UK Health Security Agency

Publications gateway number: GOV-11414

Pneumococcal polysaccharide conjugate vaccine (13-valent, adsorbed) Patient Group Direction (PGD)

This PGD is for the administration of pneumococcal polysaccharide conjugate vaccine (13-valent, adsorbed) (PCV13) to individuals from 12 weeks to under 2 years of age in accordance with the national immunisation programme for active immunisation against pneumococcal disease and to individuals from 6 weeks of age recommended PCV13 in response to an outbreak of pneumococcal disease.

This PGD is for the administration of PCV13 by registered healthcare practitioners identified in Section 3, subject to any limitations to authorisation detailed in Section 2.

Reference no:	PCV PGD
Version no:	v04.00
Valid from:	1 March 2022
Review date:	1 September 2023
Expiry date:	28 February 2024

The UK Health Security Agency (UKHSA) 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 the product is to be supplied, in accordance with Human Medicines Regulations 2012 (HMR2012)[1]. **The PGD is not legal or valid without signed authorisation in accordance with HMR2012 Schedule 16 Part 2.**

Authorising organisations must not alter, amend or add to the clinical content of this document (sections 4, 5 and 6); such action will invalidate the clinical sign-off with which it is provided. In addition, authorising organisations must not alter section 3 'Characteristics of staff'. Only sections 2 and 7 can be amended 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 period 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 UKHSA PGD templates for authorisation can be found from: https://www.gov.uk/government/collections/immunisation-patient-group-direction-pgd

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

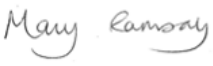
[1] This includes any relevant amendments to legislation (such as 2013 No.235, 2015 No.178 and 2015 No.323).

Change history

Version number	Change details	Date
V01.00	New PHE PGD template	19 January 2016
V02.00	PHE PCV PGD amended to: • include early administration from 6 weeks of age • include administration for the management of outbreaks • include additional healthcare practitioners in Section 3 • add paragraph on patient consent to the off-label section • reference the protocol for ordering storage and handling of vaccines • include additional stability data from products SPC • refer to PHE vaccine incident guidance within the off-label and storage sections • include rewording, layout and formatting changes for clarity and consistency with other PHE PGDs	28 November 2018
V03.00	PHE PCV PGD amended to: • reflect the 1+1 schedule for individuals born on or after 1 Jan 2020 and immunisation from 12 weeks of age • refer to the PCV Risk Groups PGD for the immunisation of individuals with asplenia, splenic dysfunction, complement disorder and severe immunocompromise • include rewording, layout and formatting changes for clarity and consistency with other PHE PGDs	20 December 2019
V04.00	UKHSA PCV PGD amended to: • include minor rewording of standard text, layout and formatting changes for clarity and consistency with organisation change and other UKHSA PGD and updated references. • remove from actions following exclusion, off label and dose/frequency sections, information pertaining to the 2+1 schedule • add in the exclusion section the recommendation to have minimum 4 weeks interval between PCV13 vaccinations • include in the off-label the information for partially immunised as per the 'Green Book', Chapter 25 13 January 2020 • provide detail to primary dose and schedule for premature infant in cautions section • include in the dose and frequency section immunisation recommendations for premature infants and unimmunised or partially immunised children as per Green Book Chapter 25, 13 January 2020 • include to the special considerations information for immunisation for bone marrow transplant • update the dose and frequency in line with the Green Book Chapter 25, 13 January 2020	16 February 2022

1. PGD development

This PGD has been developed by the following health professionals on behalf of the UKHSA:

Developed by:	Name	Signature	Date
Pharmacist (Lead Author)	Suki Hunjunt Lead Pharmacist Immunisation Services, Immunisation and Vaccine Preventable Diseases Division, UKHSA		16/02/2022
Doctor	Mary Ramsay Consultant Epidemiologist, Immunisation and Vaccine Preventable Diseases Division, UKHSA		16/02/2022
Registered Nurse (Chair of Expert Panel)	David Green Nurse Consultant, Immunisation and Vaccine Preventable Diseases Division, UKHSA		16/02/2022

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

Expert Panel

Name	Designation
Nicholas Aigbogun	Consultant in Communicable Disease Control, Yorkshire and Humber Health Protection Team, UKHSA
Sarah Dermont	Clinical Project Coordinator and Registered Midwife, NHS Infectious Diseases in Pregnancy Screening Programme, NHSEI
Michael Gregory	Medical Director for Commissioning, NHSEI North West region
Ed Gardner	Advanced Paramedic Practitioner / Emergency Care Practitioner, Medicines Manager, Proactive Care Lead
Shamez Ladhani	Paediatric Infectious Disease Consultant, UKHSA
Jacqueline Lamberty	Lead Pharmacist Medicines Governance, UKHSA
Michelle Jones	Principal Medicines Optimisation Pharmacist, NHS Bristol North Somerset and South Gloucestershire CCG
Vanessa MacGregor	Consultant in Communicable Disease Control, East Midlands Health Protection Team, UKHSA
Alison Mackenzie	Consultant in Public Health Medicine, Screening and Immunisation Lead, NHS England and Improvement NHSEI (South West))
Gill Marsh	Principal Screening and Immunisation Manager, NHSEI (North West)
Lesley McFarlane	Screening and Immunisation Manager: Clinical (COVID-19 and Influenza), NHSEI (Midlands)
Tushar Shah	Lead Pharmacy Advisor, NHSEI (London Region)

2. Organisational authorisations

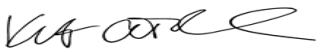
This PGD is not legally valid until it has had the relevant organisational authorisation.

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 (North East and Yorkshire)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 & Improvement (NHSE&I) commissioned immunisation services providing immunisation services.
Limitations to authorisation
Authorisation is limited to those registered practitioners listed in Section 3 who are employed by organisations/providers commissioned by NHSE&I North East and Yorkshire (NEY) to deliver immunisation programmes within the whole of the NHSE&I region of North East and Yorkshire

Organisational approval (legal requirement)			
Role	**Name**	**Sign**	**Date**
Assistant Medical Director and Responsible Officer, NHS England and NHS Improvement –NEY	**James Gossow**		**23/02/2022**

Additional signatories according to locally agreed policy			
Role	**Name**	**Sign**	**Date**
NHSE&I NEY PGD Governance assurance review (Medicines Optimisation Pharmacist Lead, NHS NECS)	**Kurt Ramsden**		**21/02/2022**
NHSE&I NEY PGD Governance assurance review Screening & Immunisation Manager, West Yorkshire, NHSE&I Yorkshire and the Humber, NEY	**Mary Law**		**18/02/2022**

Local enquiries regarding the use of this PGD may be directed to your local NHSE/I Screening and Immunisation Teams. See area specific contacts below:

For North East and North Cumbria Area (i.e. Northumberland, Tyne & Wear, Durham Darlington and Tees and North Cumbria) use the following:
NHS England Screening and Immunisation Team:
email **england.cane.screeingimms@nhs.net** or
NECS Medicine Optimisation Pharmacists: Kurt Ramsden: **kurtramsden@nhs.net** or Sue White: **sue.white14@nhs.net**
Please note - All North East and North Cumbria PGDs can be found at:
https://medicines.necsu.nhs.uk/resources/patient-group-directions/

For Yorkshire and Humber Area use the following:

West Yorkshire **england.wysit@nhs.net**
South Yorkshire and Bassetlaw **england.sybsit@nhs.net**
North Yorkshire and Humber **england.nysit@nhs.net** or
The UKHSA Health Protection Team, Acute Response Centre: Telephone: **0113 3860 300**.
Please note - All Yorkshire and Humber PGDs can be found at:
https://www.england.nhs.uk/north-east-yorkshire/our-work/information-for-professionals/pgds/
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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 Health and Care Professions Council (HCPC) The practitioners above must also fulfil the Additional requirements detailed below. Check Section 2 Limitations to authorisation 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.**
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 the UKHSA and/or NHSEI 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 12 weeks to under 2 years of age for the prevention of pneumococcal disease in accordance with the national immunisation programme and recommendations given in Chapter 25 of Immunisation Against Infectious Disease: the 'Green Book'. • individuals from 6 weeks of age recommended PCV13 in accordance with Guidelines for the public health management of clusters and outbreaks of pneumococcal disease in closed settings with high-risk individuals.
Criteria for inclusion	Individuals from 12 weeks to under 2 years of age who: • require a primary dose of PCV13 • require a reinforcing booster dose of PCV13 against pneumococcal disease Individuals from 6 weeks of age recommended PCV13 in accordance with Guidelines for the public health management of clusters and outbreaks of pneumococcal disease in closed settings with high-risk individuals. Note: Individuals with an underlying medical condition which puts them at increased risk from pneumococcal disease may require additional vaccination outside the inclusion criteria for this PGD - see PCV Risk Groups PGD and Chapter 25 of the 'Green Book'.
Criteria for exclusion[2]	Individuals for whom no valid consent has been received. Individuals who: • are less than 12 weeks of age, unless PCV13 is recommended in response to an outbreak of pneumococcal disease • are aged 2 years and over, unless PCV13 is recommended in response to an outbreak of pneumococcal disease • have received a dose of PCV13 within the last 4 weeks (Note: national schedule recommends an 8-week interval, see Dose and frequency of administration section) • have had a confirmed anaphylactic reaction to a previous dose of pneumococcal vaccine or to any component of the vaccine, including diphtheria toxoid • are suffering from acute severe febrile illness (the presence of a minor infection is not a contraindication for immunisation)
Cautions including any relevant action to be taken continued over page	The immunogenicity of the vaccine could be reduced in immunosuppressed individuals and additional doses may be recommended, see the 'Green Book' Chapter 7 and Chapter 25 and the PCV Risk Groups PGD.

[2]Exclusion under this PGD does not necessarily mean the medication is contraindicated, but it would be outside this PGDs remit and another form of authorisation will be required

Cautions including any relevant action to be taken (continued)	Premature infants should be vaccinated in accordance with the national routine immunisation schedule according to their chronological age. The occurrence of apnoea following vaccination is especially increased in infants who are born very prematurely. Very premature infants (born ≤28 weeks of gestation) who are in hospital should have respiratory monitoring for 48-72 hrs when given their first immunisation, particularly those with a previous history of respiratory immaturity. If the child has apnoea, bradycardia or desaturations after the first immunisation, the second immunisation should also be given in hospital, with respiratory monitoring for 48-72 hrs.
Action to be taken if the patient is excluded	Immunisation can be administered to infants from 6 weeks of age if at increased risk of exposure due to an outbreak (see Dose and frequency of administration). If aged less than 6 weeks defer immunisation and provide an appointment as appropriate. If aged 2 years and over routine immunisation with pneumococcal vaccine is not indicated. If the individual is at increased risk of pneumococcal disease, in accordance with the 'Green Book' Chapter 7 and Chapter 25, refer to the PCV Risk Groups PGD. Individuals suffering acute severe febrile illness should postpone immunisation until they have recovered. Immunisers should 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 treatment	Informed consent, from the individual or a person legally able to act on the person's behalf, must be obtained for each administration. Advise the individual/parent/carer about the protective effects of the vaccine, the risks of infection and potential complications. Document advice given and the decision reached. Inform or refer to the GP as appropriate.
Arrangements for referral for medical advice	As per local policy

5. Description of treatment

Name, strength and formulation of drug	Pneumococcal polysaccharide conjugate vaccine (13-valent, adsorbed), PCV13: Prevenar®13 suspension for injection in a pre-filled syringe
Legal category	Prescription only medicine (POM)
Black triangle▼	No
Off-label use	Administration of a two-dose primary series of Prevenar®13 to pre-term infants <37 weeks gestation is contrary to the three-dose primary schedule detailed in the SPC but is in accordance with the recommendations for the Vaccination of premature infants and Chapter 25 of the 'Green Book'. Administration of a one-dose primary series of Prevenar®13 is contrary to the two or three dose primary schedule detailed in the SPC but is in accordance with the recommendations and Chapter 25 of the 'Green Book'. A single dose schedule for previously unvaccinated individuals between 12 months and up to 2 years of age is contrary to the 2-dose schedule detailed in the SPC but is in accordance with the national recommendations for the Vaccination of individuals with uncertain or incomplete immunisation status and Chapter 25 of the 'Green Book'. A single dose schedule for partially immunised individuals between 12 months and up to 2 years of age is not consistent with the SPC but is in accordance with the national recommendations for the vaccination of individuals with uncertain or incomplete immunisation status and Chapter 25 of the 'Green Book'. 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 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 injection, preferably into the anterolateral aspect of the thigh in infants under one year of age. The deltoid region of the upper arm may be used in individuals over one year of age. When administering at the same time as other vaccines care should be taken to ensure that the appropriate route of injection is used for all the vaccinations. The vaccines should be given at separate sites, preferably in different limbs. If given in the same limb, they should be given at least 2.5cm apart. The site at which each vaccine was given should be noted in the individual's records. For individuals with a bleeding disorder, vaccines normally given by an intramuscular route should be administered in accordance with the immune ns in the 'Green Book' Chapter 4 to reduce the risk of bleeding.

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Route / method of administration continued	The vaccine's normal appearance is a uniform white suspension which may sediment during storage. Shake the prefilled syringe well to uniformly distribute the suspension before administering the vaccine. The vaccine should be visually inspected prior to administration and should not be used if discoloured or foreign particles are present. The vaccine's SPC provides further guidance on administration and is available from the electronic Medicines Compendium website.
Dose and frequency of administration	Single 0.5ml dose per administration **Routine Childhood Immunisation Schedule** Infants, who do not have asplenia, splenic dysfunction, complement disorder or severe immunocompromise[3], (see Green Book Chapter 25, Table 25.2) should be offered a 1+1 PCV schedule, that is: • a single priming dose of PCV13 to be administered from 12 weeks of age, followed by • a PCV13 booster dose to be administered at one year old, on or soon after their first birthday and before 2 years of age. Routine immunisation with PCV13is not offered after the second birthday. **Premature infants** Premature infants should be vaccinated in accordance with the national routine immunisation schedule according to their chronological age, no matter how premature they are (see 'Green Book' Chapter 25). Since the immunogenicity of PCV13 will be lower if given at a younger age, any dose given before 12 weeks of age should not be counted as the single priming dose for the 1+1 schedule and the routine PCV dose should be given once the infant reaches 12 weeks of age, leaving a minimum 4-week interval between the priming dose and any preceding dose. **Use PCV Risk Groups PGD for:** Individuals with asplenia, splenic dysfunction, complement disorder and severe immunocompromise[3] should be vaccinated in accordance with the PCV Risk Groups PGD, Chapter 7 and Chapter 25 of the 'Green Book'. **Unimmunised or partially immunised children** Unimmunised or partially immunised infants who do not have asplenia, splenic dysfunction, complement disorder or severe immunocompromise[3] who: • present late for vaccination, and before one year of age, should receive a primary dose of PCV13 before the age of one year, and a booster dose at one year of age, leaving an 8-week interval between the primary PCV13 dose and the booster. Where the infant is presented very late (such as at 11 months), then a minimum interval of four weeks should be observed before the booster dose • present for vaccination between one year and under two years of age should only have a single dose of PCV13

[3]continued over page **Dose and frequency of administration** (continued)	• do not have a reliable history of previous immunisation should be assumed to be unimmunised and the routine programme should be followed (see above) • have received one or more doses of PCV10 vaccine in another country should be offered PCV13 vaccination in accordance with the UK PCV13 vaccination schedule (see above) with a minimum interval of 4 weeks between PCV13 vaccination and any preceding PCV10 dose. Where the infant is presented very late (such as at 11 months), then a minimum interval of four weeks should be observed between the PCV13 priming dose and booster dose See flow chart for Vaccination of individual with uncertain or incomplete immunisation status. **Management of a pneumococcal disease clusters and outbreaks in closed settings with high-risk individuals.** A single dose of PCV 13 may be administered to adults and children from 6 weeks of age who have not received PCV13 vaccine in the preceding 4 weeks and who are identified as requiring PCV13 immunisation in accordance with Guidelines for the public health management of clusters and outbreaks of pneumococcal disease in closed settings with high-risk individuals. Note: PPV23 would ordinarily be used in an outbreak with the exception of serotype 6A/6C disease, individuals under 2 years of age, and where PPV23 is unavailable or otherwise inappropriate.
Duration of treatment	See Dose and frequency of administration section above
Quantity to be supplied / administered	Single 0.5ml dose per administration.
Supplies	Centrally purchased vaccines for the national immunisation programme for the NHS can only be ordered via ImmForm. Vaccines for use for the national immunisation programme are provided free of charge. Protocols for the ordering, storage and handling of vaccines should be followed to prevent vaccine wastage (see the 'Green Book' Chapter 3).
Storage continued over page	Store at between +2°C to +8°C. Store in original packaging in order to protect from light. Do not freeze. Prevenar®13 is stable at temperatures up to 25°C for four days. At the end of this period Prevenar®13 should be used or discarded. These data are intended to guide health care professionals in case of temporary temperature excursions. 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

[3] Examples of severe immunocompromise include bone marrow transplant patients, patients with acute and chronic leukaemia, multiple myeloma or genetic disorders affecting the immune system (such as IRAK-4, NEMO)

Storage (continued)	continued off-label use or appropriate disposal. Refer to 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 an UN-approved puncture-resistant 'sharps' box, according to local authority arrangements 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. Vaccination is recommended even if the antibody response may be limited. May be given at the same time as other vaccines A detailed list of drug interactions is available in the SPC, which is available from the electronic Medicines Compendium website.
Identification and management of adverse reactions	Local reactions following vaccination are very common such as pain, swelling or redness at the injection site. A small painless nodule may form at the injection site. The most commonly reported adverse reactions include, fever, irritability, decreased appetite, increased and/or decreased sleep, rash, vomiting and diarrhoea. Hypersensitivity reactions, such as bronchospasm, angioedema, urticaria, and anaphylaxis can occur but are very rare. A detailed list of adverse reactions is available in the SPC, which is available from the electronic Medicines Compendium website.
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 or search for MHRA Yellow Card in the Google Play or Apple App Store. Any adverse reaction to a vaccine should be documented in the individual's record and the individual's GP should be informed.
Written information to be given to patient or carer	Offer marketing authorisation holder's patient information leaflet (PIL) provided with the vaccine. Immunisation promotional material may be provided as appropriate: • A guide to immunisations for babies up to 13 months of age • A quick guide to childhood immunisation for the parents of premature babies Available from: www.gov.uk/government/collections/immunisation
Patient advice / follow up treatment	Inform the individual/parent/carer of possible side effects and their management. The individual/parent/carer should be advised to seek medical advice in the event of an adverse reaction. Advise the individual/parent/carer when any subsequent immunisations are due. When administration is postponed advise the individual/parent/carer when to return for vaccination.

Special considerations / additional information	Ensure there is immediate access to adrenaline (epinephrine) 1 in 1000 injection and access to a telephone at the time of vaccination. Individuals with asplenia, splenic dysfunction, complement disorder and severe immunosuppression are at increased risk of pneumococcal disease and require additional doses of PCV13 in accordance with the 'Green Book' Chapter 7 and Chapter 25. The administration of PCV13 for these individuals is covered by the PCV Risk Groups PGD. Individuals who have received a bone marrow transplant after vaccination should be considered for a re-immunisation programme for all routine vaccinations and for COVID-19 (see Chapter 7 and Chapter 25 of the 'Green Book'). This is not covered by this PGD and should be provided through a Patient Specific Direction (PSD).
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. A record of all individuals receiving treatment under this PGD should also be kept for audit purposes in accordance with local policy.

6. Key references

Key references	**Pneumococcal conjugate vaccine** • Immunisation Against Infectious Disease: The Green Book Chapter 25 January 2020. https://www.gov.uk/government/publications/pneumococcal-the-green-book-chapter-25 • Summary of Product Characteristics for Prevenar® 13 suspension for injection, Pfizer Ltd. 12 October 2021. http://www.medicines.org.uk/emc/medicine/22689 • Vaccination of individuals with uncertain or incomplete immunisation status. Public Health England. 26 August 2021. https://www.gov.uk/government/publications/vaccination-of-individuals-with-uncertain-or-incomplete-immunisation-status • Changes to the infant pneumococcal conjugate vaccine schedule: Information for healthcare practitioners. Public Health England. 13 December 2019. https://www.gov.uk/government/publications/pneumococcal-vaccination-guidance-for-health-professionals • Guidelines for the public health management of clusters and outbreaks of pneumococcal disease in closed settings with high-risk individuals. Public Health England 21 January 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.england.nhs.uk/publication/management-and-disposal-of-healthcare-waste-htm-07-01/ 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. Updated March 2017. • https://www.nice.org.uk/guidance/mpg2/resources • UKHSA Immunisation Collection https://www.gov.uk/government/collections/immunisation • Vaccine Incident Guidance https://www.gov.uk/government/publications/vaccine-incident-guidance-responding-to-vaccine-errors

7. Practitioner authorisation sheet

PCV PGD v04.00 Valid from: 01/03/2022 Expiry: 28/02/2024

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.