



Publications gateway number: GOV-19752

Pneumococcal polysaccharide conjugate vaccine (20-valent, adsorbed) (PCV20) Patient Group Direction (PGD)

This PGD is for the administration of 20-valent, pneumococcal polysaccharide conjugate vaccine (PCV20) to individuals from 65 years of age, individuals from 2 years of age in a clinical risk group and individuals under 2 years of age with asplenia, splenic dysfunction, complement disorder or severe immunocompromise in accordance with the national immunisation programme for active immunisation against pneumococcal disease and for the public health management of clusters of severe pneumococcal disease in closed settings in accordance with the UK guidelines.

This PGD is for the administration of PCV20 by registered healthcare practitioners identified in Section 3, subject to any limitations to authorisation detailed in Section 2.

Reference no: PCV20 PGD

Version no: v1.0

Valid from: 17 December 2025

Review date: 17 July 2028

Expiry date: 17 December 2028

The UK Health Security Agency (UKHSA) has developed this PGD to facilitate the delivery of publicly funded immunisation in England in line with national recommendations.

Those using this PGD must ensure that it is organisationally authorised and signed in <u>Section 2</u> 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 <u>HMR 2012 Schedule 16 Part 2</u>.**

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).

Sections 2 and 7 can be amended within the designated editable fields provided, but only for the purposes for which these sections are provided, namely the responsibilities and governance arrangements of the NHS organisations using the PGD. The fields in sections 2 and 7 cannot be used to alter, amend or add to the clinical contents. Such action will invalidate the UKHSA clinical content authorisation which is provided in accordance with the regulations.

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.

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¹ This includes any relevant amendments to legislation.

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 the UKHSA PGDs for authorisation can be found from:

Immunisation patient group direction (PGD) templates

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

Enquiries relating to the availability of organisationally authorised PGDs and subsequent versions of this PGD should be directed to: Vaccination Team, NHS England – Midlands, responsible for your area:

East: england.emids-imms@nhs.net

- Derby and Derbyshire
- Lincolnshire
- · Leicester, Leicestershire and Rutland
- Northamptonshire
- Nottingham and Nottinghamshire

West: england.wmid-imms@nhs.net

- · Herefordshire and Worcestershire
- Birmingham and Solihull
- Staffordshire and Stoke-on-Trent
- Shropshire, Telford and Wrekin
- Black Country
- · Coventry and Warwickshire

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Change history

Version number	Change details	Date
V1.0	New PGD following the introduction of PCV20 vaccine to the immunisation programme for:	9 December 2025
	adults aged 65 years and over (as replacement for PPV23)	
	 individuals from 2 years of age in a clinical risk group (as replacement for PPV23) 	
	 individuals under 2 years of age with asplenia, splenic dysfunction, complement disorder or severe immunocompromise (as replacement for PCV13 or PCV15) 	
	public health management of clusters of severe pneumococcal disease in closed settings in accordance with the UK guidelines	

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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 Programmes, UKHSA	Sulik Huyant	9 December 2025
Doctor	Professor Shamez Ladhani Paediatric Infectious Diseases Consultant, St George's Hospital London, Professor of Paediatric Infections and Vaccinology, St George's University London and Consultant Epidemiologist, Immunisation and Vaccine Preventable Diseases Division, UKHSA	Sadhani	9 December 2025
Registered Nurse (Chair of Expert Panel)	David Green Nurse Consultant, Immunisation Programmes, UKHSA	Dagen.	9 December 2025

This PGD has been peer reviewed by the UKHSA Immunisations PGD Expert Panel in accordance with the UKHSA PGD and Protocol Policy. It has been ratified by the UKHSA Medicines Governance Committee.

Expert Panel

Nicholas Aigbogun	Consultant in Communicable Disease Control, Yorkshire and Humber Health Protection Team, UKHSA	
Gayatri Amrithalingam	Consultant Epidemiologist, Immunisation Programmes, UKHSA	
Jessica Baldasera	Health Protection Practitioner, North East Health Protection Team Regions Directorate, UKHSA	
Alison Campbell	Screening and Immunisation Coordinator, Public Health Commissioning NHS England (NHS England) Midlands	
Jane Freeguard	Deputy Director of Vaccination – Medicines and Pharmacy NHS England	
Rosie Furner	Advanced Specialist Pharmacist - Medicines Governance, Specialist Pharmacist Services (SPS)	
Ed Gardner	Advanced Paramedic Practitioner/Emergency Care Practitioner, Medicines Manager, Proactive Care Lead	
Shilan Ghafoor	Lead Pharmacist Medicines Governance, UKHSA	
Helen Eley	Lead Immunisation Nurse Specialist, Immunisation Programmes, UKHSA	
Naveen Dosanjh	Senior Clinical Advisor - Vaccinations, NHS England	
Elizabeth Luckett	Senior Screening and Immunisation Manager, NHS England South West	
Briony Mason	Vaccination Manager, Professional Midwifery Advocate, Vaccination and Screening, NHS England, West Midlands	
Vanessa MacGregor Consultant in Communicable Disease Control, East Midlands He Protection Team, UKHSA		

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Lesley McFarlane	Lead Immunisation Nurse Specialist, Immunisation Programmes, UKHSA
Tushar Shah	Lead Pharmacy Adviser, NHS England London

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2. Organisational authorisations

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

The fields in this section cannot be used to alter, amend or add to the clinical or other PGD content (sections 3 to 6 inclusive). Such action will invalidate the UKHSA clinical content authorisation which is provided in accordance with the regulations. See page 1 for full details.

NHS England authorises this P	GD for use by the serv	ices of providers listed	a below:	
Authorised for use by the follow	owing organisations an	d/or services		
Primary care services and/or all organisations commissioned or contracted by NHS England – Midlands to provide immunisation services in:				
Derby and Derbyshire				
Lincolnshire				
• Leicester, Leicestershire, and	Rutland			
Northamptonshire				
 Nottingham and Nottinghamsh 				
Herefordshire and Worcesters	hire			
Birmingham and Solihull Staffandahina and Stake and Tru				
Staffordshire and Stoke-on-Tree Shropshire, Tolford, and Wroke				
Shropshire, Telford, and WrekBlack Country	.IT1			
Coventry and Warwickshire				
Covernity and TvarWickerine				
Limitations to authorisation				
None				
Organisational approval (le				
Role	Name	Sign	Date	
Regional Director of	Roz Lindridge	10 0	18/12/2025	
Commissioning Integration,		& haide		
NHS England - Midlands				
Additional signatories according to locally agreed policy				
Role Name Sign Date				
11010	Name	Olgii	Date	

PCV20 PGD v1.0 Valid from: 17 December 2025 Expiry: 17 December 2028 Page 6 of 21 Local enquiries regarding the use of this PGD may be directed to Local enquiries regarding the use of this PGD may be directed to: Vaccination Team, NHS England – Midlands, responsible for your area:

East: england.emids-imms@nhs.net

- Derby and Derbyshire
- Lincolnshire
- · Leicester, Leicestershire and Rutland
- Northamptonshire
- Nottingham and Nottinghamshire

West: england.wmid-imms@nhs.net

- Herefordshire and Worcestershire
- Birmingham and Solihull
- Staffordshire and Stoke-on-Trent
- Shropshire, Telford and Wrekin
- Black Country
- · Coventry and Warwickshire

<u>Section 7</u> 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.

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3. Characteristics of staff

Qualifications and professional registration

All practitioners should only administer vaccination where it is within their clinical scope of practice to do so. Practitioners must also fulfil the additional requirements and continued training requirements to ensure their competency is up to date, as outlined in the section below:

Practitioners working to this PGD must also be a registered professional with one of the following bodies:

- nurses and midwives currently registered with the Nursing and Midwifery Council (NMC)
- pharmacists and pharmacy technicians currently registered with the General Pharmaceutical Council (GPhC) (Note: this PGD is not relevant to privately provided community pharmacy services)
- paramedics, physiotherapists, dieticians, podiatrists, and occupational therapists 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</u> (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 <u>NICE Competency framework</u> for health professionals using <u>PGDs</u>)
- must be familiar with the vaccine product and alert to changes in the Summary of Product Characteristics (SPC), Immunisation Against Infectious Disease (the <u>Green Book</u>), 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 Standards and Core</u> Curriculum for Immunisation Training
- must be competent in intramuscular injection techniques
- 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

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, NHS England and other sources of medicines information.

Continued training

Note: The most current national recommendations should be followed but a Patient Specific Direction (PSD) or a prescription may be required to

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(continued)	administer the vaccine in line with updated recommendations that are outside
	the criteria specified in this PGD.

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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, individuals from 2 years of age in a clinical risk group and individuals under 2 years of age with asplenia, splenic dysfunction, complement disorder or severe immunocompromise for the prevention of pneumococcal disease, and for the public health management of clusters of severe pneumococcal disease in closed settings, in accordance with the national immunisation programme and UK guidelines.

Note: The remaining stocks of PPV23 should be used for individuals from 65 years of age and from 2 years of age in a clinical risk group before changing to PCV20.

For reference, see <u>Managing clusters of pneumococcal disease in closed</u> <u>settings</u> and recommendations given in <u>Chapter 25</u> of Immunisation Against Infectious Disease: the Green Book.

Criteria for inclusion

Individuals who:

- are aged 65 years and over
- are aged 2 years and over and have a medical condition included in the clinical risk groups defined in the Green Book Chapter 25, Table 25.2.
- have asplenia, splenic dysfunction, or chronic kidney disease and require a pneumococcal vaccine booster (see Chapter 25)
- are under 2 years of age with asplenia, splenic dysfunction, complement disorder or severe immunocompromise (Chapter 25, Table 25.3)
- are identified as requiring vaccination by the local Health Protection Team for the public health management of pneumococcal disease in accordance with <u>Managing clusters of pneumococcal disease in closed</u> <u>settings</u>

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 is an occupational health vaccination and is not a NHS service.
 This is outside the remit of this PGD.

Criteria for exclusion²

Individuals for whom valid consent or best-interests decision in accordance with the <u>Mental Capacity Act 2005</u>, has not been obtained (for further information on consent, see <u>Chapter 2</u> of the Green Book). Several resources are available to inform consent (see <u>written information to be given to individual or carer section</u>).

Individuals who:

- are less than 6 weeks of age
- are in a clinical risk group who have previously received PPV23 or PCV20 except individuals with asplenia, splenic dysfunction, complement disorder, severe immunocompromise or chronic kidney disease (see Green Book <u>Chapter 25</u>)
- are not recommended to receive the vaccination in accordance with the <u>Managing clusters of pneumococcal disease in closed settings guidelines.</u>
- have had a confirmed anaphylactic reaction to a previous dose of a pneumococcal vaccine or diphtheria toxoid or a confirmed anaphylactic reaction to any component or residue from the manufacturing process (see SPC)

Criteria for exclusion

Continued over page

 have received PPV23 or PCV (any valency) vaccine in the preceding 4 weeks

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²Exclusion 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

(continued)

• 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

Facilities for management of anaphylaxis should be available at all vaccination premises (see <u>Chapter 8</u> of the Green Book and advice issued by the <u>Resuscitation Council UK</u>).

The vaccine must be administered with caution to individuals with thrombocytopenia or a bleeding disorder since bleeding may occur following an intramuscular administration (see Route and administration).

Individuals with impaired immune response, may have reduced immune responses to PCV20. Antibody levels are likely to decline rapidly in individuals with asplenia, splenic dysfunction (including sickle cell disease) or chronic renal disease and, therefore, re-immunisation with PCV20 is recommended. See dose and frequency and special considerations sections regarding appropriate timing of vaccination.

Individuals with immunosuppression and HIV infection (regardless of CD4 count) should be given pneumococcal vaccines according to the recommendations in <u>Chapter 25</u>.

Vaccination is recommended for all individuals with asplenia or splenic dysfunction, including individuals with coeliac disease who are diagnosed with splenic dysfunction and all individuals with haemoglobinopathies such as homozygous sickle cell disease Chapter 25 and Chapter 7.

Syncope (fainting) can occur following, or even before any vaccination, especially in adolescents as a psychogenic response to the needle injection. This can be accompanied by several neurological signs such as transient visual disturbance, paraesthsia and tonic-clonic limb movements during recovery. It is important that procedures are in place to avoid injury from faints.

Action to be taken if the individual is excluded

If a single dose of PCV20 or PPV23 has previously been given to an individual over the age of 2 years **and** the individual does not have asplenia, splenic dysfunction, severe immunocompromise or chronic kidney disease (see Green Book <u>Chapter 25</u>) **and immunisation is not indicated** for the individual in line with <u>Managing clusters of pneumococcal disease in closed settings</u>, further PCV20 is **not** indicated.

See <u>Table 25.3 Chapter 25</u> footnote for examples of severe immunocompromise.

If aged less than 6 weeks, defer immunisation and provide an appointment as appropriate at 8 weeks of age, or as soon as possible thereafter. Vaccination should not commence before the age of 8 weeks.

Individuals who have had a confirmed anaphylactic reaction to a previous dose of pneumococcal vaccine or diphtheria toxoid or any components of the PCV20 vaccine, should be referred to a clinician for specialist advice and appropriate management.

Individuals who have recently received PCV vaccine (any valency) should postpone PCV20 or PPV23 immunisation until 4 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 at the earliest opportunity.

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Action to be taken if the individual is excluded

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.

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(continued)	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 individual,	Advise the individual, parent or carer about the protective effects of the vaccine, the risks of infection and potential complications of disease.
parent or carer	Document advice given and the decision reached.
declines treatment	Inform or refer to the GP as appropriate.
Arrangements for referral for medical advice	As per local policy

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5. Description of treatment

Name atvanath and	Prevenar®20 suspension for injection in pre-filled syringe		
Name, strength and formulation of drug	Pneumococcal polysaccharide conjugate vaccine (20-valent, adsorbed)		
	For full formulation details see <u>SPC</u> .		
Legal category	Prescription only medicine (POM)		
Black triangle▼	YES		
	Prevenar®20		
	As a new vaccine product, the Medicines and Healthcare products Regulatory Agency (MHRA) has a specific interest in the reporting of adverse drug reactions for this product. All suspected adverse drug reactions should be reported using the MHRA Yellow Card scheme.		
Off-label use	The SPC recommends that individuals who receive a first dose of PCV20 complete the vaccination course with PCV20, however, the vaccine can be interchanged in accordance with the national guidance, see Chapter 25 .		
	Where the SPC states that an 8-week interval from the last pneumococcal conjugate vaccination should be observed, the vaccine can be given at a minimum 4-week interval in accordance with the Green Book, Chapter 25 .		
	Administration of a further dose of PCV20 to high-risk individuals who have already received a dose of PCV20 more than 12 months previously is off-label but may be recommended in accordance with the Managing pneumococcal disease in closed settings and Chapter 25 .		
	Vaccines should be stored according to the conditions detailed in the <u>storage</u> section below. However, in the event of an inadvertent or unavoidable deviation of these conditions, refer to <u>Vaccine Incident Guidance</u> . Where vaccines are 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 or carer that the vaccine is being offered outside of product licence but in accordance with national guidance.		
Route and method of administration	Administer by intramuscular injection, preferably into the deltoid muscle of the upper arm or, for infants 1 year and under, into the anterolateral aspect of the thigh.		
	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 into different limbs. If given into 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.		
	Individuals with bleeding disorders may be vaccinated intramuscularly if, in the opinion of a doctor familiar with the individual's bleeding risk, vaccines or similar small volume intramuscular injections can be administered with reasonable safety by this route. Individuals on stable anticoagulation therapy, including individuals on warfarin who are up to date with their scheduled INR testing and whose latest INR was below the upper threshold of their therapeutic range, can be vaccinated via the intramuscular route. If the individual receives medication or other treatment to reduce bleeding, for example treatment for haemophilia, intramuscular vaccination can be scheduled shortly after such medication or other treatment is		
Continued over page	administered. A fine needle (equal to 23 gauge or finer calibre such as 25 gauge) should be used for the vaccination, followed by firm pressure applied to the site		
Route and method of administration	should be used for the vaccination, followed by first pressure applied to the site		
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(without rubbing) for at least 2 minutes. The individual, parent or carer should be informed about the risk of haematoma from the injection.

For individuals with an unstable bleeding disorder (or where intramuscular injection is otherwise not considered suitable), vaccines normally given by an intramuscular route should be given by deep subcutaneous injection, in accordance with Chapter 4 of the Green Book.

The vaccine's normal appearance is a homogeneous white suspension.

The vaccine should be shaken well to obtain a white homogeneous suspension.

The vaccine should be visually inspected for foreign particulate matter and other variation of expected appearance prior to preparation and administration. Should either occur, do not administer the dose and discard the vaccine in accordance with local procedures.

The vaccine **SPC** provides further guidance on preparation and administration.

Dose and frequency of administration

Single 0.5ml dose.

A minimum interval of 4 weeks should be observed between any 2 doses of any PCV vaccine (regardless of the valency).

Adults aged 65 years and over

a single dose of 0.5ml of PCV20

If an individual has already received PPV23 or PCV20 because they are in a **clinical risk group**, they do not require another dose of PCV20 at 65 years of age and over, irrespective of the interval since they received PPV23 or PCV20.

Whilst PPV23 is available for the routine programme for adults aged 65 years and over, if an individual **not in a clinical risk group** becomes eligible for PPV23 at age 65 years but has already received PCV20, PPV23 can still be offered at any interval after this but it is recommended that a minimum 4-week interval is observed (refer to <u>PPV23 PGD</u> and <u>Pneumococcal vaccination for older adults</u> and for individuals in a clinical risk group: Information for healthcare practitioners).

All clinical risk groups aged from 2 years of age (except severely immunocompromised)

 a single dose of 0.5ml of PCV20 at 2 years of age, at least 4 weeks after the last PCV dose

(**Note:** Start using PCV20 once the PPV23 stocks are exhausted)

Vaccination of individuals under 2 years of age with asplenia, splenic dysfunction, complement disorder or severe immunocompromise is as follows:

Individuals under one year of age

- two doses of PCV20 at least 4 weeks apart, commencing with their first visit at 8 weeks of age, or as soon as possible thereafter
- individuals diagnosed after 16 weeks who have already received PCV13 should receive two doses of PCV20 with an interval of at least 4 weeks between any doses

Individuals from 1 year to under 2 years of age

Continued over page

Dose and frequency of administration

a single dose of routine booster of PCV20 is administered at one year of age (on or after the first birthday)

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(continued)	If the routine booster of PCV13 dose has been given at one year (on or after the first birthday), then give a single dose of PCV20 at least 4 weeks later.
	Note: Continue to use <u>PCV risk groups PGD</u> for individuals under 2 years of age with asplenia, splenic dysfunction, complement disorder or severe immunocompromise until stocks of PCV20 are available.
	Severely immunocompromised individuals aged from 2 years of age
	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) (see Chapter 25).
	two PCV20 doses, at 2 years of age, at least 4 weeks apart and at least 4 weeks after the last PCV dose (or if first diagnosed or presenting at any time after the 2nd birthday)
	5 yearly booster doses
	Individuals with asplenia, splenic dysfunction (including sickle cell disease), or chronic kidney disease should be revaccinated at every 5 years with PCV20.
	Revaccination with PCV20 is currently not recommended for any other clinical risk groups or age groups.
	Testing of antibody levels prior to vaccination is not required for these or any other risk groups.
	Pneumococcal outbreaks in closed settings
	PCV20 should be offered to high-risk individuals recommended to receive vaccination by the local Health Protection Team for the public health management of pneumococcal disease in accordance with Managing pneumococcal disease in closed settings, unless they have received PPV23 or PCV20 in the previous 12 months.
	Note: PCV20 can be used, when available, instead of PPV23 in pneumococcal outbreaks in closed settings, including care homes.
	Individuals with unknown or incomplete vaccination histories
	For an individual in a clinical risk group, if their PCV dose in the routine programme is given very late (for example at 23 months), then a minimum interval of 4 weeks should be observed before giving a booster dose of PCV20.
	For further information for the changeover see Pneumococcal vaccination for older adults and for individuals in a clinical risk group: Information for healthcare practitioners.
Duration of treatment	Single 0.5ml dose, repeated at recommended intervals as outlined above in dose and frequency of administration.
Quantity to be supplied and administered	Single 0.5ml dose.
Supplies	Protocols for the ordering, storage and handling of vaccines should be followed to prevent vaccine wastage (see Green Book <u>Chapter 3</u>).
	Centrally purchased vaccines for the national immunisation programme for the NHS can only be ordered via ImmForm. Vaccines used for the national immunisation programme are provided free of charge.
Storage	Store in a refrigerator (+2 °C to +8 °C).
<u> </u>	

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Pre-filled syringes should be stored in the refrigerator horizontally to minimise the resuspension time. Do not freeze. Discard if the vaccine has been frozen. From a microbiological point of view, once removed from the refrigerator, the vaccine should be used immediately. Stability data indicate that the vaccine is stable for: 96 hours when stored at temperatures from +8 °C to +25 °C, or 72 hours when stored at temperatures from 0 °C to +2 °C At the end of these time periods the vaccine should be used or discarded. These data are intended to provide guidance in case of temporary temperature excursion only. During storage, a white deposit and clear supernatant may be observed in the pre-filled syringe containing the suspension. In the event of an inadvertent or unavoidable deviation of these conditions. vaccines that have been stored outside the conditions stated above should be quarantined and risk assessed on a case-by-case basis for suitability of continued off-label use or appropriate disposal. Refer to Vaccine Incident Guidance. Contact the vaccine manufacturer where more specific advice is required about managing a temperature excursion. **Disposal** Follow local clinical waste policy and NHS standard operating procedures to ensure safe and secure waste disposal. Equipment used for immunisation, including used vials, ampoules, or discharged vaccines in a syringe or applicator, should be disposed of safely in an UNapproved puncture-resistant sharps box, according to local authority arrangements and NHSE guidance (HTM 07-01): safe and sustainable management of healthcare waste. **Drug interactions** The immunological response may be diminished in those receiving immunosuppressive treatment, but it is important to still immunise this group. Vaccination is recommended even if the antibody response may be limited. PCV20 may be given at the same time as other vaccines (Chapter 25, Chapter 11 and SPC). A list of drug interactions associated with Prevenar®20 is available from the SPC. In children, the most common reactions are irritability, drowsiness, and pain at Identification and injection site, decreased appetite, drowsiness or increased sleep, restless sleep management of or decreased sleep, redness at the injection site, muscle pain, fatigue, swelling at adverse reactions the injection site, and fever ≥ 38.0°C. Most adverse reactions occurred within 1 to 2 days following vaccination and were mild or moderate and of short duration (1 to 2 days). In adults, the most commonly reported reactions were pain at the injection site, muscle pain, fatigue, headache and joint pain. A detailed list of adverse reactions and from post marketing experience is available in the vaccine SPC. Healthcare professionals and individuals, parents and carers are encouraged to Reporting procedure of adverse reactions report suspected adverse reactions to the Medicines and Healthcare products Regulatory Agency (MHRA) using the Yellow Card reporting scheme or by searching for MHRA Yellow Card in the Google Play or Apple App Store. Continued over page Any adverse reaction to a vaccine should be documented in the individual's record and the individual's GP should be informed. Reporting procedure of adverse reactions

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(continued)	
Written information to be given to	Offer marketing authorisation holder's patient information leaflet (PIL) provided with the vaccine.
individual, parent or carer	For resources in accessible formats and alternative languages, please visit Home Discover Public Health Resource Library .
	Where applicable, inform the individual/parent/carer that the PIL with large print, Braille or audio CD can be ordered from the manufacturer (see electronic medicines compendium).
	For resources in accessible formats and alternative languages, please visit Home- Health Publications .
	Immunisation promotional material may be provided as appropriate: Splenectomy leaflet
Advice and follow up treatment	Inform the individual, parent or 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 or carer should be advised to seek medical advice in the event of an adverse reaction and report this via the Yellow Card reporting scheme .
	When applicable, advise the individual, parent or carer when to return for vaccination or when a subsequent vaccine dose is due.
Special considerations and	Ensure there is immediate access to adrenaline (epinephrine) 1 in 1000 injection and access to a telephone at the time of vaccination.
additional information	The remaining stocks of PPV23 should be used for individuals from 65 years of age and from 2 years of age in a clinical risk group before changing to PCV20.
	In outbreak settings it is recommended to use PCV20 before all stocks of PPV23 have been used up.
	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.
	All other individuals under 2 year of age should be fully vaccinated in accordance with the routine PCV immunisation programme (see the <u>UKHSA PCV routine</u> <u>PGD</u> and the <u>Vaccination of individuals with uncertain or incomplete immunisation status</u> guidance).
	Individuals who are a contact of pneumococcal disease do not usually require PCV20. Immunisation may be indicated where there is a confirmed cluster of severe pneumococcal disease in a closed setting and should be on the advice of your local Health Protection Team.
Continued over page	Pneumococcal vaccines may be given to pregnant women when the need for protection is required without delay. There is no evidence of risk from vaccinating pregnant women or those who are breast-feeding with inactivated viral or bacterial vaccines or toxoids.
Special considerations and	Testing of antibody levels prior to vaccination is not required for any clinical risk groups (see Chapter 25).
additional information	Protection against pneumococcal disease

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(continued)

Prevenar®20 will only protect against Streptococcus pneumoniae serotypes included in the vaccine and will not protect against other microorganisms that cause invasive disease, pneumonia or otitis media (OM).

As with any vaccine, Prevenar®20 may not protect all individuals receiving the vaccine from pneumococcal invasive disease, OM or pneumonia.

Premature infants

Premature infants should be vaccinated in accordance with the national routine immunisation schedule according to their chronological age. Premature infants should be vaccinated in accordance with the national guidance. Very premature infants (born ≤28 weeks of gestation) who are in hospital should have respiratory monitoring for 48 to 72 hours 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 to 72 hours. If the premature infant was stable at discharge and has no history of apnoea and/or respiratory compromise, further vaccinations can be given in the community setting.

Timing of vaccination

Individuals with immunosuppression and HIV infection (regardless of CD4 count) should be given pneumococcal vaccines according to the recommendations.

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 2 weeks before treatment begins. 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, PCV20 should be given at least 4 weeks before elective splenectomy or initiation of treatment such as chemotherapy or radiotherapy. Where this is not possible, it can be given up to 2 weeks before treatment (see Green Book Chapter 25).

If it is not practical to vaccinate 2 weeks or more before splenectomy, immunisation should be delayed until at least 2 weeks after the operation.

If it is not practicable to vaccinate 2 weeks or more before initiation of either chemotherapy or radiotherapy (or both), immunisation should be delayed until at least 3 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.

For the timing of vaccination for individuals with leukaemia or anticipating bone marrow transplantation, see the Green Book Chapter 25.

Splenectomy, chemotherapy or radiotherapy should never be delayed allowing time for vaccination.

For further timings of vaccination see Chapter 25.

Records

The practitioner should ensure the following is recorded:

- that valid informed consent was given or a decision to vaccinate was made in the individual's best interests in accordance with the Mental Capacity Act 2005
- name of individual, address, date of birth and GP with whom the individual is registered

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- 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 password-controlled 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 or 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.

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6. Key references

Key references

Pneumococcal polysaccharide vaccine

- Immunisation Against Infectious Disease: the Green Book Chapter 25, last updated 6 August 2025 www.gov.uk/government/publications/pneumococcal-the-green-bookchapter-25
- Summary of Product Characteristic for Prevenar®20 suspension for injection in pre-filled June 2025 www.medicines.org.uk/emc/product/13461/smpc
- Guidelines for the public health management of clusters of severe pneumococcal disease in closed settings. Updated 21 February 2020 www.gov.uk/government/publications/managing-clusters-of-pneumococcaldisease-in-closed-settings
- Pneumococcal vaccination for older adults and for individuals in a clinical risk group: Information for healthcare practitioners www.gov.uk/government/collections/immunisation

General

- NHS England Health Technical Memorandum 07-01: safe and sustainable management of healthcare waste, last updated 26 January 2024Error! Bookmark not defined.
 - <u>www.england.nhs.uk/publication/management-and-disposal-of-healthcarewaste-htm-07-01/</u>
- National Minimum Standards and Core Curriculum for Immunisation Training, published 31 July 2025 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, updated 27 March 2017 www.nice.org.uk/guidance/mpg2
- NICE MPG2 Patient group directions: competency framework for health professionals using patient group directions, updated 4 January 2018 www.nice.org.uk/guidance/mpg2/resources
- Immunisation Collection www.gov.uk/government/collections/immunisation
- Vaccine Incident Guidance <u>www.gov.uk/government/publications/vaccine-incident-guidance-responding-to-vaccine-errors</u>

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7. Practitioner authorisation sheet

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Before signing this PGD, check that the document has had the necessary authorisations in section 2. 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.

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