Public Health England

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PATIENT GROUP DIRECTION (PGD)

Administration of pneumococcal polysaccharide conjugate vaccine (13-valent, adsorbed) (PCV13) to individuals with an underlying medical condition which puts them at increased risk from pneumococcal disease.

This PGD is for the administration of pneumococcal polysaccharide conjugate vaccine (13-valent, adsorbed) (PCV13) by currently registered nurses.

Reference no:	PCV Risk Groups PGD
Version no:	v02.00
Valid from:	1 June 2017
Review date:	1 December 2018
Expiry date:	31 May 2019

Public Health England has developed this PGD template to facilitate the delivery of immunisations in the NHS in line with national recommendations.

Those using this PGD must ensure that it is organisationally authorised and signed in Section 2 by an appropriate authorising person, relating to the class of person by whom the product is to be supplied, in accordance with Human Medicines Regulations 2012 (HMR2012)[1]. **THE PGD IS NOT LEGAL OR VALID WITHOUT SIGNED AUTHORISATION IN ACCORDANCE WITH HMR2012 SCHEDULE 16 Part 2.**

Authorising organisations must not alter, amend or add to 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.

INDIVIDUAL PRACTITIONERS 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 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

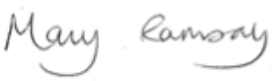
[1] This includes any relevant amendments to legislation (eg 2013 No235, 2015 No.178 and 2015 No.323).

Change history

Version number	Change details	Date
V01.00	New PHE PGD template	03/02/2017
V02.00	PHE PCV13 Risk Groups PGD amended to: • reworded inclusion criteria to be specific to those at risk of pneumococcal disease requiring additional PCV13 • reworded dose section to reflect revised Green Book chapter 25 and clarify when you would provide PCV13 to previously unvaccinated or partially vaccinated individuals	10/05/2017

1. PGD template development

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

Developed by:	Name	Signature	Date
Pharmacist (Lead Author)	Elizabeth Graham Lead Pharmacist Immunisation Services, PHE		12/05/2017
Doctor	Mary Ramsay Consultant Epidemiologist and Head of Immunisation, Hepatitis & Blood Safety Department, PHE		11/05/2017
Registered Nurse (Chair of Expert Panel)	David Green Nurse Consultant – Immunisations, PHE		12/05/2017

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

Expert Panel

Name	Designation
Shamez Ladhani	Paediatric Infectious Disease Consultant, Public Health England
Jacqueline Lamberty	Lead Pharmacist Medicines Management Services, Public Health England
Vanessa MacGregor	Consultant in Communicable Disease Control, Public Health England, East Midlands Health Protection Team
Alison Mackenzie	Consultant in Public Health Medicine, Screening and Immunisation Lead, Public Health England / NHS England South (South West)
Gill Marsh	Senior Screening and Immunisation Manager Public Health England / NHS England (Lancashire and South Cumbria)
Lesley McFarlane	Screening and Immunisation Co-ordinator (SIC) NHS England Leicestershire, Lincolnshire and Northamptonshire
Sally Millership	Consultant in Communicable Disease Control, Public Health England, East of England Health Protection Team
Sue Mulvenna	Head of Pharmacy - NHS England South West
Matthew Olley	Immunisation Manager, Public Health England / NHS England- London Region
Lisa Rees	Medicines Management Pharmacist, Bristol Clinical Commissioning Group
Kelly Stoker	Senior Health Protection Nurse, North East Health Protection Team, Public Health England Centre North East

2. Organisational authorisations

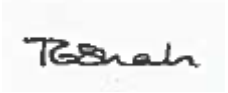
The PGD is not legally valid until it has had the relevant organisational authorisation.

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 authorises 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 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 practice under it.
Limitations to authorisation
None

Organisational approval (legal requirement)			
Role	**Name**	**Sign**	**Date**
Director of Nursing / Deputy Regional Chief Nurse NHS England (London Region)	**Jane Clegg**		**30/05/2017**

Additional signatories according to locally agreed policy			
Role	**Name**	**Sign**	**Date**
Interim Director of Nursing (South London) NHS England London Region	**Gwen Kennedy**		**26/05/17**
Pharmacy Advisor, NHS England London Region	**Tushar Shah**		**25/05/2017**

Section 7 provides a practitioner authorisation sheet. Individual practitioners must be authorised by name to work to this PGD. Alternative practitioner authorisation sheets may be used where appropriate in accordance with local policy but this should be an individual agreement or a multiple practitioner authorisation sheet 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 (SPC), 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 INDIVIDUAL 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 with an underlying medical condition which puts them at increased risk from pneumococcal disease in accordance with the national immunisation programme and recommendations given in Chapter 7 and Chapter 25 of Immunisation Against Infectious Disease: "The Green Book". This PGD does not cover the routine childhood PCV13 immunisation programme which is covered by the PHE PCV PGD template.
Criteria for inclusion	Individuals who are: • under 2 years who have asplenia, splenic dysfunction, a complement disorder or are severely immunocompromised • from 2 years to under 10 years of age who are previously unvaccinated or partially vaccinated (ie did not complete their 2+1 PCV course as part of the national schedule) and who have a medical condition included in Appendix A • over 2 years of age and severely immunocompromised Note: all individuals with a medical condition included in Appendix A should receive a dose of PPV23 after their second birthday (see PPV PGD)
Criteria for exclusion[2]	Individuals for whom no valid consent has been received. Individuals who: • have had a confirmed anaphylactic reaction to a previous dose of pneumococcal vaccine or to any component of the vaccine including diphtheria toxoid • have received a dose of PCV13 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, however vaccination is still recommended.
Action to be taken if the patient is excluded	If a dose of PCV13 was received within the last 4 weeks defer immunisation for an appropriate interval (see Dose and frequency of administration). In case of postponement due to acute severe febrile illness, advise when the individual can be vaccinated and ensure another appointment is arranged. Seek appropriate advice from the local Screening and Immunisation Team, a Consultant in Health Protection or the individual's clinician when a vaccine is indicated outside the remit of this PGD rather than delay immunisation. 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

Continued over page

[2] 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)	individual's clinical records. In a GP practice setting, inform or refer to the GP or a prescriber as appropriate.
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 of disease. 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

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5. Description of treatment

Name, strength & formulation of drug	Pneumococcal polysaccharide conjugate vaccine (13-valent, adsorbed), PCV13, eg: • Prevenar® 13 suspension for injection in a pre-filled syringe
Legal category	Prescription only medicine (POM)
Black triangle▼	No
Off-label use	No
Route / method of administration	Administer by intramuscular injection. 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 visually inspected for particulate matter and discoloration prior to administration. In the event of any foreign particulate matter and/or variation of physical aspect being observed, do not administer the vaccine. The SPC provides further guidance on administration and is available from the electronic Medicines Compendium website: www.medicines.org.uk
Dose and frequency of administration continued over page	Single 0.5ml dose per administration **Individuals under 1 year of age** All individuals should be fully vaccinated in accordance with the routine PCV13 immunisation programme (see the PHE PCV PGD and the vaccination of individuals with uncertain or incomplete immunisation status guidance). An additional PCV13 booster dose is also recommended between 1 and 2 years of age for individuals with asplenia, splenic dysfunction, a complement disorder or severely immunocompromised[3]. An interval of 2 months is required between the routine PCV13 booster (usually given at 12 months) and the additional PCV13 booster dose (see below).

[3] Examples of severely immunocompromised include bone marrow transplant patients, patients with acute and chronic leukaemia, multiple myeloma or genetic disorders affecting the immune system (e.g. IRAK-4, NEMO, complement deficiency)

Dose and frequency of administration (continued)	**Individuals from 1 year to under 2 years of age** Individuals with asplenia or splenic dysfunction (see Appendix A), a complement disorder, or severely immunocompromised[4], aged between their first and second birthday should receive an additional booster dose of PCV13 with an interval of 2 months between the routine PCV13 booster (usually given at 12 months) and the additional PCV13 booster dose. Note: This is the schedule to follow regardless of whether the child had none, one or both of the routine primary doses of PCV13 in infancy. The intervals may be reduced to one month if necessary to ensure that the immunisation schedule is completed. **Individuals from 2 years to under 10 years of age** Individuals from 2 years to under 10 years of age, with a medical condition included in Appendix A (excluding the severely immunocompromised[4]), who have completed the routine PCV immunisation schedule (with PCV7 or PCV13) do not require further PCV13. Individuals from 2 years to under 10 years of age who are previously unvaccinated or partially vaccinated (ie did not complete their 2+1 PCV course as part of the national schedule) and who have a medical condition included in Appendix A should receive a single dose of PCV13. Severely immunocompromised[4] individuals should be offered a single dose of PCV13 irrespective of any routine childhood vaccinations they have already received. **Individuals from 10 years of age** Individuals from 10 years of age, with a medical condition included in Appendix A (excluding the severely immunocompromised[4]) do not require PCV13. Severely immunocompromised[4] individuals should be offered a single dose of PCV13 irrespective of any routine childhood vaccinations they have already received. **Pneumococcal polysaccharide vaccine (PPV23)** Additionally, all individuals with a medical condition included in Appendix A should receive a dose of PPV23 after their second birthday (see PPV PGD). Individuals eligible for both PCV13 and PPV23 should have the PCV13 dose first followed by PPV23 at least 2 months later.
Duration of treatment	Single 0.5ml dose
Quantity to be supplied / administered	Single 0.5ml dose per administration.

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[4] Examples of severely immunocompromised include bone marrow transplant patients, patients with acute and chronic leukaemia, multiple myeloma or genetic disorders affecting the immune system (e.g. IRAK-4, NEMO, complement deficiency)

Supplies	PCV13 for additional doses for at risk groups is not centrally procured and these should be ordered from the manufacturer. Details are given in the Green Book Chapter 25. Centrally purchased vaccines for the national childhood routine PCV13 immunisation programme for the NHS can only be ordered via ImmForm. Vaccines for use for the national childhood routine immunisation programme are provided free of charge. Protocols for the ordering, storage and handling of vaccines should be followed to prevent vaccine wastage (see protocol for ordering storage and handling of vaccines and Green Book Chapter 3).
Storage	Store at +2°C to +8°C. Store in original packaging in order to protect from light. Do not freeze. Note: Prevenar 13 is stable at temperatures up to 25°C for four days. At the end of this period Prevenar 13 should be used or discarded. These data are intended to guide health care professionals in case of inadvertent temporary temperature excursions only.
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 UN-approved 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	Immunological response may be diminished in those receiving immunosuppressive treatment. May be given at the same time as other vaccines. A detailed list of interactions is available in the SPC, which is available from the electronic Medicines Compendium website: www.medicines.org.uk
Identification & management of adverse reactions	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, diarrhoea, arthralgia, myalgia and headache. 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 SPC, 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 the marketing authorisation holder's patient information leaflet (PIL) provided with the vaccine. Immunisation promotional material may be provided as appropriate: • Splenectomy leaflet Available from: www.gov.uk/government/collections/immunisation
Patient advice / follow up treatment	Inform the individual/carer of possible side effects and their management. Vaccination may not result in complete protection in all recipients. Patients at especially increased risk of serious pneumococcal infection (eg asplenics and those who have received immunosuppressive therapy for any reason), should be advised regarding the possible need for early antimicrobial treatment in the event of severe, sudden febrile illness. The individual/carer should be advised to seek medical advice in the event of an adverse reaction.
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. Patients on Eculizumab (Soliris®) therapy are not at increased risk of pneumococcal disease and do not require PPV23 or additional doses of PCV13. Wherever possible, immunisation or boosting of immunosuppressed individuals should be either carried out before immunosuppression occurs or deferred until an improvement in immunity has been seen (see Chapter 25). Immunisation of these patients should not be delayed if this is likely to result in failure to vaccinate. Splenectomy, chemotherapy or radiotherapy should never be delayed to allow time for vaccination.
Records Continued over page	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 immuniser's record on e-records). All records should be clear, legible and contemporaneous.

Records (continued)	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 3 March 2017 https://www.gov.uk/government/publications/pneumococcal-the-green-book-chapter-25 • Summary of Product Characteristics for Prevenar 13 suspension for injection, Pfizer Ltd. 27 March 2017. http://www.medicines.org.uk/emc/medicine/22689 • NHS public health functions agreement 2017-18. Service specification No.8. Pneumococcal immunisation programme. April 2017. https://www.england.nhs.uk/wp-content/uploads/2017/04/service-spec-08.pdf • Vaccination of individuals with uncertain or incomplete immunisation status. Public Health England. Updated 30 June 2016. https://www.gov.uk/government/publications/vaccination-of-individuals-with-uncertain-or-incomplete-immunisation-status **General** • PHE Immunisation Collection https://www.gov.uk/government/collections/immunisation • British National Formulary (BNF) and British National Formulary for Children (BNF-C) 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 • Protocol for ordering storage and handling of vaccines. April 2014. https://www.gov.uk/government/publications/protocol-for-ordering-storing-and-handling-vaccines • 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. Multiple practitioner authorisation sheet

PCV Risk Groups PGD v02.00 Valid from: 01/06/2017 Expiry: 31/05/2019

Practitioner

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 and professional code of conduct.

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.			
Name	Designation	Signature	Date

Authorising manager

I confirm that the practitioners named above have declared themselves suitably trained and competent to work under this PGD. I give authorisation on behalf of the following organisation …… for the above named health care professionals who have signed the PGD to work under it.			
Name	Designation	Signature	Date

Note to authorising manager

Score through unused rows in the list of practitioners to prevent practitioner additions post managerial authorisation.

This authorisation sheet should be retained to serve as a record of those practitioners authorised to work under this PGD.

APPENDIX A

Clinical risk groups who should receive the pneumococcal immunisation
(Green Book Chapter 25 Table 25.1)

Clinical risk group	Examples (decision based on clinical judgement)
Asplenia or dysfunction of the spleen	This also includes conditions such as homozygous sickle cell disease and coeliac syndrome that may lead to splenic dysfunction. (Re-immunisation with PPV23 is recommended every 5 years)
Chronic respiratory disease	This includes chronic obstructive pulmonary disease (COPD), including chronic bronchitis and emphysema; and such conditions as bronchiectasis, cystic fibrosis, interstitial lung fibrosis, pneumoconiosis and bronchopulmonary dysplasia (BPD). Children with respiratory conditions caused by aspiration, or a neurological disease (e.g. cerebral palsy) with a risk of aspiration. Asthma is not an indication, unless so severe as to require continuous or frequently repeated use of systemic steroids (as defined in Immunosuppression below).
Chronic heart disease	This includes those requiring regular medication and/or follow-up for ischaemic heart disease, congenital heart disease, hypertension with cardiac complications, and chronic heart failure.
Chronic kidney disease	Nephrotic syndrome, chronic kidney disease at stages 4 and 5 and those on kidney dialysis or with kidney transplantation. (Re-immunisation with PPV23 is recommended every 5 years)
Chronic liver disease	This includes cirrhosis, biliary atresia and chronic hepatitis.
Diabetes	Diabetes mellitus requiring insulin or oral hypoglycaemic drugs. This does not include diabetes that is diet controlled.
Immunosuppression	Due to disease or treatment, including patients undergoing chemotherapy leading to immunosuppression, bone marrow transplant, asplenia or splenic dysfunction, HIV infection at all stages, multiple myeloma or genetic disorders affecting the immune system (e.g. IRAK-4, NEMO, complement deficiency) Individuals on or likely to be on systemic steroids for more than a month at a dose equivalent to prednisolone at 20mg or more per day (any age), or for children under 20kg, a dose of 1mg or more per kg per day.
Individuals with cochlear implants	It is important that immunisation does not delay the cochlear implantation.
Individuals with cerebrospinal fluid leaks	This includes leakage of cerebrospinal fluid such as following trauma or major skull surgery.