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

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

Lead Author: PGD adapted from PHS template by 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/Rotarix/ MGPG1217	**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 2.1.1 (Amended April 2022)

(Adapted from the Public Health Scotland PGD Template)

Revision History:

Reference and approval date of PGD that has been adapted and/or superseded	PGD adapted from PHS national PGD template and supersedes NoS/PGD/Rotarix/MGPG1217, Version 2.1	
Date of change	**Summary of Changes**	**Section heading**
September 2021	Yearly updated PGD adapted from PHS PGD template. This PGD has undergone minor rewording, layout, formatting changes.	
September 2021	Exclusion criteria updated with additional text on those on systemic (oral or injectable) immunosuppressive treatment.	Exclusion criteria
September 2021	Section updated as per PHS National template.	Action if Excluded
September 2021	Section updated to include all available forms of rotavirus vaccine.	Name form and strength of vaccine
September 2021	Section updated to include advice from Green Book on risk of intussusception.	Identifying and managing possible adverse reactions
September 2021	Section updated to include advice to promptly report symptoms indicative of intussusception.	Advice verbal
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
April 2022	Minor amendment to Authorisation of Administration section due to omission of occupational therapist, orthoptist/prosthetists, radiographers and speech and language therapists to include all registered healthcare professionals that may be authorised to operate under this PGD.	Authorisation of administration

NoS Identifier: NoS/PGD/Rotarix/MGPG1217
Keyword(s): PGD Patient Group Direction Rotarix, Rotavirus, Nurse, Health Visitor, Vaccine

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:	September 2021
	Completed:	November 2021
	Approved:	November 2021 (published – December 2021)
	Amended and reauthorised:	March 2022 and April 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 William Moore **Health Board:** NHSG **Title:** Consultant in Public Health Medicine **Contact email:** N/A **Signature:** ..... William Moore ..... **Date signing:** 01/04/2022
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:** ..... Fiona Browning ..... **Date signing:** 15/03/2022
Lead author	**Name:** Frances Adamson **Health Board:** NHSG **Title :** Medicines Management Specialist Nurse **Contact email:** frances.adamson@nhs.scot **Signature:** ..... F Adamson ..... **Date signing:** 01/03/2022
Pharmacist	**Name:** Alison-Jane Smith **Health Board:** NHSG **Title :** Medicines Management Pharmacist **Contact email:** alisonjane.smith@nhs.scot **Signature:** ..... A Smith ..... **Date signing:** 02/03/2022

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		04/04/2022

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
Alison-Jane Smith	**Pharmacist:** Medicines Management Pharmacist NHSG
Dr William Moore	**Medical Practitioner:** Consultant in Public Health NHSG
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Patient Group Direction For The Administration Of Rotavirus Live Vaccine (Rotarix®) By Approved Healthcare Professionals 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 rotavirus live vaccine (Rotarix®) to individual's to provide active immunisation against rotavirus in line with Scottish Government Health Directorate immunisation programme. This PGD should be used in conjunction with the recommendations in the current British National Formulary for Children (BNFC), The Green Book, Chapter 27b and the individual Summary of Product Characteristics (SmPC).
Inclusion criteria	Infants from 6 weeks to 24 weeks (i.e. by 23 weeks and 6 days) as part of routine immunisation schedule. Prior to the administration of the vaccine, valid consent to receiving treatment under this PGD must be obtained. Consent must be in line with current individual NHS Boards consent policy.
Exclusion criteria	Individuals: • Who have had an anaphylactic reaction to previous dose of the vaccine or to any of its excipients • Known to have previous history of intussusception • Who have not received their first dose before 15 weeks of age (i.e. older than 14 weeks and 6 days) • Over 24 weeks of age (i.e. older than 23 weeks and 6 days) • Known to have Severe Combined Immunodeficiency Disorder (SCID) • Known to have a malformation of the gastrointestinal tract that could predispose them to intussusception • Known to have rare hereditary problems of fructose intolerance, glucose-galactose malabsorption or sucrase-isomaltase insufficiency • Whose mothers are known to have received immunomodulating biologics (such as monoclonal antibodies or receptor antagonists which interfere with the immune system, e.g. anti-TNF agents) in pregnancy • Known to have immunosuppression or those on systemic (oral or injectable) immunosuppressive treatment. • With current acute systemic or febrile illness – postpone immunisation until patient has fully recovered

	• With current acute diarrhoea or vomiting – postpone immunisation until patient has fully recovered • Where there is no valid consent.
Precautions and special warnings	Minor illness without fever or systemic upset is not a valid reason to postpone immunisation. If an individual is acutely unwell, immunisation may be postponed until they have fully recovered. The Green Book advises 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. 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 hours when given their first immunisation, particularly those with a previous history of respiratory immaturity. If the child has apnoea, bradycardia or desaturations after the first immunisation, the second immunisation should also be given in hospital, with respiratory monitoring for 48 to 72 hours.
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. Immunisation using a patient specific direction may be indicated. 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. Temporary exclusion: 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.

	Infants with immunosuppression (other than SCID): there are limited data on the safety and efficacy of Rotarix. In such cases the infant's GP in collaboration with the clinician dealing with the child's underlying condition should assess the infant and consider vaccination. 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. 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	Rotavirus vaccine (live, attenuated) oral suspension (Rotarix®) • Rotarix® oral suspension (1.5 mL) in pre-filled oral applicator • Rotarix® oral suspension (1.5 mL) 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.
Legal status	Rotarix® is a Prescription-only Medicine (POM).

	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. This constitutes an off-label use of the vaccine and the person with parental responsibility should be informed prior to the administration that the use is off-label.
Dosage/Maximum total dose	1.5mL
Frequency of dose/Duration of treatment	The recommended age for immunisation is a dose at eight weeks followed by a dose at 12 weeks. 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. 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.
Maximum or minimum treatment period	See Frequency of dose/Duration of treatment section above.

Route/Method of administration	Oral use only. Rotarix® must not be injected. The vaccine is presented as a clear, colourless liquid, free of visible particles, for oral administration. The vaccine is ready to use, no reconstitution or dilution is required. The vaccine should be inspected visually for any foreign particulate matter and/or abnormal physical appearance. In the event of either being observed, discard the vaccine. The vaccine should be used immediately after opening. To administer the vaccine, carefully remove the protective tip-cap from the oral applicator or tube. If using the tube, hold upright and clear any liquid from the thinnest section of the tube by flicking just below the membrane. Keeping upright and holding the sides of the tube, pierce the membrane using the spike end of the cap (press; there is no need to twist). Seat the child in a reclining position and administer the liquid gently into the side of the infant's mouth, towards the inside of their cheek. You may need to squeeze the tube presentation a few times to get all of the vaccine out; it's acceptable if a drop remains in the tip of the tube. If the infant spits out or regurgitates most of the vaccine, a single replacement dose may be given at the same vaccination visit. 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.
Quantity to be administered	One single 1.5mL dose per administration.
Storage requirements	Vaccine will be stored in a temperature controlled refrigerator between +2°C and +8°C. Refrigerators should have maximum and minimum temperatures recorded daily. Store in original packaging in order to protect from light. Do not freeze.

	Individual NHS Board guidance on the storage, handling and cold chain in relation to vaccines must be observed. Likewise, individual NHS Board guidance in relation to waste management and the disposal of all spent, partially spent or unused vaccines must also be observed.
Follow-up (if applicable)	The person with parental responsibility should not leave if they have any concerns that the vaccine recipient is 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. If appropriate remind person with parental responsibility that a further dose will be required to complete the course.
Advice (Verbal)	Advise person with parental responsibility what to expect and what to do for minor and major reactions. The person with parental responsibility 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. If serious adverse or persistent effects occur, the person with parental responsibility should be advised to contact their GP/Accident and Emergency department/NHS24. In the event of severe adverse reaction including infants with abdominal pain, vomiting and passing what looks like red currant jelly in their nappies the person with parental responsibility should be advised to seek urgent medical advice. When administration is postponed advise the person with parental responsibility when to return for vaccination. If appropriate, advise the person with parental responsibility when subsequent doses are due and if any follow up is required.

Advice (Written)	The PIL contained in the medicine(s) should be made available to the person with parental responsibility. Where this is unavailable, or unsuitable, sufficient information should be given in a language that they can understand. Immunisation promotional material may be provided as appropriate. If available provide a copy of A guide to childhood immunisations up to 5 years of age More information regarding this vaccine can be found at: https://www.nhsinform.scot/healthy-living/immunisation
Identifying and managing possible adverse reactions	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. 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 BNFC and manufacturers SmPC for details of all potential adverse reactions.** **BNFC**: 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 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 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, occupational therapists, optometrists, orthoptists, orthotist/prosthetists, paramedics, physiotherapists, podiatrists, radiographers and speech and language therapists. All authorised staff are required to read the PGD and sign the Agreement to Administer Medicines Under PGD (Appendix 1). A Certificate of Authorisation (Appendix 2) signed by the authorising professional/manager should be supplied. This should be held in the individual health professional's records, or as agreed within the individual Health Board.
Record of administration	An electronic or paper record for recording the screening of individuals and the subsequent administration, or not of the vaccine specified in this PGD must be completed in order to allow audit of practice. This should include as a minimum: • Date and time of vaccine administration • Individuals name and CHI • Exclusion criteria, record why the vaccine was not administered (if applicable) • Record that valid consent to treatment under this PGD was obtained • The name, brand, dose, form, batch number, expiry date, route/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 • Where childhood immunisations are given information of the administration must be provided to the GP Practice and Practitioner Services Division (PSD) for inclusion on the Scottish Immunisation Recall System (SIRS) • 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. • Child Health Information Services if appropriate

	• Hand–held records such as red book if 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 Rotarix® Tube and Oral Applicator – Date of revision of text 01/01/21, accessed 30/09/21. British National Formulary for Children and the British National Formulary https://about.medicinescomplete.com/ accessed 30/09/21. Department of Health (2006): 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] Rotavirus chapter 27b. American Academy of Pediatrics (2003) Active immunisation. In: Pickering LK (ed.) Red Book: 2003 Report of the Committee on Infectious Diseases, 26th edition. Elk Grove Village, IL: American Academy of Pediatrics, p 33.

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:

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

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 Rotavirus Live Vaccine (Rotarix®) By Approved Healthcare Professionals Working Within NHS Grampian, Highland, Orkney, Shetland, Tayside And Western Isles
Local clinical area(s) where the listed healthcare professionals will operate under this PGD:

Name of Healthcare Professional	Signature	Date	Name of Manager	Signature	Date

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