
Gill Marsh	Senior Health Protection Nurse Practitioner, Cheshire & Merseyside Health Protection Team, Public Health England
Lesley McFarlane	Screening and Immunisation Co-ordinator (SIC) NHS England Leicestershire and Lincolnshire
Sue Mulvenna	Pharmacist Lead - NHS England South West
Graham Munslow	Clinical Screening and Immunisation Manager, NHS England Lancashire & Greater Manchester / Public Health England.

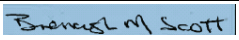
2. Organisational authorisations

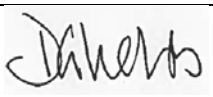
The PGD is not legally valid until it has had the relevant organisational authorisation.

It is the responsibility of the organisation that has legal authority to authorise the PGD, to ensure that all legal and governance requirements are met. The authorising body accepts governance responsibility for the appropriate use of the PGD.

NHS England London Region authorise this PGD for use by the services or providers listed below:

Authorised for use by the following organisations and/or services
This PGD must only be used by specified registered healthcare professionals working for providers that are directly commissioned by NHS England London Region, or who are administering vaccinations as part of a national immunisation programme, and who have been named and authorised to practise under it.
Limitations to authorisation
None.

Organisational approval (legal requirement)			
Role	**Name**	**Sign**	**Date**
Deputy Chief Nurse, NHS England London Region	**Bronagh Scott**		**07/03/2016**

Additional signatories according to locally agreed policy			
Role	**Name**	**Sign**	**Date**
Assistant Head of Quality (Out of Hospital Care) NHS England London Region	**Eileen Bryant**		**26.2.15**
Regional Pharmacist, NHS England London Region	**David Webb**		**25.2.16**

Organisations must add an individual practitioner authorisation sheet or list of authorised practitioners. This varies according to local policy but this should be a signature list or an individual agreement as included at the end of this PGD.

3. Characteristics of staff

Qualifications and professional registration	Registered professional with one of the following bodies: • nurses currently registered with the Nursing and Midwifery Council (NMC)
Additional requirements	Additionally practitioners: • must be authorised by name as an approved practitioner under the current terms of this Patient Group Direction before working to it • must have undertaken appropriate training for working under PGDs for supply/administration of medicines • must be competent in the use of PGDs (see NICE Competency framework for health professionals using patient group directions) • must be familiar with the vaccine product and alert to changes in the Summary of Product Characteristics, Immunisation Against Infectious Disease ("The Green Book"), and national and local immunisation programmes • must have undertaken training appropriate to this PGD as required by local policy and in line with the National Minimum Standards for Immunisation Training (2005) • must be competent to undertake immunisation and to discuss issues related to immunisation • must be competent in the handling and storage of vaccines, and management of the "cold chain" • must be competent in the recognition and management of anaphylaxis • must have access to the Patient Group Direction and associated online resources • should fulfil any additional requirements defined by local policy **THE PRACTITIONER MUST BE AUTHORISED BY NAME, UNDER THE CURRENT VERSION OF THIS PGD BEFORE WORKING ACCORDING TO IT.**
Continued training requirements	Practitioners must ensure they are up to date with relevant issues and clinical skills relating to immunisation and management of anaphylaxis, with evidence of appropriate Continued Professional Development (CPD). Practitioners should be constantly alert to any subsequent recommendations from Public Health England and/or NHS England and other sources of medicines information. Note: The most current national recommendations should be followed but a Patient Specific Direction (PSD) may be required to administer the vaccine in line with updated recommendations that are outside the criteria specified in this PGD.

4. Clinical condition or situation to which this PGD applies

Clinical condition or situation to which this PGD applies	Indicated for the active immunisation of individuals from 8 weeks to under 2 years of age for the prevention of pneumococcal disease in accordance with the national immunisation programme and recommendations given in chapter 25 of Immunisation Against Infectious Disease: "The Green Book".
Criteria for inclusion	Individuals from 8 weeks to under 2 years of age who: • require a primary course of PCV • require a reinforcing booster dose of PCV against pneumococcal disease
Criteria for exclusion[1]	Individuals for whom no valid consent has been received. Individuals who: • are less than 8 weeks of age • are aged 2 years and over • have had a confirmed anaphylactic reaction to a previous dose of pneumococcal vaccine • have had a confirmed anaphylactic reaction to any component of the vaccine or diphtheria toxoid • have received a previous dose of pneumococcal vaccine within the last 4 weeks (Note: national schedule recommends 8 week interval, see dose section) • are suffering from acute severe febrile illness (the presence of a minor infection is not a contraindication for immunisation)
Cautions including any relevant action to be taken	The immunogenicity of the vaccine could be reduced in immunosuppressed subjects. Premature infants should be vaccinated in accordance with the national routine immunisation schedule according to their chronological age. Very premature infants (born ≤28 weeks of gestation) who are in hospital should have respiratory monitoring for 48-72 hrs when given their first immunisation, particularly those with a previous history of respiratory immaturity. If the child has apnoea, bradycardia or desaturations after the first immunisation, the second immunisation should also be given in hospital, with respiratory monitoring for 48-72 hrs.
Action to be taken if the patient is excluded Continued over page	If aged less than 8 weeks advise to return for routine immunisation when the child is 8 weeks of age or over and give an appropriate appointment. Immunisation can be administered under a PSD to infants from 6 weeks of age if required eg if travelling abroad (see "The Green Book" chapter 11). If aged over 2 years routine immunisation with pneumococcal vaccine is not indicated. Assess whether immunisation with pneumococcal vaccine is indicated if individual is in a clinical risk group, in accordance with "The Green Book" chapter 7 and chapter 25, (a PSD may be required). If previous primary dose administered within last 4 weeks defer immunisation for appropriate interval, preferably allowing an 8 week interval between doses.

[1] Exclusion under this Patient Group Direction does not necessarily mean the medication is contraindicated, but it would be outside its remit and another form of authorisation will be required

Action to be taken if the patient is excluded (continued)	Seek appropriate advice from the local Screening and Immunisation Team, a Consultant in Health Protection or the individual's clinician where appropriate as a PSD may be indicated. The risk to the individual of not being immunised must be taken into account. Document the reason for exclusion and any action taken in the individual's clinical records. In a GP practice setting, inform or refer to the GP or a prescriber as appropriate. **Temporary exclusion** In case of postponement due to acute severe febrile illness, advise when the individual can be vaccinated and ensure another appointment is arranged.
Action to be taken if the patient or carer declines treatment	Informed consent, from the individual or a person legally able to act on the person's behalf, must be obtained for each administration. Advise the individual/parent/carer about the protective effects of the vaccine, the risks of infection and potential complications. Document advice given and the decision reached. In a GP practice setting, inform or refer to the GP as appropriate.
Arrangements for referral for medical advice	As per local policy

5. Description of treatment

Name, strength & formulation of drug	Pneumococcal polysaccharide conjugate vaccine (13-valent, adsorbed), PCV eg: • Prevenar® 13 suspension for injection in a pre-filled syringe
Legal category	Prescription only medicine (POM)
Black triangle▼	No
Off-label use	Administration of a two-dose primary series of Prevenar® 13 to pre-term infants <37 weeks gestation is contrary to the 3-dose primary schedule detailed in the SPC but is in accordance with PHE recommendations for the vaccination of premature infants and chapter 25 of "The Green Book". A single dose schedule for previously unvaccinated individuals between 12 months and up to 2 years of age is contrary to the two dose schedule detailed in the SPC but is in accordance with PHE recommendations for the vaccination of individuals with uncertain or incomplete immunisation status and chapter 25 of "The Green Book".
Route / method of administration	Administer by **intramuscular injection**, preferably into the anterolateral aspect of the thigh in infants under one year of age. The deltoid region of the upper arm may be used in individuals over one year of age. When administering at the same time as other vaccines care should be taken to ensure that the appropriate route of injection is used for all the vaccinations. The vaccines should be given at separate sites, preferably in different limbs. If given in the same limb, they should be given at least 2.5cm apart. The site at which each vaccine was given should be noted in the individual's records. For individuals with a bleeding disorder, vaccines normally given by an intramuscular route should be given by deep subcutaneous injection to reduce the risk of bleeding (see "The Green Book" Chapter 4). The vaccine's normal appearance is a uniform white suspension which may sediment during storage. Shake the prefilled syringe well to uniformly distribute the suspension before administering the vaccine. The vaccine should be inspected prior to and after any required reconstitution and should not be used if discoloured or foreign particles are present. The Summary of Product Characteristics (SPC) provides further guidance on administration and is available from the electronic Medicines Compendium website: www.medicines.org.uk

Dose and frequency of administration	Single 0.5ml dose per administration **Routine Childhood Immunisation Schedule** The national recommendation is for a two dose primary course of PCV vaccine at a 2 month interval and a reinforcing dose between 12 months and before 2 years of age. PCV 0.5ml should ideally be given as follows: • first primary immunisation visit (usually at age 2 months) • third primary immunisation visit (usually at age 4 months) • reinforcing booster dose (usually at age 12 months) **Unimmunised or partially immunised children** Unimmunised or partially immunised children who present late for vaccination should receive two doses of PCV two months apart* before the age of one year (if possible), and a further dose at 12 months of age (two months after the last PCV dose)*. *The immunisation interval may be reduced to one month if necessary to ensure the immunisation schedule is completed. An unimmunised or partially immunised child aged between one year and under two years of age should have a single dose of PCV. See flow chart for vaccination of individual with uncertain or incomplete immunisation status.
Duration of treatment	The primary course consists of two doses two months apart with a reinforcing dose between 1 and 2 years of age.
Quantity to be supplied / administered	Single 0.5ml dose per administration.
Supplies	Centrally purchased vaccines for the national immunisation programme for the NHS can only be ordered via ImmForm. Vaccines for use for the national immunisation programme are provided free of charge.
Storage	Store in a refrigerator at +2°C to +8°C. Store in original packaging in order to protect from light. Do not freeze.
Disposal	Equipment used for immunisation, including used vials, ampoules, or discharged vaccines in a syringe or applicator, should be disposed of at the end of a session by sealing in a proper, puncture-resistant 'sharps' box, according to local authority regulations and guidance in the technical memorandum 07-01: Safe management of healthcare waste (Department of Health, 2013).
Drug interactions[2]	Immunological response may be diminished in those receiving immunosuppressive treatment. May be given at the same time as other vaccines.

[2] Refer to British National Formulary (BNF) and Summary of Product Characteristics (SPC) for complete list

Identification & management of adverse reactions[3]	Local reactions following vaccination are very common ie pain, swelling or redness at the injection site. A small painless nodule may form at the injection site. The most commonly reported adverse reactions include vaccination-site reactions, fever, irritability, decreased appetite, increased and/or decreased sleep, rash, vomiting and diarrhoea. Hypersensitivity reactions, such as bronchospasm, angioedema, urticaria, and anaphylaxis can occur but are very rare. A detailed list of adverse reactions is available in the Summary of Product Characteristics, which is available from the electronic Medicines Compendium website: www.medicines.org.uk
Reporting procedure of adverse reactions	Healthcare professionals and patients/carers are encouraged to report suspected adverse reactions to the Medicines and Healthcare products Regulatory Agency (MHRA) using the Yellow Card reporting scheme on: http://yellowcard.mhra.gov.uk Any adverse reaction to a vaccine should be documented in the individual's record and the individual's GP should be informed.
Written information to be given to patient or carer	Offer marketing authorisation holder's patient information leaflet (PIL) provided with the vaccine. Immunisation promotional material may be provided as appropriate: • A guide to immunisations for babies up to 13 months of age • A quick guide to childhood immunisation for the parents of premature babies Available from: www.gov.uk/government/collections/immunisation
Patient advice / follow up treatment	Inform the individual/carer of possible side effects and their management. The individual/carer should be advised to seek medical advice in the event of an adverse reaction. Advise the individual/carer when any subsequent immunisations are due. When administration is postponed advise the individual/carer when to return for vaccination.
Special considerations / additional information	Ensure there is immediate access to adrenaline (epinephrine) 1 in 1000 injection and access to a telephone at the time of vaccination. 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. Individuals at increased risk of pneumococcal disease may require additional doses of PCV in accordance with "The Green Book" chapter 7 and chapter 25. The vaccination requirements for at risk individuals and administration of additional PCV doses is not covered by this PGD.

[3] Refer to British National Formulary (BNF) and Summary of Product Characteristics (SPC) for complete list

Records	Record: • that valid informed consent was given • name of individual, address, date of birth and GP with whom the individual is registered • name of immuniser • name and brand of vaccine • date of administration • dose, form and route of administration of vaccine • quantity administered • batch number and expiry date • anatomical site of vaccination • advice given, including advice given if excluded or declines immunisation • details of any adverse drug reactions and actions taken • supplied via Patient Group Direction (PGD) Records should be signed and dated (or a password controlled immunisers record on e-records). All records should be clear, legible and contemporaneous. This information should be recorded in the individual's GP record. Where vaccine is administered outside the GP setting appropriate health records should be kept and the individual's GP informed. The local Child Health Information Systems team (Child Health Records Department) must be notified using the appropriate documentation/pathway when vaccine is administered to individuals under 19 years of age. A record of all individuals receiving treatment under this PGD should also be kept for audit purposes in accordance with local policy.

6. Key references

Key references	**Pneumococcal conjugate vaccine** • Immunisation Against Infectious Disease: The Green Book chapter 25. Last updated 4 December 2013 https://www.gov.uk/government/publications/pneumococcal-the-green-book-chapter-25 • Summary of Product Characteristics for Prevenar 13 suspension for injection, Pfizer Ltd. 6 November 2015. http://www.medicines.org.uk/emc/medicine/22689 • NHS public health functions agreement 2015-16. Service specification No.8. Pneumococcal immunisation programme. December 2014. https://www.gov.uk/government/uploads/system/uploads/attachment_data/file/386243/No08_Pneumococcal_Immunisation.pdf • Vaccination of individuals with uncertain or incomplete immunisation status. Public Health England. Updated 22 September 2015. https://www.gov.uk/government/publications/vaccination-of-individuals-with-uncertain-or-incomplete-immunisation-status **General** • PHE Immunisation Collection. Accessed 11 November 2015 https://www.gov.uk/government/collections/immunisation • British National Formulary (BNF) and British National Formulary for Children (BNF-C). October 2015. www.BNF.org http://www.evidence.nhs.uk/formulary/bnf/current • National Minimum Standards for Immunisation Training (2005) https://www.gov.uk/government/publications/immunisation-training-national-minimum-standards • NICE Medicines Practice Guideline 2 (MPG2): Patient Group Directions. Published August 2013. https://www.nice.org.uk/guidance/mpg2 • NICE MPG2 Patient group directions: competency framework for health professionals using patient group directions. January 2014. https://www.nice.org.uk/guidance/mpg2/resources • Immunisation knowledge and skills competence assessment tool. Royal College of Nursing (RCN) 2015. https://www.rcn.org.uk/professional-development/publications/pub-005336 • Health Technical Memorandum 07-01: Safe Management of Healthcare Waste. Department of Health 20 March 2013 https://www.gov.uk/government/publications/guidance-on-the-safe-management-of-healthcare-waste

7. Individual practitioner authorisation sheet

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

Patient group directions do not remove inherent professional obligations or accountability.

It is the responsibility of each professional to practise only within the bounds of their own competence.

Practitioner
I confirm that I have read and understood the content of this Patient Group Direction and that I am willing and competent to work to it within my professional code of conduct.

Signed……..Date……....

Name
(Print)…….....

Designation…….....

Authorising manager

Manager to give authorisation on behalf of the following organisation

……
for the named health care professional who has signed the PGD.

Signed…… Date…….....

Name (Print)…….....

Designation…….....

Note to authorising manager

By signing above you are confirming that you have assessed the staff member as competent to work under this PGD and that they have the organisational approval to do so.

You must give this signed PGD to each authorised practitioner as it shows their authorisation to use the PGD.