Rotherham Clinical Commissioning Group

Patient Group Direction (PGD) for

The Administration of Meningococcal Group C Conjugate Vaccine (Meningitec®/NeisVac-C®/Menjugate Kit®) by Registered Nurses employed or commissioned by NHS Rotherham CCG who have been certified after completing an agreed training plan.

PGD Number:	VI 17
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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.

Patient Group Direction (PGD) for the administration of Meningococcal Group C (Brands Meningitec®/NeisVac-C®/Menjugate Kit®) by Registered Nurses employed or commissioned by NHS Rotherham CCG who have been certified after completing an agreed training plan.

1. Clinical Condition or situation to which the direction applies

Drug Name: Meningococcal Group C vaccine (Meningitec®/NeisVac-C®/Menjugate Kit®)

Clinical Indications	• Active immunisation of individuals from 3 months of age to 25 years against meningococcal Group C infection in line with the current National Immunisation Programme. • Active immunisation of any individual outside this range who may be at an increased risk of Men C disease.
Criteria for Inclusion	• All children from 3 months of age and adolescents where last dose of Men C containing vaccine was given under the age of 10 years. • Children and Adults under 25 years old (who have not been vaccinated previously). • Adults 25 years and over who may be at increased risk from meningococcal C disease.
Criteria for Exclusion	• No valid, legal consent given by the patient/carer • Pregnancy, consult GP • Breast Feeding, consult GP • Current acute illness (minor infections without systemic upset or fever are not reasons to postpone immunisation). • Infants under 3 months of age

	• Adults aged 25 years and over not at increased risk from meningococcal C disease • Adolescents who received last dose of Men C containing vaccine after 10 years of age • Vaccination for purpose of travel or going to reside abroad. • Previous severe reactions to vaccination and hypersensitivity including tetanus toxoid (*NeisVac – C®*), diphtheria toxoid or non toxic diphtheria toxin protein (*Meningitec®*)
Action if Excluded	• If excluded because of valid legal consent, obtain legal consent. • For acute febrile illness advise when vaccine may be given. • Specialist advice must be sought on the vaccines and circumstances under which they should be given. The risk to the individual of not being immunised must be taken into account. • Arrange for further appointment if needed. • Document in patient's clinical record. • Notify Child Health for under 19s. • Inform the relevant Health Visiting Team or School Nursing Team if appropriate/relevant.
Action if Patient/parent declines Treatment	• Inform GP. • Information about protective effects of vaccine and incidence and dangers of Meningococcal infection in children/young adults. • Record in patients' notes, endorse signature and date. • Inform Health Visitor and School Nurse if appropriate. • Continue to reoffer vaccination at subsequent contacts.
Notes for doctors / drug interactions	Asplenic/splenic dysfunction immunosuppression or complement deficiency: This PGD is no longer recommended for patients with asplenia or splenic dysfunction. Please refer to PGD 8 (Hib/Men C) and PGD 25 (Menveo®). Meningitec® vaccine does not provide adequate protection against meningococcal serogroup C disease when administered as single dose in infancy, and is therefore no longer recommended for use in those less than 12 months of age.

2. Description of treatment

Drug Name: Meningococcal Group C Conjugate Vaccine (Meningitec®/NeisVac-C®/Menjugate Kit®)

Name, strength and formulation of drug	Meningococcal Group C Conjugate Vaccine. Meningitec ® (0.5ml prefilled syringe). *Neis-Vac-C* ® (0.5ml prefilled syringe). Menjugate Kit® (powder for reconstitution, single dose vial with diluent).
Legal status	*POM*
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	• Intramuscular • Deep subcutaneous injection (Bleeding disorders).
Frequency of administration	**Please refer to flow diagram at end of this PGD** Primary course consists of one dose of Men C (NeisVac-C®/Menjugate® kit only-*Meningitec® no longer recommended for primary course*) at 3 months old And then 2 booster doses- A reinforcing (booster) dose of Hib/MenC (PGD No VI 8) is recommended at between 12 and 13 months of age (i.e. within a month of the first birthday) for children who have received a complete primary course of one dose of MenC vaccine. Hib/ MenC vaccine can be given at the same time as the pneumococcal and MMR vaccines. A reinforcing (booster) dose of Men C at around 14 years of age. To ensure sufficient stock for infants, Meningitec® or Menjugate kit® should be used for the adolescent programme. ***NB. If Meningitec® was used as the primary dose, a second dose of Men C (preferably Neisvac C®/Menjugate kit®) MUST be given at least 4 weeks after the first dose.*** Individuals with incomplete/unkown vaccination histories: Less than 1 year old-1 dose of Men C (Neisvac-C® or Menjugate Kit®) and follow schedule from 12-13 months (leaving at least one month between primary and booster doses)

	<u>One year to less than 10 years old</u>-1 dose of Men C (or Hib/MenC if unvaccinated for Hib-see PGD VI 8, Menitorix®) <u>10 years to less than 25 years old</u>- If never received vaccine, one dose of MenC and no further dose required If received MenC since reaching 10 years of age, no further vaccine is required If last received MenC under 10 years of age, give MenC with teenage booster (at around 14 years of age) Adults 25 years and over who may be at increased risk from meningococcal C disease-Single 0.5ml dose
Total dose number	One or two depending on age and previous vaccination history.
Patient/carer advice and follow-up treatment	• Inform individual about possible side effects and their management. • Give advice on temperature control *only* if patient become feverish. 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 as per SPC. • 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. **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 RESUSCITATION COUNCIL GUIDELINE CHANGES – Jan 2008.

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 adolescents	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 (64th edition) section 3.4.3.

(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 tripartite letters *or* 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 (adults and children).
- 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 Meningococcal Group C vaccine (Brands Meningitec®/Neisvac-C®/Menjugate Kit®) 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 64th Edition (Sep 2012); Current Summary of Product Characteristics for product.
Refer to http://www.resus.org.uk/pages/anapost1.pdf **UK Resuscitation Council (January 2008) Anaphylaxis Algorithm.**

Other reference sources.

5. Management of Patient Group Direction

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.

Developed by:-	Name & Title	Signature	Date
Prepared and approved by: *Name and title in block capitals*			
Lead pharmacist	Lisa Murray	L Murray	21.8.13
Screening and Immunisation Manager Public Health England	KATHY WAKEFIELD		26.9.13.

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This Patient Group Direction for use in NHS Rotherham CCG is authorised by us			
Job Title	**Name**	**Signed**	**Date**
NHS Rotherham CCG Clinical Governance lead	*Sue Cassin*	S.K.Cass.	12/09/13.
NHS Rotherham CCG Prescribing Lead	Dr Jason Page	Dcs. vL	21.9.13
Head of Medicines Management	Stuart Lakin		10/9/13
Senior Partner (or delegate) - for GP employed nurses only			

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

NHS Rotherham CCG based at.....*Clinic

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

are authorised to administer/supply .....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

Flow diagram for Administration of the Men C Vaccine.