Patient Group Direction (PGD) for

The Administration of Haemophilus influenzae Type B and Meningococcal C Conjugate Vaccine (Hib/MenC) (Brand *Menitorix* ®) to Children aged from 12 months to 10 years by Registered Nurses employed or commissioned by NHS Rotherham who have been certified after completing an agreed training plan.

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Date Uploaded & By Whom:	

Patient Group Directions are written instructions for the supply or administration of medicines to groups of patients who may not be individually identified before presentation for treatment.

The majority of clinical care should be provided on an individual, patient-specific basis. The supply and administration under a PGD should be reserved for those limited situations where this offers an advantage for patient care (without compromising patient safety), and where it is consistent with appropriate professional relationships and accountability.

- Each PGD has a unique identifier allocated by the Prescribing Adviser responsible for the management of Patient Group Directions for the organisation.
- Once a PGD has been given approval, the date on which the PGD comes into effect will be inserted by the Prescribing Adviser prior to submission onto the NHS Rotherham intranet.
- The PGD must be reviewed within two years of authorisation
- PGDs that have failed to be reviewed and re-ratified ***must not*** be used past their expiry date and patient specific direction (prescriptions) must be used to authorise supply of medicines.

The Administration of vaccine Haemophilus influenzae Type B and Meningococcal C Conjugate Vaccine (Hib/MenC) (Brand *Menitorix* ®) to patients aged from 12 months by Registered Nurses employed or contracted by Registered Nurses employed or commissioned by NHS Rotherham who have been certified after completing an agreed training plan.

1. Clinical Condition or situation to which the direction applies

Drug Name: Haemophilus influenzae Type B and Meningococcal C Conjugate Vaccine (Hib/MenC) (*Menitorix*®)

Clinical Indications	For active immunisation against invasive diseases caused by *Haemophilus influenzae type b (Hib)* and *Neisseria meningitidis serotype C (MenC).*
Criteria for Inclusion	Parent/guardian consent has been given for the child to receive the vaccine: • as a booster dose in previously Hib-vaccinated children from 12 months of age • as a primary immunisation in children from 12 months to 10 years of age who have not previously been vaccinated with a primary course of either Hib or MenC • individuals with unknown/incomplete vaccination history-please follow HPA advice. Adult and child over one year with asplenia/splenic dysfunction.
Criteria for Exclusion	• no valid, legal consent • confirmed anaphylactic reaction to a previous dose of either Hib or MenC conjugate vaccine • confirmed anaphylactic reaction to any component of the vaccine including tetanus

	toxoid • Current acute febrile illness • Infants under 12 months.
Action if Excluded	• If excluded because of valid legal consent, obtain legal consent. • Specialist advice must be sought on the vaccines and circumstances under which they could be given. The risk to the individual of not being immunised must be taken into account. • Arrange for further appointment if needed. • Notify Child Health. • Inform the relevant Health Visiting Team • Record in patient's record.
Action if Parent/Legal Guardian declines Treatment	• Advise about the protective effects of the vaccine and the risks of infection, diseases and complications if not vaccinated. • Document advice given and decision reached. • Inform or refer to GP as appropriate. • Advise about symptom recognition and when to seek medical advice.
Notes for doctors / drug interactions	Individuals with immunosuppression or with HIV infection (regardless of CD4 counts) should be considered for Hib/Men C vaccines in accordance with the recommendations in the Green Book. However, individuals who are immunosuppressed may not develop a full antibody response. Re-immunisation should be considered after treatment is finished or recovery has occurred. Specialist advice may be required.

2. Description of treatment

Drug Name: Haemophilus influenzae Type B and Meningococcal C Conjugate Vaccine (Hib/MenC) (*Menitorix*®)

Name, strength and formulation of drug	*Haemophilus influenzae* type b and Meningococcal C conjugate vaccine (Hib/MenC -*Menitorix*® as powder in a single-dose vial with a pre-filled syringe containing a clear colourless diluent.
Legal status	POM - Prescription only medicine.
Storage	• Vaccines must be stored, transported and disposed according to manufacturers and the Department of Health guidelines and current legislation.
Dose/dose range	0.5ml.
Method /route	Reconstitute the vaccine by adding the entire

	contents of the pre-filled syringe of diluent to the vial containing the powder. Shake the mixture until the powder is completely dissolved in the solvent. Menitorix® is routinely administered by intramuscular injection. Vaccination by deep subcutaneous route should be reserved **only** for individuals with a **bleeding disorder.** **NB. Shake the vaccine well immediately before administration.** Menitorix® can be given at the same time as other vaccines such as PCV and MMR. The vaccines should be given at a separate site, preferably a separate limb. If given in the same limb, they should be given at least 2.5cm apart. The site of injection should be documented in clinical records.
Frequency of administration	**Routine childhood vaccination**- One dose between 12 and 13 months old (within one month of 1st birthday). **Asplenia/splenic Dysfunction, immunosuppression or complement deficiency see Appendix 1 at end of PGD for dose scheduling.** For planned splenectomy, one dose given two weeks before surgery (ideally).
Total dose number	See above.
Patient/carer advice and follow-up treatment	• Inform individual about possible side effects and their management. • Give advice on temperature control • Whilst paracetamol and ibuprofen can lower the duration of fever and reduce distress, there is no evidence that they prevent febrile convulsions. It is not therefore recommended that these drugs are used routinely to prevent fever following vaccination as there is some evidence that prophylactic administration of antipyretic drugs around the time of vaccination may lower antibody responses to some vaccines. • Give advice regarding normal reaction to the injection.

	• Inform patient when subsequent doses are due when applicable. • Please include a copy of any patient information to be given with this medicine. (Provision of the Patient Information Leaflet is a legal requirement). • Local reactions (pain, erythema, induration and oedema) within 48 hours after vaccination, and persisting for 1-2 days. • Inform Child Health Department that vaccination has been given. **Following immunisation/vaccination:** The patient should be observed for an immediate adverse reaction, usually 5-10 minutes and should remain under observation until they have been seen to be in good health and not to be experiencing an immediate adverse reaction.

3. Records

1. The following records should be kept either paper or computer based
   For all vaccinations, the following information should be entered on all manual records including the Personal Child Health Record (PCHR-red book), computerised records and data collection for Child Health Information Services (CHIS):

   Records should be kept at ……. and information passed to patient and GP.
   - Complete Record of Attendance documentation and if appropriate enter on record 'Protocol fulfilled'
   - Patient's name, address, date of birth and consent given
   - Diagnosis
   - Name of medication
   - Dose given.
   - Brand, Batch Number and Expiry Date (if supplied)
   - Signature & name of staff who administered or supplied the medication, and also, if relevant, signature & name of staff who removed/discontinued the treatment
   - Route and site of administration (record all sites of administration to allow any reactions to be related to the site of the injection
   - Contact details of GP (if registered)
   - Information & advice given to patient (including side effects)
   - Details of any adverse drug reaction and actions taken, including documentation in the patient's medical record. Any adverse reaction must be notified to GP.
   - Referral arrangements (including self care)
   - Date administered / supplied
   - Any serious adverse events that may be attributable to black triangled drugs ▼ should be reported via SUI trust procedure and then to the MHRA using the yellow card system.

2. **Audit Trail Data Collection**

- A record of all individuals receiving treatment under this Patient Group Direction should also be kept for audit purposes within each practice/service.

- **Reconciliation**: Stock balances should be reconcilable with Receipts, Administration, Records and Disposals on a patient-by-patient basis
- **Storage**: Standards must be consistent with the Summary of Product Characteristics. All medication must be stored in a secure locked environment away from the direct patient care area

4. Anaphylaxis - Emergency Treatment

Before administering any medication the possibility of anaphylaxis must be discussed and documented with the patient/carer prior to administration of any medication, which may produce an anaphylactic reaction.
When giving any medication the following should always be readily available:

- Access to the patients notes
- Adrenaline (Epinephrine) 1 in 1000 for intramuscular (i.m.) injection for use in emergency (NB: **check expiry dates** regularly)
- Syringes and needles of **suitable size** and capacity for dose.
- Patient Group Direction for the Administration of Adrenaline (Epinephrine) 1 in 1000.
- Access to a telephone

PLEASE BE AWARE OF CURRENT RESUSCITATION COUNCIL GUIDELINES.

Adrenaline (Epinephrine) 1 in1000 (1mg/ml)	**For intramuscular injection**	
Age	Dose	Volume
Children under 6 years	150 micrograms	0.15ml
Children 6 – 12 years	300 micrograms	0.3ml
Adults and child 12-18 years	500 micrograms	0.5ml
These doses may be repeated if necessary at 5-minute intervals according to blood pressure, pulse and respiratory function.		
Special cautions: see BNF 3.4.3	Epinephrine/ Adrenaline	

BNF (62nd edition) section 3.4.3 page 199-202

(Updated Jan 2008)

Professional Responsibility All practitioners

- The practitioner will ensure he/she has the relevant training and is competent, including contra-indications. He/she will attend training updates as appropriate. **Details of the competency programme developed for use with this PGD must be attached (see PGD process above).**
- The practitioner will have due regard for the their Professional Conduct and Guidelines for the Administration / Supply of Medicines
- It is the responsibility of the individual practitioner to ensure that he/she has appropriate knowledge of the product prior to proceeding. Refer to the Summary of Product Characteristics (SPC) or current BNF for further details on the product.
- Each individual must have received a personal copy of the PGD and signed on the list of individual professionals who may work within this PGD (kept with master copy of this PGD)
- Must be competent in the recognition and management of anaphylaxis.
- Must have access to all relevant DH advice, including the relevant CMO letters o*r* training and competent in all aspects of immunisation including contraindications and recognition and treatment of anaphylaxis where appropriate.

- Must have access to a current copy of the BNF and *Immunisation against infectious disease* (The 'Green book') and comply with its recommendations (available on DH website – www.dh.gov.uk/greenbook) where appropriate.
- Annual attendance at the NHS Rotherham's or workplace update on resuscitation skills and the management of anaphylaxis within the community.
- Maintenance of own level of updating with evidence of continued professional development (PREP requirements).
- Regular updates in immunisation, vaccination, anaphylaxis and cardiopulmonary resuscitation where appropriate.
- To reinforce and update knowledge and skills in this area of practice, including basic resuscitation and anaphylaxis training, with particular reference to changes and national directives.
- Such practitioners that meet the above criteria for training have NHS Rotherham approval to administer/supply Haemophilus influenzae Type B and Meningococcal C Conjugate Vaccine (Hib/MenC) (*Menitorix*®) in accordance with this PGD without a doctor's prescription, and with the patient's informed consent.
- Storage and handling of medicines should be carried out accordance with NHS Rotherham's Medicines Policy.
- The EC Labelling and Leaflet Directive 92/27 applies to all supplies of medicine, including those supplied under Patient Group Directions and all products other than those immediately administered must be labelled for supply to patients.

Sources: HSC 200/026 Patient Group Directions; BNF 62nd Edition (Sep 2011); Current Summary of Product Characteristics for product.
Refer to NHS Rotherham Procedure N1 Procedure for Emergency Treatment of Anaphylactic Reactions in the **Community (link http://websrv.rotherhampct.nhs.uk/?FileID=9575) UK Resuscitation Council (January 2008)**

Other reference sources.

5. Management of Patient Group Direction

Developed by:-	**Name & Title**	**Signature**	**Date**
Prepared and approved by: *Name and title in block capitals*			
Advice sought from	*SUZANNA MATHEWS*		
Lead pharmacist	*LISA MURRAY*		
Lead health professional from group who will administer/supply medicine *e.g. Sister XXXX Diabetic Nurse Specialist*	*MARGARET MURPHY*		
Health Protection and Infection Prevention Manager	*KATHY WAKEFIELD*		

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This Patient Group Direction for use in NHS Rotherham is authorised by us			
Job Title	**Name**	**Signed**	**Date**
Director of Public Health	*Dr. John Radford*		
Medical Director	*Dr. David Plews*		
Head of Medicines Management	*Stuart Lakin*		
TRFT Chief of Community Service	*Andy Irvine*		
Senior Partner (or delegate) - for GP employed nurses only			

This patient group direction is to be read, agreed to and signed by all healthcare professionals to whom it applies. One copy should be given to each practitioner with the original signed with a copy being kept by the nominated doctor with responsibility for PGDs within the organisation.

The …… named below, being employees or contractee's of

NHS Rotherham based at……..*Clinic

OR GP Employer Name* ……..……..
***delete/complete as appropriate**

are authorised to administer/supply Haemophilus influenzae Type B and Meningococcal C Conjugate Vaccine (Hib/MenC) (Menitorix®) as specified under this Patient Group Direction

Register of Staff Trained and Assessed to Administer or Supply this Medicine:
(additional sheets may be attached)

"I confirm that I have read and understood the content of this patient group direction and that I am willing and competent to work under it within my professional code of conduct".

Name of authorised practitioner	Signature of authorised practitioner	Clinical manager or GP	Signature of clinical manager or GP	Date

Appendix 1: Algorhithm for Vaccination schedule for individuals with asplenia, splenic dysfunction, immunosuppression or complement deficiency.