Patient Group Direction template

Administration of
Rotavirus Vaccine, Live (Rotarix®)

Version 4.0

Revised following change of vaccine presentation

This specimen Patient Group Direction template has been produced by the Health Protection Scotland to assist NHS Boards

NHS Boards should amend/adapt this Patient Group Direction template and must ensure that the Patient Group Direction is considered and approved in line with local clinical governance arrangements for Patient Group Directions

PGD Rotavirus vaccine, Live (Rotarix®)

Authorisation

This specimen Patient Group Direction (PGD) template has been produced by Health Protection Scotland to assist NHS Boards. NHS Boards should ensure that the final PGD is considered and approved in line with local clinical governance arrangements for Patient Group Directions.

The qualified health professionals who may administer Rotavirus vaccine, Live (Rotarix®) 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 marketing authorisation holder's summary of product characteristics (SPC) for all vaccines administered in accordance with this PGD.

NHS Board governance arrangements will indicate how records of staff authorised to operate this PGD will be maintained. Under PGD legislation there can be no delegation. Administration of the vaccine has to be by the same practitioner who has assessed the patient under the PGD.

This PGD has been produced for NHS (*insert details*) by

Doctor	_____	Signature	_____
Pharmacist	_____	Signature	_____
Nurse	_____	Signature	_____

Approved on behalf of NHS (*insert details*) by

Medical Director	_____	Signature	_____
Director of Pharmacy/Senior Pharmacist	_____	Signature	_____
Clinical Governance Lead	_____	Signature	_____

Date Approved _____

Effective from	01/11/2017	Review Date	31/10/2019

Clinical Situation

Indication	Active immunisation against rotavirus in line with Scottish Government Health Directorate immunisation programme.
Inclusion Criteria	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.
Exclusion Criteria	Confirmed anaphylactic reaction to a previous dose of rotavirus vaccine. Confirmed anaphylactic reaction to any component of the vaccine. Practitioners must check the marketing authorisation holder's summary of product characteristics (SPC) for details of vaccine components. Known to have previous history of intussusception. 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. Infants who have not received their first dose before 15 weeks of age (i.e. older than 14 weeks and 6 days). Infants 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. Known to have immunosuppression. Acute severe febrile illness –postpone immunisation until patient has fully recovered. Acute diarrhoea or vomiting - postpone immunisation until patient has fully recovered.
Cautions /Need for further advice/ Circumstances when further advice should be sought from a doctor	Minor illnesses without fever or systemic upset are not valid reasons to postpone immunisation.
Action if Excluded	Specialist advice must be sought on the vaccine and circumstances

	under which it could be given. The risk to the individual of not being immunised must be taken into account. 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. Temporary exclusion: In case of postponement due to acute severe febrile illness, arrange a future date for immunisation. Temporary exclusion: In case of postponement due to acute diarrhoea or vomiting, arrange a future date for immunisation. Document in clinical records.
Action if Patient Declines	Advise about the protective effects of the vaccine, the risks of infection and complications. Document advice given and decision reached. In GP practice setting, inform or refer to GP.

Description of Treatment

Name of Medicine	Rotavirus vaccine, Live (Rotarix®).
Form/Strength	Oral suspension in a prefilled oral applicator or a tube.
Route of administration	Oral use only. Rotarix® must not be injected.
Dosage	1.5ml.
Frequency	The course consists of two doses with an interval of at least four weeks between the doses. The recommended age for immunisation is the first dose at two months of age (approximately eight weeks) followed by the second dose 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. 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.
Duration of treatment	See Frequency section.
Maximum or minimum treatment period	See Frequency section.
Quantity to supply/administer	See Frequency section.
▼ black triangle medicines	No
Legal Category	POM – prescription only medicine.
Is the use outwith the SPC	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.
Storage requirements	Vaccine should be stored at a temperature of +2° to +8°C. If the vaccine has been frozen, it should be discarded. NHS board guidance on Storage and Handling of vaccines should be observed.
Additional Information	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. 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. Very premature infants (born ≤ 28 weeks of gestation) who are in hospital should have respiratory monitoring for 48-72 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 48-72 hrs.

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. For full details/information on possible side effects, refer to the marketing authorisation holder's SPC. As with all vaccines there is a very small possibility of anaphylaxis

	and facilities for its management must be available. In the event of severe adverse reaction 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.
Reporting procedure for adverse reactions	Any adverse events that may be attributable to Rotavirus vaccine, Live (Rotarix®) should be reported using the yellow card system on http://yellowcard.mhra.gov.uk/ Any serious adverse reaction to the vaccine should be documented in an individual's record. GP should also be informed.
Advice to Patient/carer including written information	Supply marketing authorisation holder's patient information leaflet (PIL) provided with vaccine. Inform of possible side effects and their management. Advise parents/guardians to seek medical advice if there is any abdominal pain, vomiting and passing what looks like red currant jelly in their nappies. 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.
Monitoring	Following immunisation patients remain under observation in line with NHS Board policy.
Follow-up	If appropriate remind parents/guardian that a further dose will be required to complete the course.
Additional Facilities	Immediate access to Epinephrine (adrenaline) 1 in 1000 injection Access to telephone.

Characteristics of staff authorised under the PGD

Professional qualifications	Those registered health care professionals that are listed and approved in legislation as able to operate under patient group directions
Specialist competencies or qualifications	Approved by the organisation as competent: · to undertake immunisation and discuss issues related to immunisation, · to assess the person's capacity to understand the nature and purpose of the immunisation in order to give or refuse consent, · to work with this patient group direction, · in the recognition and management of anaphylaxis.

Continuing education and training	The practitioner must be familiar with the SPC for all vaccines administered in accordance with this PGD. It is the responsibility of the individual to keep up to date with all aspects of immunisation and in the recognition and management of anaphylaxis.

Audit Trail

Record/Audit Trail	The approved practitioner must ensure maintenance of records for each vaccine administered and may be required to share information with appropriate parties in line with confidentiality protocols.The information relating to immunisation of each individual must include as a minimum: · Patient's name and date of birth, · Dose, · Site and route of injection, · Brand, batch number and expiry date of vaccine, · Date given and by whom(name/signature). All records must be clear and legible and, ideally, in an easily retrievable format. Depending on the clinical setting where immunisation is undertaken, the information should be recorded manually or electronically, in one (or more) of the following systems, as appropriate: · GP practice computer, · Individuals GP records, · Child Health Systems (e.g. SIRS) · Personal Held Child Record (red book)
Additional references	Practitioners operating the PGD must be familiar with: Department of Health (2006): Immunisation against Infectious Disease [Green Book] Immunisation against Infectious Disease [Green Book] Rotavirus chapter 27a Current edition of British National Formulary Marketing authorisation holder's Summary of Product Characteristics All relevant Scottish Government Health Directorate advice including the relevant CMO letter(s) NMC (2015) Code of Professional Conduct. NMC (2010) Standards for Medicines Management

PGD for administration of Rotavirus vaccine, Live (Rotarix®) – Authorisation

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

Note to Authorising Managers

Authorised staff should be provided with an individual copy of the clinical content of the PGD and a photocopy of the document showing their authorisation.

I have read and understood the Patient Group Direction. I agree to administer Rotavirus vaccine, Live (Rotarix®) only in accordance with this PGD.

Name of Professional	Signature	Date

I agree that the professionals listed above are authorised to supply/administer medicines in accordance with this PGD to patients cared for in this service area.

Lead Clinician for the service area (Doctor)		
Name:	Signature:	Date: