



PHE publications gateway number: 2018057

PATIENT GROUP DIRECTION (PGD)

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 *Haemophilus influenzae* type b and meningococcal C conjugate vaccine (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: v03.00
Valid from: 1 August 2018
Review date: 1 February 2020
Expiry date: 31 July 2020

Public Health England has developed this PGD template to facilitate the delivery of publicly funded immunisations in line with national recommendations.

Those using this PGD must ensure that it is organisationally authorised and signed in Section 2 by an appropriate authorising person, relating to the class of person by whom the product is to be supplied, in accordance with Human Medicines Regulations 2012 (HMR2012)¹. **THE PGD IS NOT LEGAL OR VALID WITHOUT SIGNED AUTHORISATION IN ACCORDANCE WITH [HMR2012 SCHEDULE 16 Part 2](#).**

Authorising organisations must not alter, amend or add to the clinical content of this document (sections 4, 5 and 6); such action will invalidate the clinical sign-off with which it is provided. In addition authorising organisations must not alter section 3 'Characteristics of staff'. Only sections 2 and 7 can be amended.

Operation of this PGD is the responsibility of commissioners and service providers.

INDIVIDUAL PRACTITIONERS MUST BE AUTHORISED BY NAME, UNDER THE CURRENT VERSION OF THIS PGD BEFORE WORKING ACCORDING TO IT.

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

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

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


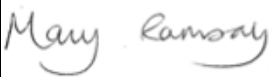

¹ This includes any relevant amendments to legislation (eg [2013 No235](#), [2015 No.178](#) and [2015 No.323](#)).

Change history

Version number	Change details	Date
V01.00	New PHE PGD template	19/01/2016
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 	20/07/2016
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 	24/04/2018

1. PGD template development

This PGD template has been developed by the following health professionals on behalf of Public Health England:

Developed by:	Name	Signature	Date
Pharmacist (Lead Author)	Elizabeth Graham Lead Pharmacist Immunisation Services, PHE		27/04/2018
Doctor	Mary Ramsay Consultant Epidemiologist and Head of Immunisation, Hepatitis & Blood Safety Department, PHE		26/04/2018
Registered Nurse (Chair of Expert Panel)	David Green Nurse Consultant – Immunisations, PHE		26/04/2018

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

Expert Panel

Name	Designation
Ed Gardner	Advanced Paramedic Practitioner/Emergency Care Practitioner, Medicines Manager, Proactive Care Lead
Shamez Ladhani	Paediatric Infectious Disease Consultant, Public Health England
Jacqueline Lamberty	Lead Pharmacist Medicines Management Services, Public Health England
Vanessa MacGregor	Consultant in Communicable Disease Control, Public Health England, East Midlands Health Protection Team
Alison Mackenzie	Consultant in Public Health Medicine, Screening and Immunisation Lead, Public Health England / NHS England South (South West)
Gill Marsh	Senior Screening and Immunisation Manager Public Health England / NHS England Lancashire and South Cumbria
Lesley McFarlane	Screening and Immunisation Co-ordinator (SIC) NHS England Leicestershire, Lincolnshire and Northamptonshire
Sally Millership	Consultant in Communicable Disease Control, Public Health England, East of England Health Protection Team
Tushar Shah	Pharmacy Advisor, NHS England London Region
Kelly Stoker	Senior Health Protection Nurse, North East Health Protection Team, Public Health England Centre North East
Sharon Webb	Programme Manager/Registered Midwife, NBHS Infectious Diseases in Pregnancy Screening Programme, Public Health England
Helen Wilkinson	Deputy Head of Medicines Management, NHS South Gloucestershire Clinical Commissioning Group

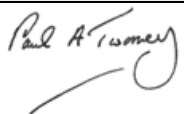
2. Organisational authorisations


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

Authorised for use by the following organisations and/or services
<p>The PGD has been authorised following NHS England's governance processes so that it meets the legal requirements for PGDs. The PGD has been authorised as a Yorkshire and the Humber Local Office wide PGD for the Administration of 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</p> <p>Authorisation is limited to those registered practitioners listed in Section 3 where they are directly employed by organisations/providers commissioned by NHS England North (Yorkshire and the Humber).</p> <p>Paramedics are excluded from the use of this PGD as this service is not commissioned by NHS England North (Yorkshire and the Humber).</p> <p>In accordance with NICE Medicines Practice Guideline for PGDs, it is recommended as good practice that the PGD be formally adopted by the Governance Lead within each provider organisation signing the additional signatory's box (page 5). Individual practitioners working under the PGD must be authorised to do so by their employing organisation.</p> <p>This PGD has been reviewed by designated members of the NHSE Y&H PGD steering group.</p>
Limitations to authorisation
<p>Each practitioner is professionally accountable for ensuring they have undergone appropriate training, are competent to vaccinate and understand the contents of this PGD and the requirements of the individual vaccination programme, including route of administration, eligibility criteria, exclusions and contra-indications etc</p>

Organisational approval (legal requirement)			
Role	Name	Sign	Date
Medical Director/Governance Lead – NHS England North (Yorkshire and the Humber)	Paul Twomey		25.07.18

Additional signatories according to locally agreed policy			
Role	Name	Sign	Date
Lead Pharmacist Medicines Management Team, NHS Barnsley Clinical Commissioning Group	Caron Applebee		20.07.18

Screening and Immunisation Coordinator PHE Yorkshire and the Humber, NHS England North (Yorkshire and the Humber)	Sarah Dearns		09.07.18
Screening and Immunisation Lead - PHE Yorkshire and the Humber, NHS England North (Yorkshire and the Humber)	Phil Kirby		17.07.2018
Organisational Governance Lead			

Local enquiries regarding the use of this PGD may be directed to your local screening and immunisation team or the Health Protection Team Acute Response Centre (ARC): Contact Number: **0113 3860 300**

Section 7 provides a practitioner authorisation sheet. Individual practitioners must be authorised by name to work to this PGD. Alternative practitioner authorisation sheets may be used where appropriate in accordance with local policy but this should be an individual agreement or a multiple practitioner authorisation sheet as included at the end of this PGD.

3. Characteristics of staff

<p>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 Public Health England and/or NHS England and other sources of medicines information.</p> <p>Note: The most current national recommendations should be followed but a Patient Specific Direction (PSD) may be required to administer the vaccine in line with updated recommendations that are outside the criteria specified in this PGD.</p>

4. Clinical condition or situation to which this PGD applies

<p>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, from their first birthday to under 10 years of age; and to individuals of any age for the prevention of secondary cases of meningococcal group C disease, 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 Men C disease, following specific advice from Public Health England Health Protection Teams <p>Note: Individuals with an underlying medical condition which puts them at increased risk from <i>Haemophilus influenzae</i> type b and/or <i>Neisseria meningitidis</i> capsular group C, ie individuals with asplenia, splenic dysfunction or complement disorders (including those on, or to receive, complement inhibitor treatment ie eculizumab), may require additional ‘routine’ vaccination outside the inclusion criteria for this PGD - see Hib/MenC Risk Groups PGD, MenACWY Risk Groups PGD and Chapter 7 of “The Green Book”.</p>
<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 Men C 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 is 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 eg GP or paediatrician).</p>

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

<p>Cautions including any relevant action to be taken (continued)</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> <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 and incompletely immunised, assess for immunisation in accordance with PHE recommendations for the vaccination of individuals with uncertain or incomplete immunisation status – a PSD may be required. If immunisations are up to date inform the patient/carer when next immunisations are due in accordance with the routine schedule.</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 or is at increased risk of invasive Hib disease. Individuals at risk of invasive Hib disease should be vaccinated in accordance with the recommended schedules in Chapter 7, Chapter 16 and Chapter 22 of “The Green Book”, see PHE Hib/MenC Risk Groups PGD.</p> <p>Individuals suffering acute severe febrile illness should postpone immunisation until they have recovered; immunisers should advise when the individual can be vaccinated and ensure another appointment is arranged.</p> <p>Seek appropriate advice from the local Screening and Immunisation Team, local Health Protection Team or the individual’s clinician as required.</p> <p>The risk to the individual of not being immunised must be taken into account.</p> <p>Document the reason for exclusion and any action taken in the individual’s clinical records.</p> <p>In a GP practice setting, inform or refer to the GP or a prescriber as appropriate.</p>
<p>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>In a GP practice setting, inform or refer to the GP as appropriate.</p>
<p>Arrangements for referral for medical advice</p>	<p>As per local policy</p>

5. Description of treatment

Name, strength & formulation of drug	<p><i>Haemophilus influenzae</i> type b and meningococcal group C conjugate vaccine (conjugated to tetanus toxoid as carrier protein) eg:</p> <ul style="list-style-type: none"> • Menitorix[®], powder in vial and solvent for solution for injection in a prefilled syringe
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 PHE recommendations for the vaccination of individuals with uncertain or incomplete immunisation status and the relevant chapters of “The Green Book”.</p> <p>The Menitorix[®] SPC states “Menitorix[®] 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 PHE recommendations following advice from JCVI (see MenC vaccination schedule: planned changes from July 2016).</p> <p>The Menitorix[®] SPC also states “The timing of the booster dose should be from the age of 12 months onwards and at least 6 months after the last priming dose.” However, when primary vaccination has been delayed, the Hib booster dose may be given at the scheduled visit provided it is at least 1 month since the last primary dose was administered in accordance with PHE 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 PHE Guidance for Public Health Management of Meningococcal Disease in the UK.</p> <p>Administration of Menitorix[®] by deep subcutaneous injection to patients with a bleeding disorder is off-label administration in line with advice in Chapter 4 and Chapter 22 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 PHE Vaccine Incident Guidance. Where vaccine is assessed in accordance with these guidelines as appropriate for continued use this would constitute off-label administration under this PGD.</p> <p>Where a vaccine is recommended off-label consider, as part of the consent process, informing the individual/parent/carer that the vaccine is being offered in accordance with national guidance but that this is outside the product licence.</p>

Continued over page

<p>Route / method of administration</p>	<p>The vaccine must be reconstituted in accordance with the manufacturer's instructions prior to administration.</p> <p>Administer by intramuscular injection. The deltoid region of the upper arm may be used in individuals over one year of age. The anterolateral aspect of the thigh should be used for infants under one year vaccinated for the prevention of secondary cases of MenC disease.</p> <p>When administering at the same time as other vaccines, care should be taken to ensure that the appropriate route of injection is used for all the vaccinations. The vaccines should be given at separate sites, preferably in different limbs. If given in the same limb, they should be given at least 2.5cm apart. The site at which each vaccine was given should be noted in the individual's records.</p> <p>For individuals with a bleeding disorder, vaccines normally given by an intramuscular route should be given by deep subcutaneous injection to reduce the risk of bleeding (see "The Green Book" 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 discoloration prior to administration. In the event of any foreign particulate matter and/or variation of physical aspect being observed, do not administer the vaccine.</p> <p>The vaccine's SPC provides further guidance on administration and is available from the electronic Medicines Compendium website: www.medicines.org.uk</p>
<p>Dose and frequency of administration</p> <p>continued over page</p>	<p>Single 0.5ml dose</p> <p>Routine Childhood Immunisation Schedule</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 1 month since the last primary Hib dose was administered.</p> <p>Incomplete immunisation history</p> <p>Children 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 children under 10 years of age require one dose of Hib and MenC over the age of 1 year in accordance with the vaccination of individuals with uncertain or incomplete immunisation status flow chart.</p> <p>Secondary prevention of MenC disease</p> <p>Vaccination for the prevention of secondary cases of MenC disease should be in accordance with recommendations from the local Public Health England Health Protection Team and informed by the Public Health England Guidance for Public Health Management of</p>

Dose and frequency of administration (continued)	Meningococcal Disease in the UK. 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. Individuals less than one year of age should receive two doses of MenC containing vaccine one month apart.
Duration of treatment	A single dose from 1 year of age or a two dose course for contacts under 1 year of age. Other meningococcal vaccines (eg MenACWY) are used for subsequent routine boosters in adolescence.
Quantity to be supplied / administered	Single 0.5ml dose per administration.
Supplies	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. Vaccine for the management of contacts of MenC disease should ideally be ordered from the manufacturer/wholesalers. Protocols for the ordering, storage and handling of vaccines should be followed to prevent vaccine wastage (see protocol for ordering storage and handling of vaccines and Green Book Chapter 3).
Storage	Store between +2°C to +8°C. Store in original packaging in order to protect from light. Do not freeze. 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, it should be discarded. 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 PHE Vaccine Incident Guidance .
Disposal	Equipment used for immunisation, including used vials, ampoules, or discharged vaccines in a syringe or applicator, should be disposed of at the end of a session by sealing in a UN-approved puncture-resistant 'sharps' box, according to local authority regulations and guidance in the technical memorandum 07-01 : Safe management of healthcare waste (Department of Health, 2013).
Drug interactions	Immunological response may be diminished in those receiving immunosuppressive treatment. Vaccination is recommended even if the antibody response may be limited. May be given at the same time as other vaccines. A detailed list of drug interactions is available in the SPC, which is available from the electronic Medicines Compendium website: www.medicines.org.uk

<p>Identification & management of adverse reactions</p>	<p>Local reactions following vaccination are very common ie pain, swelling or redness at the injection site. A small painless nodule may form at the injection site.</p> <p>Mild side effects such as irritability, loss of appetite, drowsiness and slightly raised temperature commonly occur. Less commonly crying, 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: www.medicines.org.uk</p>
<p>Reporting procedure of adverse reactions</p>	<p>Healthcare professionals and patients/carers are encouraged to report suspected adverse reactions to the Medicines and Healthcare products Regulatory Agency (MHRA) using the Yellow Card reporting scheme on: http://yellowcard.mhra.gov.uk</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"> • Immunisations up to 13 months of age <p>Available from: www.gov.uk/government/collections/immunisation</p>
<p>Patient advice / 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 / 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 (ie Hib/MenC and DTaP/IPV/Hib or 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.</p> <p>For further information on preventing secondary cases see the Public Health England Guidance for Public Health Management of Meningococcal Disease in the UK.</p>
<p>Records</p> <p>Continued over page</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

<p>Records (continued)</p>	<ul style="list-style-type: none"> • 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 Patient Group Direction (PGD) <p>Records should be signed and dated (or a password controlled immunisers record on e-records).</p> <p>All records should be clear, legible and contemporaneous.</p> <p>This information should be recorded in the individual's GP record. Where vaccine is administered outside the GP setting appropriate health records should be kept and the individual's GP informed.</p> <p>The local Child Health Information Systems team (Child Health Records Department) must be notified using the appropriate documentation/pathway as required by any local or contractual arrangement.</p> <p>A record of all individuals receiving treatment under this PGD should also be kept for audit purposes in accordance with local policy.</p>
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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, 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. 08 March 2016. http://www.medicines.org.uk/emc/medicine/17189• NHS public health functions agreement 2017-18, Service Specification No.7. Hib/Men C vaccination programme. April 2017. https://www.england.nhs.uk/publication/public-health-national-service-specifications/• Vaccination of individuals with uncertain or incomplete immunisation status. Updated 13 November 2017. 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, Public Health England, updated February 2018. Published 13 March 2018 https://www.gov.uk/government/publications/meningococcal-disease-guidance-on-public-health-management <p>General</p> <ul style="list-style-type: none">• British National Formulary (BNF) www.BNF.org https://bnf.nice.org.uk/drug/haemophilus-influenzae-type-b-with-meningococcal-group-c-vaccine.html• Health Technical Memorandum 07-01: Safe Management of Healthcare Waste. Department of Health 20 March 2013 https://www.gov.uk/government/publications/guidance-on-the-safe-management-of-healthcare-waste• 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. January 2014. https://www.nice.org.uk/guidance/mpg2/resources• PHE Immunisation Collection https://www.gov.uk/government/collections/immunisation• PHE Vaccine Incident Guidance https://www.gov.uk/government/publications/vaccine-incident-guidance-responding-to-vaccine-errors• Protocol for ordering storage and handling of vaccines. April 2014. https://www.gov.uk/government/publications/protocol-for-ordering-storing-and-handling-vaccines
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7. Practitioner authorisation sheet

Hib/MenC PGD v03.00 Valid from: 01/08/2018 Expiry: 31/07/2020

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

Practitioner

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

Patient group directions do not remove inherent professional obligations or accountability.

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

I confirm that I have read and understood the content of this Patient Group Direction and that I am willing and competent to work to it within my professional code of conduct.

Name	Designation	Signature	Date

Authorising manager

I confirm that the practitioners named above have declared themselves suitably trained and competent to work under this PGD. I give authorisation on behalf of **INSERT NAME OF ORGANISATION** for the above named health care professionals who have signed the PGD to work under it.

Name	Designation	Signature	Date

Note to authorising manager

Score through unused rows in the list of practitioners to prevent practitioner additions post managerial authorisation.

This authorisation sheet should be retained to serve as a record of those practitioners authorised to work under this PGD.