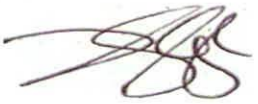
NHS Grampian NHS Highland NHS Orkney NHS Shetland NHS Tayside NHS Eileanan Siar Western Isles

Patient Group Direction for the Administration of Oral Cholera Vaccine for Travel by Approved Healthcare Professionals Working Within NHS Grampian, Highland, Orkney, Shetland, Tayside and Western Isles

Lead Author: Adapted from PHS National PGD by the Medicines Management Specialist Nurse NHSG	**Consultation Group:** See relevant page in the PGD	**Approver:** NoS PGD Group **Authorisation:** NHS Grampian
Signature: 		**Signature:** 
NoS Identifier: NoS/PGD/Travel_Cholera/ MGPG1256	**Review Date:** June 2024 **Expiry Date:** June 2025	**Date Approved:** June 2022

NHS Grampian, Highland, Orkney, Shetland, Tayside and Western Isles have authorised this Patient Group Direction to help individuals by providing them with more convenient access to an efficient and clearly defined service within the NHS Boards. This Patient Group Direction cannot be used until Appendix 1 and 2 are completed.

Uncontrolled when printed

Version 1

Revision History:

Reference and approval date of PGD that has been adapted and/or superseded	New PGD adapted from PHS national PGD for travel.	
Date of change	**Summary of Changes**	**Section heading**
March 2022	New PGD	

NoS Identifier: NoS/PGD/Travel_Cholera/MGPG1256
Keyword(s): PGD Patient Group Direction cholera vaccine dukoral®

Policy Statement:
It is the responsibility of the individual healthcare professional and their line managers to ensure that they work within the terms laid down in this PGD and to ensure that staff are working to the most up to date PGD. By doing so, the quality of the services offered will be maintained, and the chances of staff making erroneous decisions which may affect individual, staff or visitor safety and comfort will be reduced. Supervisory staff at all levels must ensure that staff using this PGD act within their own level of competence.

The lead author is responsible for the review of this PGD and for ensuring the PGD is updated in line with any changes in clinical practice, relevant guidelines, or new research evidence.

Review date: The review date for a PGD needs to be decided on a case-by-case basis in the interest of safety. The expiry date should not be more than 3 years, unless a change in national policy or update is required.

Document:	Drafted:	March 2022
	Completed:	June 2022
	Approved:	June 2022 (published –July 2022)
	Amended & reauthorized:	

Organisational Authorisations

This PGD is not legally valid until it has had the relevant organisational authorisation.

PGD Developed/Reviewed by;

Medical practitioner	**Name:** Dr Jenny Wares **Health Board:** NHSH **Title:** Consultant in Public Health Medicine (Health Protection) **Contact email:** jenny.wares@nhs.scot **Signature** ..... **Date:** 13/07/2022
Senior representative of the professional group who will provide care under the direction	**Name:** Sarah Buchan **Health Board:** NHSG **Title:** Pharmaceutical Care Services Manager **Contact email:** sarah.buchan3@nhs.scot **Signature** ..... **Date:** 30/06/2022
Lead author	**Name:** Frances Adamson **Health Board:** NHSG **Title :** Medicines Management Specialist Nurse **Contact email:** frances.adamson@nhs.scot **Signature** ..... **Date:** 22/06/2022
Pharmacist	**Name:** Jackie Agnew **Health Board:** NHSH **Title :** Head of Community Pharmacy Services **Contact email:** jackie.agnew@nhs.scot **Signature** ..... **Date:** 23/06/2022

Approved for use within NoS Boards by;

North of Scotland (NoS) PGD Group Chair	Signature	Date Signed
Lesley Coyle		20/06/2022

Authorised and executively signed for use within NoS Boards by;

NHS Grampian Chief Executive	Signature	Date Signed
Professor Caroline Hiscox		14/07/2022

Management and Monitoring of Patient Group Direction

PGD Consultative Group

The consultative group is legally required to include a medical practitioner, a pharmacist and a representative of the professional group who will provide care under the direction.

Name:	Title:
Frances Adamson	**Lead Author:** Medicines Management Specialist Nurse NHSG
Jackie Agnew	**Pharmacist:** Head of Community Pharmacy Services NHSH
Dr Jenny Wares	**Medical Practitioner:** Consultant in Public Health Medicine (Health Protection) NHSH
Sarah Buchan	**Senior Representative:** Pharmaceutical Care Services Manager NHSG
Mary McFarlane	Principal Pharmacist NHSS
Alistair Brand	Lead Locality Pharmacist NHST
Liam Callaghan	Chief Pharmacist NHSWI
Russell Mackay	Clinical Pharmacist NHSO

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Clinical indication to which this PGD applies

Definition of situation/Condition	This Patient Group Direction (PGD) will authorise approved healthcare professionals as detailed in the characteristics of staff authorised to work under this PGD to administer oral cholera vaccine for active immunisation of adults and children over 2 years who are deemed to be at risk of disease caused by *Vibrio cholerae* serogroup O1 related to travel. This PGD should be used in conjunction with the recommendations in the current British National Formulary (BNF), British National Formulary for Children (BNFC), The Green Book Chapter 14, TRAVAX, NaTHNaC and the individual Summary of Product Characteristics (SmPC).
Inclusion criteria	Adults and children over 2 years old who: • Intend to travel to or reside in countries where cholera vaccination is currently recommended for travel in accordance with national recommendations issued by TRAVAX www.travax.nhs.uk/destinations/ The risk of exposure should be determined after careful risk of assessment of an individual's itinerary, duration of stay, planned activities and medical history. Prior to the administration of the vaccine, valid consent to receiving treatment under this PGD must be obtained. Consent must be in line with current individual NHS Boards consent policy.
Exclusion criteria	Individuals who: • Are under 2 years of age • Require vaccination unrelated to travel purposes • Have had a confirmed anaphylactic reaction to a previous dose of cholera vaccine or to any of the components of the vaccine these may include formaldehyde (refer to relevant SmPC) • Are suffering from acute gastro-intestinal illness, immunisation should be postponed until fully recovered. Pre-existing gastro-intestinal disorders are not a contraindication to giving the vaccine

	• Are suffering from acute severe febrile illness (the presence of a minor infection is not a contraindication for immunisation) • Where there is no valid consent.
Precautions and special warnings	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. The Green Book advises there are very few individuals who cannot receive cholera vaccine. When there is doubt, appropriate advice should be sought from the lead clinician rather than withholding the vaccine. Immunisation does not protect against *Vibrio cholerae* serogroup O139 or other species of Vibrio and, as such, vaccination is not a substitute for adhering to standard protective hygiene measures to avoid cholera. Individuals with immunosuppression and HIV infection can be given cholera containing vaccines. However, these individuals may not develop a full antibody response and vaccine efficacy has not been studied. Specialist advice may be required. Immunological response may be diminished in those receiving immunosuppressive treatment. Pregnancy and breastfeeding: No data available on the safety of oral cholera vaccine. There is no evidence of risk from vaccinating these individuals with other inactivated viral or bacterial vaccines or toxoids. Vaccination should be considered when the risk of infection is high and benefits are considered to outweigh the risks. Dukoral® contains approximately 1.1g sodium per dose which should be taken in to consideration by patients on a controlled sodium diet.
Action if excluded from treatment	Specialist advice must be sought on the vaccine and circumstances under which it could be given as immunisation using a patient specific direction may be indicated. The risk to the individual of not being immunised must be taken into account. Inform or refer to the lead clinician in charge. Individuals who have had a confirmed anaphylactic reaction to a previous dose of cholera vaccine, or any components of the vaccine, should be referred to a clinician for specialist advice and appropriate management. Advise the individual/person with parental consent of preventative measures to reduce exposure to cholera

	including careful attention to food and water hygiene and scrupulous hand washing. In case of postponement due to acute severe febrile illness, advise when the individual can be vaccinated at a later date and ensure another appointment is arranged Document the reason for exclusion under the PGD and any action taken in the individual's appropriate clinical records.
Action if treatment is declined	Advise about the protective effects of the vaccine and the risk of infection and disease complications. Advise how future immunisation may be accessed if they subsequently decide to receive the vaccine. Ensure they have additional reading material e.g. the Patient Information Leaflet (PIL) available to print here. Document advice given and decision reached. Advise of preventative measures to reduce exposure to cholera including careful attention to food and water hygiene and scrupulous hand washing. Document that the administration of the vaccine was declined, the reason and advice given in appropriate clinical records.

Description of vaccine available under the PGD

Name form and strength of vaccine	Dukoral® Inactivated oral cholera vaccine plus buffer sodium hydrogen carbonate as effervescent granules. Each dose of vaccine suspension (3mL) contains four strains of killed *Vibrio cholerae* O1 bacteria and 1mg of recombinant cholera toxin B subunit (rCTB) (as detailed in product SmPC).
Legal status	Dukoral® oral cholera vaccine is a Prescription-only Medicine (POM). Vaccine should be stored according to the conditions detailed below. However, in the event of an inadvertent or unavoidable deviation of these conditions refer to NHS board guidance on storage and handling of vaccines guidance. Where vaccine is assessed in accordance with these guidelines as appropriate for continued use, administration under this PGD is allowed.
Dosage/Maximum total dose	One dose on each occasion as per the Frequency of dose/Duration of treatment section below.

Frequency of dose/Duration of treatment	**Primary immunisation schedule:** Immunisation should be completed at least one week prior to potential exposure to *V. cholerae* O1. **Children 2 to 6 years of age:** **Three** doses administered with at least one week interval between doses, but less than 6 weeks* between doses. **Adults and children over 6 years of age:** **Two** doses with an interval of at least 1 week but less than 6 weeks***** between doses. *****If more than six weeks have elapsed between doses, the primary immunisation course should be restarted. **Reinforcing (booster) dose:** **Children 2 to 6 years of age:** For continuous protection against cholera a single booster dose is required six months after completion of the primary immunisation schedule. **Adults and children over 6 years of age:** For continuous protection against cholera a single booster dose is required at two years following completion of the primary immunisation schedule. There is no evidence to support further booster doses. But if more than two years have elapsed since the last vaccination (or more than *6 months* for children aged 2 to 6 years), then the primary course should be repeated. Repeating the primary schedule is unique to this vaccination.
Maximum or minimum treatment period	See both Dosage/Maximum total dose section and Frequency of dose/Duration of treatment.
Route/Method of administration	The vaccine is intended for oral use and must be reconstituted in accordance with the manufacturer's instructions prior to administration. **Adults and children over 6 years:** The sodium hydrogen carbonate effervescent granules, should be dissolved in approximately 150ml of cool water. The entire contents of the

	vaccine vial should then be mixed with the sodium hydrogen carbonate solution and the dose drunk within 2 hours. **Children 2-6 years:** The sodium hydrogen carbonate effervescent granules, should be dissolved in approximately 150ml of cool water. Half of this buffer solution should be discarded and the remaining part (approx. 75 ml) mixed with the entire contents of the vaccine vial and the dose drunk within 2 hours. The suspension, supplied in a bottle, is a whitish colour. The effervescent granules, supplied in a sachet are white. The vaccine must be drunk within 2 hours of reconstitution. **Food, drink, and other oral medicines should be avoided for 1 hour before and after administration of Dukoral®.**
Quantity to be administered	See Frequency of dose/Duration of treatment section above.
Storage requirements	Vaccine will be stored in a temperature controlled refrigerator between +2°C and +8°C. Refrigerators should have maximum and minimum temperatures recorded daily. Store in original packaging in order to protect from light. Do not freeze. Individual NHS Board guidance on the storage, handling and cold chain in relation to vaccines must be observed. Likewise, individual NHS Board guidance in relation to waste management and the disposal of all spent, partially spent or unused vaccines must also be observed. 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.
Follow-up (if applicable)	Following immunisation patients should remain under observation in line with individual NHS Board policy. Individuals should not leave if they are feeling unwell without speaking to the healthcare professional who administered the vaccine first. If necessary a doctor or the individuals GP should be contacted for advice. Where proof of vaccination is required, a certificate, stamped vaccination booklet or equivalent must be supplied.

Advice (Verbal)	Advise individual/person with parental responsibility what to expect and what to do for minor and major reactions. Advise the individual/person with parental responsibility of preventative measures to reduce exposure to cholera including careful attention to food and water hygiene and scrupulous hand washing. Advise that for continuous protection against cholera a booster dose is recommended as detailed in this PGD. If serious adverse or persistent effects occur, the individual/person with parental responsibility should be advised to contact their GP/Accident and Emergency department/NHS24. The individual/person with parental responsibility should be advised to report suspected adverse reactions to the Medicines and Healthcare products Regulatory Agency (MHRA) using the Yellow Card reporting scheme. When administration is postponed advise the individual/person with parental responsibility when to return for vaccination. If appropriate, advise the individual/person with parental responsibility when subsequent doses are due and if any follow up is required.
Advice (Written)	The PIL contained in the medicine(s) should be made available to the individual/person with parental responsibility. Where this is unavailable, or unsuitable, sufficient information should be given in a language that they can understand. Further information on travel health is available at https://www.fitfortravel.nhs.uk/home
Identifying and managing possible adverse reactions	Most commonly reported adverse reactions to cholera vaccine are usually mild and confined to the first few days after immunisation. The most common reactions are mild gastrointestinal symptoms including nausea, diarrhoea, abdominal pain, cramping. As with all vaccines there is a very small possibility of anaphylaxis and facilities for its management must be available. **This list is not exhaustive. Please also refer to current BNF/BNFC and manufacturers SmPC for details of all potential adverse reactions.**

	BNF/BNFC: BNF British National Formulary - NICE BNF for Children British National Formulary - NICE **SmPC/PIL/Risk Minimisation Material:** Home - electronic medicines compendium (emc) MHRA Products | Home RMM Directory - (emc) If an adverse reaction does occur give immediate treatment and inform relevant medical practitioner as soon as possible. Report any severe reactions using the Yellow Card System. Yellow Card Scheme - MHRA
Facilities and supplies required	The following are to be available at sites where the vaccine is to be administered: • Pharmaceutical refrigerator (or a validated cool box for storing vaccine if mobile unit) • An acceptable level of privacy to respect individual's right to confidentiality and safety • Basic airway resuscitation equipment (e.g. bag valve mask) • Immediate access to Epinephrine (Adrenaline) 1 in 1000 injection • Access to a working telephone • Another competent adult, who can summon urgent emergency support if required should ideally be present • Access to medical support (this may be via the telephone) • Approved equipment for the disposal of used materials • Clean and tidy work areas, including access to hand washing facilities or alcohol hand gel • A copy of this PGD in print or electronically

Characteristics of staff authorised to administer vaccine under PGD

Professional qualifications	Those registered healthcare professionals that are listed and approved in legislation as able to operate under Patient Group Directions, as identified and included in individual Board immunisation delivery plans.
Specialist competencies	**Approved by the organisation as:** • Competent to assess the individual's/person with parental responsibilities capacity to understand the nature and purpose of vaccination in order to give or refuse consent • Competent to undertake administration of the vaccine and discuss issues related to vaccination

	• Competent in the handling and storage of vaccines, and management of the "cold chain" • Competent to work under this PGD.

Ongoing training and competency	**All professionals working under this PGD must:**
	• Have undertaken NoS PGD module training on TURAS Learn
	• Have attended basic life support training either face to face or online and updated in-line with individual Board requirements
	• Have undertaken immunisation training where available
	• Have undertaken NHS e-anaphylaxis training or equivalent which covers all aspects of the identification and management of anaphylaxis updated in-line with individual Board requirements
	• Maintain their skills, knowledge and their own professional level of competence in this area according to their individual Code of Professional Conduct
	• Have knowledge and familiarity of the following;
	  ○ Current edition of the Green Book
	  ○ SmPC for the vaccine to be administered in accordance with this PGD
	  ○ Relevant policy relating to vaccine storage and immunisation procedures for use within their Health Board
	  ○ Relevant Scottish Government Health Directorate advice including the relevant CMO letter(s).

Responsibilities of professional manager(s)	**Professional manager(s) will be responsible for;** Ensuring that the current PGD is available to all staff providing care under this direction. Ensuring that staff have received adequate training in all areas relevant to this PGD and meet the requirements above. Maintain up to date record of all staff authorised to administer the vaccine specified in this direction.

Documentation

Authorisation of administration	Qualified health professionals working within NHS Grampian, Highland, Orkney, Shetland, Tayside and Western Isles listed and approved in legislation as able to operate under PGD can be authorised to administer the vaccine specified in this PGD in accordance with local delivery plans and by agreement at individual Board level as per the following:

	Nurses, midwives and health visitors can be authorised by their line manager. Pharmacists working within NHS Grampian, Highland, Orkney, Shetland, Tayside and Western Isles can be authorised to administer the medicine(s) specified in this PGD when they have completed local Board requirements for service registration. The following list of healthcare professionals can be authorised by their Line Manager, Head of Service or Vaccine Coordinator: Chiropodists, dental hygienists, dental therapists, dieticians, occupational therapists, optometrists, orthoptists, orthotist/prosthetists, paramedics, physiotherapists, podiatrists, radiographers and speech and language therapists. All authorised staff are required to read the PGD and sign the Agreement to Administer Medicines Under PGD (Appendix 1). A Certificate of Authorisation (Appendix 2) signed by the authorising professional/manager should be supplied. This should be held in the individual health professional's records, or as agreed within the individual Health Board.
Record of administration	An electronic or paper record for recording the screening of individuals and the subsequent administration, or not of the vaccine specified in this PGD must be completed in order to allow audit of practice. This should include as a minimum: • Date and time of vaccine administration • Individuals name and CHI • Exclusion criteria, record why the vaccine was not administered (if applicable) • Record that valid consent to treatment under this PGD was obtained • The name, brand, dose, form, batch number, expiry date, route • Advice given, including advice given if excluded or declined treatment under this PGD • Signature and name in capital letters of the healthcare professional who administered the vaccine • Record of any adverse effects (advise individuals GP/relevant medical practitioner). Depending on the clinical setting where administration is undertaken, the information should be recorded manually or electronically on the individual service specific system, as appropriate. • Individual service specific systems.

Audit	All records of the vaccine specified in this PGD will be filed with the normal records of medicines in each practice/service. A designated person within each practice/service where the PGD will be used will be responsible for annual audit to ensure a system of recording medicines administered under a PGD.
References	Electronic Medicines Compendium http://www.medicines.org.uk Dukoral® cholera vaccine suspension and effervescent granules – Date of revision of text 16/07/20, accessed 15/03/2022. British National Formulary for Children and the British National Formulary https://about.medicinescomplete.com/ accessed 15/03/2022. Department of Health (2006): Immunisation against Infectious Disease [Green Book] https://www.gov.uk/government/collections/immunisation-against-infectious-disease-the-green-book Cholera: the green book, chapter 14 - GOV.UK (www.gov.uk)

NHS Grampian NHS Highland NHS Orkney NHS Shetland NHS Tayside NHS Eileanan Siar Western Isles

Appendix 1

Healthcare Professional Agreement to Administer Vaccine Under Patient Group Direction

I: _____ (Insert name)

Working within: _____ e.g. Area, Practice

Agree to administer the vaccine contained within the following Patient Group Direction:

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I have completed the appropriate training to my professional standards enabling me to administer the vaccine under the above direction. I agree not to act beyond my professional competence, nor out with the recommendations of the direction.

Signed: _____

Print Name: _____

Date: _____

Profession: _____

Professional Registration number/PIN _____

NHS Grampian NHS Highland NHS Orkney NHS Shetland NHS Tayside NHS Eileanan Siar Western Isles

Appendix 2

Healthcare Professionals Authorisation to Administer Vaccine Under Patient Group Direction

The Lead manager/Professional of each clinical area is responsible for maintaining records of all clinical areas where this PGD is in use, and to whom it has been disseminated.
The Senior Nurse/Professional who approves a healthcare professional to administer the vaccine under this PGD is responsible for ensuring that he or she is competent, qualified and trained to do so, and for maintaining an up-to-date record of such approved persons.
The Healthcare Professional that is approved to administer the vaccine under this PGD is responsible for ensuring that he or she understands and is qualified, trained and competent to undertake the duties required. The approved person is also responsible for ensuring that administration is carried out within the terms of the direction, and according to his or her individual code of professional practice and conduct.
Patient Group Direction for the Administration of Oral Cholera Vaccine for Travel by Approved Healthcare Professionals Working Within NHS Grampian, Highland, Orkney, Shetland, Tayside and Western Isles
Local clinical area(s) where the listed healthcare professionals will operate under this PGD:

Name of Healthcare Professional	Signature	Date	Name of Manager	Signature	Date

Patient Group Direction for the Administration of Oral Cholera Vaccine for Travel by Approved Healthcare Professionals Working Within NHS Grampian, Highland, Orkney, Shetland, Tayside and Western Isles					
Name of Healthcare Professional	**Signature**	**Date**	**Name of Manager**	**Signature**	**Date**