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PATIENT GROUP DIRECTION (PGD)

Administration of *Haemophilus influenzae* type b and meningococcal C conjugate vaccine (Hib/MenC) to individuals, from their second birthday, with an underlying medical condition which puts them at increased risk from *Haemophilus influenzae* type b and *Neisseria meningitidis* capsular group C.

This PGD is for the administration of *Haemophilus influenzae* type b and meningococcal C conjugate vaccine (Hib/MenC) by currently registered nurses.

Reference no: Hib/MenC Risk Groups PGD
Version no: v01.00
Valid from: 01 November 2016
Review date: 01 May 2018
Expiry date: 31 October 2018

Public Health England has developed this PGD template to facilitate the delivery of immunisations in the NHS 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 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


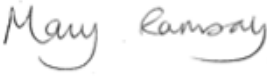

¹ This includes any relevant amendments to legislation (eg [2013 No235](#), [2015 No.178](#) and [2015 No.323](#)).

Change history

Version number	Change details	Date
V01.00	New PHE PGD template	19/10/2016

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		19/10/2016
Doctor	Mary Ramsay Consultant Epidemiologist and Head of Immunisation, Hepatitis & Blood Safety Department, PHE		19/10/2016
Registered Nurse	David Green Nurse Consultant – Immunisations, PHE		19/10/2016

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 PHE Medicines Management Group and PHE Quality and Clinical Governance Steering Group.

Acknowledgements

Name	Designation
Dr Shamez Ladhani	Paediatric Infectious Disease Consultant, Public Health England
Jacqueline Lamberty	Medicines Management Adviser – Public Health England
Alison Mackenzie	Consultant in Public Health Medicine, Screening and Immunisation Lead, Public Health England / NHS England South (South West)
Gill Marsh	Senior Health Protection Nurse Practitioner, Cheshire & Merseyside Health Protection Team, Public Health England
Lesley McFarlane	Screening and Immunisation Co-ordinator (SIC) NHS England Leicestershire, Lincolnshire and Northamptonshire
Sue Mulvenna	Head of Pharmacy - NHS England South West
Graham Munslow	Clinical Screening and Immunisation Manager, NHS England / Public Health England Greater Manchester Health and Social Care partnership
Matthew Olley	Immunisation Manager, Public Health England / NHS England- 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 South (South Central) authorise this PGD for use by the services or providers listed below:

Authorised for use by the following organisations and/or services
All NHS England South (South Central) directly commissioned immunisation services (eg Sirona) providing this vaccination should have this PGD signed by their governance lead prior to use. Provider organisation staff will be expected to follow local policies and procedures.
Limitations to authorisation
None stated.

Organisational approval (legal requirement)			
Role	Name	Sign	Date
Medical Director	Shahed Ahmad		8/2/17

Additional signatories according to locally agreed policy			
Role	Name	Sign	Date

Local enquiries regarding the use of this PGD may be directed to england.southcentral-pgd@nhs.net

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	Registered professional with one of the following bodies: <ul style="list-style-type: none"> nurses currently registered with the Nursing and Midwifery Council (NMC)
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 Patient Group Direction 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 patient group directions) must be familiar with the vaccine product and alert to changes in the Summary of Product Characteristics, 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 for Immunisation Training (2005) 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 Patient Group Direction 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 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

Clinical condition or situation to which this PGD applies	<p>Indicated for the active immunisation of individuals, from their second birthday, with an underlying medical condition which puts them at increased risk from <i>Haemophilus influenzae</i> type b and <i>Neisseria meningitidis</i> capsular group C, in accordance with the recommendations given in Chapter 7, Chapter 16 and Chapter 22 of Immunisation Against Infectious Disease: "The Green Book".</p>
Criteria for inclusion	<p>Individuals who:</p> <ul style="list-style-type: none"> • are asplenic or have splenic dysfunction, including sickle cell disease and coeliac disease with known splenic dysfunction. • have a complement disorder or are receiving complement inhibitor therapy
Criteria for exclusion²	<p>Individuals for whom no valid consent has been received.</p> <p>Individuals who:</p> <ul style="list-style-type: none"> • are less than 2 years of age • have had a confirmed anaphylactic reaction to a previous dose of Hib or MenC containing vaccine or to any components of the vaccine, including tetanus toxoid • have received Hib or MenC containing vaccine in the preceding 4 weeks • are suffering from acute severe febrile illness (the presence of a minor infection is not a contraindication for immunisation)
Cautions including any relevant action to be taken	<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> <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>
Action to be taken if the patient is excluded	<p>For individuals who do not have an underlying medical condition as detailed in the inclusion criteria or require a routine Hib/MenC dose, please refer to the Hib/MenC PGD for the routine immunisation programme.</p> <p>If aged less than 2 years and incompletely immunised, assess for immunisation in accordance with the national schedule, Chapter 7 and PHE recommendations for the vaccination of individuals with uncertain or incomplete immunisation status. If immunisations are up to date inform the patient/carer when next immunisations are due.</p>

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

<p>continued over page</p> <p>Action to be taken if the patient is excluded</p> <p>(continued)</p>	<p>Individuals who have been immunised against Hib or MenC within the last 4 weeks, defer immunisation until at least 4 weeks have elapsed.</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.</p> <p>Seek appropriate advice from the local Screening and Immunisation Team, a Consultant in Health Protection 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 under this PGD in accordance with PHE recommendations for the vaccination of individuals with uncertain or incomplete immunisation status and recommendations for the immunisation of individuals with underlying medical conditions in Chapter 7 of “The Green Book”.</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>Where a vaccine is recommended off-label consider, as part of the consent process, informing the individual/patient/carer that the vaccine is being offered in accordance with national guidance but that this is outside the product licence. Off-label vaccine leaflets may be used to support this information.</p>
Route / method of administration	<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.</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 Summary of Product Characteristics (SPC) provides further guidance on administration and is available from the electronic Medicines Compendium website:</p>

	www.medicines.org.uk
Dose and frequency of administration	<p>Single 0.5ml dose</p> <p>Immunisation of individuals with asplenia, splenic dysfunction (including sickle cell disease and coeliac disease with known splenic dysfunction), complement disorder or receiving complement therapy</p> <p>Individuals under 10 years of age should be fully immunised according to the national schedule (see routine Hib/MenC PGD). They should also receive one additional dose of Hib/MenC after their second birthday.</p> <p>Individuals diagnosed at age 10 years and over should receive one dose of Hib/MenC regardless of their previous vaccination history.</p> <p>Note: The dosing information for at risk individuals in Green Book Chapter 16 (published March 2011) differs from and has been superseded by the advised dosing in Chapter 7 (published Sept 2016).</p> <p>Incomplete immunisation history</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 (see routine Hib/MenC PGD). Individuals under 10 years of age with underlying medical conditions as detailed above also require an additional dose of Hib/MenC over the age of 2 years. Where the routine Hib/MenC dose has been delayed a minimum interval of 4 weeks should elapse between Hib/MenC doses.</p> <p>Individuals now over 10 years of age but diagnosed under 10 years of age and incompletely immunised in that they have not previously received an additional Hib/MenC dose, should receive one dose of Hib/MenC over the age of 10 years.</p> <p>Note: Individuals with underlying medical conditions are also recommended additional vaccination against meningococcal disease (see Chapter 7).</p>
Duration of treatment	<p>Up to two doses of Hib/MenC, at appropriate intervals may be indicated (see Dose and frequency of administration section).</p> <p>Other meningococcal vaccines are used for additional cover against meningococcal disease in accordance with national recommendations and Chapter 7 of "The Green Book".</p>
Quantity to be supplied / administered	Single 0.5ml dose
Supplies	<p>Supplies for additional doses for individuals with underlying medical conditions should be ordered directly from manufacturers.</p> <p>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).</p>

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Storage	<p>Store in a refrigerator between +2°C to +8°C. Store in original packaging in order to protect from light. Do not freeze.</p> <p>After reconstitution, the vaccine should be administered promptly or allowed to stand in a refrigerator (+2°C to +8°C) and used within 24 hours. If not used after this time it should be discarded.</p>
Disposal	<p>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).</p>
Drug interactions³	<p>Immunological response may be diminished in those receiving immunosuppressive treatment.</p> <p>May be given at the same time as other vaccines.</p> <p>A detailed list of drug interactions is available in the Summary of Product Characteristics, which is available from the electronic Medicines Compendium website: www.medicines.org.uk</p>
Identification & management of adverse reactions³	<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 Summary of Product Characteristics, which is available from the electronic Medicines Compendium website: www.medicines.org.uk</p>
Reporting procedure of adverse reactions	<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>
Written information to be given to patient or carer	<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"> • Splenectomy leaflet • Off-label vaccines: a guide for parents <p>Available from: www.gov.uk/government/collections/immunisation</p>

³ Refer to British National Formulary (BNF) and Summary of Product Characteristics (SPC) for complete list

<p>Patient advice / follow up treatment</p>	<p>Inform the individual/carer of possible side effects and their management.</p> <p>The individual/carer should be advised to seek medical advice in the event of an adverse reaction.</p> <p>When administration is postponed advise the individual/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>Minor illnesses without fever or systemic upset are not valid reasons to postpone immunisation. If an individual is acutely unwell, immunisation may be postponed until they have fully recovered.</p> <p>To reduce the risk of vulnerable individuals being exposed to vaccine preventable conditions, all household and close contacts of immunosuppressed individuals should be fully vaccinated according to the national schedule.</p> <p>Two Hib containing vaccines may be given at the same time (ie Hib/MenC and DTaP/IPV/Hib) when required to catch-up immunisations in individuals who are un- or incompletely immunised (see vaccination of individuals with uncertain or incomplete immunisation status). When not provided at the same visit a period of 4 weeks should elapse between immunisations.</p> <p>Hyposplenism in coeliac disease is uncommon in children, and the prevalence correlates with the duration exposure to gluten. Therefore patients diagnosed with coeliac disease early in life and well managed are unlikely to require additional Hib and meningococcal vaccines. Only those with known splenic dysfunction should be offered additional Hib/MenC vaccination.</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 Patient Group Direction (PGD) <p>Records should be signed and dated (or a password controlled</p>

<p>continued over page</p> <p>Records</p> <p>(continued)</p>	<p>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 when vaccine is administered to individuals under 19 years of age.</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">• MenC vaccination schedule: planned changes from July 2016. PHE/NHS England. 24 March 2016. https://www.gov.uk/government/publications/menc-vaccination-schedule-planned-changes-from-july-2016• Immunisation Against Infectious Disease: The Green Book Chapter 16, last updated March 2011, Chapter 22, last updated 20 September 2016 and Chapter 7, last updated 29 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 2016-17, Service Specification No.7. Hib/Men C vaccination programme. 5 February 2016. https://www.england.nhs.uk/commissioning/wp-content/uploads/sites/12/2016/02/serv-spec-07.pdf• Vaccination of individuals with uncertain or incomplete immunisation status. Updated 30 June 2016. https://www.gov.uk/government/publications/vaccination-of-individuals-with-uncertain-or-incomplete-immunisation-status General <ul style="list-style-type: none">• PHE Immunisation Collection https://www.gov.uk/government/collections/immunisation• British National Formulary (BNF) and British National Formulary for Children (BNF-C) www.BNF.org http://www.evidence.nhs.uk/formulary/bnf/current• National Minimum Standards for Immunisation Training (2005) https://www.gov.uk/government/publications/immunisation-training-national-minimum-standards• NICE Medicines Practice Guideline 2 (MPG2): Patient Group Directions. Published August 2013. 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• Immunisation knowledge and skills competence assessment tool. Royal College of Nursing (RCN) 2015. https://www.rcn.org.uk/professional-development/publications/pub-005336• Protocol for ordering storage and handling of vaccines. April 2014. https://www.gov.uk/government/publications/protocol-for-ordering-storing-and-handling-vaccines• 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
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7. Multiple practitioner authorisation sheet

Hib/MenC Risk Groups PGD v01.00 Valid from: 01/11/2016 Expiry: 31/10/2018

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 **NHS England South (South Central)** 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.