



PHE publications gateway number: 2015118

PATIENT GROUP DIRECTION (PGD)

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 currently registered nurses.

Reference no: Rotavirus PGD
Version no: v03.00
Valid from: 01 July 2017
Review date: 01 January 2019
Expiry date: 30 June 2019

Public Health England has developed this PGD template to facilitate the delivery of immunisations in the NHS 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.

Operation of this PGD is the responsibility of commissioners and service providers.

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>

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


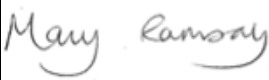

¹ This includes any relevant amendments to legislation (eg [2013 No235](#), [2015 No.178](#) and [2015 No.323](#)).

Change history

Version number	Change details	Date
Final version	New PHE Rotavirus PGD	1 July 2013
Version 02.00	<ul style="list-style-type: none"> • 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	<p>PHE Rotavirus PGD v02.00 reviewed and amended to:</p> <ul style="list-style-type: none"> • 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

1. PGD template development

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

Developed by:	Name	Signature	Date
Pharmacist (Lead Author)	Elizabeth Graham Lead Pharmacist Immunisation Services, PHE		12/05/2017
Doctor	Mary Ramsay Consultant Epidemiologist and Head Immunisation, Hepatitis & Blood Safety Department, PHE		11/05/2017
Registered Nurse (Chair of Expert Panel)	David Green Nurse Consultant – Immunisations, PHE		12/05/2017

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

Acknowledgements

Name	Designation
Dr Shamez Ladhani	Paediatric Infectious Disease Consultant, Public Health England
Jacqueline Lamberty	Lead Pharmacist Medicines Management Services, Public Health England
Vanessa MacGregor	Consultant in Communicable Disease Control, Public Health England, East Midlands Health Protection Team
Alison Mackenzie	Consultant in Public Health Medicine, Screening and Immunisation Lead, Public Health England / NHS England South (South West)
Gill Marsh	Senior Screening and Immunisation Manager Public Health England / NHS England (Lancashire and South Cumbria)
Lesley McFarlane	Screening and Immunisation Co-ordinator (SIC) NHS England Leicestershire, Lincolnshire and Northamptonshire
Sally Millership	Consultant in Communicable Disease Control, Public Health England, East of England Health Protection Team
Sue Mulvenna	Head of Pharmacy, NHS England South West
Matthew Olley	Immunisation Manager, Public Health England / NHS England London Region
Lisa Rees	Medicines Management Pharmacist, Bristol Clinical Commissioning Group
Kelly Stoker	Senior Health Protection Nurse, North East Health Protection Team, Public Health England Centre North East


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 South (South Central) authorises this PGD for use by the services or providers listed below:

Authorised for use by the following organisations and/or services
All NHS England South (South Central) commissioned immunisation services. In addition, PGD adoption by provider organisations (e.g. Sirona) providing this vaccination should have this PGD signed by their governance lead prior to use. Provider organiser staff will be expected to follow local policies and procedures.
Limitations to authorisation
None Stated

Organisational approval (legal requirement)			
Role	Name	Sign	Date
Medical Director	Shahed Ahmad		24/5/17

Additional signatories according to locally agreed policy			
Role	Name	Sign	Date

Local enquiries regarding the use of this PGD may be directed to england.southcentral-pgd@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

<p>Qualifications and professional registration</p>	<p>Registered professional with one of the following bodies:</p> <ul style="list-style-type: none"> nurses currently registered with the Nursing and Midwifery Council (NMC)
<p>Additional requirements</p>	<p>Additionally practitioners:</p> <ul style="list-style-type: none"> must be authorised by name as an approved practitioner under the current terms of this Patient Group Direction 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 patient group directions) 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 for Immunisation Training (2005) 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 Patient Group Direction and associated online resources should fulfil any additional requirements defined by local policy <p>THE INDIVIDUAL PRACTITIONER MUST BE AUTHORISED BY NAME, UNDER THE CURRENT VERSION OF THIS PGD BEFORE WORKING ACCORDING TO IT.</p>
<p>Continued training requirements</p>	<p>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).</p> <p>Practitioners should be constantly alert to any subsequent recommendations from Public Health England and/or NHS England and other sources of medicines information.</p> <p>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.</p>

4. Clinical condition or situation to which this PGD applies

<p>Clinical condition or situation to which this PGD applies</p>	<p>Rotavirus vaccine is indicated for the active immunisation of infants aged 6 weeks to 23 weeks and 6 days for the prevention of gastroenteritis due to <i>rotavirus</i> infection, in line with the recommendations given in Chapter 27b of the Immunisation Against Infectious Disease: “The Green Book”.</p>
<p>Criteria for inclusion</p>	<p>Infants presenting for the administration of their first or second rotavirus vaccine in the correct time window ie:</p> <ul style="list-style-type: none"> • infants aged 6 weeks to 14 weeks and 6 days of age presenting for first dose primary immunisation against rotavirus <p>Note:</p> <ul style="list-style-type: none"> ○ 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 <ul style="list-style-type: none"> • infants aged up to 23 weeks and 6 days who have received their first dose of rotavirus vaccine a minimum of 4 weeks previously <p>Note:</p> <ul style="list-style-type: none"> ○ the maximum age for the second dose of rotavirus vaccine is 23 weeks and 6 days <p>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.</p>
<p>Criteria for exclusion²</p>	<p>Infants for whom no valid consent has been received.</p> <p>Rotavirus vaccine should NOT be given to infants who:</p> <ul style="list-style-type: none"> • 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 e.g. 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/IV) immunosuppressive treatment • are suffering from acute severe febrile illness (the presence of a minor infection is not a contra-indication for immunisation) • are suffering from acute diarrhoea or vomiting

² Exclusion under this Patient Group Direction does not necessarily mean the medication is contraindicated, but it would be outside its remit and another form of authorisation will be required

<p>Cautions including any relevant action to be taken</p>	<p>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.</p> <p>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 eg wash their hands after changing infant's nappies.</p>
<p>Action to be taken if the patient is excluded</p>	<p>Important - see above exclusion criteria regarding age of infant, no further action will be required for individuals exceeding the age for vaccination.</p> <p>Infants excluded for reasons other than immunosuppression (see below) or acute illness (see below) are excluded because rotavirus vaccine is contraindicated or the risk vs benefit is unlikely to support vaccination; parents/carers should be advised accordingly.</p> <p>Infants who are immunosuppressed or those on systemic (oral/IV) 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 Patient Specific Direction (PSD).</p> <p>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.</p> <p>Seek appropriate advice from the local Screening and Immunisation Team, local Health Protection Team or the infant's clinician, when a vaccine is indicated outside the remit of this PGD rather than delay immunisation, as a PSD may be indicated.</p> <p>The risk to the infant of not being immunised must be taken into account.</p> <p>Document reason for exclusion and any action taken in infant's clinical records.</p> <p>In a GP practice setting, inform or refer to the GP or a prescriber as appropriate.</p>

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

5. Description of treatment

Name, strength & formulation of drug	<p>Rotavirus vaccine (live, attenuated) oral suspension eg:</p> <ul style="list-style-type: none"> • Rotarix[®] oral suspension (1.5 ml) in pre-filled oral applicator • Rotarix[®] oral suspension (1.5 ml) in a squeezable tube <p>Rotarix[®] is not known to be interchangeable with other rotavirus vaccines. However, Rotarix[®] tube and oral applicator (oral syringe) presentations may be used interchangeably.</p>
Legal category	<p>Prescription Only Medicine (POM).</p>
Black triangle▼	<p>No.</p>
Off-label use	<p>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).</p> <p>Where a vaccine is recommended off-label consider, as part of the consent process, informing the individual/patient/carer that the vaccine is being offered in accordance with national guidance but that this is outside the product licence.</p>
Route / method of administration	<p>Rotavirus vaccine is given orally.</p> <p>The vaccine is presented as a clear, colourless liquid, free of visible particles, for oral administration.</p> <p>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.</p> <p>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.</p> <p>Instructions for administration of the vaccine</p> <p>To administer the vaccine, carefully remove the protective tip-cap from the oral applicator or tube.</p> <p>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).</p> <p>The vaccine should be used immediately after opening.</p> <p>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.</p> <p>You may need to squeeze the tube presentation a few times to get all of the vaccine out; it is okay if a drop remains in the tip of the tube.</p> <p>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</p>

<p>Dose and frequency of administration</p>	<p>Rotavirus vaccine should be administered as a course consisting of two doses (1.5ml per administration) separated by at least 4 weeks.</p> <p>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.</p> <p>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.</p> <p>The second dose must be given by the age of 23 weeks and 6 days.</p> <p>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.</p> <p>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.</p>
<p>Duration of treatment</p>	<p>Two dose schedule (see Dose and frequency of administration).</p>
<p>Quantity to be supplied / administered</p>	<p>Single (1.5ml) dose</p> <p>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.</p>
<p>Supplies</p>	<p>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. Vaccines for private prescriptions, outbreaks, occupational health use or travel, are NOT provided free of charge and should be ordered from the manufacturers.</p> <p>Protocols for the ordering, storage and handling of vaccines should be followed to prevent vaccine wastage (see protocol for ordering storage and handling of vaccines and Green Book Chapter 3).</p>
<p>Storage</p>	<p>Store at +2°C to +8°C.</p> <p>Store in original packaging in order to protect from light.</p> <p>Do not freeze</p>
<p>Disposal</p>	<p>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).</p>
<p>Drug interactions</p>	<p>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.</p> <p>A detailed list of drug interactions is available in the SPC, which is available from the electronic Medicines Compendium website: www.medicines.org.uk</p>

<p>Identification & management of adverse reactions</p>	<p>The most common adverse reactions observed after administration of rotavirus vaccine are diarrhoea and irritability. Other reactions uncommonly reported include abdominal pain, flatulence, and dermatitis.</p> <p>A detailed list of adverse reactions is available in the vaccine's SPC, which is available from the electronic Medicines Compendium website: www.medicines.org.uk</p> <p>Intussusception</p> <p>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.</p> <p>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.</p>
<p>Reporting procedure of adverse reactions</p>	<p>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</p> <p>Any adverse reaction to the vaccine should be documented in the infant's record and the infant's GP should be informed.</p>
<p>Written information to be given to patient or carer</p>	<p>Offer marketing authorisation holder's patient information leaflet (PIL) provided with the vaccine.</p> <p>Immunisation promotional material may be provided as appropriate:</p> <ul style="list-style-type: none"> • A guide to immunisations for babies up to 13 months of age • A quick guide to childhood immunisation for the parents of premature babies <p>Available from: www.gov.uk/government/collections/immunisation</p>
<p>Patient advice / follow up treatment</p> <p>Continued over page</p>	<p>Inform parent/carer of possible side effects and their management.</p> <p>The parent/carer should be advised to seek medical advice in the event of a severe adverse reaction.</p> <p>Parents/carers should be advised to promptly report any of the following symptoms indicative of intussusception:</p> <ul style="list-style-type: none"> • severe abdominal pain • persistent vomiting • bloody stools • abdominal bloating • high fever <p>When applicable, advise parent/carer when the subsequent dose is due.</p> <p>When administration is postponed advise when the infant should</p>

<p>Patient advice / follow up treatment continued</p>	<p>return for immunisation, with due consideration of the infants age to ensure they will meet the inclusion criteria for rotavirus immunisation.</p> <p>Those in close contact with recently vaccinated infants should observe good personal hygiene eg wash their hands after changing infant's nappies (see Cautions).</p>
<p>Special considerations / additional information</p>	<p>Ensure there is immediate access to adrenaline (epinephrine) 1 in 1000 injection and access to a telephone.</p> <p>Consider giving the oral rotavirus vaccine before administration of any vaccine injections which may unsettle the infant.</p> <p>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.</p> <p>There are no restrictions on an infant's consumption of food or drink before or after immunisation.</p> <p>Minor illnesses without fever or systemic upset are NOT valid reasons to postpone immunisation. If an individual is acutely unwell, immunisation should be postponed until they have fully recovered. This is to avoid confusing the differential diagnosis of any acute illness by wrongly attributing signs or symptoms to adverse effects of the vaccine.</p> <p>Individuals with acute diarrhoea or vomiting should postpone vaccination until they have recovered to ensure that the vaccine is not regurgitated, or passed through the intestines too quickly, which could reduce its effectiveness.</p>
<p>Records</p>	<p>Record:</p> <ul style="list-style-type: none"> • that valid informed consent was given • name of individual, address, date of birth and GP with whom the individual is registered • name of immuniser • name and brand of vaccine • date of administration • dose, form and route of administration of vaccine • quantity administered • batch number and expiry date • advice given, including advice given if excluded or declines immunisation • details of any adverse drug reactions and actions taken • supplied via Patient Group Direction (PGD) <p>Records should be signed and dated (or a password controlled immunisers record on e-records).</p> <p>All records should be clear, legible and contemporaneous.</p> <p>This information should be recorded in the infant's GP record and the infant's Personal Child Health Record ("Red Book") completed.</p> <p>The local Child Health Information Systems team (Child Health Records Department) must be notified using the appropriate documentation/pathway.</p> <p>A record of all individuals receiving treatment under this PGD should also be kept for audit purposes in accordance with local policy.</p>

6. Key references

Key references	<p>Rotavirus</p> <ul style="list-style-type: none">• Summary of Product Characteristics for Rotarix[®]. GlaxoSmithKline UK Updated 10 March 2017 http://www.medicines.org.uk/emc/medicine/17840• Immunisation Against Infectious Disease: The Green Book, Chapter 27b. Updated 28 August 2015. <p>General</p> <ul style="list-style-type: none">• PHE Immunisation Collection https://www.gov.uk/government/collections/immunisation• British National Formulary (BNF) and British National Formulary for Children (BNF-C) www.BNF.org http://www.evidence.nhs.uk/formulary/bnf/current• National Minimum Standards for Immunisation Training (2005) https://www.gov.uk/government/publications/immunisation-training-national-minimum-standards• NICE Medicines Practice Guideline 2 (MPG2): Patient Group Directions. Published August 2013. https://www.nice.org.uk/guidance/mpg2• NICE MPG2 Patient group directions: competency framework for health professionals using patient group directions. January 2014. https://www.nice.org.uk/guidance/mpg2/resources• Immunisation knowledge and skills competence assessment tool. Royal College of Nursing (RCN) 2015. https://www.rcn.org.uk/professional-development/publications/pub-005336• Protocol for ordering storage and handling of vaccines. April 2014. https://www.gov.uk/government/publications/protocol-for-ordering-storing-and-handling-vaccines• 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
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7. Multiple practitioner authorisation sheet

Rotavirus PGD v03.00 Valid from: 01/07/2017 Expiry: 30/06/2019

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 NHS England (South Central) 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.