



PHE publications gateway number: 2015618

## PATIENT GROUP DIRECTION (PGD)

Administration of pneumococcal polysaccharide conjugate vaccine (13-valent, adsorbed) (PCV13) to individuals from 6 weeks (routinely from 8 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 pneumococcal polysaccharide conjugate vaccine (13-valent, adsorbed) (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: v02.00  
Valid from: 1 February 2019  
Review date: 1 August 2020  
Expiry date: 31 January 2021

**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 the product is to be supplied, in accordance with Human Medicines Regulations 2012 (HMR2012)<sup>1</sup>. **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 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](mailto:immunisation@phe.gov.uk)


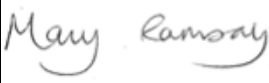

<sup>1</sup> This includes any relevant amendments to legislation (eg [2013 No.235](#), [2015 No.178](#) and [2015 No.323](#)).

## Change history

Version number	Change details	Date
V01.00	New PHE PGD template	19 January 2016
V02.00	PHE PCV PGD amended to: <ul style="list-style-type: none"><li>• include early administration from 6 weeks of age</li><li>• include administration for the management of outbreaks</li><li>• include additional healthcare practitioners in Section 3</li><li>• add paragraph on patient consent to the off-label section</li><li>• reference the protocol for ordering storage and handling of vaccines</li><li>• include additional stability data from products SPC</li><li>• refer to PHE vaccine incident guidance within the off-label and storage sections</li><li>• include rewording, layout and formatting changes for clarity and consistency with other PHE PGDs</li></ul>	28 November 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
<b>Pharmacist</b> (Lead Author)	Elizabeth Graham Lead Pharmacist Immunisation and Countermeasures, PHE		13/12/2018
<b>Doctor</b>	Mary Ramsay Consultant Epidemiologist and Head of Immunisation and Countermeasures, PHE		13/12/2018
<b>Registered Nurse</b> (Chair of Expert Panel)	David Green Nurse Consultant, Immunisation and Countermeasures, PHE		03/12/2018

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
Shamez Ladhani	Paediatric Infectious Disease Consultant, Public Health England
Jacqueline Lamberty	Lead Pharmacist Medicines Management Services, Public Health England
Vanessa MacGregor	Consultant in Communicable Disease Control, Public Health England, East Midlands Health Protection Team
Alison Mackenzie	Consultant in Public Health Medicine / Screening and Immunisation Lead, Public Health England / NHS England South (South West)
Gill Marsh	Senior Screening and Immunisation Manager, Public Health England / NHS England Lancashire and South Cumbria
Lesley McFarlane	Screening and Immunisation Co-ordinator, 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
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, NHS Infectious Diseases in Pregnancy Screening Programme, Public Health England
Helen Wilkinson	Principal Pharmacist, Bristol, North Somerset & South Gloucestershire Clinical Commissioning Group


## 2. Organisational authorisations

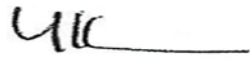
This PGD is not legally valid until it has had the relevant organisational authorisation.

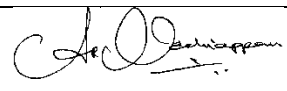

It is the responsibility of the organisation that has legal authority to authorise the PGD, to ensure that all legal and governance requirements are met. The authorising body accepts governance responsibility for the appropriate use of the PGD.

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

<p><b>Authorised for use by the following organisations and/or services</b></p> <p>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 pneumococcal polysaccharide conjugate vaccine (13-valent, adsorbed) (PCV13) to individuals from 6 weeks (routinely from 8 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.</p> <p>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 immunisation programmes.</p> <p>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.</p> <p>This PGD has been reviewed by designated members of the NHSE Y&amp;H PGD steering group</p>
<p><b>Limitations to authorisation</b></p> <p>Each practitioner is professionally accountable for ensuring they have undergone appropriate training in line with national guidance, are competent to vaccinate and understand the contents of this PGD and the requirements of the individual vaccine and vaccination programme, including route of administration, eligibility criteria, exclusions and contra-indications etc</p> <p>Paramedics and physiotherapists <b>not</b> employed directly by a commissioned provider are excluded from the use of this PGD.</p> <p>Practitioners should not Y&amp;H have currently not adopted the PHE PCV Risk Groups PGD, all patients considered as at risk, requiring PCV should be individually assessed and vaccinated under a PSD.</p>

<b>Organisational approval (legal requirement)</b>			
<b>Role</b>	<b>Name</b>	<b>Sign</b>	<b>Date</b>
NHS England North (Yorkshire and the Humber) Associate Medical Director and Governance Lead,	Yasmin Khan		21/1/19

<b>Additional signatories according to locally agreed policy</b>			
<b>Role</b>	<b>Name</b>	<b>Sign</b>	<b>Date</b>
Pharmacy Reviewer – controlled drugs accountable officer	Yasmin Khan		21.1.19

<b>Medical Reviewer - PHE Yorkshire and the Humber - CCDC</b>	<b>Nachi Arunachalam</b>		<b>02.01.19</b>
<b>Registered Professional Reviewer – Senior Screening and Immunisation Manager (RGN)</b>	<b>Kathy Wakefield</b>		<b>02.01.19</b>
<b>Organisational Governance Lead -</b>			

Local enquiries regarding the use of this PGD may be directed to your local screening and immunisation team – see SIT update for contact details or the Health Protection Team Acute Response Centre (ARC) for clinical application of the PGD via the 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

<p><b>Qualifications and professional registration</b></p>	<p>Registered professional with one of the following bodies:</p> <ul style="list-style-type: none"> <li>nurses and midwives currently registered with the Nursing and Midwifery Council (NMC)</li> <li>pharmacists currently registered with the General Pharmaceutical Council (GPhC) (Note: This PGD is not relevant to privately provided community pharmacy services)</li> <li>paramedics and physiotherapists currently registered with Health and Care Professions Council (HCPC)</li> </ul> <p>The practitioners above must also fulfil the <a href="#">Additional requirements</a> detailed below.</p> <p>Check <a href="#">Section 2 Limitations to authorisation</a> to confirm whether all practitioners listed above have organisational authorisation to work under this PGD.</p>
<p><b>Additional requirements</b></p>	<p>Additionally practitioners:</p> <ul style="list-style-type: none"> <li>must be authorised by name as an approved practitioner under the current terms of this PGD before working to it</li> <li>must have undertaken appropriate training for working under PGDs for supply/administration of medicines</li> <li>must be competent in the use of PGDs (see <a href="#">NICE Competency framework</a> for health professionals using PGDs)</li> <li>must be familiar with the vaccine product and alert to changes in the Summary of Product Characteristics (SPC), Immunisation Against Infectious Disease (“<a href="#">The Green Book</a>”), and national and local immunisation programmes</li> <li>must have undertaken training appropriate to this PGD as required by local policy and in line with the <a href="#">National Minimum Standards and Core Curriculum for Immunisation Training</a></li> <li>must be competent to undertake immunisation and to discuss issues related to immunisation</li> <li>must be competent in the handling and storage of vaccines, and management of the “cold chain”</li> <li>must be competent in the recognition and management of anaphylaxis</li> <li>must have access to the PGD and associated online resources</li> <li>should fulfil any additional requirements defined by local policy</li> </ul> <p><b>THE INDIVIDUAL PRACTITIONER MUST BE AUTHORISED BY NAME, UNDER THE CURRENT VERSION OF THIS PGD BEFORE WORKING ACCORDING TO IT.</b></p>
<p><b>Continued training requirements</b></p>	<p>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).</p> <p>Practitioners should be constantly alert to any subsequent recommendations from Public Health England and/or NHS England and other sources of medicines information.</p> <p>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.</p>

#### 4. Clinical condition or situation to which this PGD applies

<p><b>Clinical condition or situation to which this PGD applies</b></p>	<p>Indicated for the active immunisation of individuals from 6 weeks (routinely from 8 weeks) to under 2 years of age for the prevention of pneumococcal disease in accordance with the national immunisation programme and recommendations given in <a href="#">Chapter 25</a> of Immunisation Against Infectious Disease: “The Green Book” and to individuals from 6 weeks of age recommended PCV13 in accordance with <a href="#">PHE Guidelines for the public health management of clusters and outbreaks of pneumococcal disease in closed settings with high-risk individuals</a>.</p>
<p><b>Criteria for inclusion</b></p>	<p>Individuals from 6 weeks (routinely from 8 weeks) to under 2 years of age who:</p> <ul style="list-style-type: none"> <li>• require a primary course of PCV13</li> <li>• require a reinforcing booster dose of PCV13 against pneumococcal disease</li> </ul> <p>Individuals from 6 weeks of age recommended PCV13 in accordance with <a href="#">PHE Guidelines for the public health management of clusters and outbreaks of pneumococcal disease in closed settings with high-risk individuals</a>.</p> <p>Note: Individuals with an underlying medical condition which puts them at increased risk from pneumococcal disease may require additional ‘routine’ vaccination outside the inclusion criteria for this PGD - see PCV Risk Groups PGD and <a href="#">Chapter 7</a> of “The Green Book”.</p>
<p><b>Criteria for exclusion<sup>2</sup></b></p>	<p>Individuals for whom no valid consent has been received.</p> <p>Individuals who:</p> <ul style="list-style-type: none"> <li>• are less than 6 weeks of age</li> <li>• are aged 2 years and over, unless PCV13 is recommended in response to an outbreak of pneumococcal disease</li> <li>• have had a confirmed anaphylactic reaction to a previous dose of pneumococcal vaccine or to any component of the vaccine, including diphtheria toxoid</li> <li>• are suffering from acute severe febrile illness (the presence of a minor infection is not a contraindication for immunisation)</li> </ul>
<p><b>Cautions including any relevant action to be taken</b></p>	<p>The immunogenicity of the vaccine could be reduced in immunosuppressed subjects and additional doses may be recommended, see “The Green Book” <a href="#">Chapter 7</a> and <a href="#">Chapter 25</a> and the PCV Risk Groups PGD.</p> <p>Premature infants should be vaccinated in accordance with the national routine immunisation schedule according to their chronological age. Very premature infants (born <math>\leq 28</math> 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.</p>

<sup>2</sup> 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

<p><b>Action to be taken if the patient is excluded</b></p>	<p>If aged less than 6 weeks advise to return for routine immunisation when the child is 8 weeks of age or over and give an appropriate appointment. Immunisation can be administered to infants from 6 weeks of age if required eg if at increased risk of exposure due to an outbreak or travelling abroad (see “The Green Book” <a href="#">Chapter 11</a>).</p> <p>If aged over 2 years routine immunisation with pneumococcal vaccine is not indicated. If the individual is at increased risk of pneumococcal disease, in accordance with “The Green Book” <a href="#">Chapter 7</a> and <a href="#">Chapter 25</a>, refer to the PCV Risk Groups PGD.</p> <p>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.</p> <p>Seek appropriate advice from the local Screening and Immunisation Team, local Health Protection Team or the individual’s clinician as required.</p> <p>The risk to the individual of not being immunised must be taken into account.</p> <p>Document the reason for exclusion and any action taken in the individual’s clinical records.</p> <p>In a GP practice setting, inform or refer to the GP or a prescriber as appropriate.</p>
<p><b>Action to be taken if the patient or carer declines treatment</b></p>	<p>Informed consent, from the individual or a person legally able to act on the person’s behalf, must be obtained for each administration.</p> <p>Advise the individual/parent/carer about the protective effects of the vaccine, the risks of infection and potential complications.</p> <p>Document advice given and the decision reached.</p> <p>In a GP practice setting, inform or refer to the GP as appropriate.</p>
<p><b>Arrangements for referral for medical advice</b></p>	<p>As per local policy</p>



## 5. Description of treatment

<b>Name, strength &amp; formulation of drug</b>	<p>Pneumococcal polysaccharide conjugate vaccine (13-valent, adsorbed), PCV13, eg:</p> <ul style="list-style-type: none"> <li>• Prevenar<sup>®</sup> 13 suspension for injection in a pre-filled syringe</li> </ul>
<b>Legal category</b>	<p>Prescription only medicine (POM)</p>
<b>Black triangle▼</b>	<p>No</p>
<b>Off-label use</b>	<p>Administration of a two-dose primary series of Prevenar<sup>®</sup> 13 to pre-term infants &lt;37 weeks gestation is contrary to the 3-dose primary schedule detailed in the SPC but is in accordance with PHE recommendations for the <a href="#">vaccination of premature infants</a> and <a href="#">Chapter 25</a> of “The Green Book”.</p> <p>A single dose schedule for previously unvaccinated individuals between 12 months and up to 2 years of age is contrary to the two dose schedule detailed in the SPC but is in accordance with PHE recommendations for the <a href="#">vaccination of individuals with uncertain or incomplete immunisation status</a> and <a href="#">Chapter 25</a> of “The Green Book”.</p> <p>Vaccine should be stored according to the conditions detailed in the <a href="#">Storage section</a> below. However, in the event of an inadvertent or unavoidable deviation of these conditions refer to <a href="#">PHE Vaccine Incident Guidance</a>. Where vaccine is assessed in accordance with these guidelines as appropriate for continued use this would constitute off-label administration under this PGD.</p> <p>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.</p>
<b>Route / method of administration</b>	<p>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.</p> <p>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.</p> <p>For individuals with a bleeding disorder, vaccines normally given by an intramuscular route should be given by deep subcutaneous injection to reduce the risk of bleeding (see “The Green Book” <a href="#">Chapter 4</a>).</p> <p>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.</p> <p>The vaccine should be visually inspected prior to administration and should not be used if discoloured or foreign particles are present.</p> <p>The vaccine’s SPC provides further guidance on administration and is available from the electronic Medicines Compendium website: <a href="http://www.medicines.org.uk">www.medicines.org.uk</a></p>

<p><b>Dose and frequency of administration</b></p>	<p>Single 0.5ml dose per administration</p> <p><b>Routine Childhood Immunisation Schedule</b></p> <p>The national recommendation is for a two dose primary course of PCV13 vaccine at a 2 month interval and a booster dose to be administered, usually on or after their first birthday and before 2 years of age.</p> <p>PCV13 0.5ml should ideally be given as follows:</p> <ul style="list-style-type: none"> <li>• first primary immunisation visit (usually at age 8 weeks of age)</li> <li>• third primary immunisation visit (usually at age 16 weeks of age)</li> <li>• booster on or after the first birthday</li> </ul> <p>If required in certain circumstances, eg if at increased risk of exposure due to a local cluster or travelling abroad, the first primary dose may be given early from six weeks of age.</p> <p><b>Unimmunised or partially immunised children</b></p> <p>Unimmunised or partially immunised children who present late for vaccination should receive two doses of PCV13 two months apart* before the age of one year (if possible), and a further dose at 1 year of age (two months after the last PCV13 dose)*.</p> <p>*The immunisation interval may be reduced to one month if necessary to ensure the immunisation schedule is completed.</p> <p>An unimmunised or partially immunised child aged between one year and under two years of age should have a single dose of PCV13.</p> <p>See flow chart for <a href="#">vaccination of individual with uncertain or incomplete immunisation status</a>.</p> <p><b>Management of a pneumococcal disease clusters and outbreaks in closed settings with high-risk individuals.</b></p> <p>A single dose 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 <a href="#">PHE Guidelines for the public health management of clusters and outbreaks of pneumococcal disease in closed settings with high-risk individuals</a>. 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.</p>
<p><b>Duration of treatment</b></p>	<p>See dose section above</p>
<p><b>Quantity to be supplied / administered</b></p>	<p>Single 0.5ml dose per administration.</p>
<p><b>Supplies</b></p>	<p>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.</p> <p>Protocols for the ordering, storage and handling of vaccines should be followed to prevent vaccine wastage (see <a href="#">protocol for ordering storage and handling of vaccines</a> and Green Book <a href="#">Chapter 3</a>).</p>

<b>Storage</b>	<p>Store between +2°C to +8°C. Store in original packaging in order to protect from light. Do not freeze.</p> <p>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.</p> <p>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 <a href="#">PHE Vaccine Incident Guidance</a>.</p>
<b>Disposal</b>	<p>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 <a href="#">technical memorandum 07-01: Safe management of healthcare waste</a> (Department of Health, 2013).</p>
<b>Drug interactions</b>	<p>Immunological response may be diminished in those receiving immunosuppressive treatment. Vaccination is recommended even if the antibody response may be limited.</p> <p>May be given at the same time as other vaccines.</p> <p>A detailed list of drug interactions is available in the SPC, which is available from the electronic Medicines Compendium website: <a href="http://www.medicines.org.uk">www.medicines.org.uk</a></p>
<b>Identification &amp; management of adverse reactions</b>	<p>Local reactions following vaccination are very common ie pain, swelling or redness at the injection site. A small painless nodule may form at the injection site.</p> <p>The most commonly reported adverse reactions include vaccination-site reactions, fever, irritability, decreased appetite, increased and/or decreased sleep, rash, vomiting and diarrhoea.</p> <p>Hypersensitivity reactions, such as bronchospasm, angioedema, urticaria, and anaphylaxis can occur but are very rare.</p> <p>A detailed list of adverse reactions is available in the SPC, which is available from the electronic Medicines Compendium website: <a href="http://www.medicines.org.uk">www.medicines.org.uk</a></p>
<b>Reporting procedure of adverse reactions</b>	<p>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: <a href="http://yellowcard.mhra.gov.uk">http://yellowcard.mhra.gov.uk</a></p> <p>Any adverse reaction to a vaccine should be documented in the individual’s record and the individual’s GP should be informed.</p>
<b>Written information to be given to patient or carer</b>	<p>Offer marketing authorisation holder's patient information leaflet (PIL) provided with the vaccine.</p> <p>Immunisation promotional material may be provided as appropriate:</p> <ul style="list-style-type: none"> <li>• <a href="#">A guide to immunisations for babies up to 13 months of age</a></li> <li>• <a href="#">A quick guide to childhood immunisation for the parents of premature babies</a></li> </ul> <p>Available from: <a href="http://www.gov.uk/government/collections/immunisation">www.gov.uk/government/collections/immunisation</a></p>

<p><b>Patient advice / follow up treatment</b></p>	<p>Inform the individual/parent/carer of possible side effects and their management.</p> <p>The individual/parent/carer should be advised to seek medical advice in the event of an adverse reaction.</p> <p>Advise the individual/parent/carer when any subsequent immunisations are due.</p> <p>When administration is postponed advise the individual/parent/carer when to return for vaccination.</p>
<p><b>Special considerations / additional information</b></p>	<p>Ensure there is immediate access to adrenaline (epinephrine) 1 in 1000 injection and access to a telephone at the time of vaccination.</p> <p>Individuals at increased risk of pneumococcal disease require additional doses of PCV13 in accordance with “The Green Book” <a href="#">Chapter 7</a> and <a href="#">Chapter 25</a>. The administration of additional PCV13 doses for these individuals is not covered by this PGD (see PCV Risk Groups PGD).</p>
<p><b>Records</b></p>	<p>Record:</p> <ul style="list-style-type: none"> <li>• that valid informed consent was given</li> <li>• name of individual, address, date of birth and GP with whom the individual is registered</li> <li>• name of immuniser</li> <li>• name and brand of vaccine</li> <li>• date of administration</li> <li>• dose, form and route of administration of vaccine</li> <li>• quantity administered</li> <li>• batch number and expiry date</li> <li>• anatomical site of vaccination</li> <li>• advice given, including advice given if excluded or declines immunisation</li> <li>• details of any adverse drug reactions and actions taken</li> <li>• supplied via Patient Group Direction (PGD)</li> </ul> <p>Records should be signed and dated (or a password controlled immuniser’s record on e-records).</p> <p>All records should be clear, legible and contemporaneous.</p> <p>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.</p> <p>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 arrangement.</p> <p>A record of all individuals receiving treatment under this PGD should also be kept for audit purposes in accordance with local policy.</p>

## 6. Key references

<b>Key references</b>	<p><b>Pneumococcal conjugate vaccine</b></p> <ul style="list-style-type: none"><li>• Immunisation Against Infectious Disease: The Green Book <u>Chapter 25</u>. Last updated 16 January 2018 <a href="https://www.gov.uk/government/publications/pneumococcal-the-green-book-chapter-25">https://www.gov.uk/government/publications/pneumococcal-the-green-book-chapter-25</a></li><li>• Summary of Product Characteristics for Prevenar<sup>®</sup> 13 suspension for injection, Pfizer Ltd. 3 October 2018. <a href="http://www.medicines.org.uk/emc/medicine/22689">http://www.medicines.org.uk/emc/medicine/22689</a></li><li>• NHS public health functions agreement 2018-19. Service specification No.8. Pneumococcal immunisation programme. September 2018. <a href="https://www.england.nhs.uk/publication/public-health-national-service-specifications/">https://www.england.nhs.uk/publication/public-health-national-service-specifications/</a></li><li>• Vaccination of individuals with uncertain or incomplete immunisation status. Public Health England. Updated 13 November 2017. <a href="https://www.gov.uk/government/publications/vaccination-of-individuals-with-uncertain-or-incomplete-immunisation-status">https://www.gov.uk/government/publications/vaccination-of-individuals-with-uncertain-or-incomplete-immunisation-status</a></li><li>• Guidelines for the public health management of clusters and outbreaks of pneumococcal disease in closed settings with high-risk individuals. Public Health England. November 2018. <a href="https://www.gov.uk/government/publications/managing-clusters-of-pneumococcal-disease-in-closed-settings">https://www.gov.uk/government/publications/managing-clusters-of-pneumococcal-disease-in-closed-settings</a></li></ul> <p><b>General</b></p> <ul style="list-style-type: none"><li>• Health Technical Memorandum 07-01: Safe Management of Healthcare Waste. Department of Health 20 March 2013 <a href="https://www.gov.uk/government/publications/guidance-on-the-safe-management-of-healthcare-waste">https://www.gov.uk/government/publications/guidance-on-the-safe-management-of-healthcare-waste</a></li><li>• National Minimum Standards and Core Curriculum for Immunisation Training. Published February 2018. <a href="https://www.gov.uk/government/publications/national-minimum-standards-and-core-curriculum-for-immunisation-training-for-registered-healthcare-practitioners">https://www.gov.uk/government/publications/national-minimum-standards-and-core-curriculum-for-immunisation-training-for-registered-healthcare-practitioners</a></li><li>• NICE Medicines Practice Guideline 2 (MPG2): Patient Group Directions. Published March 2017. <a href="https://www.nice.org.uk/guidance/mpg2">https://www.nice.org.uk/guidance/mpg2</a></li><li>• NICE MPG2 Patient group directions: competency framework for health professionals using patient group directions. Updated March 2017. <a href="https://www.nice.org.uk/guidance/mpg2/resources">https://www.nice.org.uk/guidance/mpg2/resources</a></li><li>• PHE Immunisation Collection <a href="https://www.gov.uk/government/collections/immunisation">https://www.gov.uk/government/collections/immunisation</a></li><li>• PHE Vaccine Incident Guidance <a href="https://www.gov.uk/government/publications/vaccine-incident-guidance-responding-to-vaccine-errors">https://www.gov.uk/government/publications/vaccine-incident-guidance-responding-to-vaccine-errors</a></li><li>• Protocol for ordering storage and handling of vaccines. April 2014. <a href="https://www.gov.uk/government/publications/protocol-for-ordering-storing-and-handling-vaccines">https://www.gov.uk/government/publications/protocol-for-ordering-storing-and-handling-vaccines</a></li></ul>
-----------------------	--

## 7. Practitioner authorisation sheet

**PCV PGD v02.00 Valid from: 01/02/2019 Expiry: 31/01/2021**

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.