Public Health England

NHS England

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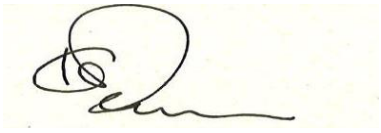
Amendment Dates:	**Page(s)**	**Brief Description**
June 2013		New PGD based on template received from Public Health England
November 2013		PGD updated following update to the Green book Chapter 27b Rotavirus.
October 2014		Updated to new PGD format

Patient Group Direction for Administration of Rotarix® oral suspension (Rotavirus vaccine, live)

Approved By

NHS England and Staffordshire Area Team	Name	Signature
Medical Director	Dr Ken Deacon	
LPN Pharmacy Chair	Dr Manir Hussain	
Head of Public Health Commissioning	Rebecca Woods	

Date of patient group direction approved	Nov 2014
Date this patient group direction becomes due for review	June 2015 or in response to new local/national guidelines.

STAFF CHARACTERISTICS

- Provider of NHS services within NHS England (Shropshire & Staffordshire Area Team)
- Registered nurse with current NMC registration

Specialist competencies or qualifications:

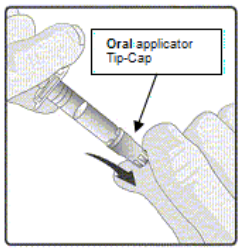
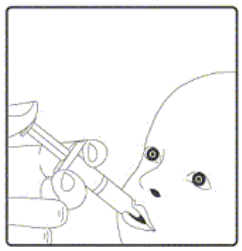
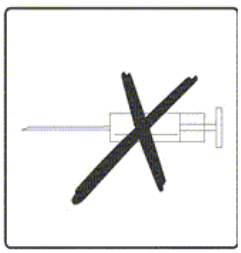
- The health care professional should undertake the Public Health England training for healthcare practitioners on the national infant rotavirus immunisation programme which can be accessed via (https://www.gov.uk/government/collections/rotavirus-vaccination-progarmme-for-infants)
- The health care professional must have a good understanding of the NICE Good Practice Guidance on Patient Group Directions.
- The NICE competency framework: For health professionals using Patient Group Directions should be used by health care professionals planning to work under this PGD to identify any gaps in their knowledge. The gaps should be addressed before the healthcare professional is authorised to work under this PGD.
- The clinical manager/ lead GP/commissioner must have evidence that the health care professional has undertaken training to carry out clinical assessment of patient leading to confirmation that the patient requires treatment according to the indications listed in the PGD.
- The healthcare professional must provide evidence of training, appropriate annual updates and continued professional development undertaken to support their competence for administration of this treatment.
- The clinical manager/ lead GP must have assessed the competency of the healthcare professional to work to this Patient Group Direction. The NICE competency framework: For health professionals using Patient Group Directions should be used to support this assessment.
- The health care professional must have undertaken training and annual updates in the recognition and treatment of anaphylaxis, including practical in Basic Life Support and has immediate access to an in-date supply of adrenaline 1mg in 1ml (1:1000) at the time of the consultation. (The practitioner must be deemed competent in basic life support and in emergency administration of adrenaline)
- The health care professional must have access to all relevant sources of information e.g. information issued by the Department of Health (Green Book), British National Formulary (BNF), Summary of Product Characteristics (SPC), and the clinical guideline concerning medicine(s) within this Patient Group Direction (PGD).
- The practitioner must be competent and knowledgeable in vaccine cold chain standards.
- The registered health care practitioner is professionally accountable for supply or administration under the PGD as defined in their own profession's Code of Professional Conduct and Ethics.

YOU MUST BE AUTHORISED BY NAME BY YOUR CLINICAL LEAD UNDER THE CURRENT VERSION OF THIS PGD BEFORE YOU ATTEMPT TO WORK ACCORDING TO IT

PGDs DO NOT REMOVE INHERENT PROFESSIONAL OBLIGATIONS OR ACCOUNTABILITY

CLINICAL CONDITION	
Clinical need addressed	Rotarix® is indicated for the active immunisation of infants aged 6 to 24 weeks for the prevention of gastroenteritis due to rotavirus infection, in line with the recommendations given in Chapter 27b of the Immunisation against infectious Disease: The Green Book.
Inclusion criteria	Children meeting criteria for rotavirus vaccination under the routine childhood immunisation schedule i.e.: **Immunisation schedule for Rotarix®** ● First dose of 1.5 ml of Rotarix® vaccine at two months (approximately eight weeks) of age. ● Second dose of 1.5 ml at least four weeks after the first dose. It is preferable that the full course of two doses of Rotarix® 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. In line with recommendations from WHO, infants should only receive the first dose of Rotarix® if they are younger than 15 weeks of age. Infants who receive the first dose before week 15 should receive the second dose of vaccine by 24 weeks of age. If the course is interrupted, it should be resumed but not repeated, provided that the second dose can be given before the 24 week cut-off. (See chapter 11 for the Green Book for schedule of UK's routine childhood immunisations) **Premature infants** It is important that premature infants have their immunisations at the appropriate chronological age, according to the schedule. Vaccination of pre-term infants using Rotarix® is indicated at a chronologic age (without correction for prematurity) of at least six weeks, 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.
Exclusion criteria (for full details of interacting medicines refer to current Summary of Product Characteristics (SPC) www.medicines.org.uk & BNF)	• Declined consent (parent/guardian) • Infants aged under six weeks of age • Infants aged 15 weeks and zero days to 24 weeks who have not yet received their first dose. • Infants aged 24 weeks or older • Infants with a confirmed anaphylactic reaction to a previous dose of rotavirus vaccine; • Infants with a confirmed anaphylactic reaction to any component of the

	vaccine; • Infants with a previous history of intussusception; • Infants with Severe Combined Immunodeficiency Disorder (SCID); • Infants who have a malformation of the gastrointestinal tract that could predispose them to intussusception (intussusception is a naturally-occurring condition where the part of the intestine prolapses, or telescopes, into another part causing an obstruction). • Infants with rare hereditary problems of fructose intolerance, glucose-galactose malabsorption or sucrase-isomaltase insufficiency. **Immunosuppression** Although the vaccine is a live attenuated virus, with the exception of severe combined immune-deficiency (SCID), the benefit from vaccination may exceed any risk in other forms of immunosuppression. Therefore in other cases of immunosuppression, the vaccine may be considered – **but this is not in the remit of this PGD.** In such cases, the infant's General Practitioner (GP) should issue a patient specific direction (PSD) or administer the vaccine themselves. As with all complex cases, it is good practice to involve the infant's specialist clinician in the decision whether to immunise. **Temporary Exclusion** Administration of rotavirus vaccine should be postponed in infants suffering from: ● acute severe febrile illness, ● acute diarrhoea or vomiting. This is to make sure that the vaccine is not regurgitated or passed through the intestines too quickly, which could reduce the effectiveness of the vaccine. Other 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. This is to avoid confusing the differential diagnosis of any acute illness by wrongly attributing any signs or symptoms to the adverse effects of the vaccine.
Management of excluded patients	Exclusion under this Patient Group Direction (PGD) does not necessarily mean the medication is contraindicated but it would be outside the remit of the PGD and another form of authorisation (PSD) will be required. • Document in the infant's notes, advise and counsel accordingly • Referral to medical practitioner or other appropriate service if necessary. **Temporary exclusion** In case of postponement due to acute illness,arrange a future date for immunisation (if the infant will still be within the age range recommended above).
Action for patients not wishing to receive care under this PGD	• Advise parent/carer about the protective effects of the vaccine, the risks of infection, disease including potential complications. • Document action and advice given • Refer to medical practitioner where appropriate - doctor or independent prescriber.

Treatment and Drug details	
Name form and strength of medicine	Rotarix® (live attenuated rotavirus) vaccine is supplied as an oral suspension of clear colourless liquid in an oral applicator containing the suspension solution (1.5 ml) with a plunger, stopper and a protective tip cap. Manufactured by GlaxoSmithKline
Legal classification	POM (Prescription only medicine)
Black triangle warning▼ Suspected adverse reactions. Should be reported using the Yellow Card reporting scheme (www.yellowcard.gov.uk).	Yes
Method of obtaining supply	In England, Rotarix® should be ordered online only via the ImmForm website (https://www.gov.uk/government/collections/immform) and it is distributed by Movianto UK (Tel: 01234 248631) as part of the national childhood immunisation programme. Centrally purchased vaccines for the national immunisation programme for the NHS can only be ordered via ImmForm. Vaccines for use for the national childhood immunisation programme are provided free of charge.
Site for treatment	GP surgeries
Route / method	Rotarix® vaccine is given orally. **Rotavirus vaccines must NOT be injected.** **Instructions for administration of the vaccine:** To administer the vaccine, carefully remove the protective tip-cap from the oral applicator. Seat the child in a reclining position and administer the entire content of the oral applicator orally (i.e. into the child's mouth, towards the inner cheek).   

	1. Remove the protective tip cap from the **oral** applicator. 2. This vaccine is for **oral administration only**. The child should be seated in a reclining position. Administer **orally** (into the child's mouth, towards the inner cheek) the entire content of the applicator. 3. **Do not inject.** The Summary of Product Characteristics for Rotarix® provides further guidance on administration. http://www.medicines.org.uk/emc/medicine/17840/SPC/rotarix Rotavirus vaccine can be given at the same time as the other vaccines administered as part of the routine childhood immunisation programme, including BCG, and so should ideally be given at the scheduled two month and three month vaccination visits. However, rotavirus vaccine can be given at any time before or after the routine infant immunisations and at any time before or after BCG vaccine. The recommendation for administering live vaccines either at the same time or after an interval of four weeks only applies to injectable live viral vaccines and, therefore, not to BCG or to the oral rotavirus vaccines. If the infant spits out or regurgitates most of the vaccine, a single replacement dose may be given at the same or a subsequent immunisation visit. There are no restrictions on an infant's consumption of food or drink before or after immunisation
Dose	**Immunisation Schedule** • First dose of 1.5 ml of Rotarix® vaccine at two months (approximately eight weeks) of age; • Second dose of 1.5 ml at least four weeks after the first dose It is preferable that the full course of two doses of Rotarix® 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. In line with recommendations from WHO, infants should only receive the first dose of Rotarix® if they are younger than 15 weeks of age. Infants who receive the first dose before week 15 should receive the second dose of vaccine by 24 weeks of age. If the course is interrupted, it should be resumed but not repeated, provided that the second dose can be given before the 24 week cut-off.
Number of times treatment may be administered	See dosage section above **Maximum two doses as per immunisation schedule**
Quantity to be supplied or administered	**One dose as per immunisation schedule**
Side effects *Suspected adverse reactions to drugs including vaccines should be reported on the yellow card available at the*	The most common adverse reactions observed after administration of Rotarix® vaccine administration are diarrhoea and irritability. Other reactions uncommonly reported are abdominal pain, flatulence, vomiting, skin inflammation, regurgitation of food, fever and loss of appetite. A detailed list of adverse reactions associated with Rotarix® is available in the

back of the BNF. Also at www.yellowcard.gov.uk	Summary of Product Characteristics for this vaccine, which is available from the European Medicines Agency website: http://www.medicines.org.uk/emc/medicine/17840/SPC/Rotarix / Research from some countries suggests that Rotarix® may be associated with a very small increase in the risk of intussusception within seven days of immunisation, by possibly two cases per 100,000 first doses given, and the Rotarix® 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 should not be given after 15 weeks of age
Additional Information	• Vaccines should be stored in the original packaging at +2°C to +8°C and protected from light. • All vaccines are sensitive to some extent to heat or cold. Heat speeds up the decline in potency of most vaccines, thus reducing their shelf life. Effectiveness will be reduced for vaccines unless they have been stored at the correct temperature. • Freezing may cause increased reactogenicity and loss of potency for Rotarix®. If the vaccine has been frozen, it should be discarded. • Equipment used for immunisation, including used vials, ampoules, or partially discharged vaccines in an oral applicator, should be disposed of at the end of a session by sealing in a proper, puncture-resistant 'sharps' box, according to local authority regulations and guidance in the technical memorandum 07-01 (Department of Health, 2006).
Advice to patient / carer	**BEFORE TREATMENT:** • Advise patient/parent/guardian of possible side effects. (For full details see product's summary of product characteristics). • Inform patient/carer of possible side effects and their management. • Give advice regarding normal reaction to the injection, for example diarrhoea and irritability. • The parent/carer should be advised to seek medical advice in the event of a severe adverse reaction. **AFTER TREATMENT:** • Supply marketing authorisation holder's patient information leaflet (PIL) provided with the vaccine • Any serious adverse reaction to the vaccine should be documented in a child's health records and on their medical records. GP should also be informed. • When applicable, advise parent/carer when the subsequent dose is due.
Follow up	Advise patients/parent/guardian of possible side effects as above and advise to seek medical advice from the most appropriate health professional (GP, HV or practice nurse).
Suspected Adverse reactions	Patient presenting with suspected adverse drug reaction should be referred to a doctor for further investigations. 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 Any serious adverse reaction to the vaccine should be documented in the infant's record. The infant's GP should also be informed.
Error reporting	Any incidents or near miss issues must be reported via the organisation's internal reporting system (Datix).
RECORD KEEPING	
Documentation needed / treatment records to be kept for audit purposes *A computer or manual record of all individuals receiving treatment under this Patient Group Direction should also be kept for audit purposes.*	• Patient's name, address, date of birth and GP • Manufacturer / brand of product, batch number, expiry date • Record of informed consent • Dose • Date of administration • Route of administration • Advice given to patient / carer (including advice given if vaccination is declined) • Details of staff who administered (sign and print name) • Details of any adverse drug reactions, and action taken including informing GP • Reconciliation – stock balances should be reconcilable with receipts, administration, records and disposal on a patient by patient basis. • Details of any Adverse Drug Reactions and actions taken; • Record supplied via Patient Group Direction (PGD). All records should be clear, legible and contemporaneous. This information should be recorded in the infant's GP record AND the personal Child Health record (PCHR) – the Red Book. A computerised or manual record of all individuals receiving treatment under this Patient Group Direction should also be kept for audit purposes. Clinical records must be kept for at least 8 years following completion of treatment. In patients who are aged under 17 years, clinical records must be kept until the patient's 25th birthday, or for 8 years following a child's death. Data must be stored in accordance with Caldicott guidance and the Data Protection Act.

REFERENCES	
	NHS England Immunisation update: Important changes to the national immunisation programme in 2013-14, and introduction of rotavirus vaccination for babies at two and three months
	The Green Book – Immunisation Against Infectious Disease: Rotavirus Chapter 27b
	Rotarix ® SPC www.medicines.org.uk

Register of practitioners qualified to administer and / or supply Administration of **Rotarix®** oral suspension (Rotavirus vaccine, live) Infants aged 6 to 24 weeks **under this Patient Group Direction**	
Name of clinical manager / GP Lead	
Signature of clinical manager / GP Lead	Date:
A copy of this page should be retained by the authorising manager for 2 years for audit purposes	
Please state clinical area where this PGD is in use	

Healthcare professional individual declaration

I have read and understood the Patient Group Direction and agree to supply this medicine only in accordance with this PGD

- **PGDs DO NOT REMOVE INHERENT PROFESSIONAL OBLIGATIONS OR ACCOUNTABILITY**.
- It is the responsibility of each professional to practice only within the bounds of their own competence.
- All practitioners operating in accordance with this PGD should have a current, signed copy of it readily available for reference.
- If a practitioner is asked to supply, or administer a medicine not covered by this or any other PGD then a patient specific direction is required from a doctor, dentist or independent prescriber.

Name of professional (please print)	Signature	Authorising Manager (Must sign against each entry)	Date of authorisation

The clinical lead should review competency of authorised practitioners annually.

Authorisation to use this PGD does not remove inherent professional responsibility and accountability

Acknowledgement: Medicines Management Team, Telford & Wrekin CCG for developing the PGD.