



PHE publications gateway number: GW-1457

Pneumococcal polysaccharide vaccine (PPV23) Patient Group Direction (PGD)

This PGD is for the administration of 23-valent pneumococcal polysaccharide vaccine (PPV23) 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 settings.

This PGD is for the administration of PPV23 by registered healthcare practitioners identified in Section 3, subject to any limitations to authorisation detailed in Section 2.

Reference no: PPV23 PGD Version no: v03.00

Valid from: 1 September 2020 Review date: 1 March 2022 Expiry date: 31 August 2022

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. The final authorised copy of this PGD should be kept by the authorising organisation completing Section 2 for 8 years after the PGD expires if the PGD relates to adults only and for 25 years after the PGD expires if the PGD relates to children only, or adults and children. Provider organisations adopting authorised versions of this PGD should also retain copies for the periods specified above.

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

Enquiries relating to the availability of organisationally authorised PGDs and subsequent versions of this PGD should be directed to:

¹ This includes any relevant amendments to legislation (eg <u>2013 No.235</u>, <u>2015 No.178</u> and <u>2015 No.323</u>). PPV PGD v03.00 Valid from: 01/09/2020 Expiry: 31/08/2022 Page 1 of 16

For East Anglia email: England.ea-phsi@nhs.net

For Essex email: England.essexatimms@nhs.net
For Bedfordshire, Hertfordshire, Luton and Milton Keynes email: England.immsqa@nhs.net

PPV PGD v03.00 Valid from: 01/09/2020 Expiry: 31/08/2022

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 off-label and storage sections include minor rewording, layout and formatting changes for clarity and consistency with other PHE PGD templates 	08 August 2018
V03.00	 PPV PGD amended to: clarify abbreviation from PPV to PPV23 as used in the the Green Book. recommend vaccination of contacts if not received PPV23 in the preceding 12 months. insert a note on immunisation of welders in the inclusion section and remove mention elsewhere update off-label section in line with revised SPC include minor rewording, layout and formatting changes for clarity and consistency with other PHE PGD templates 	19 May 2020

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 and Countermeasures, PHE	Eloha	20/05/2020
Doctor	Mary Ramsay Consultant Epidemiologist and Head of Immunisation and Countermeasures, PHE	Mary Ramson	17/06/2020
Registered Nurse (Chair of Expert Panel)	David Green Nurse Consultant, Immunisation and Countermeasures, PHE	Dagen.	21/05/2020

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
Nicholas Aigbogun	Consultant in Communicable Disease Control, Public Health England,
Ed Gardner	Advanced Paramedic Practitioner/Emergency Care Practitioner, Medicines Manager, Proactive Care Lead
Michelle Jones	Senior Medicines Optimisation Pharmacist, NHS Bristol North Somerset & South Gloucestershire CCG
Shamez Ladhani	Consultant Epidemiologist, 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 (South West) / NHS England and NHS Improvement South (South West)
Gill Marsh	Senior Screening and Immunisation Manager, Public Health England / NHS England and NHS Improvement (North West)
Lesley McFarlane	Screening and Immunisation Co-ordinator, Public Health England / NHS England and NHS Improvement (Central Midlands)
Tushar Shah	Pharmacy Advisor, NHS England and NHS Improvement (London Region)
Sharon Webb	Programme Manager / Registered Midwife, NHS Infectious Diseases in Pregnancy Screening Programme, Public Health England

2. Organisational authorisations

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

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

NHS England and NHS Improvement East of England authorises this PGD for use by the services or providers listed below:

Authorised for use by the following organisations and/or services
All NHS England and NHS Improvement East of England commissioned immunisation services or
NHS Trust providing immunisation services covering Norfolk, Suffolk, Cambridgeshire,
Peterborough, Essex, Southend-on-Sea, Thurrock, Bedfordshire, Hertfordshire, Luton and Milton
Keynes local authorities, and Health and Justice facilities where NHS England and NHS
Improvement East of England is the commissioner.
Limitations to authorisation
None
110110

Organisational approval (legal requirement)			
Role	Name	Sign	Date
Associate Medical Director	Dr. James Hickling		19/08/2020
		James Hidduig	

Additional signatories according to locally agreed policy			
Role	Name	Sign	Date
Screening and Immunisation Lead	Dr. Pam Hall	Parntbell	12/08/2020
Pharmacist	Dr. Paul Duell	D Q	10/08/2020
Screening and Immunisation Coordinator	Alex Burghelea	Burfit	04/08/2020

Local enquiries regarding the use of this PGD may be directed to

For East Anglia email: England.ea-phsi@nhs.net
For Essex email: England.ea-phsi@nhs.net

For Bedfordshire, Hertfordshire, Luton and Milton Keynes email: England.immsqa@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 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 <u>Additional requirements</u> 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 <u>NICE Competency</u> 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 <u>National Minimum</u> <u>Standards and Core Curriculum for Immunisation Training</u>
- 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.

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, 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 years old 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 25.2 (copy provided at Appendix A) have asplenia, splenic dysfunction or chronic kidney disease (see Appendix A) and require a pneumococcal polysaccharide vaccine (PPV23) booster are 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 Note: Individuals at risk of frequent or continuous occupational exposure to metal fumes (such as welders) should be considered for immunisation taking into account exposure control measures in place. This indication is outside the remit of this PGD.
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 PPV23 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 PPV23 or to any component of the vaccine have received pneumococcal conjugate vaccine (PCV) in the preceding 8 weeks are suffering from acute severe febrile illness (the presence of a minor infection is not a contraindication for immunisation)

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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 PGD does not necessarily mean the medication is contraindicated, but it would be outside its remit and another form of authorisation will be required PPV PGD v03.00 Valid from: 01/09/2020 Expiry: 31/08/2022 Page 7 of 16

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 PPV23 is not indicated, ensure PCV immunisation is up-to-date.
	If PPV23 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 PPV23 is not indicated.
	Individuals who have received PCV in the preceding 8 weeks postpone immunisation until 8 weeks 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.
	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.
	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.
	Inform or refer to the GP as appropriate.
Arrangements for referral for medical advice	As per local policy

5. Description of treatment

	1
Name, strength & formulation of drug	23-valent pneumococcal polysaccharide vaccine (PPV):
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. Pneumovax[®] 23 solution for injection in a pre-filled syringe
Legal category	Prescription only medicine (POM)
Black triangle▼	No
Off-label use	Administration of a further dose of PPV23 to high-risk individuals who have already received a dose of PPV23 more than 12 months previously is off-label but may be 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.
	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
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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. PPV PGD v03.00 Valid from: 01/09/2020 Expiry: 31/08/2022 Page 9 of 16

Route / method of administration	particulate matter and/or variation of physical aspect being observed, do not administer the vaccine.
(continued)	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	Single 0.5ml dose.
administration	Individuals with asplenia, splenic dysfunction or chronic kidney disease (see Appendix A) should be revaccinated at 5 year intervals.
	PPV23 should be offered to high-risk individuals recommended vaccination by the local Health Protection Team for the public health management of pneumococcal disease in accordance with <u>UK guidelines for the public health management of clusters of serious pneumococcal disease in closed settings</u> , unless they have received PPV23 in the previous 12 months.
	Revaccination is not routinely indicated for other individuals.
Duration of treatment	Single 0.5ml dose (see <u>Dose and frequency of administration</u> regarding indications for revaccination).
Quantity to be supplied / administered	Single 0.5ml dose.
Supplies	Vaccines that are not centrally procured should be ordered from the manufacturer/wholesalers. Vaccines that are centrally procured should be ordered via ImmForm.
	Protocols for the ordering, storage and handling of vaccines should be followed to prevent vaccine wastage (see 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 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, but it is important to still immunise this group.
	PPV23 may be given at the same time as other vaccines.
	PPV23 can also be given at the same time as shingles vaccine, Zostavax®, as 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	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 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: 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 effects and their management.
	Vaccination may not result in complete protection in all recipients.
	Individuals at especially increased risk of serious pneumococcal infection (such as individuals with asplenia, splenic dysfunction 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 PPV23. 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.
Continued over page	Pneumococcal vaccines may be given to pregnant women when the need for protection is required without delay. There is no evidence or risk from vaccinating pregnant women or those who are breast-
	feeding with inactivated viral or bacterial vaccines or toxoids. 9/2020 Expiry: 31/08/2022 Page 11 of 16

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 PPV23 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 Services team must be notified using the appropriate documentation/pathway as required by any local or contractual arrangement.

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Records	A record of all individuals receiving treatment under this PGD should
(continued)	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 13 January 2020.
 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 1 August 2019. http://www.medicines.org.uk/emc/medicine/1446
- Summary of Product Characteristic for pneumococcal polysaccharide vaccine, Merck Sharp & Dohme Limited. Last updated 1 August 2019. https://www.medicines.org.uk/emc/product/9692/smpc
- NHS public health functions agreement 2019-20 Service specification No.8: Pneumococcal immunisation programme. Published July 2019. https://www.england.nhs.uk/publication/public-health-national-service-specifications/
- Enhanced Service Specification: Seasonal influenza and pneumococcal polysaccharide vaccination programme 2020/21. Published 31 March 2020. https://www.england.nhs.uk/publication/directed-enhanced-service-specification-seasonal-influenza-and-pneumococcal-polysaccharide-vaccination-programme-2020-21/
- Guidelines for the public health management of clusters and outbreaks of pneumococcal disease in closed settings with highrisk individuals. Public Health England. Updated 21 February 2020. https://www.gov.uk/government/publications/managing-clusters-of-pneumococcal-disease-in-closed-settings

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. March 2017. 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

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

PGDs do not remove inherent professional obligations or accountability.

It is the responsibility of each professional to 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 PGD 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 25.2)

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 (such as 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 anti-diabetic medication. 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, complement disorder, HIV infection at all stages, multiple myeloma or genetic disorders affecting the immune system (e.g. IRAK-4, NEMO,).
	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 (does not include CSF shunts).