Patient Group Direction (PGD)

Administration of Cholera Vaccine

Publication date: 01 February 2022

Version 1.0
Effective from: 01 February 2022
Review date: 31 January 2024

Version history

Version	Date	Summary of changes
1.0	01/02/22	Version 1.0 new PGD

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Authorisation

PGD cholera vaccine

This Patient Group Direction (PGD) template has been produced by Public Health Scotland to assist NHS boards. NHS Borders has ensured that the final PGD is considered and approved in line with local clinical governance arrangements for PGDs.

The qualified health professionals who may administer cholera 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 (SPC) 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 of the vaccine has to be by the same practitioner who has assessed the patient under the PGD.

This PGD has been produced for NHS Borders by:

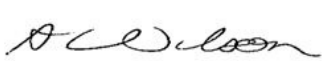
Doctor ….Dr Tim Patterson…….... **Signature** 

Pharmacist ….Adrian Mackenzie…… **Signature** 

Nurse ……Jill Madden…… **Signature** 

Approved on behalf of NHS Borders by:

Medical Director ……Dr Lynn McCallum…… **Signature** 

Director of Pharmacy/
Senior Pharmacist ……Alison Wilson…… **Signature** 

Clinical Governance Lead …Sarah Horan…… **Signature** 

Date approved: 21/02/2022

Effective from: 01/02/2022 **Review date:** 31/01/2024

Clinical situation

Category	Description
Indication	Active immunisation of adults and children over 2 years who are deemed to be at risk of disease caused by *Vibrio cholera* serogroup 01.
Inclusion criteria	Valid consent has been given to receive the vaccine 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.
Exclusion criteria	Individuals for whom no valid consent has been received Individuals who: • are under 2 years of age • 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 SPC) • 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.
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 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. Dukoral® contains approximately 1.1g sodium per dose which should be taken in to consideration by patients on a controlled sodium diet.

Category	Description
Action if excluded	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. Document the reason for exclusion and any action taken in accordance with local procedures. Advise the individual/parent/carer of preventative measures to reduce exposure to cholera including careful attention to food and water hygiene and scrupulous hand washing. Inform or refer to the lead 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. 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.
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 washing. Document advice given and decision reached. In NHS clinic setting, inform or refer to the lead clinician in charge.

Description of treatment

Category	Description
Name of medicine/Form/strength	**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 01 bacteria and 1mg of recombinant cholera toxin B subunit (rCTB) (as detailed in product SPC).
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. 75 ml) 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®.**
Dosage	One dose on each occasion as above
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 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*

Category	Description
	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.
Duration of treatment	As above
Maximum or minimum treatment period	As above
Quantity to supply/administer	Single dose on each occasion
▼ black triangle medicines	No
Legal category	Prescription Only Medicine (POM)
Is the use out with the SPC?	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 or national vaccine incident guidance. Where vaccine is assessed in accordance with these guidelines as appropriate for continued use, administration under this PGD is allowed.
Storage requirements	Vaccine should be stored at a temperature of +2° to +8°C. Store in the original packaging to protect from light. Do not freeze. NHS board guidance on Storage and Handling of vaccines should be

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

Adverse reactions

Category	Description
Warnings including possible adverse reactions and management of these	For full details/information on possible side effects, refer to the marketing authorisation holder's SPC. As with all vaccines there is a very small possibility of anaphylaxis and facilities for its management must be available. In the event of severe adverse reaction individual should be advised to seek medical advice. 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.
Reporting procedure for adverse reactions	Healthcare professionals and individuals/carers should report suspected adverse reactions to the Medicines and Healthcare products Regulatory Agency (MHRA) using the Yellow Card reporting scheme on

Category	Description
	http://yellowcard.mhra.gov.uk/ 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.
Advice to patient or carer including written information	Written information to be given to individuals: • 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. • The individual should be advised to seek medical advice in the event of a severe adverse reaction. • Inform the individual that they can report suspected adverse reactions to the MHRA using the Yellow Card reporting scheme on: http://yellowcard.mhra.gov.uk/ • Advise the individual/parent/carer of preventative measures to reduce exposure to cholera including careful attention to food and water hygiene and scrupulous hand washing. • For continuous protection against cholera a booster dose is recommended as detailed above.
Observation following vaccination	Following immunisation, patients remain under observation in line with NHS board policy.
Follow up	As above
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.

Characteristics of staff authorised under the PGD

Category	Description
Professional qualifications	The following classes of registered healthcare practitioners are permitted to administer vaccines: • nurses and midwives currently registered with the Nursing and Midwifery Council (NMC) • pharmacists 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.
Specialist competencies or qualifications	Persons must only work under this PGD where they are competent to do so. All persons operating 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 manufacturers product information/summary of product 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 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.

Category	Description
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.

Audit trail

Name	Description
Record/ audit trail	Record: • that valid informed consent was given • name of individual, address, date of birth and GP with whom the individual is registered • name of person that undertook assessment of individual's clinical suitability for vaccine • name of person that administered the vaccine • name and brand of vaccine • date of administration • dose, form and route of administration of vaccine • batch number • where possible expiry date • anatomical site of vaccination • advice given, including advice given if excluded or declines immunisation • 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.

Additional references

Name	Description
Additional references	Immunisation against Infectious Disease [Green Book] **https://www.gov.uk/government/collections/immunisation-against-infectious-disease-the-green-book** Immunisation against Infectious Disease [Green Book] chapter 14 **https://assets.publishing.service.gov.uk/government/uploads/system/uploads/attachment_data/file/263838/Green-Book-Chapter-14v2_0.pdf** Marketing authorisation holder's Summary of Product Characteristics. Professional Guidance on the Administration of Medicines in Healthcare Settings 2019 **https://www.rpharms.com/Portals/0/RPS document library/Open access/Professional standards/SSHM Admin/Admin Meds prof guidance.pdf/ver=2019-01-23-145026-567** Professional Guidance on the Safe and Secure Handling of Medicines **https://www.rpharms.com/recognition/setting-professional-standards/safe-and-secure-handling-of-medicines/professional-guidance-on-the-safe-and-secure-handling-of-medicines** NHSGGC cholera vaccine PGD ref no: 2020/2069

PGD for administration of cholera vaccine v1.0 Valid from: 01/02/2022 Expiry: 31/01/2024 - authorisation

Practitioner

This PGD does not remove professional obligations and accountability. It is the responsibility of each professional to practice within the bounds of their own competence and in accordance with their Code of Professional Conduct and to ensure familiarity with the marketing authorisation holder's summary of product characteristics for all vaccines administered in accordance with this PGD.

By signing this Patient Group Direction you are indicating that you agree to its contents and that you will work within it. I agree to administer the cholera vaccine only in accordance with this PGD.

Name of professional	Signature	Date

Authorising Manager

I confirm that the practitioners named above have declared themselves suitably trained and competent to work under this PGD. I give authorisation on behalf of **NHS Borders** for the above named health care professionals who have signed the PGD to work under it.

Lead clinician for the service area

Name ……..

Signature ……..

Date ……

Authorised staff should be provided with an individual copy of the clinical content of the PGD and a photocopy of the document showing their authorisation. This authorisation sheet should be retained to serve as a record of those practitioners authorised to work under this PGD.