This patient group direction (PGD) must only be used by registered health professionals who have been named and authorised by their organisation to practice under it. The most recent and in date final signed version of the PGD should be used.

Patient Group Direction (PGD)

For the administration or supply of

Rotavirus vaccine

By registered health care professionals for

administration of rotavirus vaccine (live) to infants aged 6 weeks to 23 weeks and 6 days for active immunisation against rotavirus

Throughout the Manx Care and those contracted by the Manx Care where appropriate within practice

PGD NUMBER 127

1. Change History

Version number	Change Details	Date
Final version	New PHE Rotavirus PGD	01/07/13
02.00	• PHE Rotavirus PGD transferred to new PHE PGD template • Complete document review with multiple changes to text • No clinical changes to the immunisation schedule the PGD supports	29/04/15
03.00	PHE Rotavirus PGD v02.00 reviewed and amended to: • include future availability of rotavirus vaccine in a tube presentation • update text to multiple sections including, but not limited to, advice regarding adverse reactions, disposal and removal of requirement for respiratory monitoring of pre-terms • update wording regarding authorisation in line with agreed PHE PGD template changes and multiple practitioner authorisation sheet • include rewording, layout and formatting changes for clarity and consistency with other PHE PGD templates	28/04/17
04.00	PHE Rotavirus PGD v03.00 reviewed and amended to: • include additional healthcare practitioners in Section 3 • refer to vaccine incident guidelines in off-label and storage sections • include minor rewording, layout and formatting changes for clarity and consistency with other PHE PGD templates	15/02/19
05.00	PHE Rotavirus PGD v04.00 reviewed and amended to: • include Rotarix® oral suspension (1.5ml) in multi-monodose (5 single dose) squeezable tube presentation connected by a bar • include minor rewording, layout and formatting changes for clarity and consistency with other PHE PGDs and updated references	25/0521

2. Medicines practice guideline 2: *Patient group directions*

Refer to the relevant sections of NICE medicines practice guideline 2: *Patient group directions* as stated in the blank template notes. For further information about PGD signatories, see the NHS and Manx Care PGD website FAQs

3. PGD development

Refer to the NICE PGD competency framework for people developing PGDs

Job Title & organisation	Name	Signature	Date
Author of the PGD			
Member of the PGD working group			

4. PGD authorisation

Refer to the NICE PGD competency framework for people authorising PGDs

Job Title	Name	Signature	Date
Medical Director			
Chief Pharmacist/ Pharmaceutical Adviser			
Senior Paramedic			
Director of Nursing			
GP Adviser			
Senior Microbiologist (if PGD contains antimicrobials)			

5. PGD adoption by the provider

Refer to the NICE PGD competency framework for people authorising PGDs

Job title and organisation	Signature	Date	Applicable or not applicable to area

6. Training and competency of registered healthcare professionals, employed or contracted by the Manx Care, GP practice or Hospice

Refer to the NICE PGD competency framework for health professionals using PGDs

	Requirements of registered Healthcare professionals working under the PGD
Qualifications and professional registration	Registered healthcare professionals, working within or contracted by the Manx Care, GP practice or Hospice who are permitted staff groups outlined within the current PGD policy Additionally practitioners: • must be familiar with the vaccine product and alert to changes in the Summary of Product Characteristics (SPC), Immunisation Against Infectious Disease ('The Green Book'), and national and local immunisation programmes • must have undertaken training appropriate to this PGD as required by local policy and in line with the National Minimum Standards and Core Curriculum for Immunisation Training • must be competent to undertake immunisation and to discuss issues related to immunisation • must be competent in the handling and storage of vaccines, and management of the 'cold chain' • must be competent in the recognition and management of anaphylaxis Practitioners must ensure they are up to date with relevant issues and clinical skills relating to immunisation and management of anaphylaxis, with evidence of appropriate Continued Professional Development (CPD)
Initial training	• Knowledge of current guidelines and the administration of the drug specified in this PGD/BNF and of the inclusion and exclusion criteria • Training which enables the practitioner to make a clinical assessment to establish the need for the medication covered by this PGD • Local training in the use of PGD's
Competency assessment	Staff will be assessed on their knowledge of drugs and clinical assessment as part the competency framework for registered health professionals using PGD's
Ongoing training and competency	The registered health care professionals should make sure they are aware of any changes to the recommendations for this medication; it is the responsibility of the registered health care professionals to keep up to date with continuing professional development. PGD updates will be held every two years

7. Clinical Conditions

Clinical condition or situation to which this PGD applies	Rotavirus vaccine is indicated for the active immunisation of infants aged 6 weeks to 23 weeks and 6 days for the prevention of gastro-enteritis due to *rotavirus* infection, in line with the recommendations given in Chapter 27b of the Immunisation Against Infectious Disease: 'The Green Book'
Inclusion criteria	Infants presenting for the administration of their first or second rotavirus vaccine in the correct time window, that is: • infants aged 6 weeks to 14 weeks and 6 days of age presenting for first dose primary immunisation against rotavirus Note: o the minimum age for the first dose of rotavirus vaccine is 6 weeks 0 days o the maximum age for the first dose is 14 weeks and 6 days • infants aged up to 23 weeks and 6 days who have received their first dose of rotavirus vaccine a minimum of 4 weeks previously Note: o the maximum age for the second dose of rotavirus vaccine is 23 weeks and 6 days Note: Vaccination of preterm infants using rotavirus vaccine is indicated (without correction for prematurity) if the infant is clinically stable. As the benefit of vaccination is high in premature and very premature infants, vaccination should not be withheld or delayed
Criteria for exclusion[1]	Infants for whom no valid consent has been received Rotavirus vaccine should NOT be given to infants who: • are under six weeks of age • are 15 weeks of age or older who have not received their first rotavirus vaccine dose • are aged 24 weeks or older • have had a confirmed anaphylactic reaction to a previous dose of rotavirus vaccine or any component of the vaccine • have a previous history of intussusception • have an uncorrected (congenital) malformation of the gastrointestinal tract that could predispose them to intussusception • have Severe Combined Immunodeficiency Disorder (SCID) • have mothers who received immunomodulating biologics

[1] Exclusion under this PGD does not necessarily mean the medication is contraindicated, but it would be outside its remit and another form of authorisation will be required

	(such as monoclonal antibodies or receptor antagonists which interfere with the immune system, for instance anti-TNF agents) in pregnancy • have rare hereditary problems of fructose intolerance, glucose-galactose malabsorption or sucrase-isomaltase insufficiency • are immunosuppressed or those on systemic (oral or parenteral) immunosuppressive treatment • are suffering from acute severe febrile illness (see below). The presence of a minor infection is not a contra-indication for immunisation • are suffering from acute diarrhoea or vomiting (see below)
Cautions (including any relevant action to be taken)	Healthcare professionals should be aware of a small but increased risk of intussusception, mostly within 7 days (but up to 21 days) after the first rotavirus vaccination dose. Parents/guardians should be advised to promptly seek medical help if their infant becomes unwell during this period. 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.
Arrangements for referral for medical advice	Patient should be referred to a more experienced clinical practitioner for further assessment
Action to be taken if patient excluded	• Patient should be referred to a more experienced clinical practitioner for further assessment **Important - see above exclusion criteria regarding age of infant, no further action will be required for individuals exceeding the age for vaccination.** Infants excluded for reasons other than immunosuppression (see below) or acute illness (see below) are excluded because rotavirus vaccine is contraindicated or the risk versus benefit is unlikely to support vaccination; parents/carers should be advised accordingly. **Infants who are immunosuppressed** or those on systemic (oral or parenteral) immunosuppressive treatment should be referred to their GP or appropriate specialist clinician to assess the risk versus benefit of rotavirus vaccination. If vaccination is to proceed this may be administered by a prescriber or under a PSD. **In case of acute illness** (febrile illness, diarrhoea or vomiting),

	postpone vaccination until the infant is recovered and, if the infant will still be within the age range recommended above, advise the parent/carer when the infant may be vaccinated. Ensure another appointment is arranged. If as a result of postponement the infant will exceed the recommended age for vaccination, advise the parent/carer of the reason why vaccination will no longer be indicated. Seek appropriate advice from the local Screening and Immunisation Team, local Health Protection Team or the infant's clinician as required. The risk to the infant of not being immunised must be taken into account. Document the reason for exclusion and any action taken in infant's clinical records. In a GP practice setting, inform or refer to the GP or a prescriber as appropriate.
Action to be taken if patient declines treatment	• A verbal explanation should be given to the patient on: the need for the medication and any possible effects or potential risks which may occur as a result of refusing treatment • This information must be documented in the patients' health records • Any patient who declines care must have demonstrated capacity to do so • Where appropriate care should be escalated • Informed consent, from the individual or a person legally able to act on the person's behalf, must be obtained for each administration

8. Details of the medicine

Name, form and strength of medicine	Rotavirus vaccine (live, attenuated) oral suspension: for instance • 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 category	Prescription Only Medicine (POM)
Black triangle▼	No

Indicate any off-label use (if relevant)	• Administration of Rotarix® vaccination to infants born before 27 weeks gestation is off-label. However, all clinically stable preterm infants, including those born before 27 weeks gestation, should be vaccinated in accordance with the recommendations in Chapter 27b of 'The Green Book' unless exclusion criteria apply (see Criteria for exclusion) • 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 PHE 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 • Where a vaccine is recommended off-label consider, as part of the consent process, informing the parent/carer that the vaccine is being offered in accordance with national guidance but that this is outside the product licence.
Route/method of administration	• Rotavirus vaccine is given orally • The vaccine is ready to use (no reconstitution or dilution is required) • The vaccine is to be administered orally without mixing with any other vaccines or solutions • The vaccine is presented as a clear, colourless liquid, free of visible particles. 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 **Instructions for administration of the vaccine** • 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 on; there is no need to twist) • The vaccine should be used immediately after opening • 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 the vaccine out; it is okay if a drop remains in the tip of the tube • The SPC for Rotarix® provides further guidance on administration and can be found inside the product packaging or from the electronic Medicines Compendium website: www.medicines.org.uk

Dose and frequency	• Rotavirus vaccine should be administered as a course consisting of two doses (1.5ml per administration) separated by at least 4 weeks • Administer the first dose of 1.5 ml of rotavirus vaccine ideally at eight weeks of age in accordance with the UK routine immunisation schedule. However, the first dose may be given from 6 weeks to 14 weeks and 6 days of age • Administer the second dose of 1.5 ml at least four weeks after the first dose, ideally at the 12 weeks of age immunisation visit. • The second dose must be given by the age of 23 weeks and 6 days • It is preferable that the full course of two doses of rotavirus vaccine be completed before 16 weeks of age, allowing at least four weeks between the first and second dose. This is to provide early protection and avoid temporal association between vaccination and intussusception • If the course is interrupted, it should be resumed but not repeated, provided that the second dose can be given before 24 weeks of age
Quantity to be administered	As per single (1.5ml) dose In the unlikely event that an infant spits out or regurgitates most of the vaccine dose, a single replacement dose may be given at the same immunisation visit
Maximum or minimum treatment period	Two dose schedule (see Dose and frequency of administration)
Storage	• Store at +2°C to +8°C • Store in original packaging to protect from light • Do not freeze • 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, refer to PHE Vaccine Incident Guidance
Adverse effects *(continued)*	The most common adverse reactions observed after administration of rotavirus vaccine are diarrhoea and irritability. Other reactions commonly reported include vomiting, abdominal pain, flatulence, skin inflammation, regurgitation of food, fever and loss of appetite. A detailed list of adverse reactions is available in the vaccine's SPC, which is available from the electronic Medicines Compendium Intussusception Intussusception is a naturally-occurring condition where the part of the intestine prolapses, or telescopes, into another part causing an obstruction. In England, 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 with age to a peak at around five months of age. Some countries

Adverse effects *(continued)*	have reported a small increase in the risk of intussusception within seven days of rotavirus immunisation and rotavirus vaccine prescribing information includes this as a possible side effect. The benefits of immunisation in preventing the consequences of rotavirus infection outweigh this small potential risk in young children. However, because of this potential risk, and to reduce the likelihood of a temporal association with rotavirus immunisation, the first dose of vaccine must not be given after 15 weeks of age and the second dose must not be given after 24 weeks of age. **Reporting procedure:** As with all vaccines, healthcare professionals and parents/carers are encouraged to report suspected adverse reactions to the Medicines and Healthcare products Regulatory Agency (MHRA) using the Yellow Card reporting scheme on: http://yellowcard.mhra.gov.uk or search for MHRA Yellow Card in the Google Play or Apple App Store. Any adverse reaction to the vaccine should be documented in the infant's record and the infant's GP should be informed.
Records to be kept	The administration of any medication given under a PGD must be recorded within the patients' medical records Please see Appendix C for more details

9. Patient information

Verbal/Written information to be given to patient or carer	• Verbal information must be given to patients and or carers for all medication being administered under a PGD • Where medication is being supplied under a PGD, written patient information leaflet must also be supplied • A patient information leaflet is available on request
Follow-up advice to be given to patient or carer	• If symptoms do not improve or worsen or you become unwell, seek medical advice immediately • When administration is postponed advise the individual/carer/parent when to return for vaccination

10. Appendix A

References

1. British National Formulary (BNF) available online: https://bnf.nice.org.uk
2. Nursing and Midwifery (2018) "The code" available online: https://www.nmc.org.uk
3. Current Health Care Professions Council standards of practice
4. General Pharmaceutical Council standards
5. The General Optical Council
6. Electronic medicines compendium available online: https://www.medicines.org.uk

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- Summary of Product Characteristics for Rotarix®. GlaxoSmithKline UK Updated 01 January 2021 http://www.medicines.org.uk/emc/medicine/17840
- Immunisation Against Infectious Disease: The Green Book, Chapter 27b . Updated August 2015 https://www.gov.uk/government/collections/immunisation-against-infectious-disease-the-green-book
- Public health commissioning in the NHS: 2020 to 2021 https://www.gov.uk/government/publications/public-health-commissioning-in-the-nhs-2020-to-2021

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- Health Technical Memorandum 07-01: Safe Management of Healthcare Waste. Department of Health 20 March 2013. https://www.gov.uk/government/publications/guidance-on-the-safe-management-of-healthcare-waste
- National Minimum Standards and Core Curriculum for Immunisation Training. Published February 2018. https://www.gov.uk/government/publications/national-minimum-standards-and-core-curriculum-for-immunisation-training-for-registered-healthcare-practitioners
- NICE Medicines Practice Guideline 2 (MPG2): Patient Group Directions. Published March 2017. https://www.nice.org.uk/guidance/mpg2
- NICE MPG2 Patient group directions: competency framework for health professionals using patient group directions. Updated March 2017. https://www.nice.org.uk/guidance/mpg2/resources
- PHE Immunisation Collection https://www.gov.uk/government/collections/immunisation
- PHE Vaccine Incident Guidance https://www.gov.uk/government/publications/vaccine-incident-guidance-responding-to-vaccine-errors

11. Appendix B

Health professionals agreed to practice

- Each registered healthcare professional will hold their own Competency framework which will be signed and agreed by their mentor
- A mentor is defined within the Manx Care policy as any ward/area managers, sisters, senior nurses, GPs, pharmacists or senior paramedics who has completed the PGD training themselves

12. Appendix C

Special considerations/ additional information	• Ensure there is immediate access to adrenaline (epinephrine) 1 in 1000 injection and access to a telephone at the time of vaccination • Consider giving the oral rotavirus vaccine before administration of any vaccine injections which may unsettle the infant • There are no restrictions on an infant's consumption of food or drink before or after immunisation • Breast-feeding may be continued during the vaccination schedule. • Postpone vaccination for infants with acute diarrhoea or vomiting until they have recovered, to ensure the vaccine is not regurgitated or passed through the intestines too quickly, which could reduce the effectiveness
Disposal	Equipment used for immunisation, including discharged vaccines in a syringe or oral applicator, should be disposed of, as medicinally-contaminated clinical waste for incineration, in a yellow UN-approved waste receptacle (this is usually a sharps box), according to local authority regulations and guidance in the technical memorandum 07-01: Safe management of healthcare waste (Department of Health, 2013).
Drug interactions	Rotavirus vaccine can be given at the same time as, or any time before or after, any of the other vaccines administered as part of the routine infant immunisation programme, including BCG vaccine. A detailed list of drug interactions is available in the SPC, which is available from the electronic Medicines Compendium
Records *(continued)*	Record: • that valid informed consent was given • name of individual, address, date of birth and GP with whom the individual is registered • name of immuniser • name and brand of vaccine • date of administration • dose, form and route of administration of vaccine • quantity administered • batch number and 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 • supplied via PGD • Records should be signed and dated (or a password-controlled immuniser's record on e-records) • All records should be clear, legible and contemporaneous. • This information should be recorded in the individual's GP record. Where vaccine is administered outside the GP setting appropriate

Records *(continued)*	health records should be kept and the individual's GP informed • The local Child Health Information Systems team (Child Health Records Department) must be notified using the appropriate documentation/pathway as required by any local or contractual arrangement • A record of all individuals receiving treatment under this PGD should also be kept for audit purposes in accordance with local policy