



Publications gateway number: GOV-12448

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: v05.00
Valid from: 31 July 2022
Review date: 29 February 2024
Expiry date: 1 August 2024

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'. Only sections 2 and 7 can be amended within the designated editable fields provided.

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

Individual practitioners must be authorised by name, under the current version of this PGD before working according to it.

Practitioners and organisations must check that they are using the current version of the PGD. Amendments may become necessary prior to the published expiry date. Current versions of UKHSA PGD templates for authorisation can be found from:

<https://www.gov.uk/government/collections/immunisation>

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

¹ This includes any relevant amendments to legislation (such as [2013 No.235](#), [2015 No.178](#) and [2015 No.323](#)).
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Enquiries relating to the availability of organisationally authorised PGDs and subsequent versions of this PGD should be directed to: england.lancashiresit@nhs.net for Lancashire and South Cumbria and england.cm-imms@nhs.net for Cheshire and Merseyside.

Change history

Version number	Change details	Date
V01.00	New PHE PGD template	19 January 2016
V02.00	PHE Hib/MenC PGD amended to: <ul style="list-style-type: none"> • reflect the removal of monovalent MenC vaccination from the routine childhood programme from 1 July 2016 • allow Hib/MenC to be used for MenC catch-up for individuals under 10 years of age • amend the eligibility criteria to “from the first birthday” rather than “from 12 months” • reference the protocol for ordering storage and handling of vaccines • update wording regarding authorisation in line with agreed PHE PGD template changes • include minor rewording, layout and formatting changes for clarity and consistency with other PHE PGD templates 	20 July 2016
V03.00	PHE Hib/MenC PGD amended to: <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
V04.00	PHE Hib/MenC PGD amended to: <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
V05.00	UKHSA Hib/MenC PGD amended to: <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

1. PGD development

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

Developed by:	Name	Signature	Date
Pharmacist (Lead Author)	Suki Hunjunt Lead Pharmacist Immunisation Services, Immunisation and Vaccine Preventable Diseases Division, UKHSA		4 May 2022
Doctor	Mary Ramsay Consultant Epidemiologist, Immunisation and Vaccine Preventable Diseases Division, UKHSA		4 May 2022
Registered Nurse (Chair of Expert Panel)	David Green Nurse Consultant, Immunisation and Vaccine Preventable Diseases Division, UKHSA		4 May 2022

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

Expert Panel

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

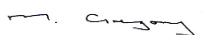
2. Organisational authorisations

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 - North West authorises this PGD for use by the services or providers listed below:

Authorised for use by the following organisations and/or services
Immunisation services in Lancashire, South Cumbria, Cheshire and Merseyside commissioned by NHS England - North West.
Limitations to authorisation
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 groups they are commissioned to immunise.

Organisational approval (legal requirement)			
Role	Name	Sign	Date
Regional Medical Director, NHS England - North West	Dr Michael Gregory		05/07/2022

Additional signatories according to locally agreed policy			
Role	Name	Sign	Date
Adoption by Independent Contractor/Provider			

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

england.lancshiresit@nhs.net for Lancashire and South Cumbria providers and
england.cm-imms@nhs.net for Cheshire and Merseyside providers.

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>Qualifications and professional registration</p>	<p>Registered professional with one of the following bodies:</p> <ul style="list-style-type: none"> nurses and midwives currently registered with the Nursing and Midwifery Council (NMC) pharmacists currently registered with the General Pharmaceutical Council (GPhC) (Note: This PGD is not relevant to privately provided community pharmacy services) paramedics and physiotherapists currently registered with the Health and Care Professions Council (HCPC) <p>The practitioners above must also fulfil the Additional requirements detailed below.</p> <p>Check Section 2 Limitations to authorisation to confirm whether all practitioners listed above have organisational authorisation to work under this PGD.</p>
<p>Additional requirements</p>	<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 health professionals using PGDs) must be familiar with the vaccine product and alert to changes in the Summary of Product Characteristics (SPC), Immunisation Against Infectious Disease (the 'Green Book'), and national and local immunisation programmes must have undertaken training appropriate to this PGD as required by local policy and in line with the National Minimum Standards and Core Curriculum for Immunisation Training must be competent to undertake immunisation and to discuss issues related to immunisation must be competent in the handling and storage of vaccines, and management of the cold chain must be competent in the recognition and management of anaphylaxis must have access to the PGD and associated online resources should fulfil any additional requirements defined by local policy <p>The individual practitioner must be authorised by name, under the current version of this PGD before working according to it.</p>
<p>Continued training requirements</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 the UKHSA and/or NHSEI 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>Clinical condition or situation to which this PGD applies</p>	<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 • 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>
<p>Criteria for inclusion</p>	<p>Individuals who:</p> <ul style="list-style-type: none"> • are aged from their first birthday to under 10 years of age 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 and are unimmunised or incompletely immunised against <i>Haemophilus influenzae</i> type b or MenC • require vaccination for the prevention of secondary cases of MenC disease, following specific advice from UKHSA Health Protection Teams
<p>Criteria for exclusion²</p>	<p>Individuals for whom no valid consent has been received.</p> <p>Individuals who:</p> <ul style="list-style-type: none"> • are less than 1 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, including any conjugate vaccines where tetanus toxoid is used in the conjugate. • are suffering from acute severe febrile illness (the presence of a minor infection or minor illnesses without fever or systemic upset are not a contraindication for immunisation)
<p>Cautions including any relevant action to be taken</p> <p>Continued over page</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 identified or the child recovers within 24 hours. However, if no underlying cause has been found and the child 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, re-immunisation may need to be considered. Seek medical advice as appropriate.</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 (continued)</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>Action to be taken if the patient is excluded</p>	<p>If aged less than 1 year, Hib/MenC is not routinely indicated.</p> <p>If aged 10 years and over or has received a dose of Hib and MenC conjugate containing vaccine from 1 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 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 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 GP or a prescriber as appropriate.</p>
<p>Action to be taken if the patient 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.</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>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>

Dose and frequency of administration (continued)	<p>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.</p> <p>Individuals less than one year of age should receive two doses of MenC containing vaccine one month apart.</p>
Duration of treatment	<p>A single dose from 1 year of age or a two dose course for contacts under 1 year of age.</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>Vaccine for the management of contacts of MenC disease should ideally be ordered from the manufacturer/wholesalers.</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	<p>Store between +2°C to +8°C.</p> <p>Store in original packaging in order to protect from light.</p> <p>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 it is 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 for suitability of continued off-label use or appropriate disposal. Refer to Vaccine Incident Guidance.</p>
Disposal	<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 arrangements and guidance in the technical memorandum 07-01: Safe management of healthcare waste (Department of Health, 2013).</p>
Drug interactions	<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.</p>

<p>Identification and management of adverse reactions</p>	<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, loss of appetite, drowsiness and slightly raised temperature commonly occur. Less commonly crying, insomnia, abdominal pain, diarrhoea, vomiting, atopic dermatitis, rash, malaise and fever over 39.5°C have been reported.</p> <p>Hypersensitivity reactions and anaphylaxis can occur but are very rare.</p> <p>A detailed list of adverse reactions is available in the vaccine's SPC, which is available from the electronic Medicines Compendium website</p>
<p>Reporting procedure of adverse reactions</p>	<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 or search 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>
<p>Written information to be given to patient or carer</p>	<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"> • A guide to immunisation for babies born on or after 1 January 2020 • Immunisations at one year of age <p>Available from: www.gov.uk/government/collections/immunisation</p>
<p>Patient advice and follow up treatment</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>When administration is postponed advise the individual/parent/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>Two 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 un- 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>Records</p>	<p>Record:</p> <ul style="list-style-type: none"> • that valid informed consent was given • name of individual, address, date of birth and GP with whom the individual is registered • name of immuniser • name and brand of vaccine • date of administration • dose, form and route of administration of vaccine • quantity administered • batch number and expiry date • anatomical site of vaccination • advice given, including advice given if excluded or declines immunisation • details of any adverse drug reactions and actions taken • supplied via PGD <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 Services team 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>
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6. Key references

Key references	Hib/MenC vaccine <ul style="list-style-type: none">• Immunisation Against Infectious Disease: The Green Book Chapter 16, last updated 19 April 2013, and Chapter 22, last updated 20 September 2016. https://www.gov.uk/government/collections/immunisation-against-infectious-disease-the-green-book• Summary of Product Characteristic for Menitorix®, GlaxoSmithKline. https://www.medicines.org.uk/emc/product/167 6 May 2020.• Vaccination of individuals with uncertain or incomplete immunisation status. 17 March 2022. 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 Updated August 2019. https://www.gov.uk/government/publications/meningococcal-disease-guidance-on-public-health-management General <ul style="list-style-type: none">• Health Technical Memorandum 07-01: Safe Management of Healthcare Waste. Department of Health 20 March 2013 https://www.england.nhs.uk/publication/management-and-disposal-of-healthcare-waste-htm-07-01/• National Minimum Standards and Core Curriculum for Immunisation Training. Published February 2018. https://www.gov.uk/government/publications/national-minimum-standards-and-core-curriculum-for-immunisation-training-for-registered-healthcare-practitioners• NICE Medicines Practice Guideline 2 (MPG2): Patient Group Directions. Published March 2017. https://www.nice.org.uk/guidance/mpg2• NICE MPG2 Patient group directions: competency framework for health professionals using patient group directions. Updated March 2017. https://www.nice.org.uk/guidance/mpg2/resources• 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 v05.00 Valid from: 31 July 2022 Expiry: 1 August 2024

Before signing this PGD, check that the document has had the necessary authorisations in section two. Without these, this PGD is not lawfully valid.

Practitioner

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

PGDs do not remove inherent professional obligations or accountability.

It is the responsibility of each professional to practise only within the bounds of their own competence and professional code of conduct.

I confirm that I have read and understood the content of this PGD and that I am willing and competent to work to it within my professional code of conduct.			
Name	Designation	Signature	Date

Authorising manager

I confirm that the practitioners named above have declared themselves suitably trained and competent to work under this PGD. I give authorisation on behalf of <u>insert name of organisation</u> 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.