



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 and UK guidelines for the public health management of clusters of serious pneumococcal disease in closed setting.

This PGD is for the administration of 23-valent pneumococcal polysaccharide vaccine (PPV) by registered healthcare practitioners identified in Section 3, subject to any limitations to authorisation detailed in Section 2.

Reference no: PPV PGD Version no: v02.00

Valid from: 1 September 2018 Review date: 1 March 2020

Expiry date: 31 August 2020

Public Health England has developed this PGD to facilitate the delivery of publicly funded immunisation 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 within the designated editable fields provided.

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 PGDs 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

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¹ This includes any relevant amendments to legislation (eg 2013 No.235, 2015 No.178 and 2015 No.323).

Change history

Version number	Change details	Date
V01.00	New PHE PGD template	01 September 2016
V02.00	 PPV PGD amended to: include vaccination in accordance with UK guidelines for the public health management of clusters of serious pneumococcal disease in closed settings include 64 year olds who may be immunised during the influenza season and who will turn 65 years by the 31 March include both vial and pre-filled syringe presentations of PPV include additional healthcare practitioners in Section 3 refer to PHE vaccine incident guidance within the offlabel and storage sections include minor rewording, layout and formatting changes for clarity and consistency with other PHE PGD templates 	08 August 2018

1. PGD development

This PGD 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	Eloha	09/08/2018
Doctor	Mary Ramsay Consultant Epidemiologist and Head of Immunisation and Countermeasures, PHE	Mary Ramony	08/08/2018
Registered Nurse (Chair of Expert Panel)	David Green Nurse Consultant – Immunisations, PHE	DGieen.	09/08/2018

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

Expert Panel

Name	Designation
Ed Gardner	Advanced Paramedic Practitioner/Emergency Care Practitioner, Medicines Manager, Proactive Care Lead
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 / Public Health England Leicestershire, Lincolnshire and Northamptonshire
Sally Millership	Consultant in Communicable Disease Control, Public Health England, East of England Health Protection Team
Richard Pebody	Consultant Medical Epidemiologist, Immunisation and Countermeasures, Public Health England
Tushar Shah	Pharmacy Advisor, NHS England London Region
Kelly Stoker	Senior Health Protection Nurse, North East Health Protection Team, Public Health England Centre North East
Sharon Webb	Programme Manager/Registered Midwife, NBHS Infectious Diseases in Pregnancy Screening Programme, Public Health England
Helen Wilkinson	Deputy Head of Medicines Management, NHS South Gloucestershire Clinical Commissioning Group

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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 (North) Yorkshire and the Humber authorises this PGD for use by the services or providers listed below:

Authorised for use by the following organisations and/or services

The PGD has been authorised following NHS England's governance processes so that it meets the legal requirements for PGDs. The PGD has been authorised as a Yorkshire and the Humber Local Office wide PGD for the 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 and UK guidelines for the public health management of clusters of serious pneumococcal disease in closed setting.

Practitioners should note that the SPC has the following statement "The vaccine should not be used during pregnancy unless clearly necessary (the potential benefit must justify any potential risk to the fetus)." However the PGD follows the advice/recommendation contained in the Green Book which should be followed and used to inform discussions with the patient.

Authorisation is limited to those registered practitioners listed in Section 3 where they are **directly employed by organisations/providers commissioned by NHS England North (Yorkshire and the Humber) to deliver vaccination services.**

Paramedics are excluded from the use of this PGD as this service is not commissioned by NHS England North (Yorkshire and the Humber).

Children under the age of 18 years vaccinated under this PGD should be notified to the Child Health Information Service.

In accordance with NICE Medicines Practice Guideline for PGDs, it is recommended as good practice that the PGD be formally adopted by the Governance Lead within each provider organisation signing the additional signatory's box (page 5). Individual practitioners working under the PGD must be authorised to do so by their employing organisation.

This PGD has been reviewed by designated members of the NHSE Y&H PGD steering group

Limitations to authorisation

Each practitioner is professionally accountable for ensuring they have undergone appropriate training, are competent to vaccinate and understand the contents of this PGD and the requirements of the individual vaccination programme, including route of administration, eligibility criteria, exclusions and contra-indications etc.

Organisational approval (legal requirement)			
Role	Name	Sign	Date
Medical Director and Governance Lead NHS England (North) Yorkshire and the Humber	Paul Twomey	Paul A (women	03.09.18

Additional signatories according to locally agreed policy			
Role	Name	Sign	Date
Head of Medicines Management, NHS Bassetlaw CCG	Rob Wise	prise.	31/08/18
CCDC – PHE Yorkshire and the Humber	Nachi Arunachalam	Ar Dadingpour	21.8.18
Screening and Immunisation Manager, North Yorkshire and Humber- Registered Midwife	Bev Frost	B. F.	21/8/2018
Provider Organisation Governance Lead			

Local enquiries regarding the use of this PGD may be directed to your local screening and immunisation team or the Health Protection Team Acute Response Centre (ARC): Contact Number: **0113 3860 300**

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 Registered professional with one of the following bodies: professional registration nurses and midwives currently registered with the Nursing and Midwifery Council (NMC) pharmacists currently registered with the General Pharmaceutical Council (GPhC) (Note: This PGD is not relevant to privately provided community pharmacy services) paramedics and physiotherapists currently registered with the Health and Care Professions Council (HCPC) The practitioners above must also fulfil the Additional requirements detailed below. Check <u>Section 2 Limitations to authorisation</u> to confirm whether all practitioners listed above have organisational authorisation to work under this PGD. Additional requirements Additionally practitioners: must be authorised by name as an approved practitioner under the current terms of this PGD 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 PGDs) 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 and Core Curriculum for Immunisation Training 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 PGD 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. Practitioners must ensure they are up to date with relevant issues Continued training requirements 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, UK guidelines for the public health management of clusters of serious pneumococcal disease in closed settings 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 (including those 64 year olds who may be immunised during the influenza season and who will turn 65 years by the 31 March)² 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 are a close contact recommended vaccination by the local Health Protection Team for the public health management of pneumococcal disease in accordance with UK guidelines for the public health management of clusters of serious pneumococcal disease in closed settings
Criteria for exclusion ³	 Individuals for whom no valid consent has been received. Individuals who: are less than 2 years of age have previously received PPV over the age of 2 years, except individuals with asplenia, splenic dysfunction and chronic kidney disease (see Appendix A) and those recommended vaccination for the public health management of clusters of serious pneumococcal disease in closed settings 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 at risk of frequent or continuous occupational exposure to metal fume (eg welders) (indication not covered by this PGD)

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² The NHS England Directed Enhanced Service (DES) for pneumococcal polysaccharide vaccination (PPV23) is renewed annually. Historically the DES allows PPV23 to be administered to those aged 64 years if they attain 65 years of age by the 31st March. This is to facilitate co-administration of both PPV23 and influenza vaccine at the same practice visit.

³ 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

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).
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 neither in a clinical risk group nor recommended vaccination for the public health management of clusters of serious pneumococcal disease in closed settings, 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) and the individual is not recommended vaccination for the public health management of clusters of serious pneumococcal disease in closed settings, 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 at risk of frequent or continuous occupational exposure to metal fume (eg 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, local Health Protection Team or the individual's clinician as required.
	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	Informed consent, from the individual or a person legally able to act on the person's behalf, must be obtained for each administration.
treatment	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 &	23-valent pneumococcal polysaccharide vaccine (PPV) eg:
formulation of drug	 Pneumococcal polysaccharide vaccine⁴, 0.5ml solution for injection in a vial or pre-filled syringe, with each 0.5ml dose 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	Concomitant administration of PPV and shingles vaccine (Zostavax®) is off-label but may occur when indicated in accordance with the advice in Chapter 28a of "The Green Book", see Drug Interactions below.
	Administration of a further dose of PPV to close contacts who have already received a dose of PPV more than two years previously is off-label but is recommended in accordance with the UK guidelines for the public health management of clusters of serious pneumococcal disease in closed settings.
	Vaccine should be stored according to the conditions detailed in the Storage section below. However, in the event of an inadvertent or unavoidable deviation of these conditions refer to PHE Vaccine Incident Guidance . Where vaccine is assessed in accordance with these guidelines as appropriate for continued use this would constitute off-label administration under this PGD.
	Where a vaccine is recommended off-label consider, as part of the consent process, informing the individual/parent/carer that the vaccine is being offered in accordance with national guidance but that this is outside the product licence.
Route / method of administration	Administer by intramuscular or subcutaneous injection. The preferred site is the deltoid region of the upper arm.
	The intramuscular route is routinely used because localised reactions are more common when vaccines are given subcutaneously. However, for individuals with a bleeding disorder, vaccines may alternatively be given by subcutaneous injection to reduce the risk of bleeding.
	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.
Continued over page	The vaccine's normal appearance is a clear colourless solution.

⁴ Given the current UK supply shortages it is anticipated vaccine presented under the Pneumovax brand may enter the UK market. This PGD includes the provision of any PPV23 vaccine where it is recommended for administration as part of the national programme and brought to the UK market as a licensed product.

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Route / method of administration (continued)	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 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. Close contacts of pneumococcal disease who have already received a dose of PPV more than two years previously should be offered a further dose of PPV in accordance with UK guidelines for the public health management of clusters of serious pneumococcal disease in closed settings.
Duration of treatment	Revaccination is not routinely indicated for other individuals. Single 0.5ml dose (see <u>Dose and frequency of administration</u>
Quantity to be supplied /	regarding indications for revaccination). Single 0.5ml dose.
Supplies	PPV is not centrally procured and therefore is not available through ImmForm. It should be ordered from the manufacturer/wholesalers. 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. In the event of an inadvertent or unavoidable deviation of these conditions, vaccine that has been stored outside the conditions stated above should be quarantined and risk assessed for suitability of continued off-label use or appropriate disposal. Refer to PHE Vaccine Incident Guidance.
Disposal	Equipment used for immunisation, including used vials, ampoules, or discharged vaccines in a syringe or applicator, should be disposed of safely in a UN-approved puncture-resistant 'sharps' box, according to local authority regulations and guidance in the <u>technical</u> <u>memorandum 07-01:</u> Safe management of healthcare waste (Department of Health, 2013).
Drug interactions	Immunological response may be diminished in those receiving immunosuppressive treatment but it is important to still immunise this group. PPV may be given at the same time as other vaccines. PPV 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 &	Local reactions following vaccination are very common including
management of adverse reactions	pain, swelling, induration and/or redness at the injection site.
reactions	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 SPC, which is available from the electronic Medicines Compendium website:
	www.medicines.org.uk
Reporting procedure of adverse reactions	Healthcare professionals and individuals/parents/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/parent/carer of possible side effect management.	
	Vaccination may not result in complete protection in all recipients.
	Individuals 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/parent/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.
	Individuals who are a contact of pneumococcal disease do not usually require PPV. Immunisation may be indicated for close contacts 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.
Continued over page	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-fooding with inactivated viral or bacterial vaccines or toxoids.
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Special considerations / additional information (continued)

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 individuals 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

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 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 as required by any local or contractual

Continued over page

Records	arrangement.	
(continued)	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 polysaccharide vaccine

- Immunisation Against Infectious Disease: The Green Book <u>Chapter 25</u> last updated 16 January 2018.
 https://www.gov.uk/government/collections/immunisation-against-infectious-disease-the-green-book
- Summary of Product Characteristic for pneumococcal polysaccharide vaccine, Merck Sharp & Dohme Limited. Last updated 30 April 2018. http://www.medicines.org.uk/emc/medicine/1446
- NHS public health functions agreement 2017-18 Service specification No.8: Pneumococcal immunisation programme. Published April 2017. https://www.england.nhs.uk/commissioning/pub-hlth-res/
- Enhanced Service Specification: Seasonal influenza and pneumococcal polysaccharide vaccination programme 2018/19. Published June 2018. https://www.england.nhs.uk/publication/gp-contract-2017-18-enhanced-service-specifications/

General

- 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
- National Minimum Standards and Core Curriculum for Immunisation Training. Published February 2018.
 https://www.gov.uk/government/publications/national-minimum-standards-and-core-curriculum-for-immunisation-training-for-registered-healthcare-practitioners
- NICE Medicines Practice Guideline 2 (MPG2): Patient Group Directions. Published March 2017. 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
- PHE Immunisation Collection https://www.gov.uk/government/collections/immunisation
- PHE Vaccine Incident Guidance https://www.gov.uk/government/publications/vaccine-incident-guidance-responding-to-vaccine-errors
- Protocol for ordering storage and handling of vaccines. April 2014. https://www.gov.uk/government/publications/protocol-for-ordering-storing-and-handling-vaccines

7. Practitioner authorisation sheet

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Before signing this PGD, check that the document has had the necessary authorisations in section two. Without these, this PGD is not lawfully valid.

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 <u>Chapter 25</u> 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.