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

Patient Group Direction For The Administration Or Supply Of Cholera Vaccine For Travel Indications By Approved Healthcare Professionals Working Within NHS Grampian, Highland, Orkney, Shetland, Tayside And Western Isles

Lead Author: Adapted from Public Health Scotland Administration or Supply of Cholera Vaccine For Travel Indications Patient group Direction (PGD) Template Version 2.1 – PHS Publication date 6th January 2025		**Approver:** NoS PGD Group **Authorisation:** NHS Grampian
Signature:		**Signature:**
NoS Identifier: NoS/PGD/Travel_Cholera/1459	**Review Date:** December 2027 **Expiry Date:** December 2027	**Date Approved by NoS:** 30th January 2025

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

Revision History for NoS:

NoS PGD that has been superseded	NoS/PGD/Travel_Cholera/MGPG1256, Version 1

Most recent changes NoS

Version	Date of change	Summary of Changes	Section heading
2.0	Unpublished	Unpublished by NOS, awaiting feedback from PHS on comments raised	
2.1	January 2025	Reference to NoS Appendix 1 and 2.	Authorisation
		Training requirements for NoS.	Continuing education and training
		Statement added about Immunisation not protecting against *Vibrio cholerae* serogroup O139.	Cautions/need for further advice/circumstances when further advice should be sought from a doctor

PHS recent changes

Version	Date	Summary of changes
2.1	January 2025	The following changes have been made to V2.0 of this PGD: • Inclusion criteria section updated in respect of recommendation sources. • Audit Section updated to request vaccinators to record the source of recommendation and instruction provided if supplied. • Additional information augmented with advice on labelling of supplied product.

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.

Contents Page

Authorisation

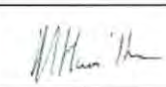
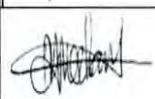
This specimen Patient Group Direction (PGD) template has been produced by Public Health Scotland and adapted by North of Scotland PGD Group (NoS) to assist NHS Boards. NHS Boards should ensure that the final PGD is considered and approved in line with local clinical governance arrangements for PGDs.

The qualified health professionals who may administer/supply vaccine under this PGD can only do so as named individuals. It is the responsibility of each professional to practice within the bounds of their own competence and in accordance with their own Code of Professional Conduct and to ensure familiarity with the manufacturer's product information/Summary of Product Characteristics (SmPC) for all vaccines administered in accordance with this PGD.

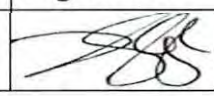
NHS Board governance arrangements will indicate how records of staff authorised to operate this PGD will be maintained. Under PGD legislation there can be no delegation. Administration/supply of the vaccine has to be by the same practitioner who has assessed the patient under the PGD.

All authorised staff are required to read the PGD and sign the Agreement to Administer/supply 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.

This PGD has been produced for NoS by:					
Doctor	Jenny Wares	Signature		Date Signed	18/02/2025
Pharmacist	Matthew Hamilton	Signature		Date Signed	04/02/2025
Nurse	Pauline Merchant	Signature		Date Signed	27/02/2025

Approved for use within NoS by:

NoS Group Chair	**Signature**	**Date Signed**
Lesley Coyle		20/01/2025

Authorised and executively signed for use within NoS by:

NHS Grampian Chief Executive	**Signature**	**Date Signed**
Adam Coldwells – Interim Chief Executive		30/01/2025

Version 2.1 – Approved for NoS from 30th January 2025

1. Clinical Situation

1.1. Indication

Active immunisation of adults and children over 2 years who are deemed to be at risk of disease caused by *Vibrio cholera* serogroup O1.

1.2. Inclusion criteria

Adults and children over 2 years old who:

- Intend to travel to or reside in countries where cholera vaccination is currently recommended by recognised Scottish or UK national travel health websites to ensure adherence to the latest recommendations.

The risk of exposure should be determined after careful risk assessment of an individual's itinerary, duration of stay, planned activities and medical history.

Valid consent has been given to receive the vaccine.

1.3. Exclusion criteria

Individuals who:

- are aged less than two years
- have had a confirmed anaphylactic reaction to a previous dose of any cholera vaccine
- have had a confirmed anaphylactic reaction to any component of the vaccine, including formaldehyde (refer to relevant SmPC)
- have a history of severe (i.e. anaphylactic reaction) to latex where the vaccine is not latex free
- are suffering from acute severe febrile illness (the presence of a minor infection is not a contraindication for immunisation)
- 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.

1.4. Cautions/need for further advice/circumstances when further advice should be sought from a doctor

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.

Individuals with immunosuppression and HIV infection can be given Dukoral®. However, these individuals may not develop a full antibody response and vaccine efficacy has not been studied. Specialist advice may be required.

Dukoral® contains approximately 1.1g sodium per dose which should be taken into consideration by patients on a controlled sodium diet.

The presence of a neurological condition is not a contraindication to immunisation but if there is evidence of current neurological deterioration, deferral of vaccination may be considered, to avoid incorrect attribution of any change in the underlying condition. The risk of such deferral should be balanced against the risk of the preventable infection and vaccination should be promptly given once the diagnosis and/or the expected course of the condition becomes clear.

Immunisation does not protect against *Vibrio cholerae* serogroup O139 or other species of *Vibrio*. As such, vaccination is not a substitute for adhering to standard protective hygiene measures to avoid cholera.

Co-administration with other vaccines

Dukoral® can be given at the same time as injected vaccines.

Pregnancy and breastfeeding

No data are available on the safety of oral cholera vaccine in pregnant or breast-feeding women. 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.

1.5. Action if excluded

Specialist advice must be sought on the vaccine and circumstances under which it could be given. Immunisation using a patient specific direction may be indicated. The risk to the individual of not being immunised must be taken into account.

Advise the individual/parent/carer of preventative measures to reduce exposure to cholera including careful attention to food and water hygiene and scrupulous hand hygiene.

Document the reason for exclusion and any action taken in accordance with local procedures.

Inform or refer to the clinician in charge.

In case of postponement due to acute severe febrile illness, advise when the individual can be vaccinated and ensure another appointment is arranged.

1.6. Action if patient declines

Advise the individual about the protective effects of the vaccine, the risks of infection and potential complications of disease.

Advise how future immunisation may be accessed if they subsequently decide to receive the vaccine.

Advise the individual/parent/carer of preventative measures to reduce exposure to cholera including careful attention to food and water hygiene and scrupulous hand hygiene.

Document advice given and decision reached.

Inform or refer to the clinician in charge.

2. Description Of Treatment

2.1. Name of medicine/form/strength

Dukoral® suspension and effervescent powder for oral suspension (Cholera vaccine (inactivated, oral)).

2.2. Route of administration

The vaccine must be reconstituted in accordance with the manufacturer's instructions prior to administration.

Adults and children over 6 years of age:

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 to 6 years of age:

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. 75mL) mixed with the entire contents of the vaccine vial and the dose drunk within 2 hours.

Food, drink and administration of other oral medicinal products should be avoided 1 hour before and after administration of Dukoral®.

2.3. Dosage

One dose on each occasion as above.

2.4. Frequency

Primary immunisation schedule

Immunisation should be completed at least one week prior to potential exposure to V. cholerae 01.

Children 2 to 6 years of age

Three doses 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 Immunisation:

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. The need to repeat a primary course of the immunisation is unique to this vaccine.

2.5. Duration of treatment

See frequency section.

2.6. Maximum or minimum treatment period

See frequency section.

2.7. Quantity to supply/administer

Single dose per administration.

2.8. ▼ black triangle medicines

No.

2.9. Legal category

Prescription only medicine (POM).

2.10. Is the use outwith the SmPC?

Vaccine should be stored according to the conditions detailed in the Storage section below. However, in the event of an inadvertent or unavoidable deviation of these conditions refer to NHS Board guidance on the storage and handling of vaccines or National Vaccine Incident Guidance.

Where vaccine is assessed in accordance with these guidelines as appropriate for continued use this would constitute off-label administration under this PGD.

2.11. Storage requirements

General requirements

Vaccine should be stored at a temperature of +2° to +8°C.

Do not freeze.

Dukoral®: Product in the unopened vial and sachet, stored in the outer carton, is stable at temperatures up to 25˚C for a period of 14 days. At the end of this period the product should be used or discarded.

During storage it is recommended that the products are stored in the original packaging/cartons, away from direct sunlight to protect from light.

NHS Board guidance on Storage and Handling of vaccines should 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 use or appropriate disposal.

2.12. Additional information

Minor illnesses without fever or systemic upset are not valid reasons to postpone immunisation. If an individual is acutely unwell, immunisation should be postponed until they have fully recovered.

Immunological response may be diminished in those receiving immunosuppressive treatment.

Where a supply is made which is intended for self-administration following an initial administration by a registrant, please note in accordance with the MHRA all medicines supplied under a PGD must either be from over-labelled stock or be labelled appropriately in accordance with the regulatory body guidelines for the labelling of medicines for the professional providing the supply. Any unused medicinal product or waste material should be disposed of in accordance with local requirements.

3. Adverse Reactions

3.1. Warnings including possible adverse reactions and management of these

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.

In the event of a severe adverse reaction individuals should be advised to seek medical advice.

For full details/information on possible adverse reaction, refer to manufacturer's product literature or SmPC.

3.2. Reporting procedure for adverse reactions

Healthcare professionals and individuals/carers should report all suspected adverse reactions to the Medicines and Healthcare products Regulatory Agency (MHRA) using the Yellow Card reporting scheme on http://www.mhra.gov.uk/yellowcard.

Any adverse reaction to a vaccine should be documented in accordance with locally agreed procedures in the individual's record and the individual's GP should be informed.

3.3. Advice to patient or carer including written information

Written information to be given to individual:

- Provide manufacturer's consumer information leaflet/patient information leaflet (PIL) provided with the vaccine.

Individual advice/follow up treatment:

- Inform the individual/carer of possible side effects and their management.
- Advise the individual/parent/carer of preventative measures to reduce exposure to cholera including careful attention to food and water hygiene and scrupulous hand hygiene.
- The individual should be advised to seek medical advice in the event of a severe adverse reaction.
- For continuous protection against cholera a booster dose is recommended as detailed above.
- Inform the individual that they can report suspected adverse reactions to the MHRA using the Yellow Card reporting scheme on: http://www.mhra.gov.uk/yellowcard
- When administration is postponed advise the individual how future vaccination may be accessed.
- Where a supply for subsequent self-administration is made, the individual should be counselled on appropriate intervals, storage, and advice on how to access further information, as necessary.

3.4. Observation following vaccination

Following immunisation, patients remain under observation in line with NHS Board policy.

3.5. Follow up

See frequency section.

3.6. Additional facilities

A protocol for the management of anaphylaxis and an anaphylaxis pack must always be available whenever vaccines are given. Immediate treatment should include early treatment with intramuscular adrenaline, with an early call for help and further IM adrenaline every 5 minutes.

The health professionals overseeing the immunisation service must be trained to recognise an anaphylactic reaction and be familiar with techniques for resuscitation of a patient with anaphylaxis.

4. Characteristics Of Staff Authorised Under The PGD

4.1. Professional qualifications

The following classes of registered healthcare practitioners are permitted to administer and/or supply this vaccine:

- nurses and midwives currently registered with the Nursing and Midwifery Council (NMC).

- pharmacists currently registered with the General Pharmaceutical Council (GPhC).
- pharmacy technicians currently registered with the General Pharmaceutical Council (GPhC).
- chiropodists/podiatrists, dieticians, occupational therapists, orthoptists, orthotists/prosthetists, paramedics, physiotherapists, radiographers and speech and language therapists currently registered with the Health and Care Professions Council (HCPC).
- dental hygienists and dental therapists registered with the General Dental Council.
- optometrists registered with the General Optical Council.

4.2. Specialist competencies or qualifications

Persons must only work under this PGD where they are competent to do so.

All persons operating this PGD:

- demonstrate appropriate knowledge and skills to work under this PGD.
- must be authorised by name by their employer as an approved person under the current terms of this PGD before working to it.
- must be familiar with the vaccine product and alert to changes in the manufacturer's product information/summary of product characteristics information.
- must be competent to undertake immunisation and to discuss issues related to immunisation to assess patients for vaccination and obtain consent.
- must be competent in the correct storage, preparation and/or supply of vaccines and management of the cold chain if receiving, responsible for, or handling the vaccine.
- must be competent in the recognition and management of anaphylaxis or under the supervision of persons able to respond appropriately to immediate adverse reactions.
- must have access to the PGD and associated online resources.
- should fulfil any additional requirements defined by local policy.

Employer

- The employer is responsible for ensuring that persons have the required knowledge and skills to safely deliver the activity they are employed to provide under this PGD.
- As a minimum, competence requirements stipulated in the PGD must be adhered to.

4.3. Continuing education and training

All practitioners operating under the PGD are responsible for ensuring they remain up to date with the use of vaccines included. If any training needs are identified these should be discussed with the individuals in the organisation responsible for authorising individuals to act under this PGD.

- 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.

5. Audit Trail

Record the following information:

- valid informed consent was given
- name of individual, address, date of birth and GP with whom the individual is registered if possible
- name of person that undertook assessment of individual's clinical suitability and subsequently administered the vaccine
- details of the source of the recommendation to vaccinate
- name and brand of vaccine
- date of administration
- dose, form and route of administration of vaccine
- batch number
- where possible expiry date
- advice given, including advice given if excluded or declines immunisation and where doses are supplied, any advice provided
- details of any adverse drug reactions and actions taken
- administered under PGD

Records should be kept in line with local procedures.

Local policy should be followed to encourage information sharing with the individual's General Practice.

All records should be clear, legible and contemporaneous and in an easily retrievable format.

6. Additional References

Practitioners operating the PGD must be familiar with:

- Immunisation against Infectious Disease [Green Book].
- Immunisation against Infectious Disease [Green Book] Cholera
- Professional Guidance on the Safe and Secure Handling of Medicines
- Professional Guidance on the Administration of Medicines in Healthcare Settings 2019
- Marketing authorisation holder's Summary of Product Characteristics

7. PHS Version History

Version	Date	Summary of changes
1.0	01 February 2022	Version 1.0 New PGD
2.0	01 February 2024	• This PGD has undergone minor rewording, layout, formatting changes for clarity and consistency with other PHS national specimen PGDs. • PGD updated to support supply where appropriate. • Storage section updated with advice on stability if unopened at room temperature.
2.1	06 January 2025	The following changes have been made to V2.0 of this PGD: • Inclusion criteria section updated in respect of recommendation sources. • Audit Section updated to request vaccinators to record the source of recommendation and instruction provided if supplied. • Additional information augmented with advice on labelling of supplied product.

Version history NoS

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Appendix 1 - Healthcare Professional Agreement to Administer or Supply Medicine(s) Under Patient Group Direction

I: _____ (Insert name)

Working within: _____ e.g. Area, Practice

Agree to administer or supply the medicine(s) contained within the following Patient Group Direction:

Patient Group Direction For The Administration Or Supply Of Cholera Vaccine For Travel Indications By Approved Healthcare Professionals Working Within NHS Grampian, Highland, Orkney, Shetland, Tayside And Western Isles, Version 2.1

I have completed the appropriate training to my professional standards enabling me to administer or supply the medicine(s) 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 or Supply Medicine(s) 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 or supply the medicine(s) under this PGD is responsible for ensuring that they are 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 or supply the medicine(s) under this PGD is responsible for ensuring that they understand and are qualified, trained and competent to undertake the duties required. The approved person is also responsible for ensuring that administration or supply is carried out within the terms of the direction, and according to their individual code of professional practice and conduct.
Patient Group Direction For The Administration Or Supply Of Cholera Vaccine For Travel Indications By Approved Healthcare Professionals Working Within NHS Grampian, Highland, Orkney, Shetland, Tayside And Western Isles, Version 2.1
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 Or Supply Of Cholera Vaccine For Travel Indications By Approved Healthcare Professionals Working Within NHS Grampian, Highland, Orkney, Shetland, Tayside And Western Isles, Version 2.1

Name of Healthcare Professional	Signature	Date	Name of Manager	Signature	Date