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

Patient Group Direction For The Administration Of Rotavirus Vaccine, Live (Rotarix®) By Approved Healthcare Professionals Working Within NHS Grampian, Highland, Orkney, Shetland, Tayside And Western Isles

Lead Author: Adapted from Public Health Scotland Administration Of Rotavirus Vaccine, Live (Rotarix®) Patient Group Direction (PGD) Template Version 7.1 – PHS Publication date 22nd July 2024		**Approver:** NoS PGD Group **Authorisation:** NHS Grampian
Signature:		**Signature:**
NoS Identifier: NoS/PGD/Rotarix/1554	**Review Date:** 28th February 2026 **Expiry Date:** 28th February 2026	**Date Approved by NoS:** 6th November 2024

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 7.1

Revision History for NoS:

NoS PGD that has been superseded	NoS/PGD/Rotarix/MGPG1217, Version 2.1.1

Most recent changes NoS

Version	Date of change	Summary of Changes	Section heading
7.0	1st September 2023 (PHS Version Unpublished by NoS)	As per PHS version history see section 7	
7.1	07 August 2024	Reference to NoS Appendix 1 and 2.	Authorisation
		Training requirements for NoS.	Continuing education and training

PHS recent changes

Version	Date	Summary of changes
7.1	22 July 2024	• Exclusion criteria and Section 1.4 updated to include information on use of vaccine in breastfeeding.

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.

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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 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 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 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	Dr Claire-Louise Walker	Signature		Date Signed	28/10/2024
Pharmacist	Fiona Marion	Signature		Date Signed	26/09/2024
Nurse	Pauline Merchant	Signature		Date Signed	19/09/2024

Approved for use within NoS by:

NoS Group Chair	**Signature**	**Date Signed**
Lesley Coyle		01/11/2024

Authorised and executively signed for use within NoS by:

NHS Grampian Chief Executive	**Signature**	**Date Signed**
Adam Coldwells – Interim Chief Executive		06/11/2024

Version 7.1 – Approved for NoS from 6th November 2024

1. Clinical Situation

1.1. Indication

Rotavirus vaccine (live, attenuated) oral suspension (Rotarix®) is indicated for active immunisation for the prevention of gastro-enteritis due to rotavirus infection in line with Scottish Government immunisation programme and JCVI advice/recommendations as set out in Green Book Chapter 27b and subsequent correspondence/publications from Scottish Government.

1.2. Inclusion criteria

Individuals who:

- Are infants from 6 weeks to 24 weeks (i.e. by 23 weeks and 6 days) as part of routine immunisation schedule.

Valid consent has been given to receive the vaccine.

1.3. Exclusion criteria

Individuals who:

- Have had a confirmed anaphylactic reaction to a previous dose of rotavirus vaccine or to any component of the vaccine Practitioners must check the marketing authorisation holder's (SmPC) for details of vaccine components.
- Have had a previous history of intussusception.
- Are under six weeks of age.
- Are infants who have not received their first dose before 15 weeks of age (i.e. older than 14 weeks and 6 days).
- Are over 24 weeks of age (i.e. older than 23 weeks and 6 days).
- Have had a severe combined immunodeficiency disorder (SCID).
- Have had a malformation of the gastrointestinal tract that could predispose them to intussusception.
- Are known to have rare hereditary problems of fructose intolerance, glucose-galactose malabsorption or sucrase-isomaltase insufficiency.
- Whose mothers have received immunomodulating biologics (such as monoclonal antibodies or receptor antagonists which interfere with the immune system, e.g. anti-TNF agents) in pregnancy.
- Breastfeeding infants whose mothers are using biological medicines such as infliximab.
- Are known to have immunosuppression or those on systemic (oral or injectable) immunosuppressive treatment.
- Are suffering from acute severe febrile illness (the presence of a minor infection is not a contraindication for immunisation).
- Have had acute diarrhoea or vomiting – postpone immunisation until patient has fully recovered.

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

The Green Book advises that there are very few individuals who cannot receive rotavirus vaccine. Where there is doubt, rather than withholding vaccination, appropriate advice should be sought from the relevant specialist, or from the local immunisation or health protection team.

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.

Co-administration of other vaccines

Rotarix® can be given at the same time as the other vaccines administered as part of the childhood immunisation programme including BCG. Rotarix® and BCG can be given at any time before or after each other.

Breastfeeding

There are no restrictions on the infant's feeding, including breastfeeding, before or after immunisation.

Further advice on administering rotavirus vaccine to breastfed infants whose mothers are receiving immunosuppressive therapy can be found in the UKHSA information for healthcare professionals.

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.

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

Inform or refer to the clinician in charge.

Infants with immunosuppression (other than SCID): there are limited data on the safety and efficacy of Rotarix®. In such cases the local immunisation or health protection team in collaboration with the infant's GP and/or the clinician dealing with the child's underlying condition should assess the infant and consider vaccination. If vaccination is to proceed this may be administered by a prescriber or under a patient specific direction.

If aged less than 6 weeks advise to return for routine immunisation when the child is eight weeks of age or over and give an appropriate appointment. Immunisation can be administered from six weeks of age if required, e.g. if travelling to an endemic country or given early with the first dose of the hexavalent vaccine to provide protection against hepatitis B infection.

Temporary exclusion

In case of postponement due to acute severe febrile illness, acute diarrhoea or vomiting, arrange a future date for immunisation.

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.

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

Rotavirus vaccine (live, attenuated) oral suspension (Rotarix®).

- Rotarix® oral suspension (1.5mL) in pre-filled oral applicator.
- Rotarix® oral suspension (1.5mL) in a squeezable tube.
- Rotarix® oral suspension (1.5mL) in multi-monodose (5 single dose) squeezable tube presentation connected by a bar.

Rotarix® is not known to be interchangeable with other rotavirus vaccines. However, Rotarix® tube and oral applicator (oral syringe) presentations may be used interchangeably.

2.2 Route of administration

Oral use only.

Rotarix® must not be injected.

The vaccine should be visually inspected for particulate matter and discoloration prior to administration. In the event of any foreign particulate matter and/or variation of physical aspect being observed, do not administer the vaccine.

2.3 Dosage

1.5mL

2.4 Frequency

The first dose of primary immunisations can be given at 6 weeks of age if required in certain circumstances, e.g. travel to an endemic country or given early with the first dose of the hexavalent vaccine to provide protection against hepatitis B infection.

The course consists of two doses with an interval of four weeks between the doses, although the second dose may be given up to a week early when required if primary immunisations are being given before the scheduled date, e.g. due to impending travel to an endemic country.

The recommended age for immunisation is a dose at eight weeks followed by a dose at 12 weeks.

It is preferable that the full course of two doses of Rotarix® be completed before 16 weeks of age.

Infants older than 15 weeks of age (i.e. older than 14 weeks and 6 days), who have not yet received their first dose of Rotarix®, should not be commenced on Rotarix®. Infants who receive the first dose before 15 weeks of age should complete the course by 24 weeks of age (i.e. by 23 weeks and 6 days).

If the course is interrupted it should be resumed but not repeated, provided that the second dose can be given by 24 weeks of age (i.e. by 23 weeks and 6 days).

If the infant spits out or regurgitates most of the vaccine, a single replacement dose may be given at the same vaccination visit.

2.5 Duration of treatment

See frequency section.

2.6 Maximum or minimum treatment period

See frequency section.

2.7 Quantity to supply/administer

See frequency section.

2.8 ▼ black triangle medicines

No

2.9 Legal category

Prescription only medicine (POM).

2.10 Is the use out with the SmPC?

Rotarix® Summary of Product Characteristics recommends Rotarix® for preterm infants born after at least 27 weeks gestation. National recommendations advise Rotarix® vaccination for all clinically stable preterm infants including those born before 27 weeks gestation, unless exclusion criteria apply.

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 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

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 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.

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 may be postponed until they have fully recovered.

If the infant spits out or regurgitates most of the vaccine, a single replacement dose may be given at the same vaccination visit. Very premature infants (born less than or equal to 28 weeks of gestation) who are in hospital should have respiratory monitoring for 48 to 72 hrs when given their first routine immunisations, particularly those with a previous history of respiratory immaturity. If the child has apnoea, bradycardia or desaturations after the first routine immunisations, the second immunisation should also be given in hospital, with respiratory monitoring for 48 to 72 hrs.

There is a potential for transmission of the live attenuated vaccine strain in rotavirus vaccine from the immunised infant to severely immunocompromised contacts through faecal material for at least 14 days. However, vaccination of the infant will offer protection to household contacts from wild-type rotavirus disease and outweigh any risk from transmission of vaccine virus to any immunocompromised close contacts. Those in close contact with recently vaccinated infants should observe good personal hygiene, for instance wash their hands after changing infant's nappies and before food preparation or direct contact with the immunocompromised person (see Green Book Chapter 6).

3. Adverse Reactions

3.1 Warnings including possible adverse reactions and management of these

The most common adverse reactions observed after administration of Rotarix® vaccine are diarrhoea and irritability. Other reactions commonly reported are vomiting, abdominal pain, flatulence, skin inflammation, regurgitation of food, fever and loss of appetite.

Intussusception is a naturally occurring condition where the part of the intestine prolapses, or telescopes, into another part causing an obstruction. Intussusception has a background annual incidence of around 120 cases per 100,000 children aged under one year. The background risk of intussusception in the UK increases to peak at around 5 months of age.

Some countries have reported a small increase in the risk of intussusception within seven days of vaccination, possibly two cases per 100,000 first doses given and the Rotarix® prescribing information includes this as a possible side effect.

The benefits of vaccination in preventing the consequences of rotavirus infection outweigh this small potential risk in young children. Because of the potential risk, and to reduce the likelihood of a temporal association with rotavirus vaccine, the first dose of vaccine should not be given after 15 weeks of age and the second dose must not be given after 24 weeks of age.

For full details/information on possible side effects, refer to the marketing authorisation holder's SmPC.

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 including infants with abdominal pain, vomiting and passing what looks like red currant jelly in their nappies parents/guardians should be advised to seek urgent medical advice.

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 individuals:

- Provide manufacturer's consumer information leaflet/patient information leaflet (PIL) provided with the vaccine.
- Supply immunisation promotional material as appropriate.

Individual advice / follow up treatment:

- Inform the individual/carer of possible side effects and their management.
- Parents/carers should be advised to promptly report any of the following symptoms indicative of intussusception:
  - severe abdominal pain
  - persistent vomiting
  - bloody stools
  - abdominal bloating
  - high fever
- Advise parents/guardians that contacts of infants who have had Rotarix® vaccine should observe good personal hygiene, e.g. wash their hands after changing vaccinee's nappies.

3.4 Observation following vaccination

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

3.5 Follow up

If appropriate, remind parents/guardian that a further dose will be required to complete the course.

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 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:

- 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/SmPC.
- 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.

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
- 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.

6. Additional References

Practitioners operating the PGD must be familiar with:

- Immunisation against Infectious Disease [Green Book]
- Immunisation against Infectious Disease [Green Book] chapter 27b
- Rotavirus vaccination programme: information for healthcare professionals (UKHSA)
- All relevant Scottish Government Health Directorate advice including the relevant CMO letter(s).
- Current edition of British National Formulary.
- Marketing authorisation holders Summary of Product Characteristics.
- Professional Guidance on the Administration of Medicines in Healthcare settings 2019.
- Professional Guidance on the Safe and Secure Handling of Medicines.

7. Version history

Version	Date	Summary of changes
5.0	April 2019	• Action if excluded section updated with information for those aged under six weeks. • Frequency section updated to state that first dose can be given from 6 weeks and that the second dose may be given up to a week early when required if primary immunisation are being given before the scheduled date, e.g. due to impending travel to an endemic country. • Use out with SmPC section updated to recommend assessment following inadvertent or unavoidable deviation from recommended storage conditions. • Storage section updated to include additional information on action required following inadvertent or unavoidable deviation from recommended storage conditions.
6.0	1 September 2021	This PGD has undergone minor rewording, layout, formatting changes for clarity and consistency with other PHS national specimen PGDs. The following sections have been updated: • Exclusion section updated with additional text on those on systemic (oral or injectable) immunosuppressive treatment. • Form/strength section updated to include all available forms of rotavirus vaccine. • Warning section updated to include advise from Green Book on risk of intussusception. • Advice to patient/carer section updated to include advice to promptly report symptoms indicative of intussusception.
7.0	1 September 2023	Version 7.0 produced after expiry of version 6.0 This PGD has undergone minor rewording, layout, formatting changes for clarity and consistency with other PHS national specimen PGDs. • Section 2.12 updated to include potential for transmission of the live attenuated virus strain from the immunised infant to severely immunocompromised contacts.
7.1	22 July 2024	• Exclusion criteria and Section 1.4 updated to include information on use of vaccine in breastfeeding.

Version History NoS

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7.0	1st September 2023 (PHS Version Unpublished by NoS)	As per PHS version history see section 7	
7.1	07 August 2024	Reference to NoS Appendix 1 and 2.	Authorisation
		Training requirements for NoS.	Continuing education and training

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

I: _____ (Insert name)

Working within: _____ e.g. Area, Practice

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

Patient Group Direction for the Administration of Rotavirus Vaccine, Live (Rotarix®) by Approved Healthcare Professionals Working Within NHS Grampian, Highland, Orkney, Shetland, Tayside and Western Isles, Version 7.1

I have completed the appropriate training to my professional standards enabling me to administer 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 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 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 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 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 of Rotavirus Vaccine, Live (Rotarix®) by Approved Healthcare Professionals Working Within NHS Grampian, Highland, Orkney, Shetland, Tayside and Western Isles, Version 7.1
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

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Name of Healthcare Professional	Signature	Date	Name of Manager	Signature	Date