This patient group direction (PGD) must only be used by registered health professionals who have been named and authorised by their organisation to practice under it. The most recent and in date final signed version of the PGD should be used.

Patient Group Direction (PGD)

For the administration or supply of

Haemophilus Influenza Type B and Meningococcal C Conjugate Vaccine (Hib/MenC)

By registered health care professionals for

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

Throughout the Manx Care and those contracted by the Manx Care where appropriate within practice

PGD NUMBER 101

Change history (see next page)

1. Change history

Version number	Change details	Date
V01.00	New PHE PGD template	19/01/2016
V02.00	PHE Hib/MenC PGD amended to: • 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: • 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
V04.00	PHE Hib/MenC PGD amended to: • 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	05/03/2020
V05.00	UKHSA Hib/MenC PGD amended to: • 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	04/05/2022

2. Medicines practice guideline 2: *Patient group directions*

Refer to the relevant sections of NICE medicines practice guideline 2: *Patient group directions* as stated in the blank template notes. For further information about PGD signatories, see the NHS and Manx Care PGD website FAQs

3. PGD development

Refer to the NICE PGD competency framework for people developing PGDs

Job Title & organisation	Name	Signature	Date
Author of the PGD			
Member of the PGD working group			

4. PGD authorisation

Refer to the NICE PGD competency framework for people authorising PGDs

Job Title	Name	Signature	Date
Medical Director			
Pharmaceutical Adviser			
Senior Paramedic			
Director of Nursing			
GP Adviser			
Senior Microbiologist (if PGD contains antimicrobials)	n/a	n/a	n/a

5. Training and competency of registered healthcare professionals, employed or contracted by the Manx Care, GP practice or Hospice

Refer to the NICE PGD competency framework for health professionals using PGDs

	Requirements of registered Healthcare professionals working under the PGD
Qualifications and professional registration	• Registered healthcare professionals, working within or contracted by the Manx Care, GP practice or Hospice who are permitted staff groups outlined within the current PGD policy • Pharmacists must be practising in Manx Care authorised premises i.e. contracted pharmacy premises Additionally practitioners: • 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 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)
Initial training	• Knowledge of current guidelines and the administration of the drug specified in this PGD/BNF and of the inclusion and exclusion criteria • Training which enables the practitioner to make a clinical assessment to establish the need for the medication covered by this PGD • Training in the use of PGDs
Competency assessment	Staff will be assessed on their knowledge of drugs and clinical assessment as part the competency framework for registered health professionals using PGDs
Ongoing training and competency	The registered health care professionals should make sure they are aware of any changes to the recommendations for this medication; it is the responsibility of the registered health care professionals to keep up to date with continuing professional development. PGD updates will be held every two years

6. Clinical Conditions

Clinical condition or situation to which this PGD applies	Indicated for the active immunisation of individuals, against Haemophilus influenzae type b and meningococcal group C disease: • 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 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
Inclusion criteria	Individuals who: • 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 *Haemophilus influenzae* 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
Exclusion criteria[1]	Individuals for whom no valid consent has been received. Individuals who: • 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)

[1] 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

Cautions (including any relevant action to be taken)	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). 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. 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.
Action to be taken if the patient is excluded (continued) … **Action to be taken if the patient is excluded** … (continued)	• If aged less than 1 year, Hib/MenC is not routinely indicated. • 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. • 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. • Seek appropriate advice from the local Screening and Immunisation Team, local Health Protection Team or the individual's clinician as required. • The risk to the individual of not being immunised must be taken into account. • Document the reason for exclusion and any action taken in the individual's clinical records. • Inform or refer to the GP or a prescriber as appropriate.
Arrangements for referral for medical advice	Patient should be referred to a more experienced clinical practitioner for further assessment
Action to be taken if patient excluded	Patient should be referred to a more experienced clinical practitioner for further assessment

Action to be taken if patient declines treatment	• A verbal explanation should be given to the patient on: the need for the medication and any possible effects or potential risks which may occur as a result of refusing treatment • This information must be documented in the patients' health records • Any patient who declines care must have demonstrated capacity to do so • Where appropriate care should be escalated • Advise the individual/parent/carer about the protective effects of the vaccine, the risks of infection and potential complications • Inform or refer to the GP or a prescriber as appropriate

7. Details of the medicine

Name, form and strength of medicine	*Haemophilus influenzae* type b and meningococcal group C conjugate vaccine (conjugated to tetanus toxoid as carrier protein): Menitorix®, powder in vial and solvent for solution for injection in a prefilled syringe; after reconstitution, each 0.5ml dose contains: *Haemophilus type b polysaccharide* (polyribosylribitol phosphate) — 5micrograms conjugated to tetanus toxoid as carrier protein — 12.5micrograms *Neisseria meningitidis* group C (strain C11) polysaccharide — 5 micrograms conjugated to tetanus toxoid as carrier protein — 5 micrograms
Legal category	Prescription only medicine (POM)
Indicate any off-label use (if relevant) *(continued)*	• 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" • 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) • 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

Indicate any off-label use (if relevant) *(continued)*	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 • 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 • 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" • 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 • 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
Route/method of administration	• The vaccine must be reconstituted in accordance with the manufacturer's instructions prior to administration • 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 • 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) • See Appendix C for more information
Dose and frequency *(continued)*	Single 0.5ml dose **Routine Childhood Immunisation Schedule** • A single dose to be administered, usually on or after their first birthday, although it may be administered until 10 years of age • 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 **Incomplete immunisation history**

Dose and frequency *(continued)*	• 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 • 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 guidance algorithm **Secondary prevention of MenC disease** • Vaccination for the prevention of secondary cases of MenC disease should be in accordance with recommendations from Public Health Protection Team and informed by the Public Health England Guidance for Public Health Management of 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
Quantity to be administered and/or supplied	Single 0.5ml dose per administration.
Maximum or minimum treatment period	• A single dose from 1 year of age or a two dose course for contacts under 1 year of age • Other meningococcal vaccines (such as MenACWY) are used for subsequent routine boosters in adolescence
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

Adverse effects	• 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 • 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 • Hypersensitivity reactions and anaphylaxis can occur but are very rare • 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 • 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: http://yellowcard.mhra.gov.uk • Any adverse reaction to a vaccine should be documented in the individual's record and the individual's GP should be informed
Records to be kept	• The administration of any medication given under a PGD must be recorded within the patient's medical records • See Appendix C for more information

8. Patient information

Verbal/Written information to be given to patient or carer	• Verbal information must be given to patients and or carers for all medication being administered under a PGD • Where medication is being supplied under a PGD, written patient information leaflet must also be supplied • A patient information leaflet is available on request • Offer marketing authorisation holder's patient information leaflet (PIL) provided with the vaccine • Immunisation promotional material may be provided as appropriate: Immunisations up to 13 months of age Available from: www.gov.uk/government/collections/immunisation
Follow-up advice to be given to patient or carer	If symptoms do not improve or worsen or you become unwell, seek medical advice immediately • Inform the individual/parent/carer of possible side effects and their management • The individual/parent/carer should be advised to seek medical advice in the event of an adverse reaction • When administration is postponed advise the individual/parent/carer when to return for vaccination

9. Appendix A

References

1. British National Formulary (BNF) available online: https://bnf.nice.org.uk
2. Nursing and Midwifery "The code" available online: https://www.nmc.org.uk
3. Current Health Care Professions Council standards of practice
4. General Pharmaceutical Council standards
5. The General Optical Council
6. Electronic medicines compendium available online: https://www.medicines.org.uk

Hib/MenC vaccine

- 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

- 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

10. Appendix B

Health professionals agreed to practice
• Each registered healthcare professional will hold their own Competency framework which will be signed and agreed by their mentor • A mentor is defined within the Manx Care policy as any ward/area managers, sisters, senior nurses, GPs, pharmacists or senior paramedics who has completed the PGD training themselves

11. Appendix C

Route/method of administration	• 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 • The vaccine's normal appearance is a white powder and a clear colourless solvent. Following reconstitution the vaccine is a clear colourless solution • 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 • The vaccine's SPC provides further guidance on administration and is available from the electronic Medicines Compendium website: www.medicines.org.uk
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

Records to be kept	Record: • 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) Records should be signed and dated (or a password controlled immunisers record on e-records) All records should be clear, legible and contemporaneous This information should be recorded in the individual's GP record. Where vaccine is administered outside the GP setting appropriate health records should be kept and the individual's GP informed The local Child Health Information Systems team (Child Health Records Department) must be notified using the appropriate documentation/pathway as required by any local or contractual arrangement A record of all individuals receiving treatment under this PGD should also be kept for audit purposes in accordance with local policy
Special considerations/ additional information (continued) …	• Ensure there is immediate access to adrenaline (epinephrine) 1 in 1000 injection and access to a telephone at the time of vaccination • 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) • 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 • For further information on preventing secondary cases see the Public Health England Guidance for Public Health Management of Meningococcal Disease in the UK • Ensure there is immediate access to adrenaline (epinephrine) 1 in 1000 injection and access to a telephone at the time of

Special considerations/ additional information … (continued)	vaccination • 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) • 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