Patient Group Direction (PGD) for

The Administration of cholera vaccine (Dukoral®) to adults and children over two years old by Registered Nurses employed or commissioned by NHS Rotherham CCG who have been certified after completing an agreed training plan.

PGD Number:	VI 29
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Date Uploaded & By Whom:	

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Patient Group Direction No. VI 29 Rotherham Clinical Commissioning Group

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 CCG 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 cholera vaccine (Dukoral®) to adults and children over two years old 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: Cholera Vaccine (*Dukoral®*)

Clinical Indications	Immunisation against cholera fever for adults and children over two years of age.
Criteria for Inclusion	• Valid, legal consent obtained. • relief or disaster aid workers • persons with remote itineraries in areas where cholera epidemics are occurring and there is limited access to medical care The most current information is available in the current edition of MIMS. Further information available Communicable Disease Surveillance Centre (020 8200 6868). Travellers can obtain personal information from MASTA (0906 8224 100) or websites www.fitfortravel.scot.nhs.uk. www.nathnac.org/travel/
Criteria for Exclusion	• Valid, legal consent not given. • Age under two years. • Patients with known sensitivity to any of the components. • Severe reaction to a previous dose of the same type of vaccine.

	• Acute febrile illness. • Pregnancy- except if high risk of infection. Please refer to above websites for assessment of risk. • Breastfeeding-except if high risk of infection. Please refer to above websites for assessment of risk. • Occupational Exposure: e.g. Laboratory workers handling specimens which may contain cholera organisms. Employers are required to undertake their own Occupational Health Risk Assessment to determine if immunisation is required through their own occupational health provider.
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. • Document the reason for exclusion and any action taken in patient's clinical record. • Arrange for further appointment if needed.
Action if Patient/Legal Guardian declines Treatment	• Advise about the protective effects of the vaccine and the risks of infection and disease complications. • Inform or refer to Medical Practitioner. • Document action and advice given in patients clinical record.
Notes for doctors / drug interactions	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. This is to avoid confusing the differential diagnosis of any acute illness by wrongly attributing any signs or symptoms to the adverse effects of the vaccine. Individuals with immunosuppression or with HIV infection (regardless of CD4 counts) should be considered for cholera-containing vaccines in accordance with the recommendations above. However, these individuals may not develop a full antibody response if they are immunosuppressed, and vaccine protective efficacy has not been studied.

	Food and drink should be avoided 1 hour before and 1 hour after vaccination. Oral administration of other medicinal products should be avoided within 1 hour before and after administration of DUKORAL. Re-immunisation should be considered after treatment is finished and recovery has occurred. Specialist advice may be required.

2. Description of treatment

Drug Name: Cholera vaccine (Brand Dukoral®)

Name, strength and formulation of drug	Cholera vaccine (inactivated) suspension and effervescent granules for oral suspension.
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	**Adults and children over 6 years**-3ml mixed with sodium hydrogen carbonate solution. The sodium hydrogen carbonate is supplied as effervescent granules, which should be dissolved in a glass of cool water (approx. 150 ml). The vaccine suspension (3ml) should then be mixed with the sodium hydrogen carbonate solution and drunk within 2 hours. **Children 2 to 6 years of age**- half of the sodium hydrogen carbonate solution is poured away and the remaining part (approx. 75 ml) is mixed with the entire contents of the vaccine vial (3ml).
Method /route	Oral
Frequency of administration	**Primary Immunisation** **Adults and children over 6 years**-2 doses at least 1 week apart. If more than 6 weeks has elapsed between these doses the primary course should be re-started. **Children aged 2-6 years old**-3 doses at least 1 week apart. If more than 6 weeks has elapsed between these doses the primary course should be re-started. Immunisation should be completed at least 1 week prior to potential exposure. **Booster Dose** **Adults and children over 6 years**-a single booster within 2 years. If more than 2 years has elapsed since primary

	vaccination then the primary course needs repeating. **Children aged 2-6 years old**- a single booster after 6 months.
Total dose number	Primary course-2 or 3 (dependent upon age). Booster dose-1.
Patient/carer advice and follow-up treatment	• Give advice on temperature control if they become feverish. • 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 Package Leaflet is a legal requirement). • Local reactions (pain, erythema, induration and oedema) within 48 hours after vaccination, and persisting for 1-2 days. • Advise on need for revaccination if needed **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.

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 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 (65th 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 CMO 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 CCG'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 CCG approval to administer/supply cholera vaccine (Dukoral®) 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 CCG 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 65th Edition (Sept. 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

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*	L. Murray	21.8.13
Lead health professional from group who will administer/supply medicine *e.g. Sister XXXX Diabetic Nurse Specialist*	*Margaret Murphy*		
Screening and Immunisation Manager Public Health England	Kathy Wakefield	Kathy Wakefield	26.9.13.

Supply / Administration of cholera vaccine (Dukoral®) by Registered Nurses employed or contracted by NHS Rotherham CCG working within GP Practices registered in Rotherham who have been certified after completing an agreed training plan.

This Patient Group Direction for use in NHS Rotherham is authorised by us

Job Title	Name	Signed	Date
NHS Rotherham CCG Clinical Governance Lead	*Sue Cassin*	S.K. Cassin	12/09/13
NHS Rotherham CCG Prescribing Lead	*Dr. Jason Page*	Jason Page	21.8.13
Head of Medicines Management	*Stuart Lakin*	[illegible]	10/9/13
Senior Partner (or delegate) - for GP employed nurses only			

The registered nurses 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 cholera Vaccine (Dukoral®) 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