Public Health England

NHS

PHE publications gateway number: 2016262

PATIENT GROUP DIRECTION (PGD)

Administration of 23-valent pneumococcal polysaccharide vaccine (PPV) to individuals from 65 years of age and individuals from 2 years of age in a clinical risk group in accordance with the national immunisation programme for active immunisation against pneumococcal disease.

This PGD is for the administration of 23-valent pneumococcal polysaccharide vaccine (PPV) by currently registered nurses, paramedics and pharmacists.

Reference no:	PPV PGD
Version no:	v01.00
Valid from:	1 September 2016
Review date:	1 March 2018
Expiry date:	31 August 2018

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 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

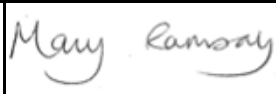
[1] This includes any relevant amendments to legislation (eg 2013 No235, 2015 No.178 and 2015 No.323).

Change history

Version number	Change details	Date
V01.00	New PHE PGD template	01/09/2016

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		31/08/2016
Doctor	Mary Ramsay Consultant Epidemiologist and Head of Immunisation, Hepatitis & Blood Safety Department, PHE		30/8/2016
Registered Nurse	David Green Nurse Consultant – Immunisations, PHE		30/8/2016

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.

Acknowledgements

Name	Designation
Richard Pebody	Consultant Medical Epidemiologist, Head of Influenza Surveillance and Acting Head of Respiratory Diseases, Centre for Infectious Disease Surveillance and Control
Jacqueline Lamberty	Medicines Management Adviser – Public Health England
Alison Mackenzie	Consultant in Public Health Medicine, Screening and Immunisation Lead, Public Health England / NHS England South (South West)
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 / Public Health England Leicestershire, Lincolnshire and Northamptonshire
Sue Mulvenna	Head of Pharmacy - NHS England South West
Graham Munslow	Clinical Screening and Immunisation Manager, NHS England / Public Health England Greater Manchester Health and Social Care partnership
Matthew Olley	Immunisation Manager, Public Health England / NHS England - London Region

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 South, (South West) authorise this PGD for use by the services or providers listed below:

Authorised for use by the following organisations and/or services
All NHS England South, (South West) commissioned immunisation services. This patient group direction (PGD) must only be used by registered nurses, pharmacists and paramedics who have been named by their organisation to practice under it. The most recent in-date final version signed off by NHS England South, (South West) must be used.
Limitations to authorisation
This PGD includes vaccination of individuals across the national immunisation programme. Users of this PGD should note that where they are commissioned to immunise certain groups this PGD does not constitute permission to offer immunisation beyond the groups they are commissioned to immunise.

Organisational approval (legal requirement)			
Role	**Name**	**Sign**	**Date**
Medical Director, NHS England South, (South West)	**Dr Caroline Gamlin**		**21.09.16**

Additional signatories according to locally agreed policy			
Role	**Name**	**Sign**	**Date**
Head of Pharmacy, NHS England South, (South West)	**Sue Mulvenna**		**19.09.16**

Local enquiries regarding the use of this PGD may be directed to england.bnsssg.imms@nhs.net

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) • paramedics currently registered with the Health and Care Professions Council (HCPC) • pharmacists currently registered with the General Pharmaceutical Council (GPhC)
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 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 from 65 years of age and individuals from 2 years of age in a clinical risk group, 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 who: • are aged 65 years and over • are aged 2 years and over and have a medical condition included in the clinical risk groups defined in the Green Book Chapter 25 Table 25.1 (copy provided at Appendix A) • have asplenia, splenic dysfunction or chronic kidney disease (see Appendix A) and require a pneumococcal polysaccharide vaccine (PPV) booster
Criteria for exclusion[2]	Individuals for whom no valid consent has been received. Individuals who: • are less than 2 years of age • are aged from 2 years to less than 65 years, except those who have a medical condition included in the clinical risk groups defined in the Green Book Chapter 25 Table 25.1 (see copy at Appendix A) • have previously received PPV over the age of 2 years, except individuals with asplenia, splenic dysfunction and chronic kidney disease (see Appendix A) • have had a confirmed anaphylactic reaction to a previous dose of PPV or to any component of the vaccine • have asplenia, splenic dysfunction or chronic kidney disease (see Appendix A) and received PPV in the preceding 5 years • have received pneumococcal conjugate vaccine (PCV) in the preceding 2 months • are suffering from acute severe febrile illness (the presence of a minor infection is not a contraindication for immunisation) • are a contact of pneumococcal disease (indication not covered by this PGD) • are at risk of frequent or continuous occupational exposure to metal fume (e.g. welders) (indication not covered by this PGD)
Cautions including any relevant action to be taken	Antibody response may be impaired in those with immunological impairment and those with an absent or dysfunctional spleen (see Special considerations / additional information section regarding appropriate timing of vaccination).

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	If aged less than 2 years PPV is not indicated, ensure PCV immunisation is up-to-date. If aged from 2 years to less than 65 years and not in a clinical risk group, PPV is not indicated. If PPV has previously been received over the age of 2 years and the individual does not have asplenia, splenic dysfunction or chronic kidney disease (see Appendix A) further PPV is not indicated. Individuals with asplenia, splenic dysfunction or chronic kidney disease (see Appendix A), who have received PPV within the preceding 5 years, defer immunisation until appropriate interval. Individuals who have received PCV in the preceding 2 months postpone immunisation until 2 months has elapsed. In case of postponement due to acute severe febrile illness, advise when the individual can be vaccinated and ensure another appointment is arranged. Individuals who are a contact of pneumococcal disease do not usually require PPV. Immunisation may be indicated where there is a confirmed cluster of serious pneumococcal disease in a closed setting and should be on the advice of your local health protection team. This is outside the remit of this PGD. Individuals who are at risk of frequent or continuous occupational exposure to metal fume (e.g. welders) should be considered for immunisation taking into account exposure control measures in place. This is outside the remit of this PGD. 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 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

5. Description of treatment

Name, strength & formulation of drug	23-valent pneumococcal polysaccharide vaccine eg: • Pneumococcal polysaccharide vaccine, Sanofi Pasteur MSD, solution for injection in a vial, containing 25 micrograms of each of the following 23 pneumococcal polysaccharide serotypes: 1, 2, 3, 4, 5, 6B, 7F, 8, 9N, 9V, 10A, 11A, 12F, 14, 15B, 17F, 18C, 19F, 19A, 20, 22F, 23F, 33F.
Legal category	Prescription only medicine (POM)
Black triangle▼	No
Off-label use	Yes, only with respect to concomitant use of pneumococcal and shingles (Zostavax®) vaccine, see section on drug interactions below.
Route / method of administration	Administer by intramuscular or subcutaneous injection. The intramuscular route is routinely used because localised reactions are more common when vaccines are given subcutaneously. The preferred site is the deltoid region of the upper arm. 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 clear colourless solution. 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 vaccine's 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. Individuals with asplenia, splenic dysfunction or chronic kidney disease (see Appendix A) should be revaccinated at 5 year intervals. Revaccination is not routinely indicated for other individuals.
Duration of treatment	Single 0.5mL dose (except for those with asplenia, splenic dysfunction or chronic kidney disease (see Appendix A) who should be revaccinated every 5 years).
Quantity to be supplied / administered	Single 0.5ml dose.

Supplies	PPV is not centrally procured and therefore is not available through ImmForm. It should be ordered from the manufacturer. Details are given in the Green Book Chapter 25. 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 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 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. 23-valent pneumococcal vaccine can also be given at the same time as shingles vaccine, Zostavax®**;** Such administration is off-label but recommended in "The Green Book" following assessment of the evidence concluding that there is no reduction in the effectiveness of Zostavax®.
Identification & management of adverse reactions[3]	Local reactions following vaccination are very common including pain, swelling, induration and/or redness at the injection site. A low grade fever may occur. The most common systemic adverse events reported are asthenia/fatigue, myalgia and headache. Hypersensitivity reactions and anaphylaxis can occur but are very rare. Other adverse events have been reported in clinical trials and post-marketing surveillance but the frequency of these is not known. A detailed list of adverse reactions is available in the vaccine's 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.

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

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 (e.g.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 Continued over page	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. Pneumococcal vaccines may be given to pregnant women when the need for protection is required without delay. There is no evidence of risk from vaccinating pregnant women or those who are breast-feeding with inactivated viral or bacterial vaccines or toxoids. **Timing of vaccination** Wherever possible, immunisation or boosting of immunosuppressed or HIV-positive individuals should be either carried out before immunosuppression occurs or deferred until an improvement in immunity has been seen. The optimal timing for any vaccination should be based upon a judgement about the relative need for rapid protection and the likely response. For individuals due to commence immunosuppressive treatments, inactivated vaccines should ideally be administered at least two weeks before commencement. In some cases this will not be possible and therefore vaccination may be carried out at any time and re-immunisation considered after treatment is finished and recovery has occurred. Ideally PPV should be given four to six weeks before elective splenectomy or initiation of treatment such as chemotherapy or radiotherapy. Where this is not possible, it can be given up to two weeks before treatment. If it is not practicable to vaccinate two weeks or more before splenectomy, immunisation should be delayed until at least two weeks after the operation. If it is not practicable to vaccinate two weeks or more before initiation of chemotherapy and/or radiotherapy, immunisation should be delayed until at least three months after completion of therapy in order to maximise the response to the vaccine. Immunisation of these patients should not be delayed if this is likely

Special considerations / additional information (continued)	to result in failure to vaccinate. Splenectomy, chemotherapy or radiotherapy should never be delayed to allow time for vaccination.
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 immuniser's 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.

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6. Key references

Key references	**Pneumococcal polysaccharide vaccine** • Immunisation Against Infectious Disease: The Green Book Chapter 25 last updated 4 December 2013. https://www.gov.uk/government/collections/immunisation-against-infectious-disease-the-green-book • Summary of Product Characteristic for pneumococcal polysaccharide vaccine, Sanofi Pasteur MSD Ltd. Last updated 18 July 2016. http://www.medicines.org.uk/emc/medicine/1446 • NHS public health functions agreement 2016-17 Service specification No.8: Pneumococcal immunisation programme. Published 5 February 2016. https://www.england.nhs.uk/commissioning/wp-content/uploads/sites/12/2016/02/serv-spec-08.pdf • Enhanced Service Specification: Seasonal influenza and pneumococcal polysaccharide vaccination programme 2016/17. Published March 2016 https://www.england.nhs.uk/commissioning/wp-content/uploads/sites/12/2016/04/SFLandPneumococcal-2016-17.pdf **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

PPV PGD v01.00 Valid from: 01/09/2016 Expiry: 31/08/2018

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 **INSERT NAME OF 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 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 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.