Yorkshire and the Humber

PATIENT GROUP DIRECTION (PGD)

The Administration of Cholera vaccine (Dukoral®) to adults and children over two years of age

For the administration of Cholera (Dukoral®) to eligible patients in line with national guidance by nurses currently registered with the Nursing and Midwifery Council (NMC) and/or other registered healthcare professionals employed by organisations commissioned by NHS England North (Yorkshire and the Humber).

Reference:	Dukoral
Version no:	V02
Valid from:	1st September 2018
Review date:	May 2020
Expiry date:	31st August 2020

The PGD has been authorised following NHS England North (Yorkshire and the Humber) governance processes so that it meets the legal requirements for a PGD as a Yorkshire and the Humber Local Office wide PGD for the 'Administration of Cholera vaccine (Dukoral®) to adults and children over two years of age' . Each provider organisation using this PGD should formally adopt it via a signature from the provider's governance lead or lead practitioner.

Practitioners intending to work under the PGD must be individually authorised by their/the designated manager, under the current version of this PGD before working according to it. Each practitioner is professionally accountable for ensuring they have undergone appropriate training and are competent and understand the contents of this PGD and the requirements of the individual vaccine programme, including route of administration, contra-indications etc.

1. Clinical condition or situation to which the direction applies

Indication	Immunisation against cholera fever for adults and children over two years of age.
Objective of programme	To protect adults and children over 2 years of age travelling to endemic or epidemic areas against disease caused by *Vibrio cholera* serogroup 01. The vaccine does not protect against serogroup 0139 and other species of Vibrio.
Criteria for inclusion	• Relief or disaster aid workers • Persons with remote itineraries in areas where cholera epidemics are occurring and there is limited access to medical care • Travellers to potential cholera risk areas, for whom vaccination is considered potentially beneficial. AND • Is an adult or child over 2 years of age • Has valid, legal consent obtained Information relating to cholera outbreaks can be found on the Public Health England website at the following link: https://www.gov.uk/foreign-travel-advice **or** https://travelhealthpro.org.uk/
Criteria for Exclusion	• Patient does not meet inclusion criteria • A confirmed anaphylactic reaction to a previous dose of any component of the vaccine. • A severe general or local reaction to a previous dose of any component of this vaccine • A confirmed anaphylactic reaction to latex • Acute severe febrile illness (having a minor illness without a fever e.g. a cold is not a reason to delay immunisation) • Acute diarrhoeal illness. Pre-existing gastro-intestinal disorders are not a contraindication to giving the vaccine. • Consent not given/obtained • Pregnancy and breastfeeding • 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 to be taken if excluded	• Consider referring to medical practitioner • For acute severe febrile illnesses and acute diarrhoeal illnesses, advise when the vaccine may be given and arrange a further appointment if needed. • For severe general or local reactions refer to GP who may wish to discuss further with the Consultant in Communicable Disease Control (CCDC) – contact details below. • For confirmed anaphylactic reaction to latex, undertake a risk assessment and refer to GP, who may wish to discuss further with the CCDC (contact details below). Further information is also available in Chapter 6 of Immunisation against Infectious Disease (The Green Book): https://www.gov.uk/government/uploads/system/uploads/attachment_data/file/147824/Green-Book-Chapter-6-v2_0.pdf • Pregnancy and Breastfeeding - Where there is a high risk of infection and following a careful benefit/risk assessment the vaccine may be administered during pregnancy and to breast-feeding women although no specific clinical studies have been performed to address this issue. A medical practitioner should be consulted and the vaccine administered under a Patient Specific Direction

	• Document exclusions or deferrals in clinical record. • Individuals excluded for occupational reasons should be advised to contact their organisations occupational health department. Local enquiries regarding the use of this PGD may be directed to your local screening and immunisation team or the Health Protection Team Acute Response Centre (ARC): Contact Number: **0113 3860 300**
Action if patient or carer declines treatment/vaccination	• Advise about the protective effects of the vaccine and the risk of infection and disease complications. • Inform or refer to medical practitioner if patient declines treatment. (For non GP practice personnel – ask patient/carer permission first) • Document refusal and reason if possible in clinical records.
Reference to National / Local policies or Guidelines	• Public Health England. Immunisation against infectious diseases. The Green Book. Chapter 14. Cholera. Available at: https://www.gov.uk/government/uploads/system/uploads/attachment_data/file/263838/Green-Book-Chapter-14v2_0.pdf Accessed <08.8.18> • Summary of product characteristics. Dukoral®. December 2015. Available at: http://www.medicines.org.uk/emc/medicine/31272 Accessed <08.8.18>
Precautions	• Minor illness, without fever or systemic upset, is not a valid reason 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 signs or symptoms to adverse effects of the vaccine. • Individuals who are immunosuppressed or have HIV infection may not make a full antibody response and revaccination on cessation of treatment/recovery may be required. This should be discussed with the appropriate/relevant specialist. • Vaccination should be delayed in individuals suffering from acute gastro-intestinal illness. Pre-existing gastro-intestinal disorders are not a contraindication to giving the vaccine. • Vaccination is not a substitute for adhering to standard protective hygiene measures to avoid cholera. Good food, water, personal and hand hygiene should be reiterated at the time of the travel consultation. • Formaldehyde is used during the manufacturing process, therefore trace amounts may be present in the final product. Caution should be taken in patients with known hypersensitivity to formaldehyde. • Special consideration should be given to individuals on a controlled sodium diet as each dose of vaccine contains 1.1g of sodium. • The vaccine is acid labile. Food and/or drink will increase acid production in the stomach and the effect of the vaccine may be Impaired. Consequently, food and drink should be avoided 1 hour before and 1 hour after administration.

2. Description of Treatment

Name, & formulation of drug	Cholera vaccine (inactivated) suspension and effervescent granules for oral suspension. Dukoral®
Presentation	Suspension and effervescent granules for oral suspension. The suspension, supplied in a bottle is whitish. The effervescent granules, supplied in a sachet, are white
Storage	The storage of vaccines must comply with the Public Health England protocol updated March 2014. This can be accessed via the link below: https://www.gov.uk/government/uploads/system/uploads/attachment_data/file/300304/Protocol_for_ordering__storing_and_handling_vaccines_March_2014.pdf Store in a refrigerator (2°C – 8°C). Do not freeze.

Legal Status	POM
Black Triangle▼	No
Unlicensed / Off label use	No
Route / method of administration	**Oral administration only** Adults and children over 6 years - 3ml vaccine suspension mixed with sodium hydrogen carbonate solution. • Dissolve the sodium hydrogen carbonate (effervescent granules) 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 - 3ml vaccine suspension mixed with half of the sodium hydrogen carbonate solution (approx. 75 ml) • Dissolve the sodium hydrogen carbonate (effervescent granules) in a glass of cool water (approx. 150 ml). Pour away half of this solution leaving approximately 75ml. The vaccine suspension (3ml) should then be mixed with the sodium hydrogen carbonate solution and drunk within 2 hours. Under no circumstances should it be given by intravenous or intradermal injection. NB: As the vaccine is acid labile, food and drink should be avoided 1 hour before and 1 hour after administration
Dose	Adults and children over 6 years Dissolve the sodium hydrogen carbonate (effervescent granules) 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 Dissolve the sodium hydrogen carbonate (effervescent granules) in a glass of cool water (approx. 150 ml). Pour away half of this solution leaving approximately 75ml. The vaccine suspension (3ml) should then be mixed with the sodium hydrogen carbonate solution and drunk within 2 hours
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 (Where continual protection Is required) **Adults and children over 6 years** - a single booster, within 2 years after completing the primary course. If more than 2 years has elapsed since primary vaccination then the primary course should be repeated. **Children aged 2-6 years old** - a single booster within 6 months after completing the primary course. If more than 6 months has elapsed since primary vaccination then the primary course should be repeated

Total doses	Primary Immunisation • 2 doses for adults and children over 6 years of age • 3 doses for children between 2years of age and 6 years of age. Booster dose • 1 dose within 2 years for adults and children over 6 years of age • 1 dose within 6 months for children between 2 years of age and 6 years of age
Disposal	Equipment used for Cholera immunisation, including used vials, ampoules, or partially discharged vaccines in an oral applicator, should be disposed of at the end of a session by sealing in a UN approved 'sharps' container, with yellow coloured lid according to local sharps and/or waste management policy and HTM 07-01 the Safe Management of Healthcare Waste (Department of Health, 2013). Plastic cups should be disposed of in a yellow clinical waste bag. https://www.gov.uk/government/publications/guidance-on-the-safe-management-of-healthcare-waste
Drug Interactions	• Oral administration of other vaccines and medicinal products should be avoided 1 hour before and 1 hour after administration. • Although studies are limited there is no evidence of interaction when Dukoral is given at the same time as live oral vaccines against typhoid or yellow fever vaccine.
Potential Adverse Reactions	Some reactions to vaccination are predictable (although it is not possible to predict who will be affected and to what extent), most are mild and resolve quickly, however some people will have a more severe reaction to the vaccine administered. **Commonly reported symptoms** • Low grade fever, headache, malaise, fatigue, shivering, aching muscles and joint pains • The above symptoms usually disappear within one to two days without treatment **Other adverse events may include (but are not limited to):** • Loss of or poor appetite, dehydration, headache, dizziness, drowsiness, insomnia, fainting , reduced sense of taste , diarrhoea, abdominal cramps, abdominal pain, stomach/abdominal gurgling (gas), abdominal discomfort. Advice is available from: • Your screening and immunisation coordinator within the South Yorkshire and Bassetlaw Screening and Immunisation Team • The Consultant in Communicable Disease Control (CCDC) at your local Public Health England Health Protection Team Local enquiries regarding the use of this PGD may be directed to your local screening and immunisation team or the Health Protection Team Acute Response Centre (ARC): Contact Number: 0113 3860 300
Reporting procedure of adverse reactions and events/faults	All vaccine related incidents (including adverse events, administration errors, vaccine quality, device defects etc.) must be reported to the local Screening and Immunisation Team at NHS England and to the MHRA You can now report any of the following on a Yellow Card: •suspected adverse drug reactions •medical device incidents •defective medicines •suspected counterfeit medicines

	Please continue to report all suspected adverse drug reactions that are: •serious, medically significant, or result in harm - serious reactions are any of the following: •fatal •life-threatening •a congenital abnormality •disabling or incapacitating •those that result in or prolong hospitalisation •associated with new drugs and vaccines (denoted by a ▼); see list of black triangle medicines Report via Yellow Card at www.gov.uk/yellowcard. Information on what to report can be found in the Green Book (Chapter 9) https://www.gov.uk/government/uploads/system/uploads/attachment_data/file/147870/Green-Book-Chapter-9.pdf
Advice to patient / carer including written information and follow up treatment	• The purpose and benefits of immunisation • Possible side effects and their management • Advise to seek urgent medical attention if the patient develops swelling, rash or breathlessness • offer the vaccine manufacturer's Patient Information Leaflet (PIL). • If treatment is deferred, explain why and arrange a new appointment • Whilst paracetamol and ibuprofen can lower the duration of fever and reduce distress, there is no evidence that they prevent febrile convulsions. It is recommended that these drugs are not routinely used 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 and/or may mask other reasons for/causes of the temperature and delay diagnosis. The use of paracetamol prophylactically should only be used on the specific recommendation of the JCVI. • Give advice re: discomfort, swelling, fever, aching muscles and joint pains: - usually disappear within one to two days, but can treat with self-administration of paracetamol or ibuprofen if required. NB Ibuprofen should be avoided in pregnancy. Patients/carers may be referred to the local community pharmacist for further advice. • Health professionals can refer to the British National Formulary or British National Formulary for children as applicable • Dosage and frequency of follow-up treatment should be as per manufacturer's instructions.

Special considerations and additional information	• As with most vaccines, anaphylactic reactions are extremely rare. An anaphylaxis pack which enables immediate access to epinephrine (adrenaline) 1 in 1000 injection and access to a telephone must always be readily available in case of an anaphylactic event following the administration of the vaccine. A PGD for adrenaline 1 in 1000 injection is not required as it is exempt from the prescription-only medicine requirement when administered for the purpose of saving a life in an emergency.
	  • There are only very limited data on protective efficacy of the vaccine in subjects aged 65 years and more.
	  • Dukoral confers protection specific to Vibrio cholerae serogroup O1. Immunisation does not protect against V. cholerae serogroup O139 or other species of Vibrio

Records	In all cases, regardless of the setting where the vaccine is administered, vaccinators must ensure that records are kept in line with professional codes of practice as applicable. Documentation includes the Personal Held Child Record (PHCR – red book), other hand held records (e.g. maternity),

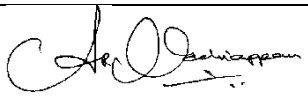
	GP records, computerised records and data collection for Child Health Information Services (CHIS), where applicable (in accordance with the NHS public health functions agreement 2018-19 Core service specification National immunisation programme, this should be within 48 hours). The patient's clinical record must be updated as soon after vaccination as is reasonably practicable (ideally within one working day) as delays may result in clinical error. For providers outside of general practice and who therefore do not hold the patient's clinical record, notification of vaccination should ideally be reported to the practice within one working day but must be in accordance with any local Service Specification. The record should include: • Assessment of the patient's need in relation to the intervention • Patient's name, address, date of birth and GP with whom the patient is registered. • Dose and form of vaccine administered • Site and route of administration • Brand, batch number and expiry date of vaccine • Date given • Name of the practitioner administering the vaccine • Consent – following local guidelines • Advice given to the patient/carer • Advice given if excluded or declines treatment • For any contraindications/exclusions the course of action taken and the outcome. • Record how the patient's central record or GP surgery record will be updated, where applicable • Details of any adverse drug reactions and actions taken • Record that the supply was made via PGD Medications given under a PGD must be appropriately READ coded in the patients clinical record. The READ codes to be used are: • SystmOne - XaQA7 • Emis – 8BMN Entries made in any record should ensure the practitioner delivering the care is clearly identifiable. Clinical records must be kept for at least 8 years following completion of treatment. In patients aged under 17 years, clinical records must be kept until the patient's 25th birthday, or for 8 years following a child's death.

3. Characteristics of Staff

Qualifications required	Registered Nurse, currently registered with the NMC, or other registered healthcare professional employed by organisations commissioned by NHS England North (Yorkshire and the Humber) and who has completed a relevant immunisation training programme recognised by their employing organisation. This should ideally be in accordance with the HPA national standards for immunisation training. https://www.gov.uk/government/publications/national-minimum-standards-and-core-curriculum-for-immunisation-training-for-registered-healthcare-practitioners
Additional requirements	All health professionals responsible for immunisation must have appropriate training for resuscitation of a patient with anaphylaxis to prevent disability and loss of life. They must be familiar with their employing organisations'

	policy on the management of anaphylaxis for adults and children. If the employing organisation does not have such a policy/protocol then vaccination under this PGD is not permitted. Knowledge of and access to: • Resuscitation Council (UK) (2008): Emergency treatment of anaphylactic reactions http://www.resus.org.uk/pages/reaction.htm • NICE (2011): Clinical Guideline 134. Anaphylaxis http://guidance.nice.org.uk/CG134 • Summary of Product Characteristics (SPC) for Dukoral® available at: http://www.medicines.org.uk/emc/ • Patient information leaflet (PIL) for Dukoral® available at: http://www.medicines.org.uk/emc/ • NMC The Code - Professional standards of practice and behaviour for nurses and midwives) • NMC Standards for Medicines Management (Nurses and Midwives) • Relevant professional code of practice • Immunisation against infectious disease (*The Green Book*), relevant updates and compliance with its recommendations (now only available electronically) https://www.gov.uk/government/organisations/public-health-england/series/immunisation-against-infectious-disease-the-green-book • CCG or individual organisations' Consent Policy • NICE (2013): Medicines Practice Guidelines 2. Patient Group Directions – Section 2.5 Using patient group directions http://www.nice.org.uk/guidance/mpg2/chapter/2-recommendations#/using-patient-group-directions
Continued training requirements	○ Maintenance of own level of updating with evidence of continued professional development as appropriate and in line with PREP (Post Registration Education and Practice) or other professional registration requirements. ○ Annual vaccination and immunisation updates are recommended for all staff involved in immunisation. ○ Annual updates on resuscitation skills for adults and children (including defibrillation training where defibrillator is available) and the management of anaphylaxis within the community.

4. PGD Development Team

Developed & Produced by:	Name of Developer, Job Title and Employing Organisation	Signature	Date
Senior Pharmacist	Raz Saleem – Pharmacist NHS Rotherham CCG		21/08/2018
Doctor (Lead Author)	Nachi Arunachalam – CCDC PHE Yorkshire and the Humber		08.8.18
Senior Registered Nurse	Kathy Wakefield – PHE Senior Screening and Immunisation Manager (on behalf of NHS England)		08.8.18

Acknowledgements (this may include representatives from CCG Medicine Management Teams who have contributed via consultation)

Name	Designation
Yorkshire and the Humber PGD steering group	

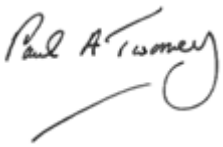
4.1 Version Control

Version	Change
V01	New PGD for use across Yorkshire and the Humber
V02	Routine review. Changes made: • Updated contacts details • Updated links • Clarification of process for reporting all adverse reactions, faults and events

5. 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.

Approved by:	***Name and Job Title***	***Signature***	***Date***
NHS England	Paul Twomey Medical Director and Governance Lead (North) - Yorkshire and the Humber		22.08.18

Adoption for use by the provider organisation (to be determined locally if relevant i.e may not be applicable if independent single pharmacy)

Name of Provider Organisation	Name of Person accepting on behalf of provider organisation (please print)	Designation of Person accepting on behalf of provider organisation (please print)	Signature of Person accepting on behalf of provider organisation	Date

The Administration of Cholera vaccine (Dukoral®) to adults and children over two years of age (valid from 1st September 2018 to 31st August 2020)

Individual Practitioner Authorisation

Organisations must complete an Individual Practitioner Authorisation sheet for each person planning to practice under this PGD. You do not need to return signed sheets to the Area Team but you should retain copies as part of your organisation's internal governance arrangements. You may wish to retain a copy in the individual's personal file.

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.

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

Signed…….. Date…….....

Name (Print) ……..……

Designation……

Authorising Manager

Designated Manager to give authorisation * for the Health Care Professional named above and who has signed the PGD

Signed…….. Date…….....

Name (Print) ……...

Designation……

On behalf of: Name of organisation …….

***Note to Authorising Manager**

By signing about you are confirming that you have assessed the staff member as competent to work under this PGD and that they have the organisational approval to do so.

You must give this signed PGD to each Authorised Practitioner as it shows their authorisation to use the PGD.