Public Health England

NHS

PHE publications gateway number: GOV-8462

Rotavirus vaccine Patient Group Direction (PGD)

This PGD is for the administration of rotavirus vaccine (live) to infants aged 6 weeks to 23 weeks and 6 days for active immunisation against rotavirus.

This PGD is for the administration of rotavirus vaccine (live) by registered healthcare practitioners identified in Section 3, subject to any limitations to authorisation detailed in Section 2.

Reference no:	Rotavirus PGD
Version no:	v05.00
Valid from:	01 July 2021
Review date:	01 January 2023
Expiry date:	30 June 2023

Public Health England has developed this PGD to facilitate the delivery of publicly funded immunisation in line with national recommendations.

Those using this PGD must ensure that it is organisationally authorised and signed in Section 2 by an appropriate authorising person, relating to the class of person by whom the product is to be supplied, in accordance with Human Medicines Regulations 2012 (HMR2012)[1]. **The PGD is not legal or valid without signed authorisation in accordance with HMR2012 Schedule 16 Part 2.**

Authorising organisations must not alter, amend or add to the clinical content of this document (sections 4, 5 and 6); such action will invalidate the clinical sign-off with which it is provided. In addition, authorising organisations must not alter section 3 'Characteristics of staff'. Only sections 2 and 7 can be amended within the designated editable fields provided.

Operation of this PGD is the responsibility of commissioners and service providers. The final authorised copy of this PGD should be kept by the authorising organisation completing Section 2 for 25 years after the PGD expires. Provider organisations adopting authorised versions of this PGD should also retain copies for the period specified above.

Individual practitioners must be authorised by name, under the current version of this PGD before working according to it.

Practitioners and organisations must check that they are using the current version of the PGD. Amendments may become necessary prior to the published expiry date. Current versions of PHE PGD templates for authorisation can be found from: https://www.gov.uk/government/collections/immunisation-patient-group-direction-pgd

Any concerns regarding the content of this PGD should be addressed to: immunisation@phe.gov.uk

Enquiries relating to the availability of organisationally authorised PGDs and subsequent versions of this PGD should be directed to: england.londonimms@nhs.net

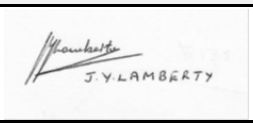
[1] This includes any relevant amendments to legislation (for instance 2013 No.235, 2015 No.178 and 2015 No.323).

Change history

Version number	Change details	Date
Final version	New PHE Rotavirus PGD	1 July 2013
Version 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 April 2015
Version 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 April 2017
Version 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 February 2019
Version 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 May 2021

1. PGD development

This PGD has been developed by the following health professionals on behalf of Public Health England:

Developed by:	Name	Signature	Date
Pharmacist (Lead Author)	Jacqueline Lamberty Lead Pharmacist Medicines Management Services, PHE		26 May 2021
Doctor	Dr Gayatri Amirthalingam Consultant Epidemiologist, Immunisation, Hepatitis and Blood Safety Department, National Infection Service. PHE		26 May 2021
Registered Nurse (Chair of Expert Panel)	David Green Nurse Consultant – Immunisation and Countermeasures, PHE		26 May 2021

This PGD has been peer reviewed by the PHE Immunisations PGD Expert Panel in accordance with PHE PGD Policy. It has been ratified by the PHE Medicines Governance Group and the PHE Quality and Clinical Governance Delivery Board.

Expert Panel

Name	Designation
Nicholas Aigbogun	Consultant in Communicable Disease Control, Yorkshire and Humber Health Protection Team, Public Health England
Sarah Dermont	Clinical Project Coordinator and Registered Midwife, NHS Infectious Diseases in Pregnancy Screening Programme, Public Health England
Ed Gardner	Advanced Paramedic Practitioner / Emergency Care Practitioner, Medicines Manager, Proactive Care Lead
Michelle Jones	Senior Medicines Optimisation Pharmacist, NHS Bristol North Somerset & South Gloucestershire CCG
Vanessa MacGregor	Consultant in Communicable Disease Control, East Midlands Health Protection Team, Public Health England
Alison Mackenzie	Consultant in Public Health Medicine, Screening and Immunisation Lead, Public Health England (South West) / NHS England and NHS Improvement South (South West)
Gill Marsh	Senior Screening and Immunisation Manager, Public Health England / NHS England and NHS Improvement (North West)
Lesley McFarlane	Screening and Immunisation Manager: Clinical (COVID-19 and Influenza), Public Health England / NHS England and NHS Improvement (Midlands)
Tushar Shah	Lead Pharmacy Advisor, NHS England and NHS Improvement (London Region)

2. Organisational authorisations

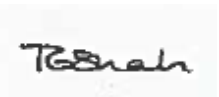
The PGD is not legally valid until it has had the relevant organisational authorisation.

It is the responsibility of the organisation that has legal authority to authorise the PGD, to ensure that all legal and governance requirements are met. The authorising body accepts governance responsibility for the appropriate use of the PGD.

NHS England and NHS Improvement London Region authorises this PGD for use by the services or providers listed below:

Authorised for use by the following organisations and/or services
This PGD must only be used by specified registered healthcare professionals working for providers that are directly commissioned by NHS England and NHS Improvement London Region, or who are administering vaccinations as part of a national immunisation programme, and who have been named and authorised to practice under it
Limitations to authorisation
None

Organisational approval (legal requirement)			
Role	**Name**	**Sign**	**Date**
Joint Regional Chief Nurse, NHS England and NHS Improvement London Region	Jane Clegg		23/06/2021

Additional signatories according to locally agreed policy			
Role	**Name**	**Sign**	**Date**
Director of Nursing Leadership and Quality, NHS England and NHS Improvement London Region	Gwen Kennedy		18/06/2021
Lead Pharmacy Advisor, NHS England and NHS Improvement London Region	Tushar Shah		17/06/2021

Local enquiries regarding the use of this PGD may be directed to england.londonimms@nhs.net

Section 7 provides a practitioner authorisation sheet. Individual practitioners must be authorised by name to work to this PGD. Alternative practitioner authorisation sheets may be used where appropriate in accordance with local policy but this should be an individual agreement or a multiple practitioner authorisation sheet as included at the end of this PGD.

3. Characteristics of staff

Qualifications and professional registration	Registered professional with one of the following bodies: • nurses and midwives currently registered with the Nursing and Midwifery Council (NMC) • pharmacists currently registered with the General Pharmaceutical Council (GPhC) (Note: This PGD is not relevant to privately provided community pharmacy services) • paramedics and physiotherapists currently registered with the Health and Care Professions Council (HCPC) The practitioners above must also fulfil the Additional requirements detailed below. Check Section 2 Limitations to authorisation to confirm whether all practitioners listed above have organisational authorisation to work under this PGD.
Additional requirements	Additionally practitioners: • must be authorised by name as an approved practitioner under the current terms of this PGD before working to it • must have undertaken appropriate training for working under PGDs for supply/administration of medicines • must be competent in the use of PGDs (see NICE Competency framework for health professionals using PGDs) • 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 • must have access to the PGD and associated online resources • should fulfil any additional requirements defined by local policy **The individual practitioner must be authorised by name, under the current version of this PGD before working according to it.**
Continued training requirements	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). Practitioners should be constantly alert to any subsequent recommendations from Public Health England and/or NHS England and NHS Improvement and other sources of medicines information. Note: The most current national recommendations should be followed but a Patient Specific Direction (PSD) may be required to administer the vaccine in line with updated recommendations that are outside the criteria specified in this PGD.

4. Clinical condition or situation to which this PGD applies

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'.
Criteria for inclusion	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[2]	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 (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)

[2] 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

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.
Action to be taken if the patient is excluded	**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 the patient or carer declines treatment	Informed consent, from a person legally able to act on the infant's behalf, must be obtained for each administration. Advise the parent/carer about the protective effects of the vaccine, the risks of infection and potential complications of disease. Document advice given and decision reached. In a GP practice setting, inform or refer to the GP as appropriate.

Arrangements for referral for medical advice	As per local policy

5. Description of treatment

Name, strength & formulation of drug	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.
Off-label use	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 Continued over page	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.

Route / method of administration (continued)	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 of administration	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.
Duration of treatment	Two dose schedule (see Dose and frequency of administration).
Quantity to be supplied / administered	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.
Supplies	Centrally purchased vaccines for the national immunisation programme can only be ordered via ImmForm. Vaccines for use for the national childhood immunisation programme are provided free of charge. Protocols for the ordering, storage and handling of vaccines should be followed to prevent vaccine wastage (see the 'Green Book' Chapter 3).
Storage	Store at +2°C to +8°C. Store in original packaging in order 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.
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
Identification & management of adverse reactions	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 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 of adverse reactions	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.
Written information to be given to patient or carer	Offer the marketing authorisation holder's patient information leaflet (PIL) provided with the vaccine. Immunisation promotional material may be provided as appropriate: • A guide to immunisations for babies up to 13 months of age • A quick guide to childhood immunisation for the parents of premature babies Available from: www.gov.uk/government/collections/immunisation
Patient advice / follow up treatment Continued overleaf	Inform parent/carer of possible side effects and their management. The parent/carer should be advised to seek medical advice in the event of a severe adverse reaction. Parents/carers should be advised to promptly report any of the following symptoms indicative of intussusception:

Patient advice / follow up treatment (continued)	• severe abdominal pain • persistent vomiting • bloody stools • abdominal bloating • high fever When applicable, advise parent/carer when the subsequent dose is due. When administration is postponed, advise when the infant should return for immunisation, with due consideration of the infant's age to ensure they will meet the inclusion criteria for rotavirus immunisation. Those in close contact with recently vaccinated infants should observe good personal hygiene, for instance wash their hands after changing the infant's nappies (see Cautions).
Special considerations / additional information	Ensure there is immediate access to adrenaline (epinephrine) 1 in 1000 injection and access to a telephone. 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.
Records	Record: • that valid informed consent was given • name of infant, 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 • 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 immunisers record on e-records). All records should be clear, legible and contemporaneous. The local Child Health Information Services 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.

6. Key references

Key references	**Rotavirus** • 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 **General** • 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

7. Practitioner authorisation sheet

Rotavirus PGD v05.00 Valid from: 01/07/2021 Expiry: 30/06/2023

Before signing this PGD, check that the document has had the necessary authorisations in section two. Without these, this PGD is not lawfully valid.

Practitioner

By signing this patient group direction you are indicating that you agree to its contents and that you will work within it.

Patient group directions do not remove inherent professional obligations or accountability.

It is the responsibility of each professional to practise only within the bounds of their own competence and professional code of conduct.

I confirm that I have read and understood the content of this Patient Group Direction and that I am willing and competent to work to it within my professional code of conduct.			
Name	Designation	Signature	Date

Authorising manager

I confirm that the practitioners named above have declared themselves suitably trained and competent to work under this PGD. I give authorisation on behalf of the following named organisation …… for the above named health care professionals who have signed the PGD to work under it.			
Name	Designation	Signature	Date

Note to authorising manager

Score through unused rows in the list of practitioners to prevent practitioner additions post managerial authorisation.

This authorisation sheet should be retained to serve as a record of those practitioners authorised to work under this PGD.