GIG CYMRU NHS WALES
Bwrdd Iechyd Addysgu Powys
Powys Teaching Health Board

Bronllys Hospital, Bronllys, Brecon, Powys, LD3 0LU

This Patient Group Direction (PGD) must only be used by registered healthcare 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. Health professionals should always access the PGD via the PTHB internet to ensure that they are always working to the most up to date version

Patient Group Direction

for the administration of

oral rotavirus vaccine (live)

to

infants aged 6 weeks to 23 weeks and 6 days

for **active immunisation against rotavirus**

by registered healthcare practitioners

in Powys Teaching Health Board

Version number: PGD 0065 E

Reference Number: PGD 0065 E
Valid from: 30/06/2025
Review Date: 30/01/2028
Expiry Date: 30/06/2028

Change History

Version number	Change details	Date
PGD0065	Initial issue	14/07/2013
PGD0065A	Review Issue Minor changes/clarifications only	01/09/2015
PGD0065B	Review of issue and put in to new PTHB vaccine PGD template Change to Rotarix presentation from an oral syringe to tube. Both may be available during the cross over period so both have been mentioned in this PGD.	06/08/2018
PGD0065C	PHE template adopted	01/07/2021
PGD0065D	Updated according to UKHSA template version 6.00. Amended to: • add HIV infants in the inclusion section • include facilities for management for anaphylaxis statement in cautions section • delete Rotarix® oral suspension in multi monodose as per the SPC • add formulation of the product in the name, formulation section • add additional statements for use of the tube for clarity in the route and method of administration section • add additional information in patient advice section as per SPC • include minor rewording of standard text, layout and formatting changes for clarity and in accordance with organisation change, gateway requirements and other UKHSA PGDs for consistency • amend NHS England and NHS Improvement (NHSEI) to NHSE following completion of merger on 1 July 2022 • update references	30/06/2023

PGD 0065 E	Review issue in line with UKHSA Rotavirus PGD template v7.0 to: • add pharmacy technicians in Section 1; qualifications and professional registration • add dieticians, podiatrists, and occupational therapists to HCP • update expert panel • include sensitivity to phenylalanine statement in the cautions section • add excipients with known effects, phenylalanine, glucose and sucrose in the formulation section • update disposal guidance • update written information to include accessible information • update references Reviewed to include minor rewording of standard text, layout and formatting changes for clarity and consistency with other PTHB PGDs.	30/06/2025

This Powys Teaching Health Board (PTHB) PGD is based on the UKHSA Rotavirus PGD template v7.0 developed by the following health professionals on behalf of the UKHSA and peer reviewed by the UKHSA Immunisations PGD Expert Panel in accordance with the UKHSA PGD Policy (also ratified by the UKHSA Medicines Governance Committee). The UKHSA template has been adapted for use in PTHB.

Developed by the following health professionals on behalf of the UKHSA:

Developed By:	Name
Pharmacist (Lead Author)	Suki Hunjunt Lead Pharmacist, Immunisation Programmes Division, UKHSA
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Registered Nurse (Chair of Expert Panel)	David Green, Nurse Consultant for Immunisations, Immunisation Programmes Division, UKHSA

Expert Panel

Nicholas Aigbogun	Consultant in Communicable Disease Control, Yorkshire and Humber Health Protection Team, UKHSA
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Jessica Baldasera	Health Protection Practitioner, North East Health Protection Team Regions Directorate, UKHSA
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PGD Authorisation

Name	Job title and organisation	Signature	Date
Senior doctor **Dr Kate Wright**	Lead doctor for PTHB	DocuSigned by: Kate Wright 1F267952823F473...	6/18/2025
Chief Pharmacist **Jonathan Boyd**	Chief Pharmacist for PTHB	Signed by: Jon Boyd 6D8ECFE8C9EB423...	6/19/2025
Senior representative of professional group using the PGD **Claire Roche**	Executive Director of Nursing and Midwifery for PTHB	DocuSigned by: Claire Roche F07413E114E04B1...	6/19/2025
Clinical Governance Lead **Amanda Edwards**	Clinical Governance Lead for PTHB – Assistant Director for Innovation and Improvement	DocuSigned by: Amanda Edwards 74A4E51A42E9473...	6/25/2025

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. Appendix A provides a staff accreditation sheet. Individual practitioners must be authorised by name, under the current version of this PGD before working according to it.

Those using this PGD must ensure that it is organisationally authorised and signed 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.**

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 for 25 years after the PGD expires. Provider organisations adopting authorised versions of this PGD should also retain copies for 25 years after the PGD expires.

[1] This includes any relevant amendments to legislation

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. Enquiries relating to the availability of organisationally authorised PGDs and subsequent versions of this PGD should be directed to: info.medicinesmanagement.powys@wales.nhs.uk

PGD adoption by the provider

Name	Job title and organisation	Signature	Date
Signatures to be determined locally, if relevant			

1. Characteristics of staff

Qualifications and professional registration	All practitioners should only administer vaccination where it is within their clinical scope of practice to do so. Practitioners must also fulfil the additional requirements and continued training requirements to ensure their competency is up to date, as outlined in the section below. Registered professional with one of the following bodies: • nurses and midwives currently registered with the Nursing and Midwifery Council (NMC) • pharmacists and pharmacy technicians currently registered with the General Pharmaceutical Council (GPhC) (Note: this PGD is not relevant to privately provided community pharmacy services) • paramedics, physiotherapists, dieticians, podiatrists, and occupational therapists currently registered with the Health and Care Professions Council (HCPC) The practitioners above must also fulfil the Additional requirements detailed below. Check Appendix A – Staff Accredited to use this Patient Group Direction 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 have completed eLfH PGD eLearning Patient Group Directions training (available via learning@wales, PTHB staff to access via ESR). Evidence of ongoing PGD training to be submitted to Line Manager annually– this should include an annual completion certificate of PGD e-learning or a dated screenshot of the PGD e-learning assessment results as proof of completion. • must be competent in the use of PGDs (see NICE Competency framework for health professionals using PGDs). Individuals operating under this PGD must be assessed as competent (see Appendix A). • 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 and online training. Please contact PTHB immunisation co-ordinator for further information. • must be trained on administration of the vaccine – see below • 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'. Completion of cold chain training (also available via ESR). • must be familiar with All Wales Advisory document on Ordering Storage and Handling of Vaccines • must be competent in the recognition, management and reporting of adverse drug reactions, including anaphylaxis. Must be competent in the administration of adrenaline 1 in 1000 and have up to date Life Support skills (Basic Life Support Skills are PTHB standard). • 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	Updating at least every 2 years on the administration of rotavirus vaccine (live). 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 must make a self-declaration of competency on PADR (if relevant). The **personal development plan** (yellow) section of the PADR booklet should be used to record completion of Statutory and Mandatory training, including annual PGD e-learning. Compliance with all mandatory NHS training (if relevant).

	Practitioners should be constantly alert to any subsequent recommendations from Welsh Government and/or Public Health Wales and/or NHS Wales and/or the UKHSA and/or NHSE 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. **It is the responsibility of the healthcare professional to maintain their own competency to practice within this PGD.**

2. 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'. **It is the responsibility of the administering healthcare professional to ensure that the individual is within the inclusion criteria, and that there are no reasons for exclusion before proceeding with the vaccination. If there is any reason for concern, seek medical advice.**
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: ○ the minimum age for the first dose of rotavirus vaccine is 6 weeks 0 days ○ 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:

	○ the maximum age for the second dose of rotavirus vaccine is 23 weeks and 6 days • Medical and drug history taken, no reason for exclusion • Informed consent, from the individual or a person legally able to act on the individual's behalf, must be obtained prior to administration. NB Refer to PTHB Consent to Treatment and Examination Policy Note: Vaccination of preterm infants using rotavirus vaccine is indicated (without correction for prematurity) if the infant is clinically stable (see Special Considerations). As the benefit of vaccination is high in premature and very premature infants, vaccination should not be withheld or delayed. Vaccination is advised in infants with HIV who are asymptomatic or mildly symptomatic. Additionally, infants with unknown HIV status but born to HIV positive mothers should be offered vaccination (see Chapter 27b and SPC). Refer to Special considerations. Any vulnerable adult or child protection concerns should be referred to Safeguarding and PTHB safeguarding policies followed. Where there are safeguarding concerns (Child Protection or Protection of Vulnerable Adults, POVA) advice from the local Safeguarding team should be sought (see below).
Criteria for exclusion (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)	Infants for whom no valid consent has been received (for further information on consent see Chapter 2 of 'The Green Book'). Rotavirus vaccine should NOT be given to infants who: • are under 6 weeks and zero days of age • are 15 weeks and zero days of age or older who have not received their first rotavirus vaccine dose • are aged 24 weeks and zero days of age 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) Refer to sections "Action to be taken if the patient is excluded" and "Action to be taken if the patient or carer declines treatment".
Cautions including any relevant action to be taken	Facilities for management of anaphylaxis should be available at all vaccination sites (see Chapter 8 of the Green Book) and advice issued by the Resuscitation Council UK. Rotarix® vaccine contains 0.15 microgram phenylalanine in each dose. Though phenylalanine may be harmful to individuals with phenylketonuria (PKU), the parent or carer of the individual will be well versed as to the amounts of phenylalanine tolerable in their diet. The National Society for Phenylketonuria (NSPKU) advise the amount of phenylalanine contained in vaccines is negligible and therefore strongly advise individuals with PKU to take up the offer of immunisation. 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/carers 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 and before food preparation or direct contact with the immunocompromised person (see Chapter 6). Check for any other medications that the individual is taking, including topical or inhaled products, food supplements and herbal or homeopathic products (Refer to BNF/SPC for full list). Under Section 128 and 130 of the Social Services and Wellbeing (Wales) Act 2014, staff have a duty to inform the Local Authority if they have reasonable cause to suspect that an adult or child is at risk. Any vulnerable adult or child protection concerns should be referred to Safeguarding and the PTHB safeguarding policies followed. Consider discussing with GP. Any safeguarding concerns need to be directed to Safeguarding Hub: • to generic email address: PowysTHB.Safeguarding@wales.nhs.uk and • Central Safeguarding number: 01686 252806 • Out of hours: 0345 0544847 Advice can also be sought from local Safeguarding Leads
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, PTHB Infection Control 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 the 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 and recorded appropriately. The patient information leaflet should be available to inform consent. Advise the parent/carer about the protective effects of the vaccine, the risks of infection and potential complications of disease. Document the advice given and decision reached. In a GP practice setting, inform or refer to the GP as appropriate. Inform the Child Health department if appropriate – if any vaccination is declined for a child under 19 years, Child Health must be informed and appropriate form completed. Where appropriate, inform the GP using the local agreed system.
Arrangements for referral for medical advice	Refer to GP, paediatrician or consultant in communicable disease control (CCDC) for clinical advice as necessary. Document any advice given.

3. Description of treatment

Name, strength and formulation of drug	Rotavirus vaccine (live, attenuated) oral suspension: Rotarix® oral suspension (1.5 ml) in a squeezable tube 1 dose (1.5 ml) contains: Human rotavirus RIX4414 strain (live, attenuated, produced in Vero cells) not less than $10^{6.0}CCID_{50}$ The vaccine contains: ○ sucrose and glucose (see Criteria for exclusion). ○ phenylalanine (see Cautions) Rotarix® is not known to be interchangeable with other rotavirus vaccines.
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 the All Wales Advisory document on Ordering Storage and Handling of Vaccines and 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 and method of administration	Rotavirus vaccine is given orally. **Rotavirus vaccine must not be injected**.

	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** When using the squeezable tube: • check the expiry date • check the tube has not been damaged nor is already open • pull off the cap, keep the cap to pierce the membrane • 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). After piercing, there should be a hole at the top. If the membrane has not been pierced, repeat the above step (see SPC). • 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 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: Home - electronic medicines compendium
Dose and frequency of administration	Rotavirus vaccine should be administered as a course consisting of 2 doses (1.5ml per administration) separated by at least 4 weeks. Administer the first dose of 1.5 ml of rotavirus vaccine ideally at 8 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 4 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 2 doses of rotavirus vaccine be completed before 16 weeks of age, allowing at least 4 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 administered	Single (1.5 ml) 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). Also refer to All Wales Advisory document on Ordering Storage and Handling of Vaccines.
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 Vaccine Incident Guidance and All Wales Advisory document on Ordering Storage and Handling of Vaccines. See 'MMP 427 Safe and Secure Management of Refrigerated Medicines and Vaccines SOP' for details of actions required in the event of a fridge temperature excursion. Any loss of vaccines due to expiry date or fridge failure/breaches in cold chain must be reported on ImmForm, to PTHB Immunisation co-ordinator (Powys.Immunisations@wales.nhs.uk), and via the Once for Wales Reporting System.
Disposal	Equipment used for immunisation, including discharged vaccines in a tube 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 arrangements and guidance in the Health Technical Memorandum 07-01: Safe and sustainable management of healthcare waste (NHSE) and guidance in the Welsh Health Technical Memorandum 07-01 Safer management of healthcare waste.
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 (see Chapter 27b) and vaccines given abroad. A detailed list of drug interactions is available in the SPC, which is available from the electronic Medicines Compendium.
Identification and 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 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 5 months of age. Some countries have reported a small increase in the risk of intussusception within 7 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. In case of an acute anaphylactic reaction occurring, adequate treatment provision must be available for immediate use: Anaphylaxis and resuscitation equipment including adrenaline (1 in 1000) injection and a working telephone. In case of anaphylaxis:- • Refer to adrenaline (epinephrine) PGD0017 and anaphylaxis procedure • Request medical assistance urgently. If the GP is not immediately available dial 999 to transfer to A&E • Ensure reaction is fully documented in patient notes • Ensure all patient records are marked **ALLERGIC TO ROTAVIRUS VACCINE (live, attenuated) oral suspension.** • The patient may be advised to wear a MedicAlert or similar device to alert other healthcare providers Report via Once for Wales Reporting System.
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: Yellow Card, making medicines and medical devices 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. All significant adverse drug reactions and any

	administration errors must be recorded via the Once for Wales Reporting System.
Written information to be given to patient or carer	Offer the marketing authorisation holder's patient information leaflet (PIL) provided with the vaccine. For resources in accessible formats and alternative languages, please visit Home - Health Publications. Where applicable, inform the individual/parent/carer that the PIL with large print, Braille or audio CD can be ordered from the manufacturer (see electronic medicines compendium). Immunisation promotional material may be provided as appropriate: • Babies and pre-school - Public Health Wales • phw.nhs.wales/topics/immunisation-and-vaccines/leaflets/babies-and-pre-school/what-to-expect-after-vaccinations-bilingual-leaflet/ • A quick guide to childhood immunisation for the parents of premature babies Available from: Immunisation - GOV.UK Further information for printing and website links suitable for patients can be found on the Public Health Wales intranet site Public Health Wales Immunisation and Vaccine Preventable Disease Programme, NHS 111 Wales and Health Information Resources.
Patient advice and follow up treatment	Give appropriate advice if medication is used off-label. 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: • 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 and before food preparation or direct contact with the immunocompromised person (see Cautions). There are no restrictions on the infant's consumption of food or liquid, either before or after vaccination.
Special considerations and additional information	Ensure there is immediate access to adrenaline (epinephrine) 1 in 1000 injection and access to a working telephone at the time of vaccination. In the event, an infant who inadvertently receives the first dose of rotavirus vaccine at age 15 weeks or older should still receive their second dose at least four weeks later - providing that they will still be under 24 weeks of age at the time. The reason for the 15 week age limit is to minimise a potential risk of intussusception (see adverse reactions). No specific clinical action needs to be taken if the first dose of vaccine is inadvertently given after 15 weeks and zero days of age or if the second dose is given after 24 weeks of age. For both situations, immunisers should be reminded of the age restrictions for Rotarix®, even if infants are unable to start or complete the two-dose schedule as a consequence of these restrictions. 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. Medications for gastro-oesophageal reflux are not contraindications for rotavirus vaccination. The rotavirus vaccine can also be administered before, at the same time as, or after administration of any blood

	product, including those containing antibody/ immunoglobulin. Where there is doubt, appropriate advice should be sought from the local Screening and Immunisation Team, local Health Protection Team or the infant's clinician. 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. Vaccination is advised in HIV infected infants. Additionally, infants with unknown HIV status but born to HIV positive mothers should be offered vaccination (see Chapter 27b). Rotarix® does not protect against gastro-enteritis due to other pathogens than rotavirus. **Hospitalised infants** Rotavirus vaccine is highly attenuated and does not revert to a high virulence strain. Therefore, provided that the infant is clinically stable, vaccination should not be delayed, particularly if the delay risks being too late to give the vaccine or giving the first dose of vaccine closer to the upper age limit of 15 weeks. If a recently vaccinated child is hospitalised for any reason, no precautions other than routine standard infection control precautions need to be taken to prevent the spread of vaccine virus in the hospital setting (see Chapter 27b).
Records	Record consultation details as required by local procedures. In addition, record: • that valid informed consent was given. Record name of representative who gave consent if appropriate. • name of infant, address, date of birth and GP with whom the infant is registered • medical and drug history taken, including any allergies and previous adverse events • printed name and signature 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 • any reasons for exclusion or referral, including actions taken

	• advice given, including advice received from medical cover and/or advice given if excluded or declines immunisation • details of any adverse drug reactions and actions taken • **administered via PGD, record PGD title and version number** 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. If a vaccine is administered to a child up to 19 years of age, forward a notification of vaccination given to Child Health Department using the appropriate documentation/pathway as required by any local or contractual arrangement (based in Brecon Hospital for under 5 years). A record of all individuals receiving treatment under this PGD should also be kept for audit purposes in accordance with local policy.

4. Key references

Key references	**Rotavirus** • Summary of Product Characteristics for Rotarix®. GlaxoSmithKline UK Updated 24 February 2025 Rotarix oral suspension in squeezable tube - Summary of Product Characteristics (SmPC) • Immunisation Against Infectious Disease: The Green Book, Chapter 27b . Updated 28 August 2015 • Rotavirus vaccination programme guidance: information for healthcare professionals Updated 14 May 2024 gov.uk/government/publications/rotavirus-qas-for-healthcare-practitioners/rotavirus-vaccination-programme-information-for-healthcare-professionals#background **General** • Health Technical Memorandum 07-01: Safe Management of Healthcare Waste. NHSE NHS England » Health technical memoranda • National Minimum Standards and Core Curriculum for Immunisation Training. Published February 2018. Immunisation training standards for healthcare practitioners - GOV.UK • NICE Medicines Practice Guideline 2 (MPG2): Patient Group Directions. Published March 2017. Overview | Patient group directions | Guidance | NICE • NICE MPG2 Patient group directions: competency framework for health professionals using patient group directions. Updated March 2017. Tools and resources | Patient group directions | Guidance | NICE • UKHSA Immunisation Collection Immunisation - GOV.UK • Vaccine Incident Guidance Vaccine incident guidance: responding to vaccine errors - GOV.UK • UKHSA Protocol for ordering storage and handling of vaccines. April 2014 Protocol for ordering, storing and handling vaccines - GOV.UK • All Wales Advisory document on Ordering Storage and Handling of Vaccines 7th Edition September 2017 • Welsh Health Technical Memorandum 07-01 Safer management of healthcare waste

Appendix A – Staff Accredited to use the Patient Group Direction

Authorising Manager: I confirm that the practitioners named below have declared themselves suitably trained and competent to work under this PGD. I give authorisation on behalf of Powys Teaching Health Board or a Powys GP practice for the named healthcare professionals below who have signed the PGD to work under it. *The authorising manager must use the competency checklist (below).*

Practitioner: By signing this PGD you are indicating that you agree to its contents and that you will work within it. PGDs 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.

Printed name of health professional	Signature of health professional	Printed name of senior representative authorising health professional	Signature of senior representative authorising health professional	Date

The authorising manager should retain a copy of the list, which will be requested for audit purposes. This list should be kept by PTHB (or the provider organisation adopting an authorised version of the PGD) for 25 years after the PGD expires.

The healthcare professional should retain a copy of the document after signing.

Competency check list for manager or senior team lead to use as part of the authorising process for health professionals to work to a Patient Group Direction (PGD). Review of authorisation will take place on each PGD update and at the individual's annual PADR.

Name: **Role:**		Sign / Initial	Further training identified (Y/N) Specify in " comments "	Comments
1	The PGD sign off is for the following PGD:(document the exact title and PGD number) _____			
2	We have discussed the expiry of the PGD and are using a version accessed electronically			
3	The member of staff has the appropriate qualifications and professional registration as outlined in the PGD			
4	The Patient Group Direction has been read in full by the staff member			
5	The identified training has been completed as specified in the PGD and is in date			
6	We have discussed some examples of inclusion criteria and exclusion criteria			
7	The staff member is confident in the administration method and doses			

Staff member print & sign name		Date
Manager or senior team lead to print & sign name		Date