



UKHSA publications gateway number: GOV-18478

Haemophilus influenzae type b and meningococcal C conjugate vaccine (Hib/MenC) Patient Group Direction (PGD)

This PGD is for the administration of *Haemophilus influenzae* type b and meningococcal C conjugate vaccine (Hib/MenC) to individuals from their first birthday to under 10 years of age in accordance with the national immunisation programme; and to individuals of any age for the prevention of secondary cases of meningococcal group C (MenC) disease.

This PGD is for the administration of Hib/MenC by registered healthcare practitioners identified in [section 3](#), subject to any limitations to authorisation detailed in [section 2](#).

Reference no: Hib/MenC PGD
Version no: v6.0
Valid from: 1 July 2025
Expiry date: 30 April 2026

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 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 [HMR 2012 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). **Sections 2 and 7 can be edited 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 organisation using the PGD. The fields in section 2 and 7 cannot be used to alter, amend or add to the clinical content. Such action will invalidate the UKHSA clinical content authorisation which is provided in the 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.

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:

¹ This includes any relevant amendments to legislation

[Immunisation patient group direction \(PGD\) templates](#)

Any concerns regarding the content of this PGD should be addressed to:

immunisation@ukhsa.gov.uk


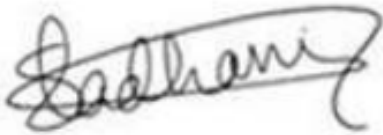

Enquiries relating to the availability of organisationally authorised PGDs and subsequent versions of this PGD should be directed to : your local screening and immunisation team

Change history

Version number	Change details	Date
v1.0 and v2.0	See previous versions of this PGD template for details	19 January 2016 to 23 April 2018
v3.0	<p>PHE Hib/MenC PGD amended to:</p> <ul style="list-style-type: none"> • include vaccination of individuals for the prevention of secondary cases of meningococcal group C disease • include additional healthcare practitioners in Section 3 • include statement on experimental storage data • refer to vaccine incident guidelines in off-label and storage sections • refer to the Hib/MenC Risk Groups PGD and MenACWY Risk Groups PGD in the inclusion criteria section • include minor rewording, layout and formatting changes for clarity and consistency with other PHE PGD templates 	24 April 2018
v4.0	<p>PHE Hib/MenC PGD amended to:</p> <ul style="list-style-type: none"> • remove reference to individuals with an underlying medical condition and the Hib/MenC Risk Groups PGD • include minor rewording, layout and formatting changes for clarity and consistency with other PHE PGDs. 	5 March 2020
v5.0	<p>UKHSA Hib/MenC PGD amended to:</p> <ul style="list-style-type: none"> • include minor rewording of standard text, layout and formatting changes for clarity and consistency with organisation change and other UKHSA PGDs • align criteria for exclusion to Green Book with reference to minor illness or systemic upset • add full list of active excipients in the drug section • add premature cohort in special considerations to align with Guidance for Public Health Management of Meningococcal Disease in the UK • update references 	4 May 2022
v6.0	<p>UKHSA Hib/MenC PGD amended to:</p> <ul style="list-style-type: none"> • include minor rewording of standard text, layout and formatting changes for clarity and consistency with other UKHSA PGDs • updated references • take account of the changes to the childhood immunisation schedule and switch off of the offer of Hib/MenC to individuals aged one year of age from 1 July 2025 (born on or after 1 July 2024) following discontinuation of the Hib/MenC (Menitorix[®]) vaccine • clarify that Menitorix[®] should continue to be offered to individuals of any age when being used for an outbreak response, including individuals born on or after 1 July 2024 • recommend MenACWY vaccine for use in outbreaks of MenC disease when Menitorix[®] is no longer available • include registered healthcare professionals named in both the Additional Roles Reimbursement Scheme (ARRS) and HMR2012 under Characteristics of staff • remove rarely reported side effects (insomnia, abdominal pain and malaise) from reported adverse events 	2 June 2025

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)	Christina Wilson Lead Pharmacist, Immunisation Programmes, UKHSA		23 May 2025
Doctor	Professor Shamez Ladhani Paediatric Infectious Diseases Consultant, Professor of Paediatric Infections and Vaccinology, St George's University London and Consultant Epidemiologist, Immunisation and Vaccine Preventable Diseases Division, UKHSA		23 May 2025
Registered Nurse (Chair of Expert Panel)	David Green Nurse Consultant for Immunisation Programmes, UKHSA		23 May 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 approved by the UKHSA Medicines Governance Committee.

Expert Panel (continued overleaf)

Name	Designation
Dr Nicholas Aigbogun	Consultant in Communicable Disease Control, Yorkshire and Humber Health Protection Team, UKHSA
Jess Baldasera	Health Protection Practitioner, North East Health Protection Team, Regions Directorate, UKHSA
Helen Beynon	Clinical Advisor, Immunisation Clinical Advice Response Service (CARS), NHSE London
Alison Campbell	Screening and Immunisation Coordinator, Clinical, NHSE Midlands
Laura Craig	Lead Immunisation Nurse Specialist, Immunisation Programmes – UKHSA
Jane Freeguard	Deputy Director of Vaccination – Medicines and Pharmacy, NHSE
Rosie Furner	Advanced Specialist Pharmacist, Medicines Governance (Patient Group Directions and Medicines Mechanisms), NHS Specialist Pharmacy Service
Ed Gardner	Advanced Paramedic Practitioner / Emergency Care Practitioner, Primary Care Based, Southbourne Surgery
Shilan Ghafoor	Medicines Governance Pharmacist, Medicines Governance, UKHSA
Greta Hayward	Consultant Midwife – Immunisation Programmes – UKHSA
Michelle Jones	Principal Medicines Optimisation Pharmacist, NHS Bristol North Somerset and South Gloucestershire Integrated Care Board
Elizabeth Lockett	Senior Screening and Immunisation Manager, Screening and Immunisation Team – Kent and Medway, NHSE South East

Dr Vanessa MacGregor	Consultant in Communicable Disease Control, East Midlands Health Protection Team, UKHSA
Briony Mason	Vaccination Manager, NHSE West Midlands
Tushar Shah	Lead Pharmacy Adviser, NHSE London

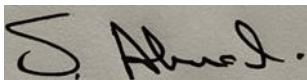
2. Organisational authorisations

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

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

NHS England (South East) 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 commissioned immunisation services within the NHS England South East Region.			
Limitations to authorisation			
This patient group direction (PGD) must only be used by the registered healthcare practitioners identified in Section 3 who have been named by their organisation to practice under it. The most recent in-date final version authorised by NHS England (South East) must be used.			
This PGD includes vaccination of individuals across the national immunisation programme. Users of this PGD should note that where they are commissioned to immunise certain groups this PGD does not constitute permission to offer immunisation beyond the groups they are commissioned to immunise.			

Organisational approval (legal requirement)			
Role	Name	Sign	Date
South East Medical Director System improvement and Professional Standards	Dr Shahed Ahmad		17/06/2025

Additional signatories according to locally agreed policy			
Role	Name	Sign	Date

Local enquiries regarding the use of this PGD may be directed to: your local screening and immunisation team.

[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	<p>All practitioners should only administer vaccinations 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 sections below.</p> <p>Practitioners working to this PGD must also be one of the following registered professionals who can legally supply and administer under a PGD:</p> <ul style="list-style-type: none"> • 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) • dieticians, occupational therapists, paramedics, physiotherapists and podiatrists currently registered with the Health and Care Professions Council (HCPC) <p>Check section 2 (Limitations to authorisation) to confirm whether all practitioners listed above have organisational authorisation to work under this PGD.</p>
Additional requirements	<p>Additionally, practitioners:</p> <ul style="list-style-type: none"> • 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 healthcare 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 intramuscular injection technique • 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 <p>The individual practitioner must be authorised by name, under the current version of this PGD before working according to it.</p>
Continued training requirements	<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 the UKHSA, NHS England (NHSE) 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

Clinical condition or situation to which this PGD applies	<p>Indicated for the active immunisation of individuals, against <i>Haemophilus influenzae</i> type b and meningococcal group C disease:</p> <ul style="list-style-type: none"> from their first birthday to under 10 years of age who were born on or before 30 June 2024 to individuals of any age for the prevention of secondary cases of meningococcal group C disease <p>Vaccination is to be given in accordance with the national immunisation programme; recommendations given in Chapter 16 and Chapter 22 of Immunisation Against Infectious Disease: the Green Book and guidance for public health management of meningococcal disease in the UK.</p>
Criteria for inclusion	<p>Individuals:</p> <ul style="list-style-type: none"> are aged from their first birthday to under 10 years of age, born on or before 30 June 2024 and require a booster or primary dose of MenC and a Hib booster (this immunisation is usually offered on or after their first birthday) are aged from their first birthday to under 10 years of age, born on or before 30 June 2024 and who are unimmunised or incompletely immunised against <i>Haemophilus influenzae</i> type b or MenC of any age requiring vaccination for the prevention of secondary cases of MenC disease, following specific advice from UKHSA Health Protection Teams
Criteria for exclusion²	<p>Individuals for whom no valid consent has been received (or for whom a best-interests decision in accordance with the Mental Capacity Act 2005, has not been obtained). For further information on consent, see Chapter 2 of the Green Book. Several resources are available to inform consent (see written information to be given to individual, parent or carer section).</p> <p>Individuals who:</p> <ul style="list-style-type: none"> (in cases of routine immunisation) were born on or after 1 July 2024 are less than one year of age, unless indicated for the prevention of secondary cases of MenC disease are aged 10 years and over, unless indicated for the prevention of secondary cases of MenC disease have had a confirmed anaphylactic reaction to a previous dose of Hib or MenC-containing vaccine or to any components of the vaccine, such as tetanus toxoid (used as a carrier protein in Menitorix[®]) are suffering from acute severe febrile illness. The presence of a minor infection or illness without fever or systemic upset are not contraindications to immunisation
Cautions including any relevant action to be taken (continued over page)	<p>Facilities for management of anaphylaxis should be available at all vaccination premises (see Chapter 8 of the Green Book and advice issued by the Resuscitation Council UK).</p> <p>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, paraesthesia and tonic-clonic limb movements during recovery. It is important that procedures are in place to avoid injury from faints.</p> <p>If a seizure associated with a fever occurred within 72 hours of a previous immunisation, immunisation should continue as recommended if a cause is</p>

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

<p>Cautions including any relevant action to be taken</p> <p>(continued)</p>	<p>identified or the individual recovers within 24 hours. However, if no underlying cause has been found and the individual did not recover completely within 24 hours, further immunisation should be deferred until the condition is stable (as assessed by an appropriate clinician such as their GP or paediatrician).</p> <p>The immunogenicity of the vaccine could be reduced in immunosuppressed subjects. Vaccination should proceed in accordance with the national recommendations. However, reimmunisation may need to be considered. Seek medical advice as appropriate.</p>
<p>Action to be taken if the individual is excluded</p>	<p>Individuals born on or after 1 July 2024 will not be offered Hib/MenC as part of their routine vaccinations, as they will instead be offered a fourth dose of hexavalent vaccine at 18 months of age, in line with the planned changes to the childhood immunisation schedule, starting 1 January 2026 (see the DTaP/IPV/Hib/HepB hexavalent PGD).</p> <p>If aged less than one year, Hib/MenC is not routinely indicated.</p> <p>If the individual is aged 10 years and over or has received a dose of Hib and MenC conjugate-containing vaccine from one year of age, Hib/MenC immunisation is not indicated unless the individual requires immunisation for the prevention of secondary cases of MenC disease.</p> <p>Individuals who have had a confirmed anaphylactic reaction to a previous dose of Hib/MenC vaccine or any of its components should be referred to a clinician for specialist advice and appropriate management.</p> <p>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.</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>Inform or refer to the individual's GP or a prescriber as appropriate.</p>
<p>Action to be taken if the individual or carer declines treatment</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 and recorded appropriately. Where a person lacks the capacity, in accordance with the Mental Capacity Act 2005, a decision to vaccinate may be made in the individual's best interests. For further information on consent, see Chapter 2 of the Green Book.</p> <p>Advise the individual, parent or 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>Inform or refer to the GP or a prescriber as appropriate.</p>
<p>Arrangements for referral for medical advice</p>	<p>As per local policy</p>

5. Description of treatment

Name, strength and formulation of drug	<p>Menitorix® powder in vial and solvent for solution for injection in a prefilled syringe.</p> <p>After reconstitution, each 0.5ml dose contains:</p> <table border="0"> <tr> <td><i>Haemophilus</i> type b polysaccharide (polyribosylribitol phosphate)</td><td>5 micrograms</td></tr> <tr> <td>conjugated to tetanus toxoid as carrier protein</td><td>12.5 micrograms</td></tr> <tr> <td><i>Neisseria meningitidis</i> group C (strain C11) polysaccharide</td><td>5 micrograms</td></tr> <tr> <td>conjugated to tetanus toxoid as carrier protein</td><td>5 micrograms</td></tr> </table>	<i>Haemophilus</i> type b polysaccharide (polyribosylribitol phosphate)	5 micrograms	conjugated to tetanus toxoid as carrier protein	12.5 micrograms	<i>Neisseria meningitidis</i> group C (strain C11) polysaccharide	5 micrograms	conjugated to tetanus toxoid as carrier protein	5 micrograms
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conjugated to tetanus toxoid as carrier protein	5 micrograms								
Legal category	Prescription only medicine (POM)								
Black triangle▼	No								
Off-label use	<p>Administration of Menitorix® to individuals aged 2 years and over is off-label but is indicated until 10 years of age under this PGD in accordance with national recommendations for the vaccination of individuals with uncertain or incomplete immunisation status and Chapter 16 and Chapter 22 of the Green Book.</p> <p>The Menitorix® SPC states it should be used in accordance with official recommendations. The use of Menitorix® to provide a single priming dose of MenC to individuals from their first birthday is not covered by the SPC but is in accordance with national recommendations.</p> <p>The Menitorix® SPC also states the booster dose should be given from the age of 12 months onwards and at least 6 months after the last priming dose. However, when primary vaccination is delayed, the Hib booster dose may be given at the scheduled visit, provided it is at least one month since the last primary dose was administered. This advice is in accordance with national recommendations for the vaccination of individuals with uncertain or incomplete immunisation status.</p> <p>Administration of Hib/MenC for the prevention of secondary cases of MenC disease is not covered by the Menitorix® SPC, but Hib/MenC vaccine may be given as an alternative to MenACWY in accordance with guidance for public health management of meningococcal disease in the UK.</p> <p>Administration of Menitorix® by deep subcutaneous injection to individuals with a bleeding disorder is off-label administration in line with advice in Chapter 4 of the Green Book.</p> <p>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 vaccines are 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 or carer that the vaccine is being offered in accordance with national guidance but outside of product licence.</p>								
Route and method of administration (continued over page)	The vaccine must be reconstituted in accordance with the manufacturer's instructions prior to administration.								

Route and method of administration (continued)	<p>Administer by intramuscular injection, preferably into the anterolateral aspect of the thigh in infants under one year of age. The deltoid muscle 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 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.</p> <p>Individuals with bleeding disorders may be vaccinated intramuscularly if, in the opinion of a clinician 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 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 (without rubbing) for at least 2 minutes. The individual, parent or carer should be informed about the risk of haematoma from the injection.</p> <p>For individuals with an unstable bleeding disorder (or where intramuscular injection is otherwise not considered suitable), vaccines normally given by the intramuscular route should be given by deep subcutaneous injection, in accordance with the recommendations in the Green Book Chapter 4.</p> <p>The vaccine's normal appearance is a white powder and a clear colourless solvent. Following reconstitution, the vaccine is a clear colourless solution.</p> <p>The vaccine should be visually inspected for 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.</p> <p>The vaccine's SPC provides further guidance on preparation and administration.</p>
Dose and frequency of administration (continued over page)	<p>Single 0.5ml dose</p> <p>(i) Routine childhood immunisation schedule (for individuals born on or before 30 June 2024)</p> <p>A single dose to be administered, usually on or after their first birthday, although it may be administered until 10 years of age.</p> <p>When primary vaccination with Hib has been delayed, the Hib booster dose (Hib/MenC) may be given at the scheduled visit, on or after their first birthday, provided it is at least 4 weeks since the last primary Hib dose was administered.</p> <p>(ii) Incomplete immunisation history</p> <p>Individuals born on or before 30 June 2024 from their first birthday to under 10 years of age who have completed a primary course of diphtheria, tetanus, pertussis and polio but have not received Hib containing vaccines should receive a single dose of Hib/MenC vaccine.</p> <p>All unimmunised or incompletely immunised individuals under 10 years of age require one dose of Hib and MenC over the age of one year in accordance with</p>

Dose and frequency of administration (continued)	<p>the vaccination of individuals with uncertain or incomplete immunisation status guidance.</p> <p>(iii) Secondary prevention of MenC disease (individuals of all ages)</p> <p>Vaccination for the prevention of secondary cases of MenC disease should be made in accordance with recommendations from the local UKHSA Health Protection Team and informed by national guidance (see guidance for public health management of meningococcal disease in the UK).</p> <p>Unless they have been vaccinated against MenC in the preceding 12 months, contacts from one year of age should receive one dose of MenC containing vaccine. Where Menitorix® is no longer obtainable and local stocks have expired, another MenC-containing conjugate vaccine may be used in its place, such as MenQuadfi®, Nimenrix® or Menveo®. See the MenACWY PGD for further information.</p> <p>Individuals less than one year of age should receive a total of 2 doses of MenC-containing vaccine, one month apart. This includes individuals born on or after 1 July 2024 requiring protection from outbreaks, who are otherwise excluded from routine vaccination under this PGD. See also special considerations and additional information section (impact of the childhood changes programme from 1 July 2025).</p>
Duration of treatment	<p>A single dose from one year of age or</p> <p>a 2 dose course for contacts under one year of age, with the second dose given at an interval of at least 4 weeks.</p> <p>Other meningococcal vaccines (such as MenACWY) are used for subsequent routine boosters in adolescence.</p>
Quantity to be supplied and administered	<p>Single 0.5ml dose per administration.</p>
Supplies	<p>Centrally purchased vaccines for the national immunisation programme can only be ordered via ImmForm. Vaccines for use for the national immunisation programme are provided free of charge.</p> <p>Vaccines for the management of contacts of MenC disease should be obtained from the manufacturer or their wholesalers.</p> <p>Menitorix® is manufactured by GSK and available from AAH Pharmaceuticals (www.vaccines.co.uk).</p> <p>Protocols for the ordering, storage and handling of vaccines should be followed to prevent vaccine wastage (see Green Book Chapter 3).</p>
Storage (continued over page)	<p>Store at +2°C to +8°C.</p> <p>Store in original packaging in order to protect from light. Do not freeze.</p> <p>After reconstitution, the vaccine should ideally be administered promptly or kept between +2°C to +8°C and used within 24 hours. Experimental data show that the reconstituted vaccine could also be kept up to 24 hours at ambient temperature (25°C). If not used within 24 hours, do not administer the vaccine</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 on a case-by-case basis for suitability of continued off-label use or appropriate disposal. Refer to Vaccine Incident Guidance.</p>

Storage (continued)	Contact the vaccine manufacturer where more specific advice is required about managing a temperature excursion.
Disposal	<p>Follow local clinical waste policy and NHS standard operating procedures to ensure safe and secure waste disposal.</p> <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 waste disposal arrangements and NHSE guidance (HTM 07-01): safe and sustainable management of healthcare waste.</p>
Drug interactions	<p>The immunological response may be diminished in those receiving immunosuppressive treatment. Vaccination is recommended even if the antibody response may be limited.</p> <p>Hib/MenC may be given at the same time as other vaccines.</p> <p>A detailed list of drug interactions is available from the SPC.</p>
Identification and management of adverse reactions	<p>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.</p> <p>Mild side effects such as irritability, decreased appetite, drowsiness and slightly raised temperature commonly occur. Crying, diarrhoea, vomiting, atopic dermatitis, rash, and fever over 39.5°C have been uncommonly reported.</p> <p>Hypersensitivity reactions and anaphylaxis can occur but are very rare.</p> <p>A detailed list of adverse reactions is available from the vaccine's SPC.</p>
Reporting procedure of adverse reactions	<p>Healthcare professionals and individuals, parents or carers are encouraged to 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.</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>
Written information to be given to individual, parent or carer	<p>Offer the marketing authorisation holder's patient information leaflet (PIL) provided with the vaccine.</p> <p>For resources in accessible formats and alternative languages, please visit Home- Health Publications.</p> <p>Immunisation promotional material may be provided as appropriate:</p> <ul style="list-style-type: none"> • a guide to immunisation for babies up to 13 months of age • immunisations at one year of age <p>For parents of children under 12 months who are contacts of cases:</p> <ul style="list-style-type: none"> • why is my child being offered an 'off-label' vaccine <p>Where applicable, inform the individual or carer that large print, Braille or audio CD PILs may be available from emc accessibility (freephone 0800 198 5000) by providing the medicine name and product code number, as listed on the product SPC.</p>
Advice and follow up treatment (continued over page)	<p>Inform the individual, parent or carer of possible side effects and their management.</p> <p>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</p>

<p>Advice and follow up treatment (continued)</p>	<p>scheme.</p> <p>Where applicable, advise the individual, parent or carer when the subsequent dose is due.</p> <p>When administration is postponed advise the individual, parent or carer when to return for vaccination.</p>
<p>Special considerations and additional information</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>2 Hib containing vaccines may be given at the same time (such as Hib/MenC and DTaP/IPV/Hib/HepB) when required to catch up immunisations in individuals who are unimmunised or incompletely immunised (see vaccination of individuals with uncertain or incomplete immunisation status).</p> <p>Meningococcal and Hib-containing vaccines may be given to pregnant women when clinically indicated. There is no evidence of risk from vaccinating pregnant women or those who are breast-feeding with inactivated bacterial vaccines. The occurrence of apnoea following vaccination is especially increased in infants who were born very prematurely. For guidance, see Chapter 7 of the Green Book.</p> <p>Impact of the childhood changes programme from 1 July 2025</p> <p>For individuals who are born on or after 1 July 2024, the routine vaccination offer of a combined Hib/MenC vaccine no longer applies. These individuals should instead be offered a dose of infant hexavalent vaccine from 18 months of age. Refer to the DTaP/IPV/Hib/HepB PGD.</p> <p>Practitioners must remain vigilant to the fact that individuals born on or before 30 June 2024 <u>continue</u> to be eligible for the routine Hib/MenC vaccination offer beyond 1 July 2025. Hib/MenC should continue to be offered under this PGD to this group of individuals as part of their routine immunisation schedule, until such time that locally held stocks have expired and Hib/MenC is no longer obtainable via ImmForm.</p> <p>Once all stocks of Menitorix® are exhausted, a dose of hexavalent vaccine should be offered to the unimmunised individual (see also the DTaP/IPV/Hib/HepB PGD).</p> <p>For other indications covered under the criteria for inclusion, such as in managing outbreaks of invasive meningococcal disease and protection against serogroup C is indicated, Hib/MenC may continue to be offered whilst it is still available via ImmForm or local supplies remain in date. Beyond this point, individuals may be vaccinated with an alternative capsular conjugate MenC vaccine, such as the MenACWY vaccine. Refer to the MenACWY PGD for further information.</p> <p>There may be a small number of individuals born on or after 1 July 2024, who were given a single dose of Hib/MenC prior to 1 July 2025 when aged under one year of age, such as in managing an outbreak case. Offering a completing dose of Hib/MenC at least one month after the previous dose is required and may be given under this PGD.</p> <p>Hib/MenC vaccine is no longer expected to be in circulation beyond April 2026.</p> <p>An interval of at least 4 weeks is preferable between Hib/MenC and MenACWY vaccination, to further boost immune response to the MenC component. Where MenACWY vaccination is urgently required – for example, as part of outbreak response, or if there is a concern that the child may be lost to follow up, both vaccines may be given together. See the MenACWY or MenACWY risk groups PGD.</p>

Records	<p>The practitioner must ensure the following is recorded:</p> <ul style="list-style-type: none"> • 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 • 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 <p>Records should be signed and dated (or password-controlled 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 Services team must be notified using the appropriate documentation or 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>
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6. Key references

Key references	<p>Hib/MenC vaccine</p> <ul style="list-style-type: none">• Immunisation Against Infectious Disease: the Green Book Chapter 16, last updated 19 April 2013 and Chapter 22• Summary of Product Characteristic for Menitorix®, GlaxoSmithKline https://www.medicines.org.uk/emc/product/167, last updated 1 October 2024• Vaccination of individuals with uncertain or incomplete immunisation status https://www.gov.uk/government/publications/vaccination-of-individuals-with-uncertain-or-incomplete-immunisation-status• Guidance for public health management of meningococcal disease in the UK, updated November 2024 https://www.gov.uk/government/publications/meningococcal-disease-guidance-on-public-health-management• Changes to the routine childhood schedule letter, published 30 April 2025 https://www.gov.uk/government/publications/changes-to-the-routine-childhood-schedule-letter <p>General</p> <ul style="list-style-type: none">• NHSE Health Technical Memorandum 07-01: safe and sustainable management of healthcare waste, updated 7 March 2023 https://www.england.nhs.uk/publication/management-and-disposal-of-healthcare-waste-hm-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, updated March 2017 https://www.nice.org.uk/guidance/mpg2• NICE MPG2 Patient group directions: competency framework for health professionals using patient group directions, updated January 2018 https://www.nice.org.uk/guidance/mpg2/resources• 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
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7. Practitioner authorisation sheet

Hib/MenC PGD v6.0

Valid from: 1 July 2025

Expiry: 30 April 2026

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 practice 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.