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 By Nurses And Pharmacists Working Within NHS Grampian, Highland, Orkney, Shetland, Tayside and Western Isles

Lead Author: 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/Cholera/ MGPG1185	**Review Date:** November 2023 **Expiry Date:** November 2024	**Date Approved:** November 2021

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 2.1 (Amended March 2022)

Revision History:

Reference and approval date of PGD that has been adapted and/or superseded	PGD supersedes NHSG/PGD/cholera/MGPG1185 Version 2	
Date of change	**Summary of Changes**	**Section heading**
August 2021	NHS Highland, NHS Tayside and NHS Western Isles to existing NoS PGD at point of review.	
November 2021	Health visitors in NHSO added to PGD.	Authorisation of administration
November 2021	Statement regarding HIV and immunosuppression added.	Precautions and special warnings
March 2022	Wording changed to include all healthcare professionals approved in current legislation that can operate under a PGD.	Professional qualifications and Authorisation of administration

NoS Identifier: NoS/PGD/Cholera/MGPG1185
Keyword(s): PGD Patient Group Direction cholera, vaccine, nurses, pharmacists

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:	August 2021
	Completed:	November 2021
	Approved:	November 2021 (published – January 2022)
	Amended and reauthorised:	March 2022

Organisational Authorisations

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

PGD Developed/Reviewed by;

Medical practitioner	**Name:** Dr Susan Laidlaw **Health Board:** NHSS **Title:** Public Health Consultant **Contact email:** susan.laidlaw@nhs.scot **Signature:** ..... **Date signed:** 21/03/2022
Senior representative of the professional group who will provide care under the direction	**Name:** Fiona Browning **Health Board:** NHSG **Title:** Health Protection Nurse Specialist **Contact email:** Fiona.browning@nhs.scot **Signature:** ..... **Date signed:** 15/03/2022
Lead author	**Name:** Frances Adamson **Health Board:** NHSG **Title :** Medicines Management Specialist Nurse **Contact email:** frances.adamson@nhs.scot **Signature:** ..... **Date signed:** 01/03/2022
Pharmacist	**Name:** Mary McFarlane **Health Board:** NHSS **Title :** Principal Pharmacist **Contact email:** mary.mcfarlane@nhs.scot **Signature:** ..... **Date signed:** 14/03/2022

Approved for use within NoS Boards by;

North of Scotland (NoS) PGD Group Chair	Signature	Date Signed
Lesley Coyle		01/03/2022

Authorised and executively signed for use within NoS Boards by;

NHS Grampian Chief Executive	Signature	Date Signed
Professor Caroline Hiscox		23/03/2022

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
Mary McFarlane	**Pharmacist:** Principal Pharmacist NHSS
Dr Susan Laidlaw	**Medical Practitioner:** Public Health Consultant NHSG
Fiona Browning	**Senior Representative:** Health Protection Nurse Specialist NHSG
Sarah Buchan	Pharmaceutical Care Services Manager NHSG
Liam Callaghan	Chief Pharmacist NHSWI
Jackie Agnew	Head of Community Pharmacy NHSH
Andrew Radley	Consultant in Public Health Pharmacy NHST
Russell Mackay	Systems Lead Pharmacist NHSO

Patient Group Direction For The Administration Of Oral Cholera Vaccine By Nurses And Pharmacists Working Within NHS Grampian, Highland, Orkney, Shetland, Tayside and Western Isles

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 to individuals aged 2 years and over. Cholera vaccine confers protection specific to *V. cholerae* serogroup O1. Immunisation does not protect against *V. cholerae* serogroup O139 or other species of *Vibrio*. Vaccination is not a substitute for adhering to standard protective hygiene measures to avoid cholera. 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, TRAVAX, NaTHNaC and the individual Summary of Product Characteristics (SmPC).
Inclusion criteria	Adults and children aged 2 years and over who: • Are relief, disaster aid workers or those travelling to work in slum/refugee camps • Are persons with remote itineraries in areas where cholera epidemics are occurring and there is limited access to medical care • Are travellers to potential cholera risk areas, for whom vaccination is considered potentially beneficial. 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	There are very few individuals who cannot receive oral cholera vaccine when it is recommended. Where there is doubt, appropriate advice should be sought from a travel health specialist. The vaccine should not be given to those who; • Are suffering from acute gastro-intestinal illness, vaccination should be delayed. Pre-existing gastro-intestinal disorders are not a contraindication to giving the vaccine • Are suffering from current acute systemic or febrile illness • Have had a confirmed anaphylactic reaction to a previous dose of oral cholera vaccine, or

	• Have had a confirmed anaphylactic reaction to formaldehyde or any of the components of the vaccine • Have not given 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. There is no evidence of risk from vaccinating pregnant women or those who are breast-feeding with inactivated viral or bacterial vaccines or toxoids. If the risk of cholera is high then the vaccine should be considered in these circumstances. In subjects infected with HIV, limited data are available on immunogenicity and safety of the vaccine. Vaccine protective efficacy has not been studied. Immunisation of HIV infected subjects could result in transient increases of viral load. Dukoral may not induce protective antibody levels in subjects with advanced HIV disease. However, an effectiveness study in a population with high HIV prevalence showed similar protection as in other populations. Dukoral® contains approximately 1.1g sodium per dose, which should be taken into consideration by patients on a controlled sodium diet.
Action if excluded from treatment	Medical advice must be sought – refer to relevant medical practitioner. If clarification is required about an individual meeting the exclusion criteria advice can be sought from the local Health Protection team. The risk to the individual of not being immunised must be taken into account. Discussion of the risk and benefits of vaccination should take place. Discussions and decisions taken should be documented in clinical records. 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. Ensure they have additional reading material, e.g. the Patient Information Leaflet (PIL) available to print here. Document advice given and decision reached. Inform/refer to the relevant medical practitioner if individual/person with parental responsibility declines treatment. 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	Cholera vaccine (inactivated, oral) Dukoral® suspension and effervescent granules for oral suspension. Each dose of vaccine suspension (3mL) contains: A total of $1.25x10^{11}$ bacteria of the following strains: *Vibrio cholerae* O1 Inaba, classical biotype (heat inactivated) — $31.25x10^9$ bacteria* *Vibrio cholerae* O1 Inaba, El Tor biotype (formalin inactivated) — $31.25x10^9$ bacteria* *Vibrio cholerae* O1 Ogawa, classical biotype (heat inactivated) — $31.25x10^9$ bacteria* *Vibrio cholerae* O1 Ogawa, classical biotype (formalin inactivated) — $31.25x10^9$ bacteria* – Recombinant cholera toxin B subunit (rCTB) 1mg (produced in *V. cholerae* O1 Inaba, classical biotype strain 213). *Bacterial count before inactivation. Excipients: Sodium dihydrogen phosphate dihydrate 2.0mg, disodium hydrogen phosphate dihydrate 9.4mg, sodium chloride 26mg, sodium hydrogen carbonate 3600mg, sodium carbonate anhydrous 400mg, saccharin sodium 30mg, sodium citrate 6mg. One dose contains approximately 1.1g sodium.
Legal status	Cholera vaccine (inactivated, oral) Dukoral® effervescent granules for oral suspension is a Prescription-only Medicine (POM).

Dosage/Maximum total dose	**Adults and children aged six years and above:** one dose consists of approximately 150mL. See Route/Method of administration below for details of reconstitution. **Children aged two to six years**: one dose consists of approximately 75mL. See Route/Method of administration below for details of reconstitution. **Adults and children over six years of age** The standard primary course of vaccination with this vaccine against cholera consists of two doses with an interval of at least one week but less than six weeks between doses. Immunisation should be completed at least one week prior to potential exposure to *V. cholerae* O1. **Children two to six years of age** The standard primary course of vaccination with this vaccine against cholera consists of three doses with an interval of at least one week but less than six weeks between doses. If more than six weeks have elapsed between doses, the primary immunisation course should be repeated. **Booster dose** For continuous protection against cholera, a single booster dose is recommended within two years after completing the primary course for adults and children over six years of age, and within six months for children aged two to six years. No clinical efficacy data have been generated on repeat booster dosing. If more than two years have elapsed since the last vaccination, the primary course should be repeated. The need to repeat a primary course of the immunisation is unique to this vaccine. No clinical data is available on the protective efficacy of this vaccine against cholera after administration of booster dose
Frequency of dose/Duration of treatment	**Primary Immunisation** • Adults and children over 6 years of age - 2 doses • Children between 2 and 6 years of age - 3 doses **Booster dose** • Adults and children over 6 years of age - 1 dose within 2 years • Children between 2 and 6 years of age - 1 dose within 6 months

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. **Adults and children over 6 years:** The buffer of sodium hydrogen carbonate is supplied as effervescent granules, which should be dissolved in a glass of cool water (approximately 150mL). The vaccine suspension should then be mixed with the sodium hydrogen carbonate solution. **Children 2-6 years:** Half of the sodium hydrogen carbonate buffer solution is poured away and the remaining part (approximately 75mL) is mixed with the entire contents of the vaccine vial. 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 vaccination.
Quantity to be administered	See Route/Method of administration section above.
Storage requirements	Vaccine should be stored at a temperature of +2° to +8°C. Store in the original package, in order to protect from light. Do not freeze. Individual NHS Board guidance on the storage of vaccines must be observed.
Follow-up (if applicable)	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.

	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, the patient should be advised to avoid food and drink, other oral vaccines and medicinal products, one hour before and one hour after vaccination. The vaccine does not provide complete protection and it is important to adhere to standard protective measures to avoid cholera, including maintaining good food, water and hand hygiene. The vaccine is unlikely to produce an effect on the ability to drive or operate machinery although some of the rare side effects such as dizziness or headache may impair this ability. Patients should be advised not to drive/operate machinery if they feel dizzy. 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.
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	In the majority of studies adverse events were assessed by passive surveillance. The most frequently reported adverse reactions, such as gastrointestinal symptoms including abdominal pain, diarrhoea, loose stools, nausea and vomiting, occurred at similar frequencies in vaccine and placebo groups. 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 PGD training as required/set out by each individual Health Board
	• 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 healthcare 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, optometrists, orthoptists, paramedics, physiotherapists and podiatrists. 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/site of the vaccination administered • 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's GP records if 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 10/08/21. British National Formulary for Children and the British National Formulary accessed 10/08/21. BNF British National Formulary - NICE BNF for Children British National Formulary - NICE Department of Health (2006): Immunisation against Infectious Disease [Green Book] https://www.gov.uk/government/collections/immunisation-against-infectious-disease-the-green-book TRAVAX http://www.travax.nhs.uk/ accessed 10/08/21.

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 By Nurses And Pharmacists 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

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Name of Healthcare Professional	**Signature**	**Date**	**Name of Manager**	**Signature**	**Date**